The Legal Liability of Caring for the Unborn in the Maltese Islands

George Gregory Buttigieg

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Student's I.D. /Code 780652M

Student's Name & Surname GEORGE GREGORY BUTTIGIEG

Course PhD

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Dedicated to my wife Annabelle and our daughters Nicola Ann Micallef Stafrace and Gabrielle Marie Vella and their families.

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ABSTRACT

In embarking on a thesis about legal liability of care of the unborn in Malta, it was clear that one had to delve deeply into both the local obstetric practice as well the local legal system. The care of the unborn is fully dependent on maternal care and this entailed a systematic assessment of the legal vulnerability of local obstetrics, which was laborious, extensive, and required the wearing of different tinted spectacles. It was however, home ground, whereas dealing with the legal aspect meant sailing in unchartered seas and understanding the legal details of how Maltese law deals with medical negligence. It was also felt essential to use the term 'the unborn' in the thesis's title in view of the unique legal standing of the Maltese laws protecting the fetus, vis-à-vis the locus standi of the unborn in the rest of the European Union.

The shock was rather severe as the truth sets in that in the twenty-first century, Malta had no proper medico-legal framework for dealing with alleged medical negligence while such a body of law had been in daily use for the last six decades or so, in such countries as the UK. Numerous local calls for amendment had been made, such as in a number of University of Malta legal theses. Furthermore, repeated references had been formally made by the judiciary in the deliberation of medical litigation. The fact remained that the local judiciary, in the twenty-first century, was still extrapolating the laws of tort and quasi-tort dealing with general negligence to adjudicate complex principles of medical practice. This also implied the lack of available guidance in establishing such basic instruments at law as the medical standard of care. As a result, the local judiciary often reverted to Italian juridical principles and increasingly to British jurisprudence.

In spite of the seeming superficial dearth of local Court medical and obstetric judgments, both general medical and legal thinking was of the opinion that there was a definite increase in medical litigious attitudes, evidenced by increase in litigation not reaching Court. Unfortunately, no relevant local medico-legal statistics exist or are even collected or have a reference point for referral. There is evidence of a complete lack of local preparedness for weathering any significant future increase in medico-legal cases. Reference to some parts of the rest of Europe showed that this state of unpreparedness was not at all rare, in spite of irrefutable evidence from countries such as Italy, France, Germany, Spain, Portugal and many others, that the threat of medical litigation is increasing rampantly. In fact, obstetrics tends to be among the front runners in the medico-legal litigation game. Malta is particularly disadvantaged with its lack of medical law as well as its lack of honing of clinical practice along the lessons learnt from long established litigation in jurisdictions such as the UK, USA, Canada, Australia and numerous other modern countries. Furthermore, Malta may also be further exposed to an as yet unconsidered obstetric medico-legal vulnerability resulting from the rapid increase of foreign residents.

The thesis constructively offers numerous propositions regarding the introduction of amendments regarding local obstetric practice, firstly to render better care to the unborn and secondly to diminish the challenge posed by legal liability. It also concludes by proposing a medico-legal body of law, entitled Lex Medica as well as the formation of

a Maltese Institute of Medico-Legal Studies. The latter is aimed at establishing local medico-legal studies on a much needed modern and solid footing as well as effecting the extensive groundwork for enacting the proposed Lex Medica.

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LIST OF ABBREVIATIONS

ABD	Assisted Breech Delivery
ABRMS	Assessment Based Risk Management System
AC	Abdominal circumference
ACOG	American College of Obstetricians and Gynaecologists
ADR	Alternative dispute resolution
AFS	Amniotic fluid sampling
AIDS	Acquired Immune Deficiency Syndrome
AMA	American Medical Association
ANC	Antenatal care
ART	Artificial reproductive Technology
AWHONN	Association of Women's Health, Obstetric and Neonatal Nurses
BMA	British Medical Association
BMI	Body mass index
BPD	Biparietal diameter

CIS	Clinical Information System
Cm	centimetre
CME	Continuing Medical Education
COCS	Court ordered caesarean section
CP	Cerebral palsy
CS	Caesarean section
CTG	Cardiotocography
CV	Curriculum vitae
CVS	Chorionic villus sampling
DIC	Disseminated intra-vascular coagulation
DOI	Digital Object Identifier
EAS	External anal sphincter
EBM	Evidence-Based Medicine
ECG	Electrocardiogram
ECtHR	European Court of Human Rights
ECT	Electroconvulsive therapy
EDD	Expected date of delivery
EFM	Electronic fetal monitoring
EFW	Estimated fetal weight
Et al.	Et alia. And others.
EU	European Union
FB	Fetal breathing
FBS	Fetal blood sampling
FDA	Food and Drug Administration

FGM	Female genital mutilation
FH	Fetal heart
FHR	Fetal heart rate
Fig	Figure
FL	Femur length
FM	Fetal movement
FRCOG	Fellow of the Royal College of Obstetricians and Gynaecologists
FRE	Federal Rules of Evidence
GMC	General Medical Council
GPP	Genu-pectoral position
HBA1C	Glycosylated haemoglobin
HIE	Hypoxic ischaemic encephalopathy
HIV	Human immunodeficiency viruses
Hr	Hour
IAS	Internal anal sphincter
Ibid.	Ibidem
I-P CTG	Intra-partum cardiotocography
IPH	Intra-partum hypoxia
IPT	Invasive prenatal testing
ITU	Intensive Treatment Unit
IUGR	Intra-uterine growth restriction
Kg	kilogram
KRF	Kiellands rotational forceps
L	litre

Liq	Liquor amnii, amniotic fluid
LLETZ	Large loop excision of transformation zone
MCOG	Maltese College of Obstetricians and Gynaecologists
MAM	Medical Association of Malta
MDH	Mater Dei Hospital
MIMLS	Maltese Institute of Medico-Legal Studies.
Min	Minute
MMC	Malta Medical Council
Mmol	Millimole
MOS	Maltese Obstetric Service
MRCOG	Member of the Royal College of Obstetricians and Gynaecologists
MSF	Médecins Sans Frontières
NGPO	Non-profit organisation
NHS	National Health Service
NHSLA	National Health Service Litigation Authority
NICE	National Institute for Health and Care Excellence
NICHD	National Institute of Child Health and Human Development
NIPT	Non-invasive prenatal testing
NOIS	National obstetric information system
OBGYN	Obstetrics and Gynaecology
OGTT	Oral glucose tolerance test
OTC	Over the counter
Pa O2	The partial pressure of oxygen in arterial blood.
PG	Prostaglandin

pH	acidity
PMU	Plovdiv Medical University
RCOG	Royal College of Obstetricians and gynaecologists
RCPI	Royal College of Physicians of Ireland
SCBU	Special care baby unit
SIDS	Sudden Infant Death Syndrome
SOP	Standard of care
ST	ST segment in an ECG
STAN	ST waveform analysis.
TOL	Trial of labour
TOLAC	Trial of labour after caesarean section
UK	United Kingdom
UN	United Nations
UR	Uterine Rupture
USA	United States of America
v.	Versus
VBAC	Vaginal Birth after caesarean section
WHO	World Health Organisation
X-ray	Radiograph

INTRODUCTION

Obstetrics tops the charts of litigation in many countries with labour issues getting the lion's share. In the face of this statement, the low profile of legal awareness of this medical specialty in the Maltese Islands is most impressive. Yet, if one delves into the matter, it is clear that the low level of Court activity in this (and other sectors) is showing clear signs of increasing. Added to this laissez-faire medico-legal attitude is the curious fact that Malta has a deficient medical law which reflects itself in a number of ways, including the fact that in the absence of laws of medical negligence, those of general negligence apply. The closer one looked, the wider appeared the medico-legal chasm between Malta and countries such as the United Kingdom a country, with which Malta identifies both historically as well as medically in several historical, academic and educational aspects. Naturally the number of Court cases between the two countries do not even begin to compare and that was one reason why necessity had not created a Maltese need to evolve medico-legally.

If one can speak of advantages of medical litigation, one such may be what this thesis refers to as the 'burnt finger phenomenon'. One example of this would be the UK's NHS learning, adapting and modifying its obstetric (and other specialties) practice under the blitzkrieg of medical litigation. This certainly came at a cost and the massive amount of litigation had led the UK to establish National Health Service Litigation Authority, the operating arm of which, since April 2017, became known as NHS Resolution. However, the 'burnt finger phenomenon' *had* and *does* lead to a negative feedback effect as understood in science and engineering and is defined as those

changes in a system which act to reduce or counteract the original forces causing the changes. Here, obviously one refers to the ameliorating changes in that medical practice which originally led to the resulting litigation. The phenomenon may serve a dual beneficial effect namely the diminution of negative clinical obstetric practice, and an academic one, where various lessons learnt serve to induce or raise academic awareness in teaching and so further pre-empty future legal vulnerability. These beneficial effects come at an exorbitant price and no sane person would choose rampant litigation for such advantages. Equally, no sane person should close his eyes to the evils of likely future litigation when the signs of the times do not augur well. Instead of serenely sailing ahead in utopian waters, with eyes closed, the Maltese establishment needs to seriously reflect on the need of waking up to what may soon be a medico-legal maelstrom. The fact that medical indemnity for practising physicians was made a legal requirement[1] for medical registration only as recently as March 2014 has two implications. One is the relative lateness of the introduction of such subsidiary legislation reflecting the general lackadaisical attitude to the problem. The second is that it is clear that, in spite of the lack of kept statistics, eyes *are* beginning to open up. They need to open much further on both medical and legal fronts for, both appear contemporarily ill-equipped for the approaching storm.

One of the original major aims of this thesis was the proposal of ways and means to diminish the vulnerability of contemporary Maltese obstetric practice. However, it soon became clearly apparent that there was another side of the equation which had to be

[1] Subsidiary legislation 528.02, legal notice 84 of 2014. 14th March 2014.Indemnity Insurance for Healthcare Professionals Regulations.

simultaneously addressed, namely the legal side. It soon became amply clear that the core legal problem was the absence of a proper medico-legal framework to guide doctors, lawyers and jurisprudence itself with regard to cases of medical and specifically obstetric negligence. As the situation stands, such cases are judged in Court by jurisprudence based on extension of the laws pertaining to *general* negligence. The more one investigated, the more one could isolate other specific acutely worrying shortages. These included the lack of criteria for establishing the medical standard of care, deficiencies in the selection process and directions to and expectations of the Court appointed expert. The complete absence of factual guidelines to guide and direct the ethics of such experts, as well as the non-existence of scrutiny of selection and rules of admissibility of expert evidence, were and are acute and dismaying needs. Furthermore, published data on medico-legal statistics is completely absent. The more one searched, the greater the clear need for a multi-faceted upheaval and the more daunting seemed the mammoth task ahead.

Comparing the situation to medical systems and jurisprudences such as those of the UK's and the USA's was both depressing and generated a yearning for improvement. Looking at the European scenario, however, one felt a flicker of encouragement, since the lack of medico-legal awareness was not so rare in certain EU communities. Like Malta, a number of EU countries were only now slowly waking up to the worrying challenge that medical litigation *was* universally increasing as evidenced by all statistics emanating from European countries such as France, Germany and Italy. These statistics reveal the clear approach of the medical litigation storm.

These factors among others are addressed by this thesis, along with the fact of the changing ethnic/nationality profile of the pregnant woman making use of the Maltese obstetric services. This factor is looked at both regarding both the sudden increase in the irregular migrant population as well as that of all other non-Maltese (particularly EU) nationals now residing in Malta, attracted by a number of factors such as employment in the I-gaming sector. These two populations pose their own different challenges, expectations and litigation liabilities which may range from the potential Court challenge, (local or at the European Court of Human Rights) to non-Court but equally nationally damaging censure by the international communities. In a country where no medico-legal statistics are published, it is not possible to quote demographic figures proving a relationship of litigation to migration shift. However, this thesis in various sections, does try to pre-empt such a potential relationship by proposing clinical amendments aimed at diminishing inherent legal vulnerability in practice.

The thesis comprises four chapters, each of which contributes important aspects to the subject of the legal liability of caring for the unborn in the Maltese Islands. In the first chapter, the definition of the unborn is evaluated by examining the locus standi of the embryo and the fetus in the Maltese jurisdiction as well as in the overseas legal arena, as represented by the well-defined jurisprudential evolution in the United States of America (USA). The USA has a number of major legal landmarks, emanating from case law, the conclusions of which have influenced other legal jurisdictions including that of the United Kingdom (UK) as well those of many European countries. This is clearly exemplified by the landmark case *Roe v Wade.*[2] Throughout this evolution with

[2] *Roe v. Wade* [16], 410 U.S. 113 (1973).

all its clinical and legal implications of the statehood of the unborn, the Maltese jurisdiction maintained its firm commitment to a fierce defence of the unborn from the very earliest existence of the conceptus.

Chapter one, also reviews some of the medico-legal consequences of the Maltese locus standi of the unborn in influencing the lack of certain OBGYN services that are freely available in the rest of Europe. These services include termination of pregnancy and such services, such as prenatal genetic testing, which, correctly or incorrectly, are considered as leading to abortion. This point is important in the potentially legally challengeable position Malta may find itself in, especially in view of the ever increasing population of foreign nationals now residing in Malta. There is an unmistakable increase in the use of the local obstetric services by foreign pregnant patients both as regards antenatal visits as well as regards birth. Another aspect of this changing profile of the local pregnant patient concerns the multi-faceted challenges resulting from the high influx of a large population of irregular migrants over a short time interval. This population may pose an under-estimated risk of litigation, which even if not necessarily at Court level, may still result in much national harm to Malta's reputation within the international community.

The second chapter is entirely devoted to the expert obstetrician assisting the Court in the role of a Court appointed referee or expert. The local scenario in this sphere contrasts sharply with that of the Court expert in the UK and USA. In the overseas situation, one finds well-honed systems for identifying the right expert with the right qualifications, well organised notifications of his appointment accompanied by all

relevant information, easily accessible codes of ethics, as well as various guidelines. Official government guidelines and guidelines originating from the British Medical Association, the Medical Council, the National Institute for Health and Care Excellence as well as the Royal College of Obstetricians and Gynaecologists lead to a well prepared, professional and safe expert testimony in Court. While one may even speak British re regulatory obsession, the other side of the coin reveals a local absence of direction in the local scene.

Chapter 2 also reviews the history of UK and USA expert immunity and of the ever-increasing liability and numerous other relevant factors. The scope in reviewing all these elements is the amelioration of the Maltese expert situation by analysing the local shortcomings and seeking their improvement by applying long evolved overseas principles. The aim is to render the local expert sufficiently adept in modern medico-legal principles such that he may, through his report, partly compensate for the present local deficiency of the Maltese legal system. The chapter also makes frequent reference, where appropriate, to both local and foreign case law. It also analyses aspects of the author's own experience and report when appointed obstetric Court expert in a local case of alleged obstetric negligence.

Chapter 3 leaves the legal world and examines the Maltese world of clinical obstetric practice at Mater Dei Hospital, the Island's national hospital. The objective of this chapter is to review the legal vulnerabilities of local contemporary obstetric practice. Ideally this would be done along published statistics showing the local incidence of the obstetric cases which led to Court litigation, and thus, pinpoint the areas of greatest

vulnerability. This concept was impossible to effect in a country lacking *any* official record keeping of medico-legal activity. However, all was not lost since most countries publishing obstetric Court litigation data seem to report broadly similar universal litigation profiles. For example, of all obstetric care, the lion's share of litigation centres on labour management with intra-partum hypoxia and trauma playing starring roles. Issues such as intra-partum cardiotocographic management and clinical conditions such as cerebral palsy often play ubiquitous super-starring roles. Based on this, it was decided to discuss the various local obstetric issues along the statistics published by the 2000-2010 report of the UK National Health Service Litigation Authority (NHSLA).

One reaches many worrying conclusions on reviewing the contemporary Maltese obstetric clinical situation from the aspect of medico-legal vulnerability. This is not synonymous at all with stating that Malta runs an inefficient service. In fact, the local OBGYN service is one of good European standing with comparative perinatal statistics to other EU countries. The lack of medico-legal awareness is unfortunately also a common one among a substantial number of European countries. Furthermore, such a lack of awareness also deprives the national system of those corrective mechanisms arising out of the 'burnt finger phenomenon'. The 2000-2010 NHSLA report is most instructive to study from this point of view. Some of this British post-litigation wisdom has been used here as a basis, in proposing constructive insights to the current Maltese obstetric scenario. Some of this advice is easy to apply, some requires much firmer resolve and some requires a strong administration and a governmental green light.

In parallel with chapter three's systematic proposals for clinical amendments to the Maltese Obstetric Service, chapter four makes a parallel pattern of proposals to the Maltese legal system. The chapter first analyses the present tort laws of general negligence in the Maltese Civil Law and evaluates what the thesis considers as inadequate concepts when applied to modern obstetric and other medical practice where negligence is alleged. It does not seek to decry the wise and much respected Roman law as concerns concepts such as the bonus paterfamilias but does point out the fact that modern concepts of medical law need to shift the local paradigm. The chapter makes reference to a number of Maltese as well as foreign (mostly from UK jurisprudence) examples to validate these arguments. In fact this reference to Maltese, U.K. and U.S.A. Court cases constitutes the primary methodology employed in developing the relevant argumentation used by this thesis. And among other conclusions this thesis concludes that the use of the present legislation is not only insufficient and inadequate when general negligence is applied to medical malpractice but furthermore is likely to offer a lower standard of care that patients have a right to expect.

Chapter four discusses the need of the practical introduction of a number of concepts which are of crucial importance. One example is that of disclosure and its worryingly low local medical, legal and jurisprudential consideration. The need for the establishment of the *legal* concept of obstetric standard of care is given much prominence due to the subject's central importance in any jurisprudence dealing with alleged medical negligence. This is a crux of the deficient legal framework which

persistently stymies Maltese medico-legal jurisprudence still labouring under such a deficiency when the UK judiciary has been led by such beacons of legal light for the last six decades.

The conclusion develops two proposals. One is the compilation of a body of law, called the Lex Medica, directed mostly at obstetric legal and jurisprudential obstetric matters, but meant to be embrace all medical specialties. The second is the proposal of the setting up of a Maltese Institute of Medico-Legal Studies, which, among its immediate scopes and responsibilities, would hopefully undertake the furtherance of the medical and legal amendments proposed by this thesis, in particular the enactment of the Lex Medica itself. Such an institute is long overdue and is the ideal way to raise Maltese medico-legal studies to its long ignored and much deserved international status.

One must also make reference to the three appendices. The first contains basic collected statistical material relating to the attendance of patients by nationality at the Mater Dei OBGYN Out-Patients Department. appendix two deals with relevant medico-legal , aspects relating to the ubiquitous obstetric investigation cardiotocography (CTG) which is to medico-legal intra-partum evaluation what the tape measure is to an architect. appendix three deals with medico-legal aspects of cerebral palsy, perhaps the most devastating of neonatal catastrophes second to stillbirth. Although, not part of the main body of the thesis, these chapters provide material which is extremely relevant to the over-all discussion, as evidenced by myriad cross references to them in the main chapters.

One should also note that the subject of abortion, is not infrequently alluded to under various aspects. It must be made clear that this thesis does not enter into the issue of Malta's rather lone standing stance in still considering abortion as a criminal act, except to evaluate some aspects of the resultant legal liability. It does not for example propose that the Lex Medica should embrace abortion among its scopes an action, which the Maltese public has, repeatedly and in great majority expressed its strong abhorrence to.

The extremely vast but crucially important subject of Assisted Reproduction has not been evaluated but should definitely be part of the finally tweaked Lex Medica. One reminds here that this body of Law must also embrace all other specialties and although in this thesis it is more of a Lex Obstetrica, the final scope is a much wider one.

In conclusion, this thesis discusses the present poorly equipped Maltese legal system in dealing with medico-legal cases, particularly in the obstetric scenario, with the aim of recommending a structure on par with more advanced EU legal systems especially in view of the increasing foreign nationals availing themselves of the Maltese obstetric services. It also seeks to propose clinical amendments aimed at diminishing legal vulnerability of local obstetric practice. Based on these facts, there is sufficient grounds for the establishment of a Maltese Institute of Medico-Legal Studies and change the organisation and delivery of practice in obstetrics to improve safety, quality and legal vulnerability while dealing appropriately with obstetric litigation when it does arise.

CHAPTER 1

On defining the legal standing of the unborn and evaluating the challenges of caring for the unborn in a locally changing patient profile

1.1 Introduction

The dictionary's answer to the question of "*who* is the unborn ?" would be that it is that embryo (from conception to ten weeks of gestation) or fetus (from ten weeks of gestation until birth), single or multiple, still growing in utero. Probably, fifty years ago or so, one could have stopped there. However, the socio-medical and legal changes incurred over the last hundred years have created a varying existential aspect to the definition. Even the geographical location of where the unborn happens to exist may affect the answer. Medico-legally one must indeed pause and reflect on the wide spectrum of influencing factors in addition to science's ever broadening frontier. One's own religious convictions may speak clearly and dogmatically. However, religion has lost much of its clout in today's materialistic society. Morality, as distinct from religion, may have a substantial role to play. Science has much to offer in the formulation of an answer to this question, but at the end of the day society is ruled by laws. The fruit of science is often interpreted by the Courts who set out to guide, rightly or wrongly, and to forward a definition which society must often contend with.

In the beginning of the twentieth century, the medical care of the unborn and its legal liability in general conformed to the classical definition. However, a look at the Court concept of the unborn, spanning the last hundred years or so, reveals an evolving and

colourful kaleidoscope of legal definitions of what constitutes the unborn. This reveals a confusing conceptual evolution or perhaps, a more fitting word would be developments. Such developments of the Court's evaluation of the fetal locus standi range from being considered simply as a maternal appendage to an entity with some autonomy and some corresponding legal rights under varying provisos, on to an acceptance of humanhood from conception, and then reverting to a concept of an appendage and its acceptable legal destruction.

While there are jurisdictions such as Malta's defending life from conception , others such as New York's,[3] legally permit the destruction of the unborn up till just before birth. The European Court of Human Rights[4] suppresses any rights of the unborn on the grounds of not posing a risk of challenge to female autonomy. This implies that in some jurisdictions, the locus standi of the unborn may also be subject to the rights of certain groups of those who have already been born. Matters are further complicated when issues involve not only the unborn while he[5] is unborn but also relate to a pre-conceptual stage and to how things may have been if the unborn had never been conceived. Here, reference is being made to the relatively new concepts of "wrongful birth" and "wrongful life".[6]

[3] Abbamonte J. New York State to Allow Abortion up to Birth. Population Research Institute. 2019 Jan 29.

[4] European Court of Human Rights ruling in *Vo v. France.* Application No. 53924/00; (2005) 40 EHRR 12; 17 BHRC 1; [2005].

[5] The use of the male gender, throughout this thesis, follows the principle of article 4 (b) of the Interpretation Act, Chapter 249 of the Laws of Malta, which states that in any law, 'words impacting the masculine gender shall include females.

[6] Often employed to denote a claim by or on behalf of an infant that a defendant's alleged negligence has wrongfully led to the infant's existence. An important local thesis on the subject is Christopher Falzon's "Wrongful Birth and Wrongful Life Legal and Moral Issues," a thesis in M.A. in Bioethics, Faculty of Theology, University of Malta, 2014.

Invoking a variety of actions under tort law, the term “wrongful life” has been applied to a number of aspects of such legislation by parents or legal guardians on behalf of their infants and even by infants against their own parents. The reasons quoted are often physical, mental, socio-economical suffering resulting from being born in a person with mental or physical anomalies. In “wrongful birth”, the basis of claims are often made by the parents or guardians, whose resulting suffering and hardship has resulted from such a birth. They claim that the infant’s very existence is wrongful because it was through obstetric negligence that the process of life was not terminated by an abortion. In the “wrongful life” claim, the plaintiff usually claims the very same suffering which could have been avoided had his own birth not occurred. Sometimes the terms are used interchangeably. In examining these claims, one may gather an outline of evolutionary conception regarding society’s definition of the unborn. It does seem as if the unborn means many things to many people.

The Maltese position, on the other hand is firm and resolute, devoid of any historical faltering of recognising the status of the unborn from the earliest moment of formation of conceptus. However noble and admirable this position is, it does present a challenge to the harmonisation of certain obstetric clinical services which, on this basis are locally unavailable, while being essentially freely available in the rest of the European Union. The prime example would of course be the lack of facilities for the termination of pregnancy, which is a criminal act in Malta. Another related example is the official unavailability of prenatal genetic services which in Malta are deemed as having no fetal therapeutic advantage while likely to lead to termination of pregnancy in the case of positively identified problems. This argument is visited in this thesis both on its own

standing as well in the light of the marked increase of the Maltese obstetric services by foreign residents.

The concept of the increased use of Maltese obstetric services by foreign nationals also leads to the consideration of another group of non-Maltese pregnant women. The arrival of a substantial community of irregular migrants over a short period of time poses new challenges with different potential litigation and their implications, even if not necessarily Court oriented. These demographic shifts, especially effected over a narrow time frame, pose heavy logistical and clinical challenges with a concomitant increase of medico-legal vulnerability.

1.2 A short jurisprudential journey in search of the legal identity of the unborn

In the 1977 case *Park v. Chessin,*[7] the case was made for the first time in US courts that a physician could be sued for wrongful life if he fails to warn parents about possible genetic defects. Having lost a child with infantile polycystic disease, the Park couple sought advice about the chance of a recurrence in a future pregnancy. Dr Chessin wrongly informed them that the chances were extremely slim, (whereas in fact they stood at 25%), and also wrongly informed them that this was not a hereditary disease. Reassured, they embarked on another pregnancy and had another affected child, judged by the court as suffering a wrongful birth for which expenses were to be claimed. The Court established that potential parents have a right to choose not to have a child, particularly when it can be reasonably established that the child would be deformed. The upholding of a "wrongful-life" judgement here is the result of negligent

[7] *Park. Chessin* [5], 60 A.D.2d 80; 400 N.Y.S.2d 110 (N.Y. App. Div. 1977).

misinformation or lack of information from someone whose duty of care demands the disclosure of accurate information which permits the conscious choice of *not* becoming parents.[8]

Park holds the key to aid us define one aspect of contemporary functional medico-legal qualities pertaining to the unborn. This Court case is considered the first precedent of "wrongful life" cases because it upheld such a claim on the grounds of a doctor's negligence in giving correct medical information which could have prevented the very conception of such suffering life.[9] Although *Park* was the first case to rule that an obstetrician could be held legally responsible for wrongful life, in a number of other cases such as *Zepeda v. Zepeda*[10] and *Williams v. State Supreme Court of Georgia*[11] Court did not uphold the argument. It is also worth quoting part of the Court's deliberation in the UK Appeal case *McKay and Another v. Essex Area Health Authority and Another*[12]:

….a doctor was under no legal obligation to the fetus to terminate its life; that the child's claim was contrary to public policy as being a violation of the sanctity of human life and a claim which could not be recognised and enforced because the court could not evaluate non-existence for the purpose of awarding damages for the denial of it and, therefore, the claim disclosed no reasonable cause of action.

[8] *Curlender v. Bio-Science Laboratories* (1980) 106 Cal. App. 3d 811 [165 Cal. Rptr. 477].

[9] One may reason that such a case could challenge the Maltese Courts for at no point is termination of pregnancy alluded to but rather the *avoidance* of pregnancy.

[10] *Zepeda v. Zepeda* (Supreme Court of South Dakota. Nos.21737, 21755. August 1, 2001.

[11] *Williams v. State of Supreme Court of Georgia* No. S13A0292.April 29, 2013.

[12] *McKay and Another v. Essex Area Health Authority and Another* [1978 M. No. 2927] [1982] Q.B.1166.

In *McKay,* the Court quote enriches jurisprudence with a welcoming ethical reflection which speaks volumes. The reference to the *sanctity of life* can be interpreted as an element of both ethics and even religious based morality in a legal world often purely ruled by bare science.

The functional definition of the unborn in *Park* is to be contrasted to that given in *Berman v. Allan*[13]in which Shirley and Paul Berman on their daughter Sharon's behalf, filed a "wrongful life" claim based on the loss of opportunity to abort their daughter in pregnancy, suffering as she was from undetected Down's syndrome. The parents claimed obstetric negligence of the defendant doctors Allan and Attardi in failing to perform amniocentesis[14] and thus failing to make the antenatal diagnosis of the condition. They claimed compensation for a "wrongful life" leading to emotional and mental anguish through the obstetrician's failure to maintain the requisite standard of care which constituted malpractice. A lower court ruling for the defendants was followed by an appeal, but the New Jersey Supreme Court upheld the trial court's ruling for the defendants on the first part of the "wrongful life" claim but found in favour of the plaintiffs on the second claim which dealt with parental mental and emotional suffering. The judges ruled that the physicians had neither caused nor increased the degree of Down's syndrome and, furthermore, the Court could not assign a value to non-life as an alternative to an impaired one. Regarding the second part, the court ruled for a reasonable compensation claim for parental, mental and emotional suffering thus

[13] *Berman v. Allan,* 80 N.J. 421; 404 A.2d 8 (1979).
[14] A surgical procedure by which amniotic fluid is withdrawn from around the fetus in utero using ultra-sound visualisation. Such fluid yields valuable information on the fetus and medical conditions it may be suffering from.

reversing the *Gleitman v. Cosgrove*[15] ruling which had excluded the medical responsibility for failure to terminate a pregnancy (as this was then illegal) following failure to detect fetal abnormalities in utero. However, one must remember that in *Berman*, the Court had the precedent of the establishment of legal abortion as set by the 1973 US Supreme Court case *Roe v. Wade.*[16] This made possible the possibility of the Court's acceptance of the second part of the *Berman*'s claim.

The above quoted landmark rulings add elements of understanding of evolving juridical views of the unborn in addition to *classical* views of what the status of the unborn is. Many serious principles are briefly brought forward in these cases. The reference to *Roe* cannot be taken as a casual one, for this ruling, however pugnacious to some, would open the door to a whole new dimension. *Park* is the first case to uphold the concept of "wrongful life" and in upholding a claim that a physician's action includes the responsibility of the very *prevention* of existence of the unborn, where evidence points to the great possibility that such a life may prove to be one of suffering. This is one example how facts uncovered by science, once processed by the juridical machinery may lay new principles governing the locus standi including the existential status of the unborn. The main argument here revolves around to what extent may a medical practitioner be held liable for "life".

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[15] *Gleitman v. Cosgrove* [15], 49 N.J. 22; 227 A.2d 689 (1967).

[16] See note 2.

Park was to open the floodgates on a "brave new world"[17] scenario of medical malpractice litigation by laying the last of three pillars. The first had been the post-1945 scientific exponential progress in medical genetics including chromosomal, biochemical and metabolic studies with molecular specialisation.[18] The second pillar had rested on the specific obstetric advances from the late 1950's onwards concerning information yielded by the invasive access of the amniotic cavity in vivo led by amniocentesis[19] and greatly assisted in later years by the ever evolving in-utero imaging techniques. Following the 1956 Fuchs and Riis'[20] first description of the use of fetal cells in the amniotic fluid to diagnose genetic disease and determine fetal sex, progress in intra-uterine diagnosis and treatment was unstoppable.

Berman would open wide the door for malpractice redress in missed or misdiagnosed genetic chromosomal or anomalous conditions in the *existent* intra-uterine fetus. *Park* effected the same in cases where the newly devised genetic tests on parents *planning* a future pregnancy would give useful information and a chance to eliminate a conception – as contrasted to aborting an existent fetus. Conditions like myotubular myopathy,[21]

[17] Apologetically borrowing the title of Aldous Huxley's dystopian novel published in 1932 and applying it to jurisprudential circumstances.

[18] Particularly in DNA sequencing, DNA methylation, Southern blotting and short tandem repeats.

[19] Carried out successfully but experimentally first (and in the third trimester of pregnancy) in 1877 by Prochownick, Von Schatz and Lambl, but developed in its clinical perfection between 1959 and 1967 by Robert Lisle Gadd.

[20] Dundar M, Subasioglu A, Ergogan M, Akbarova Y. Prediction, prevention and personalisation of medication for the prenatal period: genetic prenatal tests for both rare and common diseases. EPMA Journal. 2011 Jun; 2:181–195.

[21] Myotubular myopathy is an inherited condition where muscle tone and contraction defects lead to weakness, joint contractures, spinal curvatures and breathing and feeding problems which may lead to death in infancy and require tube feeding and assisted ventilation in older children.

sickle cell anaemia,[22] spina bifida,[23] Tay-Sachs disease,[24] and thalassemia major,[25] some of which were essentially previously virtually unknown by the public, were appearing more and more as basis for "wrongful life" claims in Courts, especially those of the USA. Even scientific laboratories, commissioned to perform the necessary biochemical tests on material passed on by obstetricians from patients or their unborn, found themselves as defendants or co-defendants for failure to detect or failure to inform of relevant results, as in *Curlender v. Bio-Science Laboratories*.[26]

One may justifiably reflect on the facts that the "*de jure*" judicial declarations reflecting the fate of the unborn, are most often the results of a jurisprudence concerned with an unhealthy unborn, whereas in normal life the vast majority of unborn foetuses are perfectly normal and healthy. Such Court cases normally involve allegations of obstetric negligence in not providing an opportunity for the destruction of a diseased (often genetically or chromosomally abnormal) unborn or a potentially diseased pre-conceptus. This automatically recognises the fact of the unborn as being a new developing entity, an independent life form, and not simply a maternal appendage. Such

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[22] Sickle-cell disease (SCD), or sickle-cell anaemia (SCA) or drepanocytosis, is a hereditary blood disorder, where a haemoglobin gene mutation leads to an abnormal sickle like shape of the erythrocytes with resultant life threatening complications.

[23] Defect in the spine and often the overlying vertebral column.

[24] Tay-Sachs is a genetic disease in which children from about six to eight months exhibit a persistent psychomotor deterioration with ensuing blindness, paralysis and bowel dysfunction over a twelve to eighteen-month period. Death usually occurs at 3-5 years. It is relatively common in Ashkenazi Jews.

[25] Thalassemia major is a rare blood disorder characterized by a marked premature destruction of red blood cells and thus a severe reduction of oxygen carrying proteins and is inherited as an autosomal recessive trait.

[26] See note 8.

reasoning flies full in the face of medico-legal history which prior to 1884 in the USA considered the fetus in utero – even of viable age and late pregnancy – as lacking locus standi in a Court of law on the grounds that it was not a separate entity from the mother.[27] In Malta, as previously stated, the position was always one giving full recognition to the unborn from the very moment of conception. Article 170 of the Civil Code grants legal rights to the unborn, providing him with a curator ad ventrem to prevent any supposition (by confirming the actuality of birth), prevent substitution of the delivered child and administer any property of the unborn up to the day of birth.

1.2.1 On using American jurisprudential rulings to legally define the unborn

The defining qualities of the unborn reached here are essentially based on American Court juridical rulings, mostly from the latter part of the 20th century onwards. The evaluation of the locus standi including the 'legal personality' of the unborn also requires going back to 19th century USA rulings. This begs the obvious question – why the *American* model?

The legal liability of contemporary care of the unborn essentially boils down to that legal liability dealing with the speciality of medicine called obstetrics,[28] itself often combined in practice with gynaecology.[29] Hence, this thesis is concerned with

[27] *Dietrich v. Inhabitants of Northampton,* 138 Mass. 14, 52 Am.Rep. 242 (1884).

[28] The medical specialty dealing with all problems related to the pregnant female and her unborn child.

[29] The medical speciality concerned with those ailments specifically associated with the female sex.

negligence[30] and malpractice[31]in caring for the unborn which may be defined as any obstetric act or omission which breaches the requisite standard of obstetric practice and leads to injury to the patient and/or her unborn child.[32] Dealing with professional negligence is a specific sub-set of tort law, itself simply and briefly defined as a body of law providing remedies for civil wrongs that are distinct from contractual wrongs or criminal wrongs.[33] In Malta, although tort has been traditionally preferred in alleged medical malpractice cases, an admixture of tort and contractual law may be invoked in dealing with such cases. The traditional favouring of tort has been somewhat challenged in the case *Rose Gauci et v. Donald Felice et,*[34] and the local Courts have shown a noticeable shift to the use of contract law in such cases since that ruling.

In seeking a sufficient amount of jurisprudential medico-legal material the local scenario revealed and absolute and relative paucity of Maltese Court cases which also confirmed in themselves the fact that Maltese medical law is conspicuous by its absence'[35] They also confirmed that lacking a healthcare legislative and juridical system, Maltese Courts deal with medical malpractice on the general legal principles

[30] The failure of exercising the care a reasonably prudent person would exercise in similar circumstances.

[31] A specific type of negligence where the physician 's practice fails to reach the standard of care resulting in harm to the patient.

[32] White GE. Tort Law in America: An Intellectual History. Oxford University Press; 2003.
[33]Bal BS. The Expert Witness in Medical Malpractice Litigation Clin Orthop Relat Res. 2009 Feb; 467 (2); 383-391.

[34]*Rose Gauci et v. Mr Donald Felice et,* Qorti tal-Appell, Onor. Imħ. Dr Vincent De Gaetano, Onor. Imħ. Dr Albert J. Magri, Onor. Imħ. Dr Tonio Mallia, Rikors Ġuramentat Nru. 1311/1999, deċ. 31/10/2008.

[35] Bernard R. Medical Malpractice - The need for local legislation. Unpublished thesis, Faculty of Laws, University of Malta, May 2008, submitted for the degree of Doctor of Laws.

of negligence. In answering this part of the research question, there was no doubt that one had to knock on the door of a foreign jurisprudence. The question was, which one?

Medical practice in Malta is, in its majority, oriented around the various British Colleges,[36] and it would have been ideal to evaluate the functional defining qualities of the unborn from cases pertaining to the British judicial system. Furthermore, the British legal system is the mother of most Commonwealth countries as well as the American systems. However, most of British medical practice is National Health Service (NHS)[37] oriented, with the major bulk of doctors ranging from family practitioners to top specialists being NHS employees. In England and Wales, it is the National Health Service Litigation Authority (NHSLA) which manages clinical negligence issues and is responsible for the payment of any damages or legal costs. There certainly is no lack of malpractice redress. Thus in 2007-2008, the NHSLA received 5,470 claims of clinical negligence cases against NHS bodies, closed 6,679 ongoing claims and paid out £633.3 million (approximately 732,683809 euros).[38] However, the lack of detailed access to these argumentations and judgements proved to be a formidable restriction to analysis. On the other hand, the NHSLA does publish full statistical details of the *nature* of all litigation cases, the money paid out and other important details. Furthermore, it also publishes clinical feedback on ameliorating practice and avoiding or diminishing further litigation. One NHSLA report[39] pertaining to the decade 2000 – 2010, has been

[36] For example, Maltese obstetrics and gynaecology practice is heavily and almost solely guided by the UK's Royal College of Obstetricians and Gynaecologists. Almost all hospital consultants are fellows of the said College (FRCOG).

[37] Founded in 1948 with the aim of providing general free health care.

[38] Medical- Malpractice Liability: United Kingdom (England and Wales). The Library of Congress. 2015.

[39] Ten Years of Maternity Claims: An Analysis of NHS Litigation Authority 2000-20010.

extensively used as the basis for constructive discussion and local application in Chapter three.

The American system on the other hand, fulfilled necessary criteria commencing with those of language, accessibility of specific judgements enriched with a juridical history going back to 1789[40] and with a catchment population of 328,585,758[41] Furthermore, its medical malpractice law was originally derived from English common law which forms the jurisprudential basis of American Law. Further evolution of American law came through rulings by the individual state courts which traditionally control it rather than the federal government – a major difference to other countries. Thus, medical malpractice law in the USA is based on common law and modified by state legislative actions that vary from state to state. This law is born out of Court decisions and judicial rulings, rather than through laws established through legislation or based on executive decisions. Of relevance to the subject at hand, American court rulings had also produced numerous landmark decisions such as those in *Park, Berman, Roe,* etc. Hence, the American system is one which not only does have the numbers and the volume but has also has an excellent track record of establishing relevant jurisprudential milestones. One should also note that the Maltese Civil Code is inspired by Roman Law which places more emphasis on the text of the law than on case law. However, Maltese Courts still quote case law, whether local or foreign, because of its authoritative and persuasive value. Thus, to a large extent the two legal systems notwithstanding diversity of origin, still make ample use of case law.

[40] Guide to Research in Federal Judicial History, Federal Judicial Center, Federal Judicial History Office, 2010.

[41] As of 12/04/2019 at 21.00 hrs.

The American Court system also has the advantage of *not* operating a no-fault system of dealing with medical malpractice as exists say in Canada and New Zealand. There *is* a difference between the US and Maltese systems in that the former employs a non-wholly Tort based system.[42] In *Rose Gauci*[43], the Maltese Court of Appeal held that the position under our law is not clear, further stating that our Courts have largely resorted to tort and quasi-tort to tackle legal issues between medical practitioners and their patients. However, in that specific case, the Court decided to rule on a contractual relationship between the patient and the doctor who was an NHS employee.

One must also add that the American system is also enriched with a massively ethnic-varied population of widespread origin with countless resultant intermingling. This bespeaks a formidable spectrum of potential medical and obstetric pathology and creates an impressively varied and fertile ground for varied clinical challenge and potential litigation. The system is also endowed with massive technological investment permitted and encouraged by the American wealth and infra-structure, including that pertaining to obstetric practice which has often given the country immense advanced technological exposure. In this aspect, one may look on the USA as both the mother of much scientific and obstetric innovation as well of the resultant medico-legal sequelae of such technology. The subject is expanded on at length in appendix two and referred to at various points on the discussion of cardiotocographic (CTG) monitoring. CTG entered the clinical obstetric world in the USA of the 1960's and was the basis of much Court actions relating to allegations of obstetric negligence in cerebral palsy causation.

[42] Lia A. The Nature and consequences of contractual relationships involving patients, medical practitioners and health institutions Doctor of Laws thesis. May 2009.

[43] See note 34.

1.3 The unborn in medico-legal confrontation: a historical and socio-medical background

The concept of medical malpractice is likely to have paralleled the evolution of medicine itself. In the Code of Hammurabi[44] we find reference to such principles:

If the doctor has treated a gentlemen with a lancet of bronze and has caused the gentleman to die, or has opened an abscess of the eye for a gentleman with a bronze lancet, and has caused the loss of the gentleman's eye, one shall cut off his hands.

By 1200 AD, Roman law had reached the rest of Europe, including Britain where evidence exists of even pre-medieval medical malpractice cases kept in the records of the Court of Common Law and the Plea Rolls.[45] However, the more "modern" principles of medical malpractice emerged in English common law in the eighteenth century,[46] when the general concept of professional malpractice was somewhat established in the theory of English Law. In the United States, medical malpractice dates to the early 1800's. with a wave of litigation occurring between 1800 – 1850.[47] In 1884, in the landmark case, *Peter Dietrich v. Inhabitants of Northampton,*[48]

[44] One of the oldest known deciphered writings incorporating the Babylonian law known as the Code of Hammurabi (ruled 1792 to 1750 BC) and dates back to 1772 BC circa. See note 45.

[45] Bal BS. An Introduction to Medical Malpractice in the United States. Orthop Relat Res. 2009 Feb; 467 (2):383-391.

[46] Kaczorowski RJ. Common-Law Background of Nineteenth Century Tort Law. The Fordham Law Archive of Scholarship and History.1990.

[47] De Ville K, Freeman RB, Gaunt K. Medical Malpractice in Nineteenth-Century America: Origins and Legacy. New York University Press;1992.

[48] See note 27.

compensation was claimed by a woman who miscarried at four to five months gestation after slipping on a defective highway. The premature child died after surviving for fifteen minutes. The famed jurist, Oliver Wendell Holmes Jr, re-attested the historical position that no legal redress could be sought for a child who died before or after birth as a result of injuries suffered in utero on the basis that the child was a maternal appendage.[49]

For the next sixty years, the case created a well quoted precedent for numerous cases. Among these we find *Walker v. Great Northern Railway Co. of Ireland,*[50] *Allaire v. St. Luke's Hospital,*[51] 184 Ill. 359 (1900), *Gorman v. Budlong,*[52] 23 R. I. 169 (1901), *Buel v. United Railways,*[53] *Magnolia Coca Cola Bottling Co. v. Jordan,*[54] *Stemmer v. Kline.*[55] Extremely few Court cases even attempted to challenge the *Dietrich* ruling. In a ten-year span between 1923 and 1933, we find *Cooper v. Blanck,*[56] *Kine v. Zuckerman*[57]

[49] A surprising ruling coming from an extremely cultured man, well aware that even the ancient Romans considered the unborn as being a distinct so much that that Caesar's Law (Lex Cesarea) had been decreed in 715 BC by Numa Pompilius (715 – 763 BC) decreeing that the unborn child of a dead mother was to be cut out of her womb and be buried separately as a distinct person.

[50] *Walker v. Great Northern Railway Co. of Ireland,* 28 L. R. (Ir.) 69 (1891).

[51] *Allaire v. St. Luke's Hospital*, 184 Ill. 359 (1900).

[52] *Gorman v. Budlong,* 23 R. I. 169 (1901).

[53] *Buel v. United Railways,* 248 Mo. 126 (1913).

[54] *Magnolia Coca Cola Bottling Co. v. Jordan,* 124 Texas, 347 (1935).

[55] *Stemmer v. Kline,* 128 N. J. L. 455 (1942).

[56] *Cooper v. Blanck,* 39 So. 2d 352 (la. App. 1923).

[57] *Kine v. Zuckerman,*[57] 4 Pa. D&C. 227 (C.P. 1924).

and *Montreal Tramways v. Léveillé.*[58] In spite of much out of Court complaints and dissent, the real challenge would only come with the 1946 case *Bonbrest v. Kotz.*[59]

In direct contrast to contemporary law, until 1820, the physician as a defendant in Court, had to prove non-negligence. The patient as a plaintiff retained much legal strength and favour until 1900, and, until then, many patients did in fact sue their doctor. Between 1835 and 1865, a large wave of malpractice lawsuits inundated the courts[60]. This was hardly surprising in view of the great increase in quackery and "popular medicine" at the time. Between 1900 and 1950, the medical profession attained further strength. This applied both to the USA as well as to Great Britain, where a great landmark was achieved with the establishment of Bolam's Law, also known as Bolam's rule and Bolam's test, emanating from the famous 1957 English tort law case, *Bolam v. Friern Hospital Management Committee*[61]. In the 1950's the medical applications of the law of Tort clearly elevated British medical jurisprudence above that required for regular trade negligence.

In the USA, the end of the nineteenth and the beginning of the twentieth century witnessed much increased strength of the medical profession as it aligned itself with government policy in a co-ordinated socio-political improvement of public and general health. Tremendous medical strides[62] preceded and followed the government's passing

[58] *Montreal Tramways v. Léveillé* (1933) Can. Sup. Ct. 456, (1933) 4 D.L.R. 337 (1933).

[59] *Bonbrest v. Kotz*, 65 F.Supp. 138 (D.D.C. 1946).

[60] Spiegel AD, Kavaler F.America's first medical malpractice crisis 1835-1865.J Community Health. Aug. 1997; 22(4); 283-308.

[61] *Bolam v. Friern Hospital Management Committee* [1957] 1 WLR 5829.

[62] Milestones for Health in America – 1900's. In the 2011 CUNY/NewYork College Calendar, "Health in America."

of health statute after statute and the medical profession itself coned on its members to quash quackery. The newly organised American Medical Association re-organised itself at both local and national levels, boosting its membership from 8000 to 70,000 (about 50% of total physicians) in 1900, even setting up its own laboratories to eliminate quack medicine.[63]

The socio-medical progress in the USA in the first half of the twentieth century was phenomenal.[64] Among a myriad other gifts to mankind, came gigantic strides in scientific progress regarding blood transfusions, electro-cardiographic heart monitoring, the treatment of tuberculosis, the prevention of cervical cancer, the discovery of insulin and the introductions of sodium pentothal and renal dialysis. The irresistible combination of government patronage, the progress of science and a number of powerful medical personalities established the first eye bank, the first national cancer institute, as well as the establishment of a massive wave of further public health measures. These included general sanitary conditions, housing regulations, food inspections, milk pasteurisation, meat inspections, maternal care and child welfare, health insurance, social security, modern hospitals. These and many other socio-medical changes and attitudes inculcated a new and enforceable respect for the worker.[65]

This was the exciting and dynamic bubbling medico-socio-political cauldron of the first half of the twentieth century which would also see a great dissemination of knowledge

[63] Fishbein M. History of the American Medical Association. JAMA.1947; 133(4):235-243.

[64] See note 62.

[65] See note 63.

to the public along with increasing awareness of one's duties and those of others including the state and the doctor. It is hardly surprising that the century would see another great surge in medical malpractice suits which mushroomed in the second half of the century. It also made for a ripe climate where the right collective psyche matured controversy into open challenge to the *Dietrich* judgement. The progress of obstetrics since 1884 had also been phenomenal and offered the right tools of increasing knowledge of fetal development. The catalyst would come with *Bonbrest.*

1.3.1 The unborn achieves both "personhood" and faces a new challenge

The arena for the second milestone of jurisprudential rulings affecting the rights of the unborn would come in the 1946 case of *Bonbrest v. Kotz*[66] with the defendant doctors accused of negligence in causing injury to the nascent child still *in utero* at the time of birth. The Court ruled that it was its prerogative to extend common law protection to a *viable*[67] fetus in utero which is born alive on a similar basis to that employed in criminal and abortion laws. It declared that:

As long as the child was viable and was born alive, the law would accord it the state of "personhood".

[66] See note 59.
[67] Viable is defined as having attained such form and development of organs as to be normally capable of living outside the uterus whereas non-viable means not capable of living, growing, or developing and functioning successfully outside the uterus. See *Wolfe v. Isbell*, 291 Ala. 327, 329 (Ala. 1973).

The viable unborn had been elevated from essentially a maternal appendage, as considered in *Dietrich,* to the status of a person under the protection of common law under the proviso of viability. The proviso of viability would be successfully challenged in the 1956 case *Hornbuckle v. Plantation Pipe Line Co.*[68] in which Justice Hawkins stated that:

Where a child is born after a tortious injury sustained at any period after conception, he has a cause of action.

Three years later, in *Puhl v. Milwaukee Auto,*[69] the Court spoke even more clearly in favour of the unborn:

Medical science is satisfied that a child en ventre sa mère is not a "part of" its mother, but, is a separate and individual creature. Furthermore, this separate character arises from the time of conception. Although the test of 'viability' has a basic quality of reducing speculation and conjecture in prenatal injury cases, it must be admitted that it does not afford an adequate remedy for an injured infant. The fundamental problem is one of proof. It is submitted that the 'moment of conception' doctrine does offer substantial legal relief to an infant injured in utero and accords with modern concepts within the science of medicine. However, a conservative and penetrating eye should carefully maintain a constant surveillance to prevent unmerited or sham claims from passing through the courts.

[68] *Hornbuckle v. Plantation PipeLine Co* 212 Ga. 504, 93 S.E. 2d 727 (1956).

[69] *Puhl v. Milwaukee Auto. Ins. Co*. 8 Wis. 2d 343, 354-357.

The 1960 *Sinkler v. Kneale* [70] ruling, in dealing with the locus standi of *a one month old child* 'en ventre sa mère' (in its mother's womb), even specifically used the word *fetus* while defending its right of action against the defendant as based on its *existence as a separate creature from the moment of conception.*

In a number of other cases[71] the Court has allowed recovery without the need of the presence of viability and thus attesting to the "personhood" of the unborn from the moment of conception. Examples include *Daley v. Meier*,[72] *LaBlue v. Specker*,[73] *Bennett v. Hymers*,[74] *Smith v. Brennan*,[75] *Kelly v. Gregory*,[76] and *Zaven Torigian administrator v. Watertown News Co., Inc & another.*[77]

However, 1960 was also the beginning of a decade of sexual liberation and the blossoming of the cult of feminism with its newly found freedom from pregnancy through the oral contraceptive pill launched in 1960. This climate catalysed the legally accepted destruction of unborn life with the ruling in the 1973 *Roe.* The case judgement involved a Supreme Court Appeal by Norma L. McCorvey ("Jane Roe"), who turned to the Supreme Court after failing to obtain a termination of pregnancy resulting from

[70] *Sinkler v. Kneale* 401 Pa. 267, 164 A. 2 d 93 (1960).

[71] Most of which were centred in the 1960 decade.

[72] *Daley v. Meier*, 33 Ill. App. 2d 218 (Ill. App. Ct. 1961).

[73] *LaBlue v. Specker*, 100 N.W.2d 445 (Mich. 1960).

[74] *Bennett v. Hymers*, 101 N.H. 483 (N.H. 1958).

[75] *Smith v. Brennan*, 157 A.2d 497 (N.J. 1960).

[76] *Kelly v. Gregory*, 282 App. Div. (N.Y.) 542.

[77] *Zaven Torigian administrator v. Watertown News Co., Inc & another.* 352 Mass. 446 March 9, 1967 - April 27, 1967.

rape. Quoting a right to privacy under the 14th Amendment, Justice Harry A. Blackmun ruled as unconstitutional a state law prohibiting abortions except to save the mother's life. He argued that the American Constitution's First, Fourth, Ninth, and Fourteenth Amendments forbade a person's "zone of privacy" to be breached by state laws. He stated that marriage, contraception, and child rearing fall within this zone, which also encompassed a woman's decision whether or not to terminate her pregnancy before the child was viable.

Between 1946 and 1960, USA law swung from considering the fetus as a maternal appendage to granting it locus standi even from conception and then in 1973, this locus standi suddenly wilted away when pitted against the "zone of privacy" as defined in the 1st, 4th, 9th and 14th amendments. In 1967, in England, Wales and Scotland, the Abortion Act would sanction such abortions when it posed a risk to a woman's physical and mental health. The practice would spread throughout most of Europe, where at least twenty-two member states would eventually legalise abortion.[78]

The European Court of Human Rights (ECtHR) has been unequivocal in its support *for* abortion and this was the case on the 13 May 1980 when the Acting President of the ECtHR in Strasbourg, in *Paton v. United Kingdom* ,[79] clearly stated that in English Law, the fetus had no right to life as this life was *intimately connected with, and cannot be regarded in isolation from, the life of the pregnant woman.* The clock of jurisprudential illumination on the fetal locus standi seems to move forward and backwards at jurisprudential will, stressing the opposing qualities of law and science.

[78] Abortion laws vary significantly across the EU. France 24. 2018 May 25.

[79] *Paton v. United Kingdom*3 EHRR 408 1980. Application No. 8416/78.European Commission of Human Rights.

A curious stand was taken by the Grand Chamber of the ECtHR in its 2004 ruling of *Vo v. France*.[80] A case brought on by the *mother* of an unborn child against the doctor who, albeit mistakenly,[81] aborted the plaintiff's unborn child at 20 weeks gestation. The mother, a woman of Vietnamese descent with inability to speak French, was the victim of gross medical negligence which had its basis on a mix-up of similar names, one of whom was pregnant and the other required exploration for a lost intra-uterine coil. The non-existent coil was obviously never found in Mrs Vo but in the process, as expected, her pregnancy was seriously damaged. She was later admitted as an emergency and proceeded to deliver a twenty-week fetus which did not survive. Her Court claim was rejected by the first Court in 1996, reversed by the Lyons Court of Appeal in 1997 by the Court of Cassation and reversed yet again in 1999 by the Superior Court. Mrs Vo brought the case to the European Court of Human Rights.

However, the ECtHR declined to recognize the "personhood" of the fetus under the European Convention, stating that *the Convention for the Protection of Human Rights and Fundamental Freedoms excluded the protection of an unborn fetus*. Furthermore, it argued that recognizing an unborn's right to life would threaten women's human rights by permitting a government to privilege the rights of a fetus over those of a pregnant woman. Hence the ECtHR here is clearly denying the status of the fetus and is preparing to sacrifice its life, not in any bid to save the mother's life, nor her volition, but simply to prevent a threat to women's human rights. The right to life of the fetus,

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[80] European Court of Human Rights ruling in *Vo v. France.* Application No. 53924/00; (2005) 40 EHRR 12; 17 BHRC 1; [2005].

[81] Not distinguishing between a non-pregnant woman and a twenty-week pregnant woman (albeit with the same name) is not only gross malpractice but extremely difficult to understand.

according to the ECtHR, was precluded by the fear of the possibility of loss of feminine rights, and such issues as human rights and autonomy *in general.*

Maltese law recognises and protects fetal life from conception with the Criminal Code in Chapter 9 of the Laws of Malta, sub-title VII Articles 241 – 244A, which states that:

(1) Whosoever, by any food, drink, medicine, or by violence, or by any other means whatsoever, shall cause the miscarriage of any woman with child, whether the woman be consenting or not, shall, on conviction, be liable to imprisonment for a term from 18 months to three years; and

(2) The same punishment shall be awarded against any woman who shall procure her own miscarriage, or who shall have consented to the use of the means by which the miscarriage is procured."

This, in addition to the already mentioned curator ad ventrem, as provided by the Maltese Civil Code[82] and which states that:

If, at the time of the death of any one of the spouses without issue, the surviving spouse declares that she is pregnant, the court may, upon the demand of any person interested, appoint a curator ad ventrem with a view to preventing any supposition of birth, or substitution of child, and administering the property up to the day of the birth, under such directions as the court may deem it proper to give.

[82] Civil Law. Article 170 Curator ad ventrem. Amended by: XXIII.2017.50.

Hence, Malta stands out by its firm stance, as governed by Maltese Law not only in not offering an abortion service, but furthermore in not offering prenatal diagnostic services[83] by which fetal anomalies may be detected – often with a view to proceeding to abortion.

Maltese Law recognises the legal standing of the fetus from the very moment of conception and the defence of life meets with the approval from the majority of the Maltese. The law criminalising abortion stands and must be respected. This does not eliminate the need to pre-empt any likely potential medico-legal challenge based on differing views of Malta and the rest of Europe. The extension of the argument of the defence of life to not allowing the detection of anomalies of the unborn may be locally considered as a logical step. However legally it may not be considered such a logical step, whatever moral abortion one holds for abortion. In this regard, one is obliged to reflect on this unique Maltese position and its bearing on the heavy influx of foreign nationalities into the current Maltese obstetric scenario. This is not the same as saying that such influx should dictate local Maltese mores but consideration of medico-legal consequences would not be an unwise step. Here we review the potential litigation element pertaining to the MOS's current stance on prenatal testing particularly as vis-à-vis the ultrasound anomaly scan, it does present a certain degree of equivocity.

1.4 A brave lone stand for the unborn and an equivocal obstetric European situation

[83] This is a challengeable statement in view of ultra-sound anomaly scanning which *is* offered by the MOS.

The Criminal Code in Chapter 9 of the Laws of Malta, sub-title VII, Articles 241 – 244A, is clear about prohibiting abortion under *any* circumstances including rape, incest, fetal malformation or disease and even risk to maternal life. Following Ireland's controversial 2013 law, Malta now essentially stands bravely alone in its stance on abortion. Potentially more equivocal is the MOS's view on prenatal genetic tests, the absence of which stands out conspicuously in the presence of an otherwise modern local obstetric service. The law makes no direct reference to this aspect of obstetric care. However, the logic about this unwritten rule of withholding such services, is encapsulated in the reasoning of the Permanent Committee on Social Affairs of the Maltese Parliament of the 11th July 2005.[84] In that session, it had been clearly stated that unless such medical procedures and testing are justified by a therapeutic indication, they were not justified as they invariably led to abortion when a fetal anomaly was detected.

Aħna x'inhu l-prinċipju sagrosant li bdejna bih fil-bidu? It-tfal. Jiġifieri aħna qed nipproteġu lit-tfal. Mela jekk hemm kura għalih allura ngħidu li għandu dritt ikun jaf fil-prenatal…. Jekk m'hemmx kura għalih dik tfisser li se toħloq pressjoni fuq l-abort. Biex nipproteġu lit-tarbija, l-eventwali wild, allura ngħidu li qabel ma jsirx jekk m'hemmx kura.

What is the sacred principle that we started off with? Children. In other words, we are protecting children. So, if there is a cure, then there is a right to prenatal knowledge…if

[84] House of Representatives, Permanent Committee on Social Affairs meeting on 11th July 2005, Valletta.

there is no cure, it will increase the pressure for abortion. To protect the child, the future progeny, I agree that it (prenatal testing) should not be done if there is no therapeutic value.

In the document entitled Prenatal Screening Policies in Europe 2010,[85] Malta is put down as not even having routine nuchal transparency screening offered and that neither amniocentesis nor chorionic villus sampling[86] are performed. Somewhat equivocally there is the statement that anomaly ultra-sound scanning for gross structural anomalies is performed at 18-20 weeks.

Although the country is free to formulate its health policies, wherever possible these must be in resonance with European standards and requirements. Sometimes this is not possible, as is clearly the case with abortion. However, extrapolating the principle of abortion to one where a future abortion is presumed as certain on diagnosing a fetal anomaly may not be completely convincing in justifying a ban on prenatal screening. One may reason, for example, that the performance of such investigations may provide a unique opportunity to offer individual help, guidance, counselling and financial assistance where required and before birth. The arguments will no doubt draw the partisan support of those for and against abortion, but in truth this reasoning transfers the argument to the wrong arena. This thesis does not in the least way intend to add support for the pro-abortion camp but perspectives should not be mixed.

[85] Eurocat. European surveillance of congenital anomalies. Prenatal Screening Policies in Europe. 2010.

[86] This entails a direct sampling of that part of the placenta known as the chorionic villus, first performed in 1983.

It is also true that such prenatal genetic tests will open a local pandora's box. State acceptance of an official screening programme faces a major enigma of how to proceed in the presence of the detection of a major fetal anomaly, especially in the perspective of similar situations in other European countries. How would the state solve this dilemma? Amend sub-title VII, Articles 241 – 244A, of Chapter 9 of the Criminal Code with all its implied socio-religious furore and the resistance of the great Maltese majority who find abortion morally unacceptable? Alternatively, one may decide not to rock the boat and maintain the status quo of "not screening" while paradoxically still effecting ultra-sound anomaly scanning the scope of which is on par with other prenatal genetic testing. However, it is an unacceptable legal argument to preclude an action because it can lead to a crime.

In *R.R. v. Poland*[87] in front of the European Court of Human Rights, a pregnant woman claimed that she had been denied timely access to genetic tests on her female unborn child who was eventually born with Turner's syndrome.[88] Ruling in favour of the plaintiff, the Court found a violation of Article 3[89] of the Convention prohibiting inhuman and degrading treatment suffered by the applicant when she was in a vulnerable state, and who also suffered a lack of counselling and information on asking for pre-screening tests. It also found a violation of Article 8[90] - the right of respect for

[87] *R.R. v. Poland* ECtHR Application No. 27617/04. Date of Judgement 26-05-2011.

[88] Turner's syndrome is a serious genetic disorder.

[89] Paragraph 1 of Article 3 of the European Convention of Human Rights of the Council of Europe states that 'No one shall be subjected to torture or to inhuman or degrading treatment or punishment.'

[90]Paragraph 1 of Article 8 of the same Convention states that (i) Everyone has the right to respect for his private and family life, his home and his correspondence. (ii) There shall be no interference by a public authority with the exercise of this right except such as is in accordance with the law and is necessary in a democratic society in the interests of national security, public safety or the economic well-being of the country, for the prevention of disorder or crime, for the protection of health or morals, or for the protection of the rights and freedoms of others.

private and family life. The ECtHR also criticized the fact that in view of Polish law allowing for abortion in cases of fetal malformation (which Malta does not have), that country should have had an effective mechanism to allow such law providing access to prenatal genetic tests. The ECtHR ruling included a sentence of particular relevance to the Maltese situation:

The Court did not agree with the Polish Government that providing access to prenatal genetic tests was in effect providing access to abortion. Women sought access to such tests for many reasons.

Considering the ECtHR attitude to the fetal locus standi, as exhibited for example in the already quoted *Vo v. France*, advice from the ECtHR on the subject of prenatal testing may not be particularly heeded. However, one should also note that there are two local inconsistencies in the MOS' decision not to introduce prenatal testing on the argumentative strength of defending Articles 241 – 244A of sub-title VII of Chapter 9 of the Maltese Criminal Code:

i. Pre-natal testing *is* carried out in the Maltese private sector, and there are also cases where on the strength of such tests, patients have proceeded overseas with termination of pregnancy. This begs the question of why are Maltese authorities not clamping down on the private obstetric sector vis-à-vis a "considered potential breach" of the criminal code, while withholding a national prenatal screening service? It also raises the inevitable conclusion that those who can afford these tests can do them, whereas others are being deprived of a service routinely offered in most of Europe.

A stronger argument involves a clear official double standard shown by the MOS. This concerns the fact that while Maltese authorities preclude prenatal screening, the OBGYN Department offers a routine ultra-sound anomaly scan. The scope of such scans is the detection of any structural congenital anomalies. The MOS even pays a Maltese obstetrician specialised in feto-maternal medicine and resident in the UK, to visit Malta regularly and among other services, review cases which require specialised anomaly scan interpretation and management. This equivocal attitude begs the question of what distinguishes ultra-sound fetal anomaly detection in utero from prenatal blood screening vis-à-vis Articles 241 – 244A of sub-title VII of Chapter 9 of the Maltese Criminal Code?

1.4.1 Detecting Down's Syndrome in the unborn

It would be appropriate to consider, as one example, the antenatal detection of Down's syndrome, a condition, where the new-born can survive and lead a much-loved existence within the caring embrace of the family.

First described in 1866 by John Langdon Down, this condition produces both mental and physical anomalies. The former includes cognitive impairment and pre-senile Alzheimer's dementia, the latter typically exhibits facial and neck stigmas, short stature, increased incidences of cardiac defects, leukaemia and gastrointestinal problems with an overall shortened life expectancy. With an incidence of approximately 1 in 800 births, it is one of the commonest genetic birth defects. Technically known as Trisomy 21, this condition results from the inclusion of an extra

chromosome 21 leading to a triplication instead of a duplication of the involved chromosome. The screening blood test[91] is often performed in the first trimester of pregnancy if done on its own, while if part of the quadruple test,[92] is often done at 15-22 weeks. In the UK, the National Institute of Clinical Excellence (NICE) has recommended that all women should be offered a screening test for Down's syndrome as part of their routine antenatal care.[93] The UK Royal College of Obstetricians and Gynaecologists itself recommends *routine* screening for Down's syndrome in pregnancy.[94]

Ultrasound scanning also has a critical role in routine searching for Down's syndrome in the unborn. At 11-13 weeks gestation, the ultrasonically performed nuchal transparency test can measure the fluid collection at the back of the fetal neck[95] and be strongly suggestive of the condition. At 16 – 22 weeks, the fetal anatomy can also be surveyed ultra-sonographically in detail for a wide range of abnormalities which may add corroborative information.

This system of antenatal screening for genetic, chromosomal and certain malformations through the use of ultrasound and protein markers is now well established in most

[91] Cell free DNA testing.

[92] This test analyses four specific proteins and may lead to an indication of the presence of Down's syndrome (Trisomy 21) as well as spina bifida, anencephaly, Tetralogy of Fallot, Turner syndrome, Edwards syndrome (Trisomy 18).

[93] Antenatal Care. Nice Clinical Guidelines 2008.

[94] Non-invasive Prenatal Testing for Chromosomal Abnormality using Maternal Plasma DNA. Non-invasive Prenatal Testing. Scientific Impact Paper No. 15March 2014. RCOG.

[95]A strong association exists between Down's syndrome and thickening in this area. This is known as the nuchal translucency test.

clinics and hospitals where contemporary obstetrics is in practice. Most European countries operate some similar system to that described for UK and USA.[96] For example the Netherlands and the Czech Republic both operate their national screening programmes.[97] In Italy, a national screening programme has been operative since 2007, Spain has a non-uniform policy but many of its autonomous regions are implementing the service,[98] while France has a very active prenatal diagnostic service especially centred around the use of specialised ultra-sound service, while tending to move away from invasive diagnostic testing for women aged 38 years and older without full prior screening.[99] In 18 European countries surveyed for antenatal Down's syndrome screening, 10 out of 18 had a *national* country wide policy while 14 out of the 18 had similar programmes centred round antenatal structural anomaly screening.[100]

Parallel reasoning applies to other genetic and chromosomal conditions already referred to in discussing the quadruple test. Genetic counselling is an integral part of such screening. If the unborn suffering from say Down's syndrome is to be allowed a chance at living and being received in a family, then such counselling is indispensable. Professional counselling also helps the mother to analyse her feelings as to the wishes

[96] Canada also has a very well established national screening programme: –see http://www.health.gov.on.ca/english/providers/program/child/prenatal/.

[97] Hall S, Chitty L, Dormandy E, Hollywood A, Wildschut HIJ, Fortuny A, Masturzo B, Santavý J, Kabra M, Ma R, Marteau TM. Undergoing prenatal screening for Down's syndrome: presentation of choice and information in Europe and Asia. European Journal of Human Genetics. 2007 May; 15(5):563–569.

[98] See note 97.

[99]Aymé S, Morichon N, Goujard J, Nisand I, Prenatal diagnosis in France.,Eur J Hum Genet., 1997. 5 Suppl (1):26-31.

[100] Boyd PA, DeVigan C, Khoshnood B, Loane M, Garne E, Dolk H. EUROCAT Working Group. Survey of prenatal screening policies in Europe for structural malformations and chromosome anomalies, and their impact on detection and termination rates for neural tube defects and Down's syndrome. BJOG. 2008 May; 115(6):689-696.

of the fate of her unborn and admittedly the great majority opt for a termination of pregnancy. In the USA, 84-91 % of those babies so diagnosed are aborted[101]. Yet, good counselling can influence a pro-life decision if they provide balanced information about the child and his future. One Harvard study[102] stressed that in cases of pro-life parental decisions, information about the condition had been supplied either in printed form or through contact with a parent or child suffering from the condition. The same study advised consistent, accurate and sensitive information coupled with establishing contact with local Down's syndrome support associations. These facts may be of great relevance to be considered by Maltese authorities if the peculiar prevalent medico-legal quandary is ever questioned with a view to changing the present stance.

1.4.2 Correcting the equivocity regarding prenatal genetic tests

The MOS, sooner or later, on its own reasoning or potentially due to medico-legal evaluation or in response to ECtHR rulings, may consider resolving the equivocity of its current prenatal screening policy. If the decision is to proceed with the introduction of such screening in addition to the present anomaly scan, it must next reflect on whether to introduce both invasive testing (IPT) or else limit itself to non-invasive prenatal testing (NIPT). Invasive prenatal testing, such as amniotic fluid sampling (AFS) and chorionic villus sampling (CVS), does carry increased risks such as predisposing to miscarriage.

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[101] Kramer RL, Jarve RK, Yaron Y, Johnson MP, Lampinen K, Kasperski SB, Evans MI. Determinants of parental decisions after the prenatal diagnosis of Down syndrome. Am J Med Genet. 1998 Sep 23; 79(3):172-174.

[102] Skotko BG. Prenatally diagnosed Down syndrome: Mothers who continued their pregnancies evaluate their health care providers. Am J Obstet Gynecol.2005; 192:670-677.

If NIPT is resorted to, it involves the drawing of maternal blood and introduces no element of risk or damage to the fetus. This testing however belongs to screening and is liable to substantial false positive and false negative results, although it is still of value particularly in Trisomy 21 (Down's syndrome), Trisomy 18, Trisomy 13, conditions involving aneuploidy, extra or missing X and Y chromosomes. The test is based on the fact that in pregnancy, the maternal blood stream contains an admixture of maternal DNA and cast-off placental cells. Since placental cell DNA is normally identical to fetal DNA, this phenomenon allows detection of certain genetic abnormalities by accessing fetal DNA without the potential risks and complications of invasive techniques.

1.5 Challenges posed by the changing patient profile using the Maltese obstetric service

The challenge posed by the atypical and limited repertoire of prenatal genetic tests in view of the Maltese laws of abortion, opens its own chapter on potential litigation in the care of the unborn. This is only one aspect of a much larger picture concerning the mutual challenge posed by foreign patients to the Maltese obstetric services. The foreign national residing in Malta may consider the present situation, justly or unjustly, as unacceptably deficient. One must stress that such considered deficiency with regard to prenatal genetic screening should not be taken as representative of the otherwise excellent local standard of obstetric care. The foreign resident can confidently expect excellent Maltese maternity services, which are generally not inferior to any other

European service. The criteria on which such a statement is responsibly made are discussed in Section 3.2.1.

The resident foreign national may note certain shortages in obstetric care, especially if she comes from geographic areas catered to by the large teaching hospitals in the UK, Germany, France and Italy. These shortages are more likely to pertain to medical law rather than to clinical shortages. For example, pre-consent disclosure *may* be noted to be much less rigorous, especially to a patient hailing from the UK with its post-2015 *Montgomery*[103] oriented disclosure awareness. A number of such disclosure-oriented facts with potential medico-legal vulnerabilities and their proposed amendments are discussed in chapter three. For example, a patient from the UK with a history of a previous caesarean section may expect to be referred to a VBAC[104] clinic which does not exist locally. The more discerning patient may also notice a relative lack of emphasis attached to disclosure to obtain consent. Another may feel patronised by certain amount of medical paternalism still *generally* ruling the obstetric scene and the Maltese medical world in general. Such an attitude may reflect an unspoken pressure to influence management decisions which lean towards what the establishment may consider the safer options. These comments pertain particularly to the European foreign national. Although they may also hold for the irregular migrant, very often other challenges apply to this group of patients. However, one may logically ask, what are the actual statistics pertinent to the presence of resident foreigners in Malta?

[103] *Montgomery v. Lanarkshire Health Board*, UKSC 11 (2015).
[104] Vaginal birth after caesarean section.

The 2017 NOIS[105] report[106] shows that 22.2% of all local deliveries were, in fact, to non-Maltese women. As Table 1 shows, the figures have been rising consistently since 2000, when the level was only 4.9%. This rise is accompanied by a fall in the number of delivered babies to local mothers, which has fallen from 4096 in 2000 to 3364 in 2017. Hence, the element of considering the various aspects related to the foreign patient is not an ignorable one. In 2015, the total population in Malta grew to 434,403 with the addition of irregular migrants slightly exceeding 5,000. This addition was equivalent to an increase at par with the number of babies born in Malta, bringing up the population of the Island to 434,403 inhabitants in 2015. In the same year, Malta registered the highest positive net migration – the difference between immigration and emigration – for the decade, standing at 4,176.[107] According to the same report third-country nationals and EU nationals accounted for 44% and 43% respectively of total immigration. The bulk of immigrants were EU nationals, with about a third hailing from western Europe and a fourth from eastern Europe respectively, with African, Asian and Middle East immigrants constituted most of the rest.

The last two decades have witnessed impressive changes in both numbers and ethnicity of patients using the Mater Dei Hospital (MDH) obstetric services. The potential litigation and medico-legal challenge profile inherent in EU nationals is dissimilar to that in non-European nationals, especially in the irregular migrant population. The latter may be vulnerable and struggling for survival in a foreign land, when a short while

[105] The National Obstetric Information System (NOIS) is an internationally recognised hospital information system, monitoring and publishing all Maltese obstetric activity, originally launched in collaboration with the WHO-OBSQID project at the beginning of 1999.

[106] NOIS Annual Report 2017.

[107] Trends in Malta 2016. Malta National Statistics Office.

before they could have been struggling with the unforgiving Mediterranean Sea after trudging the Sahara Desert and then sampling the delights of Libya. The migrant's very perception of suffering and of what constitutes obstetric care are often entirely different from that of the EU national. However, not only are all manners of complaints and indeed

medico-legal actions open to them, but they also enjoy, and rightly so, the protection and guidance of Non-Governmental Organisations (NGOs) such as Médecins Sans Frontières (MSF). This is as should be, for one hardly expects the migrant, struggling keep body and soul together, to be in a position, however aggrieved, to seek formal medico-legal retribution. These people have often suffered much, alone and in silence and NGOs may be their only source of comfort, relief and guidance.

The lack of orthodox legal retribution of the irregular migrant is not synonymous with a lack of potential serious reaction to any perceived or factual obstetric or other medical service shortage. For what may be saved in Court expenses and litigation pay-outs may prove to be much costlier to the nation in the face of international opprobrium at any exposed lack of humanity in the face of vulnerability. This was experienced, for example in March 2009, when, among much international press coverage, M.S.F. pulled back from Malta "because we felt it was impossible to offer adequate medical care under those circumstances".[108] Among the involved patients needing appropriate care were "sick people, children, and pregnant women." Although the MSF returned in July 2009, after a commitment of improvement by the Maltese authorities, much damage had been inflicted to the Island's reputation.[109] Such action must be considered

[108] Médecins Sans Frontières Returns to Ta' Kandja. Malta Independent. Saturday, 4 July 2009.

[109] Médecins Sans Frontières Returns to Ta' Kandja. Malta Independent. Saturday, 4 July 2009, 00:00.

as a formal expression of socio-medical grievance, even though expressed by a third party and not through the medium of the Courts. In fact, such actions shout out much louder than any newspaper and appeal to the most damaging of Courts, namely the judgements made by humanity at large, from which there is no reasoned appeal. With this, firmly in mind, we can turn our attention to the multi-faceted obstetric vulnerability of this group of patients.

Nationality	Maltese		Non-Maltese		Unknown	
Year	Number	%	Number	%	Number	%
2000	4096	95.0	211	4.9	4	0.1
2001	3737	95.4	178	4.5	3	0.1
2002	3662	94.6	170	4.4	41	1.1
2003	3687	92.3	220	5.5	88	2.2
2004	3558	92.7	168	4.4	112	2.9
2005	3512	92.3	237	6.2	55	1.4
2006	3491	91.3	288	7.5	43	1.1
2007	3511	91.1	308	8.0	34	0.9
2008	3729	89.8	402	9.7	23	0.6
2009	3711	90.2	376	9.1	25	0.6
2010	3581	90.6	365	9.2	6	0.2
2011	3740	88.5	479	11.3	7	0.2
2012	3668	87.9	501	12.0	6	0.1
2013	3501	86.0	564	13.8	8	0.2
2014	3533	82.6	733	17.1	9	0.2
2015	3544	80.8	838	19.1	3	0.1
2016	3565	80.0	889	19.9	1	0.1
2017	3363	77.8	958	22.2	3	0.1

Table 1 Deliveries by reported nationality of patients for the period 2000 – 2017. (NOIS 2017)

1.5.1 The irregular migrant in the Maltese Islands

Up till 2005, the non-Maltese population in Malta constituted only 3% of the total.[110] By 2011, there was an increase of 4.8% of non-Maltese residents, partly explicable by Malta becoming a full member of the EU community in 2004 and also by an increase in the arrival of irregular migrants which commenced in 2001[111] (Figure 1). In 2011, most of these asylum applications were submitted by nationals of Somalia, Nigeria, Eritrea and Syria.[112] In 2012, more than half of the requests were by Somalian nationals alone.[113] The challenge to the MOS regarding the logistics of daily praxis of obstetrics may be gathered from the fact that between 2000 and 2008, Malta received 17, 743 migrants.[114] Although not alone from facing this problem, Malta perhaps faced a unique severity of challenge to its medical services by receiving the highest number of asylum seekers per capita in the years 2008-2012, with 21.7 applicants per 1,000 inhabitants.[115]

The existent challenges are mutual. The MOS must cater for a large influx of patients over a short period of time, a population with specific medical, obstetrical and socio-cultural needs far different from the Maltese needs it has traditionally catered for. The

[110] Cassar CM Researching migration and asylum in Malta: A Guide. The people for change Foundation.2013 April.

[111] See note 110.

[112] Falzon, M-A. 2012 Dec 10; Immigration, Rituals and Transitoriness in the Mediterranean Island of Malta. Journal of Ethnic and Migration Studies. 2012 Dec 10;38(10):1661-1680.

[113] See note 110.

[114] Freeman C, Squires N. EU immigration: Malta is the smallest state, and we are carrying a burden that is much bigger than any other country. The Telegraph. 21 Jul 2013.

[115] Access to healthcare and living conditions of asylum seekers and undocumented migrants in Cyprus, Malta, Poland and Romania. (HUMA).

migrant patients themselves, must survive in an alien environment, not infrequently peppered by individual prejudice, on top of which is super-imposed an individual vulnerability brought on by the needs of pregnancy in an alien environment. The language barrier is often the first hurdle with the immediate need to involve an interpreter who may or may not be available when precisely needed and whose translation may leave much to be desired. The need for introducing a third party in the form of an interpreter has a number of issues which are often ignored. For example, a male interpreter, super-imposed on inter-tribal complex issues, plus the reticence of a retreating pregnant women to reveal intimate details may prove unassailable factors for obtaining a relevant and correct obstetric history. Furthermore, a woman, taught since childhood that certain subjects are taboo in front of males, may face the trauma of communicating with a potentially male obstetrician through a potentially male interpreter who may even belong to her tribe. The wide variation of origin and the different languages and dialects may lead to incorrect translations. Swahili, Amharic, Oromo, Hausa and Yoruba, are among the key languages spoken by the sub-Saharan (the majority of immigrants) along with countless other dialects.[116]

[116] Ouane A Towards a multilingual culture of education. Annex 2:The languages of Africa:an annotated map. 2003. Unesco Institute for Education.

Figure 1 Number of asylum seekers reaching Malta between 2000 – 2011.

Under-estimating the critical importance of the lack of proper communication may lead to serious mistakes in disclosure, diagnosis, as well as treatment. With such challenges to communication, major aspects of disclosure are easy to be conveniently forgotten or minimised. It is clear that communication must be given ever increasing priority. The first step lies in the organisation of serious efficient preparatory courses for interpreters which with language issues must add materia medica in the right socio-cultural context. In *Eldridge and Others v. Attorney General of British Columbia and Another (Attorney General of Canada and Others, intervening)*,[117] the Court clearly declared that effective communication is an integral part of medical care.

The language barrier is but one factor, that in an alien world which does not appreciate the patient's complex socio-cultural tradition, contributes to psychological isolationism

[117] *Eldridge V Constitutional law: Supreme Court judgements. Attorney General of British Columbia and Canada* [1997] 3 SCR 624.

and obstetric vulnerability. This engenders a vicious spiral of further mental resistance to communication which further raises this vulnerability. Rowe et al.[118] pinpoint the added effect of this vulnerability of women who are at risk and who are now also victims of poor communication. Serious communication issues are known to exist between patients and health care providers with different cultural backgrounds.[119] This partly explains one study's observation that such circumstances in women with a non-western background may notch up perinatal mortality by as much as 21.7%.[120] Furthermore, good communication lays the basis for effective doctor-patient bonding and the combination of the two may go a long way in mitigating a possible litigious attitude when clinical outcomes are not satisfactory,[121] especially so when the disappointment is more perceptive than factual. Yet, even with the best of intentions, good communication in these circumstances may be extremely challenging. In addition to interpreter problems limiting or even distorting correct self-expression, shyness, embarrassment, socio-cultural divide .and other factors may be extremely difficult to overcome.

[118] Rowe RE, Garcia J, Macfarlane AJ, Davidson LL. Does poor communication contribute to stillbirths and infant deaths? A review. Journal of Public Health Medicine. 2001; 23(1):23-24.

[119] Dorn T, Ceelen M, Tang MJ, Browne JL, De Keijzer KJC, Buster MCA, Das K.Health care seeking among detained undocumented migrants: A cross-sectional study. BMC Public Health. 2011; 11:190.
[120] See note 119.

[121] Buttigieg GG, Buttigieg G. Medico-Legal Litigation: The clinical contractual nature of the Obstetric Anaesthetist -Patient relationship. Malta Medical Journal. 2014; 26 (1): 44-48.

1.5.1.1 Obstetric outcomes in immigrants of African nationality

Most of the patients originating from the sub-Saharan region (the great bulk of irregular migrant patients) are known to be at a statistically greater likelihood of having low birth weight babies mainly as a result of a greater predisposition to premature births with a subsequent possible increase in morbidity.[122] These women have a statistically increased chance of emergency caesarean sections as well as an increased incidence of multiple pregnancy, particularly noticeable (four times the normal incidence) among the Yoruba tribe of southwest Nigeria.[123] These facts alone, constitute a universe of potential obstetric risk factors to be borne in mind.

The Maltese obstetrician must also be acutely aware of potential underlying *medical* problems. Not that such ethnic propensity to certain medical conditions have not been experienced before by the local obstetrician. One example comes from the ever-increasing Maltese Filipino community[124] and its high rate of propensity to tuberculosis.[125] However, the phenomenon is infinitely more challenging with the sub-Saharan and the potential wide-ranging pathology she might be harbouring. Likely to have received little or no obstetric or medical care up until reaching Malta, such a patient may present numerous as-yet undiagnosed conditions to the obstetrician. The

[122] Savona-Ventura C, Buttigieg GG, Gatt M. Obstetric outcomes in immigrants of African nationality. International Journal of Risk & Safety in Medicine. 2009;21(3):147–152.

[123] Mosuro AN, Agyapong M, Opoku-F, Deen S. Twinning rates in Ghana. Twin Research.2001; 4(4): 238–241.

[124] The Filipino community in Malta has been steadily increasing over the last 20-25 years.

[125] Manangan LP, Jumao H, Salibay C, Maclaren Wallace R, Kammerer S, Pratt R, McAllister L, Robison V. Tuberculosis Among Persons Born in the Philippines and Living in the United States, 2000–2007. Am J Public Health. 2011 January; 101(1):101–111.

problem is even more complex by the patient's inability or limitation at freely describing any symptoms she is experiencing.

The spectrum of such conditions may be daunting. They include various degrees of malnutrition, anaemias, specific vitamin deficiencies, parasitic conditions, sexually transmitted diseases including HIV/AIDS, renal failure, heart failure, mental illness, metabolic conditions and problems resulting from close consanguinity in addition to all possible tropical and sub-tropical diseases. Some patients suffer from medical conditions related to regional socio-sexual habits which increase vulnerability. For example, Sub-Saharan women are likely to suffer more from sexual and blood-borne infections such as Hepatitis B, Hepatitis C and HIV/AIDS than their Maghreb counterparts.[126]. The general local increase of previously unseen diseases is being well noted and harped upon in relation to the irregular migrant by the local media:

…in recent years it can be said that there are no borders when it comes to infectious diseases, due to the increase in global travel and the mass migration of people and the large number of people considered as displaced. This has led to the introduction of new diseases in countries that previously had no experience of them, as well as the re-emergence of diseases that had been considered controlled.[127]

[126] Elsheikh RM, Daak AA, Elsheikh MA, Karsany MS, Adam I.Hepatitis B virus and Hepatitis C virus in pregnant Sudanese women. Virol. J. 2007; 4**:**104.

[127] Micallef J. Public health: climate change, immigration having impact on infectious disease levels in Malta. Malta Independent online. 2019 May 12.

The medical and medico-legal implications of missing or misdiagnosing such conditions is not to be underestimated, and in pregnancy diagnosis may masquerade as pregnancy related. One example, unrelated to migration, but illustrating such pregnancy induced difficulty in diagnosis, relates to a disastrous outcome resulting from vitamin deficiency. In the UK case, *D v. Lechydd Morgannwg NHS Trust,* [128] a patient was awarded £535,000 for a misdiagnosis of thiamine deficiency induced by excessive vomiting of pregnancy and the symptoms of which led to an unnecessary medical abortion. The patient was left with permanent neurological damage, inability to walk unaided for any distance, psychiatric problems, memory loss and depression.

One must also remember the phenomenon of female genital mutation (FGM), relatively unknown prior to the arrival of irregular migrants. FGM admits to varying degrees of severity from simple clitoridectomy (Type 1) to clitoridectomy, removal of the labia minora, with or without the labia majora, (Type 2), to infibulation (type 3) where the vagina is virtually completely closed off either surgically or by the insertion of irritants (Type IV) such as rock salt as practised by the Bedu tribe. Both type 3 (mostly practised in north-eastern Africa, particularly Djibouti, Eritrea, Ethiopia, Somalia and Sudan [129]), and type 4, will require surgical reversal when detected in pregnancy, and if this is not feasible, then an elective caesarean section must be discussed and planned.

The presence of FGM is ideally detected and managed as early as possible in pregnancy. Disclosure and discussion of the management should be held with the patient and her

[128] Obstetrics – failure to diagnose thiamine deficiency. Lexis Library, Medicine and Public Health. Case Reviews. CR 2001; 7 5.

[129] Pieters G, Lowenfels AB.Infibulation in the Horn of Africa. New York State Journal of Medicine. 1977 April;.77(6): 729–731.

husband. Due to the frequent propensity for premature birth in this group of patients, surgery attains a degree of priority. However, if the patient presents for her first visit very late in pregnancy, revision surgery should not be carried out close to the expected date of delivery and an elective caesarean section considered instead. Vaginal surgery very close to vaginal delivery is far from desirable as these patients often return to their living quarters where hygiene may be extremely limited with a resultant high potential for wound infection.

The local obstetrician must also be prepared to encounter requests for FGM, in spite of the fact that this is a criminal offence in Malta. Such surgery also goes against United Nations FGM resolution 48/104.[130] Furthermore, legislation has been passed in 33 countries outside Africa and the Middle East, including the UK, Belgium, Britain, France, Sweden, the Netherlands, Australia, New Zealand, Europe North America, and since 2015, in 23 out of the 27 countries where FGM is most rife. With the increasing immigrant population, on the 1st January 2014, Malta amended the Criminal Code,[131] criminalising Female Genital Mutilation. A step in the right direction, the Act, however, does not direct physicians e.g., on how to proceed on diagnosing such a condition. In the present context, one must also see FGM in the light of the substantial problems it causes in childbirth.

1.5.1.2 Maternity care for the sub-Saharan /Irregular Migrant

[130] General Assembly. United Nations. 85th plenary meeting. 20th December 1993. 48/104 Declaration on the Elimination of Violence against Women.

[131] Criminal Code (Amendment) Act, 2014.

Like all national obstetric systems delivering a good European standard of care, that of the MOS is known to be adversely affected in socially deprived women.[132] This phenomenon has long been documented elsewhere and has among its multiple aetiology, the fact that such a group tends to make sub-optimal use of all healthcare benefits, including maternity care. Missed appointments may delay ultra-sound scans and blood investigations, the detection of pointers to such issues as intra-uterine growth restriction and impending signs of premature labour. There is also the human element resulting from such deficient care, namely that the obstetrician may have less patience for a woman who dresses strangely, cannot be understood and does not seem to care for her unborn. Such attitudes, needless to say, are intolerable and magnify and perpetuate the vulnerability of such a patient.

Socially deprived pregnant patients are vulnerable to all kinds of pathology at a higher rate than those who are not. They may eat less well and are more prone to anaemia and vitamin deficiency, while their sub-optimal living conditions may increase vulnerability to infections, including the more serious such as tuberculosis. All this must be borne in mind by the Maltese obstetrician long unused to seeing a population of pregnant women who have experienced hunger and serious want as a sad reality of daily life.

[132] Savona-Ventura C. Socio-biological determinants of reproductive health indicators in *Social Transition in Maltese Society*, J.A. Cutajar and G. Cassar, eds, Millers' Publ., Malta, 2009.

Existing evidence shows that factors such as social and economic standing, ethnicity, age, sex, disability and migration status impacts on an individual's level of health and ability to access healthcare.[133]

The aetiology is doubtlessly a complex one, involving among other things the evil effects of race and colour prejudice, xenophobia, immigration problems, stress, fear and communication problems in all its aspects. These, and other factors all contribute to the fact that:

Even in Europe today, where health care systems are more effective, accessible and resilient than in most other parts of the world, we face some very troubling numbers and disparities on maternal health: Every year there are about 1,800 maternal deaths in the WHO European region. One in ten pregnant women has no access to maternal healthcare during early pregnancy. The maternal mortality rate of the worst-performing EU country is ten times higher than the ones with the lowest rates • More than half of all the pregnant women who visit the Doctor of the World clinics in Europe lack access to antenatal care.[134]

Such vulnerable pregnant women often bear the brunt of society's end result of a combination of factors, the outcome of which is sub-optimal care which may range from mediocre to virtually non-existent. In the case of the pregnant immigrant, these effects may contribute to disparate rates of infant and maternal mortality, and thereby

[133] Inequalities and multiple discrimination in healthcare. FRA: European Union Agency for Fundamental.

[134] What can you do? Women Political Leaders Global Forum. Improving Maternal Healthcare for Vulnerable Women in EU28.

reflect the overall health status of the communities in which women and their families live.[135]Offering the best possible care is effective only when the migrant makes full use of it, and such lack of utilisation may be responsible for inferior clinical outcomes, which are not attributable to differences in maternal age, gravidity and parity.[136] For example, the tendency for late booking of the crucial initial antenatal visit by women of a non-western background is known to significantly contribute to a higher perinatal mortality.[137] There is a similarity in such elements between irregular migrants and disadvantaged communities such as black women in the USA which hints at the fact that the simple availability of good obstetric services per se may not improve such outcomes, unless *positive action is applied to rectify the situation.* In Austria, the phenomenon has elicited a response, which Malta might possibly consider with benefit:

We.....recommend that action should be initiated in Austria toward harmonizing obstetric procedures among the migrant and the non-migrant groups and toward minimizing risk factors.[138]

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[135] Bryant AS, Worjoloh A, Caughey AB, Washinghton AE. Racial/Ethnic Disparities in Obstetrical Outcomes and Care: Prevalence and Determinants.Am J Obstet Gynecol. 2010 April; 202(4):335–343.

[136] Choté-Omapersad A A. Ethnic Differences in Antenatal Care Use, Quality of Care and Pregnancy Outcomes: The Generation R Study. Erasmus School of Health Policy & Management (ESHPM)Erasmus University Rotterdam 2011 May 13.

[137]Ravelli AC, Tromp M, Eskes M, Droog J, Der Post JAV Jager KJ, Mol BW, Reitsma JB. Ethnic differences in stillbirth and early neonatal mortality in the Netherlands. Journal of Epidemiology and Community Health. 2010, 65 (8):696-701.

[138] Oberaigner W, Leitner H, Oberaigner K, Marth C, Pinzger G, Concin H, Steiner H, Hofmann H,Wagner T, Mörtl M, Ramoni A. Migrants and Obstetrics in Austria--applying a new questionnaire shows differences in obstetric care and outcome. Wien Klin Wochenschr. 2013 Jan;125(1-2):34-40.

The situation of such economically deprived groups whose socio-cultural ethos may further bar them from the use of adequate care is also well described in California regarding the black community and Asians:

Compared to white women, blacks suffer more aggregate morbidities, and Asians stand a high risk of all intrapartum care–sensitive conditions. Furthermore, all women of colour experience disproportionate rates of puerperal infections. Collective action is needed to reduce these disparities and improve maternal health.[139]

Somali women in Sweden were found to be at an increased risk of intrauterine fetal death, small for dates and low birth weight infants as well as serious maternal morbidity.[140] In the case of irregular migrant pregnant women, we must also bear in mind the fact that the sojourn in Malta *commences* in a default position which is much prejudicial to the woman's health and her unborn child. She may start out in the local Maltese scene, with minimal or depleted health reserves, having left places such as the sub-Sahara where conditions for pregnancy survival are atrocious. There, the chance of dying in pregnancy/childbirth stand at 1 in 16, compared to 1 in 4,000 in a developed country and the region, together with Southern Asia, accounted for 86% of maternal deaths on a global basis in 2013.[141] From this hellish scenario the pregnant migrant departs to pastures new, crossing deserts, suffering hunger and thirst, often exposed to

[139] Duendelman S, Thornton D, Gould J, Hosang N. Obstetric complications during labour and delivery: Assessing ethnic differences in California. Women's Health Issues. 2006 Jul; 16(4):189-197.
[140] Råssjö EB, Byrskog U, Samir R, Klingberg-Allvin M. Somali women's use of maternity health services and the outcome of their pregnancies: A descriptive study comparing Somali immigrants with native-born Swedish women. Sex Reprod Health. 2013 April; 4(3):99-106.

[141] The United Nations Millennium Development Goals Report 2015.

physical and sexual abuse and other ill-treatment not even deserved by chattel, until she reaches the anything but safe haven of Libya. Here, after an indeterminate period of the same, or worse hardships, she must buy her way to seriously risk her life crosses the Mediterranean Sea and lands in an island such as Malta, where an obstetrician will eventually see her, unaware of the miracle of providence in aiding such a hellish journey.

Optimal obstetric care for such women and their unborn must be motivated on a humanitarian basis. Medico-legal considerations, a distant second, are automatically catered for by the very deliverance of the best possible care. There is an acute need to study the problem at source and not manage by crisis. This implies academic stimulation of research into the original socio-economic, medical and obstetric background of these patients, the medical conditions to which they are more likely to be prey and their local presentations in Malta in the course of pregnancy. These pregnancies offer a great wealth of clinical material for academic review and analyses which are of practical value. One example comes from Savona-Ventura et al.'s showing that women from the sub-Saharan and Maghreb region were both statistically less likely to have a *planned* delivery than the overall population, less likely to deliver by spontaneous vaginal delivery and had a higher proportion of infants under 2500g.[142]

Formal Court litigation rarely features in immigrant care. However, neither can one casually dismiss it off-hand, especially at ECtHR level. One such case, involving the

[142] See note 122.

loss of a pregnancy at an early stage by an irregular migrant was that of *Aslya Aden Ahmed v. Malta.*[143] The ECtHR found a violation of Articles 3, 5-1, and 5-4 of the European Convention on Human Rights and fined Malta 30,000 euros (£26,000; $40,000), plus 3,000 euros in costs for action which led to her miscarriage. Although this was not a case of obstetric malpractice, yet it is still disconcerting, on a national basis to hear the ECtHR quoting:

….a complete lack of access to open air and exercise for periods of up to three months, an inadequate diet, and the particular vulnerability in a woman carrying an unborn child.

Furthermore, it is not unreal to expect that once sounded, a now navigated and well compensated route to the ECtHR may not be disregarded by others to plead mishaps, imaginary or otherwise, as a result of local obstetric malpractice.

In section 3.3.2.2.2**,** proposals for the improvement of antenatal care of the irregular migrant are put forward. This is in line with one of the chief scopes of chapter three, namely proposals to the MOS for improvement of the Maltese obstetric service with a view to diminishing medico-legal vulnerability.

[143] *Aslya Aden Ahmed v. Malta* ECtHR 231 (2013) 23.07.2013. Application No. 55352/12.

CHAPTER 2: Assisting the Court: The obstetric expert witness

2.1 Introduction

Allegations of obstetric negligence, like all other medical cases of the same nature, have been traditionally[144] judged in the Maltese Court along extended principles of tort and quasi-tort as applied to general negligence. In the absence of guidance from a specific medical law, such jurisprudence often borrows foreign jurisprudential rulings and principles. While such borrowed principles and case law are often derived from British jurisprudence, legal principles are often quoted from both British and Italian Court enunciations. In most obstetric and other medical cases, however limited they may be in number, the Court often also requires the assistance of a Court appointed expert or referee as he is officially known.

Article 644 of the Maltese Code of Organisation and Civil procedure empowers the Maltese Court of civil jurisdiction to appoint such a referee or Court expert:

The proof by means of a referee or referees is ordered on the demand of the parties or one of them, or by the court on its own motion.

The obstetrician who assists the Court, at the demand of either of the parties or the Court itself, carries a great responsibility. In fact, this onus is even more substantial locally in the absence of Court direction by a specific medico-legal framework. The Maltese obstetrician, acting as an expert, in line with universal expert requisites must

[144] Since the case of *Rose Gauci* (see note 34), the position seems to be favouring the law of contract.

first guide the Court by explaining the standard of practice required by a prudent obstetrician in the circumstances faced by the defendant. Then, he must evaluate any shortcomings in action or inaction in the defendant's performance. And, finally, if such shortcomings breaching the obstetric standard of care are found, they must be causally linked or rejected within scientific light to the plaintiff's sufferings as presented to the Court. Throughout all this, the obstetric expert must bear in mind that he is neither judge nor jury and his role is to assist the Court in grasping the expectations of contemporary obstetrics in the light of present scientific knowledge.

The existence of the present chapter bespeaks much concern as to a number of factors relating to the local praxis relating to the obstetric Court expert as representative of local Court experts in general. These factors range over a wide spectrum of facets. including the method of choosing the expert, the way by which he is informed of his appointment, the absence of formal expert guidelines, the choice of standard of care to be adopted, etc.

This chapter contains many references to the author's personal experience as obstetric Court expert in the case *Gambina noe et noe v. The Golden Shepard Group Limited et.*[145] The case involved the claim by 34- year old Mrs Astrid Gambina, and her husband that, on the 14 January 1999, her new-born daughter had suffered Erb's palsy due to obstetric negligence associated with shoulder dystocia during the privately managed delivery at St Philip's Hospital. The parents sought compensation for the permanent damage suffered by their daughter Carla consisting of a traumatic right post-

[145] *Albert Gambina noe v. The Golden Shepard Group Limited et*, Qorti Ċivili, Prim'Awla, Onor. Imħ. Dr Mark Chetcuti, Rikors Ġuramentat Nru. 2622/1999, deċ. 29/10/2013.

ganglionic brachial plexus lesion during delivery because of alleged carelessness or inefficiency of the obstetrician, and The Golden Shepherd Group Limited as operative company of St Philip's Hospital. The case was given a fair amount of media coverage.[146]

The obstetric expert must be aware of the four points which run true to type in all alleged cases of medical negligence. The first three points must be established by the plaintiff, whereas the fourth lies in the Court' discretion:

I. The existence of the obstetrician's duty of care to the claimant;
II. The breach of the standard of care (SOC) expected in such a duty;
III. The causal link of the claimant's complaint to the obstetrician's breach of SOC;
IV. The quantification of the damage suffered.

The challenge often lies with the second and third premise, and both hinge on the establishment of the SOC for the case in question. Even an obstetrician, who is not formally schooled as a Court expert,[147] instinctively knows that he must establish what *ought* to have been the defendant's SOC, and then weigh the defendant's actual behaviour accordingly. What he may not know is that such an SOC is guided by formal principles of medical law which in the UK, for example, have been in place for the last six decades. Unfortunately, no such formal guidance is available locally. This is one of the important needs for the establishment of a proper medico-legal framework. Such a body of law, arbitrarily named Lex Medica is proposed by this thesis in section 5.3.

[146] Mifsud M. A doctor is not necessarily responsible for the result of an intervention. Malta today. Nov 19, 2013.

[147] Essentially locally all obstetric experts fall in this category.

Among other relevant related matters, the present chapter examines other aspects related to the expert Court witness, often referring to the UK perspective as a recognised standard aided where necessary by referral to the American system. This is in contrast to the USA jurisprudential landmarks examined in chapter one in tracing the evolution of the functional legal characteristics of the unborn. There are several reasons why the UK model is favoured here and used as a basis for proposing local recommendations on the subject. Both UK and Malta employ the Adversarial Court system. This is briefly discussed in section 2.4.1. The Maltese judicial system, as already stated, often borrows case law and principles from the British jurisdiction. in its effort to fill the vacuum created by an absent local medical law. The Maltese obstetric Court expert is almost certainly although not invariably to be a member of the UK's Royal College of Obstetricians and Gynaecologists.[148] Very recently, one must add, a great interest is being expressed in European qualifications but as yet these are often sought in addition to the membership of the RCOG.

This UK bias favours the setting of the Maltese obstetric Court expert's bearings on the British compass and is further favourably weighted by the plethora of Court expert seasoned guidelines emanating from the UK. These guidelines ae set by highly respected sources such as the General Medical Council (GMC), the British Medical Association (BMA), the National Institute for Clinical Excellence (NICE) as well as from official UK Government sources. All these prove invaluable to a Maltese legal system seeking a modern and scientific overhaul. Here, in addition, some of those guidelines emanating from the American College of Obstetricians and Gynaecologists

[148] All consultants bar two are members or fellows of the RCOG.

(ACOG) which are of relevance here, are also reviewed. One must stress here the fact that the guidelines referred to here, relate to medico-legal guidance and not ones of a medical or obstetric nature such as for example criteria of impairment of glucose metabolism.

When it comes to evaluating the rules of admissibility of scientific evidence and its evolution, the chapter had to refer to that aspect of relevance in American jurisprudence dealing with the Frye and the Daubert principles. Unfortunately, the British system has little to offer in the evolution of this aspect up to this day. It is as if the U.K. has been neither impressed by the U.S. way of thinking on the subject, nor is it convinced by any homegrown concepts. As for Malta, the very concept of *scientific* admissibility does not exist, let alone do rules governing it. Nor is there a receptive soil for it as there is for say, guidance on establishing the Standard of Care. If and when a body of related medical law such as the proposed Lex Medica, is enacted, then future amendments will be able to assess the local needs at the right time for such rules.

In reviewing the origin and development of the rules of admissibility of expert evidence, it was inevitable that the American Frye and Daubert principles are examined in some detail. These considerations are important as they serve to emphasise the concept of admissibility of such evidence. This chapter should not be seen in isolation, but as preparatory to the corresponding proposals which are included in Article XVI of the Lex Medica presented in section **5.3.1.6.** The Maltese deficiencies pertaining to the subject of the Court expert are but a different part of the same spectrum comprising the non-existent crucially required medico-legal framework.

2.2 Evaluating the local expert's evidence

The Court's discretion is neither bound nor limited as to whether to partially or fully accept or reject an expert's evidence as applies to all evidence the Court hears. Albeit Court appointed, the expert's evidence is not synonymous with ipso facto acceptance. As a rule, an appropriate reason must exist for such refusal, as the local Court frequently stresses. Thus, in *Gambina,* the Court expressly stated that the expert's report must not be frivolously rejected:

Jibda biex jingħad illi f'materji speċjalizzati bħalma huma dawk mediċi speċjalment fejn jidħlu interventi, proċeduri u protokoll rikjest, il-Qorti ħafna drabi tistrieħ fuq ir-rapport tekniku liema rapport ma għandux jiġi skartat kapriċċożament u l-Qorti għandha biss tiskartah meta l-konklużjonijiet raġġunti jidhru fiċ-ċirkostanzi tal-każ bħala irraġonevoli. Tali konvinzjoni trid tkun ibbażata fuq ir-raġuni li jpoġġi fid-dubju l-opinjoni teknika.

Firstly, in specialised subjects such as medical ones, especially involving surgery and medical procedures, in most cases, the Court relies on the technical report, which should not be frivolously ignored and which the Court must only ignore, when its conclusions seem unreasonable. Such a conviction must be based on a reason which puts the expert's opinion in doubt.

In *Champalin Company Limited vs Emmanuel Debono et*,[149] the Court makes specific reference to the uniqueness of the expert evidence, putting it on par with proof, while still reminding that such evidence is accepted unless there is serious challenge to the opinion therein:

Ir-raġunament imfisser tant tajjeb fir-Rapport imressaq minnu jikkostitwixxi determinazzjoni ta' fatt li din il-Qorti sejra toqgħod fuqu għaliex, għalkemm dictum expertorum numquam transit in rem judicatam, il-konklużjonijiet ta' perit tekniku jikkostitwixxu prova u mhux sempliċi opinjoni jew suspett. Tali fehmiet għandhom is-saħħa ta' prova bħal kull prova oħra ammissibbli fil-liġi, u jibqgħu jgawdu din il-kwalità sakemm ma jiħux kontestati, jew permezz ta' provi oħrajn kuntrarji għalihom jew inkella b'sottomissjonijiet serji u tajbin biżżejjed li juruhom bħala fehmiet inattendibbli u li ma jitwemmnux. App Civ 9/2/2001.

The well explained argument expressed in the report, is good reason for this Court to rely on it, although dictum expertorum numquam transit in rem judicatam, the expert's conclusions constitute proof and not just evidence or suspicion. Such opinions have the weight of evidence as any other proof admissible in Court and retain this advantage, as long as they are not challenged or, through other evidence opposing them or serious submissions which show them to be unacceptable or unbelievable. App Civ 9/2/2001.

There are also cases of alleged obstetric negligence where the services of a Court expert may be considered superfluous. This often applies, for example, to forgotten

[149] *Champalin Company Limited v. Emmanuel Debono et*, Qorti Ċivili, Prim' Awla, Onor. Imħ. Dr Joseph R. Micallef, Ċitazz. Nru. 1319/1998, deċ. 1/3/2004.

instruments and swabs in surgical operations when the case is often considered as one of res ipsa loquitur- 'the thing speaks for itself'. In such cases, an investigation such as an x-ray or the report of a second surgeon who removed the forgotten object is evidence that the artefact was left within the operation site from the first operation. However, even in such cases, an expert opinion may serve a purpose in explaining to the Court the normal praxis of contemporary and local surgery in ensuring that such mishaps do not occur. In the case of forgotten artefacts at the operation site, such experts can explain to the Court what the standard procedure should be and if such a procedure was actually followed in the case at hand. An example of this is found in the case *Maria Dolores Farrugia vs. Dr. John Mamo et* [150] where such expert opinions were in fact appointed and served their purpose in guiding the Court. The case involved two forgotten packs after a caesarean section. These packs are sometimes used to pack away the bowels from sliding down onto the operative field and are removed at the end of the operation. In the case concerned, they were forgotten and presented later with abdominal complaints. The Court experts in this case explained to the Court the procedure involved once the child and the placenta have been delivered and the uterus repaired. They thus guided Court to reach a conclusion as to the respective duties and resultant responsibilities of the obstetrician and the theatre scrub nurse. This information helped the Court apportion the respective quantum for the obstetrician and the scrub nurse respectively.

In contrast, the Maltese Court also provides us with cases where one would certainly expect the assistance of a Court appointed expert, but neither the Court nor any of the

[150] *Maria Dolores Farrugia v. Dr John Mamo u t-Tabib Principali tal-Gvern* Civil Court, First Hall, per Hon Mr Justice Geoffrey Valenzia, 11 October 2002.

parties involved asked for such assistance. This situation for example arose in *Frankie u Sonja konjuġi Zerafa v. Olga Avramov, et,* [151] where the plaintiff claimed damages resulting from a failed sterilization performed during a caesarean section. The lack of use of Court expert assistance is difficult to explain unless both parties as well as the Court assumed a case of res ipsa loquitor. This was hardly the case for, in fact, the Court ruled for the defendant.

However, such a case cannot by any means be truly equated with a forgotten swab or instrument in an abdomen for many scientifically long-established factors may be operative in such cases. The situation calls for definite expert evaluation of a number of SOC parameters which require analysis and must be explained to the Court. Thus, as an example, since the case here involved a partial resection of the fallopian tubes, the expert would want as a *basic preliminary* to confirm that this was in fact done by reviewing the histopathological report of the excised fallopian tube sections. He would also want to ascertain if there had been adequate pre-surgical assessment of risk factors which may increase the chance of failure of the sterilisation, and if these risks had been divulged at all and adequately explained to the patient. The actual surgical technique of partial tubal excision and suturing is of extreme importance and requires peer expert assessment. Having stated all this, one must also add that the Court's final conclusion would not have been different to the one reached. However, this would still not eliminate the need for an expert for although all roads may lead to Rome, not all are safe and recommendable.

[151] *Frankie u Sonja konjugi Zerafa et v. Olga Avramov et,* Qorti Ċivili, Prim' Awla, Onor. Imħ. Dr Joseph Azzopardi, Rikors Ġuramentat Nru. 1000/2002, deċ. 30/01/2006.

There are three factors which are likely to deliver the optimal obstetric expert opinion to assist the Court in a case such as that of *Frankie u Sonja Zerafa*[152]. One is the establishing of an effective selection method of an appropriate Court expert instead of the present system based on a random and blind procedure. The second is the proper schooling of such a Court expert to deliver an organised, structured and systematic opinion which will both benefit the Court's scientific understanding as well as diminish the expert's burden.[153] The third point will involve the implementing of the much needed medical law which improves expert evidence firstly through establishing official guidelines to enable the formulation of requisite and appropriate SOC. All expert reasoning should be simplified as much as possible to allow the Court to understand it and easily follow and evaluate its logic.

2.3. Echoes of Bolitho: logic rules

The often repeated quotation in many local Court cases stressing that lack of logic of the expert's report may be one of the reasons for its rejection is most reminiscent of the British Bolitho test or principle,[154] which must itself be evaluated as a secondary principle linked to the Bolam principle.[155] Both principles emanated from important English tort law cases which have landmark status. The best known by most is the Bolam principle which, since 1957, has provided the backbone of establishing the SOC in British jurisprudential cases dealing with claims of medical negligence. This

[152] See note 151.

[153] Baskind E.The Expert Witness in England and Wales: The End of the 'Hired Gun'? An English Perspective', International Review of Law Computers & Technology.21 July 2010; 15(2):229 -246.

[154] *Bolitho v. City and Hackney Health Authority* [1996] 4 All ER 771.

[155] See note 61.

principle needs to be examined in some detail for at least three reasons. The first is Bolam's established and unequalled importance in UK jurisprudence for more than six decades in spite of much querying of its prerogative as a tool of delivering justice. The second is the illustration of the UK's evolving capacity in medical jurisprudence as evidenced by its 2015 ruling involving Bolam in *Montgomery v. Lanarkshire Health Board*[156] as discussed in Section 4.3.1. In *Montgomery,* the UK High Court swept away the use of Bolam as applied to disclosure (but not as regards diagnosis and treatment). Finally, Bolam may be one of the potential instruments which should be available locally in establishing the SOC in Maltese jurisprudence, as proposed in Section 5.3 of the Lex Medica. Having said all this, in spite of its historical pedigree and further egged on by its diminished post-2015 status, Bolam's law is in the cross-hairs of many who hope for its complete elimination in order to remove all confraternal setting of standards of care by doctors for doctors.

The case *Bolam v. Friern Hospital Management Committee* concerned a claim for compensation brought forward by Mr John Hector Bolam, a victim of severe depression. His condition had led to his invalidation out of the Royal Engineers in 1942, with his mental problems escalating further to lead to an attempted suicide in 1954.[157] He was offered electro-convulsive therapy (ECT) at Friern Hospital by a consultant psychiatrist and he entered hospital on a voluntary basis, signing the required consent form. This was 1957 and such a consent must not be judged with a 2019 vision. However, no details of potential harm or other complications were discussed with John Bolam. The concept of patient's autonomy was then virtually non-existent.

[156] See note 103.

[157] A responsible body of medical men. The Business of Discovery. 2017 September 28.

Furthermore, it was a period of time when the doctor informed the patient, what the doctor felt ought to be informed, lest fear of treatment dissuaded the patient from the necessary treatment.

The first ECT course had no effect but during the second course of treatment, the patient, on experiencing the jolting effects induced by the electricity, fell off the treatment couch. He had been lying in a supine position with a pillow placed under his back, his chin supported and a gag in his mouth, but otherwise his body was completely unrestrained. No anaesthesia or muscle relaxants had been administered to him. Although the method used on John Bolam was even then beginning to lose popularity, it was formally recognised and the management by no means innovative.The fall suffered by Mr Bolam was a serious one, dislocating both hip joints with bilateral pelvic fractures resulting from the impingement of both femoral heads through the ipsilateral acetabulae and fracturing them. Claiming compensation for his extensive damages, Mr Bolam contended that he had not been warned of the small (1:10,000) but well-recognized risk of fractures, six cases of which had in fact occurred in the very same hospital.

Bolam's claim centred on three main points:

I. He was not administered muscle relaxants;
II. He was never strapped to prevent a fall;
III. He had not been warned him about possible side effects of the treatment.

The defendants' argument held that the technique of leaving the limbs free during ECT was a recognised method in force since 1951, while the risk of fracture by omitting muscle relaxants was minimal. Regarding disclosure, the defendants argued that divulging the full details of the risks involved was likely to put the patient off treatment. Bolam's needs at that period in time required ECT and no aspect of disclosure should have jeopardised such treatment.

Mr Justice McNair putting forward the historical dictum, which would guide medical jurisprudence for the next six decades, declaring that:

A doctor is not guilty of negligence if he has acted in accordance with a practice accepted as proper by a responsible body of medical men skilled in that particular art.

… Putting it the other way round, a doctor is not negligent if he is acting in accordance with such a practice, merely because there is a body of opinion that takes a contrary view.

Applying this principle, the jury found for the defendants. Bolam's principle or the Bolam test was born and it would be eventually separately upheld by the House of Lords for disclosure, diagnosis and treatment. Bolam's prerogative in disclosure was challenged and defeated in the 2015 in *Montgomery.*[158] However, Bolam still rules as regards cases involving negligence in diagnosis and treatment.

[158] See note 103.

The Bolitho principle must be viewed in the light of the Bolam principle, which it qualifies or to use a commonly held expression 'reins it in'. The principle emanates from *Bolitho v. City and Hackney Health Authority,*[159] another English tort law case of landmark status. It occurred thirty-nine years after *Bolam,* and the Bolitho principle's qualifying of Bolam[160] would become widely considered as setting any jurisprudence based on Bolam on a much surer footing.

The case revolved around the death of Patrick Bolitho, a two-year old boy suffering from croup and admitted to St Bartholomew's Hospital under Dr Horn's care. He experienced two episodes of respiratory distress, after each of which he recovered very well. After a third episode, he suffered a combination of respiratory arrest and cardiac arrest, from which he was resuscitated but suffered brain damage and later died. His mother sued the local health authority for negligence and the health authority admitted a breach of the SOC by Dr Horn who did not attend the resuscitation as her pager had malfunctioned. However, Dr Horn was not going to take the accusation lying down. She ably argued in Court that in this particular case, even if she had been near the child, she still would not have intubated him. This reply caused some confusion and the judge, Mr Justice Hutchison asked for a panel of eight medical experts to testify. While five stated that they would have intubated after the second episode of respiratory distress, three others disagreed. All agreed that such intubation was not a routine procedure and in a young child, it would have involved anaesthesia – a major invasive undertaking with its own morbidity and mortality. The judge felt that the expert evidence of the

[159] See note 154.

[160] Bolam refers to the principle while *Bolam* refers to the tort case *Bolam v. Friern Hospital Management Committee.* The same applies to the use Bolitho and *Bolitho.*

minority three which was neither illogical nor unreasonable also made sense once explained and was therefore not to be dismissed.

Bolam was fulfilled in that the supporting opinion of a group responsible body of medical men concurred with the defendant's management. Furthermore, this expressed medical opinion was neither "unreasonable" nor "illogical". The Bolitho principle was now born as a qualifying dictum of the Bolam principle. Bolam's group of responsible medical men could not make *any* statement to support the defendant's SOC. They could not for example state that method X can raise the dead, and still fulfil Bolam's law. The Court must find *logic* in the explanations forwarded to fulfil Bolam's criteria. Bolam had been raised a step up in assisting the Court establishing the SOC in any particular action or omission-alleged to be negligent.

The opening quote from *Gambina,* and its reference to the "expert's illogical conclusions" resonates in clear concordance with Bolitho's modification of the Bolam principle:

il-Qorti għandha biss tiskartah meta l-konklużjonijiet raġġunti jidhru fiċ-ċirkostanzi tal-każ bħala irraġonevoli. Tali konvinzjoni trid tkun ibbażata fuq ir-raġuni li jpoġġi fid-dubju l-opinjoni teknika.

Court should only discard it when its conclusions, within the circumstances of the case, appear illogical. Such a conviction must be based on the reason which puts the medical opinion in doubt.

However, there are crucial differences which must be highlighted at this juncture. *Gambina's* Court pertinent reference to illogical reasoning as a criterion of expert evidence rejection was a subjective reflection, even if this principle is frequently encountered in local Court cases where an expert's assistance is sought in any genre or nature of case, be it medical or otherwise. In contrast the Bolam and Bolitho's principles are "cast in stone" principles in the UK's system of medical law which have been officially guiding medical jurisprudence since 1957 and 1996 respectively. Also, *Gambina* observation belongs to Maltese case law while Bolitho's logic hides a whole lore of medico-legal principles well-honed into practical application by a judiciary well versed into the use, misuse, advantages and abuses of principles which are forever evolving as shown by the 2015 *Montgomery* part rejection of Bolam. There *is* a difference between the use of logic in accepting or rejecting expert evidence in Malta and the UK's reasoning, with the Maltese use referring to the Court expert's opinion, whereas Bolitho's original logic refers to a much broader peer opinion as a basis of establishing the validity at law of the defendant's SOC.

2.4 Guidance for the expert: Comparing the local with overseas scenarios

The evidence delivered by the obstetric or any other Court expert is more than a simple expressed medical opinion as delivered in a medical forum or even as a professional but non-expert opinion in a Court of law. Although the basic medical and scientific conclusions may be synonymous, the obstetric expert must translocate the scientific facts from the textbook to the reality and practicality of an applied case, framing the action within the circumstances and the parameters of the particular SOC. This is one argument that substantiates the argument that, irrespective of the status, hierarchy and

ipse dixit in his specialty, the obstetric and other expert still requires particular schooling as well as the direction of officially organised guidelines.

In the UK, the obstetric Court expert does not wake up in the morning and instead of attending labour ward heads out to Court for the day. He may be a star obstetrician but for Court his evidence must be subject to rule and regulation. Although not universally so, such experts have undergone exacting courses which present the multi-faceted aspects of the subject, as well as provide a grounding in the relevant aspects of the law. With regard to specific guidelines, the obstetric expert has a great wealth of direction commencing from the very moment of receiving his letter of appointment. Much can be absorbed with advantage from such a system to standardise the whole subject of the Maltese Court expert which is still well-nigh virgin territory.

Whereas in Section 2.2, reference has been made to the need and requirements of the Court's reception and acceptance of the expert evidence, we refer here to the need of the necessary schooling of the expert witness. The Maltese expert is hardly provided with any guidance, save what lies in articles 644 to 682 of the Maltese Code of Organisation and Civil Procedure, Chapter 12 of the Laws of Malta. These contain many details concerning time limits of reports, expert remuneration and its taxation, etc.; but hardly anything resembling even the basics of a proper code of guidance equivalent to for example, the Civil Procedure Rules of the UK.[161] As an example, reference is here made to article 645 of the Maltese code, the contents of which clearly

[161] Civil Procedure Rules. UK Ministry of Justice. 109th Update – Practice Direction Amendments. 1st October Effective from 1st October 2019.

have their relevance but not in the sense of specific expert guidance as is found in the Civil Procedure Rules of the UK. Thus, local article 645 provides that:

(1) The Court shall not appoint a referee solely for the purpose of examining witnesses on oath and taking down their depositions in writing and establishing the relevant facts.

(2) In the decree appointing the referee, the Court shall –

(a) State the object of the reference;

(b) Fix the day and time when the referee is to conduct an inspection in faciem loci where necessary;

(c) Give directions for the guidance of the referee in the execution of his task.

(3) The Court may, at any time, at the request of the registrar or on its own motion, order the referee to return the records of the cause that are in his possession, to the registrar there to remain for such time as shall be specified in that order. In case of noncompliance with the court's order, the referee shall without prejudice to any other proceedings which may be instituted against him, be guilty of contempt of court.

(4) The Court may order the referee to attend for the hearing of the trial and to put to the witnesses any questions he may deem necessary or relevant to enable him to complete his report.

(5) Where affidavits have been filed in the registry of the court, the referee shall be served with a copy of such affidavits before the hearing.

One notes that in Article 645 (c), directions to the expert are alluded to but essentially none exist. By sharp contrast, overseas legislations as exemplified by those of the UK, USA and Canada provide a super abundance of guidelines, not rarely repeating themselves, about acceptance of appointment, ethical behaviour, potential pitfalls, mistakes and even conscious Court misdirection. Thus, in England and Wales, the Civil Justice Council publishes the Protocol for the Instruction of Experts[162] to give evidence in civil claims[163] offering official guidance to experts in the interpretation of, and in compliance with, Part 35 of the Civil Procedure Rules (CPR 35) and its associated Practice Direction (PD 35). It contains 24 pages packed with clear and simplified instructions spread over 19 sections and dealing with not only the expert's duty, but his appointment, the instructions issued to him by the Court, his acceptance and withdrawal, his right to ask for Court directions as well details on writing and amending reports and the procedure of dealing with written questions.

In addition to directions related to official Civil Procedure Rules, the UK obstetric expert will also find two different sources of direction, pertaining to evidence he will give in his line of profession. Thus, as a medical doctor he will find direction pertaining to the giving of medical evidence witness emanating from the BMA[164] as well as from the GMC.[165] The latter encapsulated much of the lessons learnt from the affair of Sir Roy Meadow in the Sally Clark case, discussed in section 2.8.1, and aimed at

[162] Protocol for the Instruction of Experts to give Evidence in Civil Claims. Civil Justice Council. June 2005.

[163] This replaces the old Code of Guidance on Expert Evidence.

[164] British Medical Association expert witness guidance October 2007.

[165]Acting as a witness in legal proceedings. Ethical Guidance. General Medical Council.

safeguarding the expert from infraction of professional ethics. On a similarly advisory and equivalent basis but aimed for the obstetrician, the ACOG issues the handbook of medical litigation, prepared by the ACOG's Ethics Committee on Expert Testimony[166] and first published in 2007. However, even decades before this publication, the ACOG had issued regular and formal guidelines for American obstetric Court experts. The RCOG does not publish a similar handbook, but is not short on ethical and legal advice both regarding individual clinical topics as well as the more generally directed Core Module on Ethics and Legal Issues.[167] Although both British and American guidelines will have some sections of relevance only applicable to their respective countries, the general advice is applicable anywhere and has been used as a basis for proposals relating to the subject in the proposed Lex Medica.

2.4.1 Birth and evolution of expert testimony in the UK

For a jurisdiction such as Malta's where a legal hiatus of expert witness regulation and direction is overtly present, it is both interesting and instructive to retrace the evolutionary steps of the subject in a jurisdiction abundantly endowed with a rich history of medico-legal litigation such as that of the UK's.

In the local scene, once the obstetric Court expert has been appointed, no further Court instruction is generally forthcoming. The expert stands on his ipse dixit, merited or not, and attains the status of a demi-god as long as Court does accept his opinion and his opinion speaks for the science of obstetrics. In most other countries, both the expert's

[166] Expert testimony. ACOG Committee Opinion No. 374. American College of Obstetricians and Gynecologists. Obstet Gynecol 2007;110:445–6.

[167] Medical leadership framework competence. Core Module 4. Ethics and Legal Issues. RCOG.

standing, qualifications and experience are scrutinised, and his evidence is closely regulated all of which has a long evolutionary history. Although as regards medical and obstetric guidelines, both the U.K.'s and the U.S.A.'s wealth is freely borrowed, it is the British evolution of expert testimony which is mostly referred to here. Before proceeding with a consideration of this evolution, it is important to consider the two existent Court systems, namely the Adversarial (accusatorial) and the Inquisitorial, an unfortunate name with many unhappy archetypal connotations.

Malta operates the Adversarial system, which is also used by the UK, the USA and indeed by most of the English-based Court systems such as Canada and Australia. In this system, the Court has the facts of the case presented to it and then allows both sides to parry arguments defending their sides. The Court, in the form of a judge or magistrate, is passive in hearing the arguments which must be developed by the two sides. The Court's role comes in deciding the issue of guilt or otherwise, until which time the accused is presumed innocent. The Inquisitorial system is favoured by countries such as France, Germany and Italy, and numerous African, South American, and Asian countries. In this system, the Court *actively* seeks the truth and intervenes to draw out the facts itself from both parties. The Court participates actively in seeking to draw out the facts and establish the truth of the presented situation. It questions the parties and all witnesses although it does not seek to displace the role of the advocate. However, the latter's questioning is secondary to the Court's. The actual details of the process may vary from jurisdiction to jurisdiction, but as a rule, in direct contrast to the Adversarial system, the accused may not be presumed innocent.

In addition to the sharing of the Adversarial system with the UK, Maltese jurisprudence not rarely borrows from principles and case law from the British Courts. Although the Italian jurisprudence lends itself extensively locally with regard to legal principles, the different Court systems render Italian case law potentially less amenable to local use and this is probably well exemplified in obstetric and medical cases. Although Malta does have its own codified civil and criminal laws,[168] the borrowing from British Court rulings lends support to the heavy influence of British (and some American) influence on the use of expert direction in the Lex Medica. These differences must be borne in mind in evaluating the evolution of the British expert evidence.

2.4.1.1 From Folkes to the Ikarian Reefer

Until the late eighteenth century, the English Court system only allowed Court summoned expert witnesses to assist with its deliberation and conclusions. This prevailed until the 1782 landmark case *Folkes v. Chadd,*[169] The introduction of partisan expert witnesses in this case heralded an unstoppable wave of similar experts, a move which eventually became prey to various abuses.[170] The ever increasing scientific progress made the need of such experts indispensable and along with this need, there grew the abuses of expert witnesses including the naming their price along with much erosion of the Court's confidence.[171] Even so their supremacy was more or less

[168] A legacy of the short but dynamic French rule at the end of the 18th century.

[169] *Folkes v. Chadd,* (1782) 99 Eng. Rep. 589, 590 (K.B.).

[170] Milroy C. A Brief History of the Expert Witness. Academic Forensic Pathology. 2017 Dec 1; 7(4): 516-526.

[171] See note 170.

unchecked and although it was universally acknowledged that some form of practical control was imperative, this would not be achieved before the famous 1993 case known as *The Ikarian Reefer*.[172] This case would provide the opportune show-down between Court and the expert witness by bringing to the fore the fact that the object of all evidence, including partisan expert evidence is to help the Court uncover the truth.

The Ikarian Reefer refers to the landmark insurance case *National Justice Compania Naviera SA v. Prudential Assurance Co ltd* which dealt with the loss of the vessel called *The Ikarian Reefer*. This ship was a part of the shipping empire held by the Comninos brothers (Costas and Anthony) that had been insured against inter alia perils of the sea, fire and battery and was valued at US $3 million. On 12 April 1985, disaster struck the ship as it sailed from Kiel to Abidjan, and at 23.00hrs, it ran aground off the Sherbro Island in Sierra Leone. Within a couple of hours, the ship was engulfed in flames after an engine room fire broke out and rapidly spread out forcing the crew to abandon ship.

Lloyds claimed that the loss was deliberate and in an ensuing Court case, the Court ruled for the Comninos brothers. In the appeal case, which would eventually overturn the lower Court's decision, Lloyds, argued that the whole story was a deliberate ploy to get rid of a ship which was under pressure of being scuttled. They maintained that both the running aground and the fire were all planned and executed purposefully. The case called for eight expert witnesses. It soon became clear to the judge Cresswell J, that the concept of the Court expert was misunderstood and was being grossly abused.

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[172] *National Justice Compania Naviera SA v. Prudential Assurance Co ltd (The "Ikarian Reefer*"). Court of Appeal(Civil Division). [1995] 1 Lloyd's Rep 455.

Clear guidelines were needed to light the way. His immortalised[173] enunciations, known as the Cresswell Principles stated:

I. An expert witness should provide independent assistance to the court by way of objective, unbiased opinion in relation to matters within his expertise.

II. An expert witness in the High Court should never assume the role of an advocate.

III. An expert witness should state the facts or assumptions upon which his opinion is based. He should not omit to consider material facts that could detract from his concluded opinion.

IV. An expert witness should make it clear when a particular question or issue falls outside his expertise.

V. If an expert's opinion is not properly researched because he considers that insufficient data is available, then this must be stated with an indication that the opinion is no more than a provisional one.

VI. In cases where an expert witness, who has prepared a report, could not assert that the report contained the truth, the whole truth and nothing but the truth without some qualification, that qualification should be stated in the report.

VII. If, after exchange of reports, an expert witness changes his view on a material matter having read the other side's expert's report (or for any other reason), such change of view should be communicated (through legal representatives) to the other side without delay and, when appropriate, to the court.

[173] Factsheet 4: The Cresswell Principles of Expert Evidence. Expert Support Services from the UK Register of Expert Witnesses. Last updated: 21 July 2000.

VIII. Where expert evidence refers to photographs, plans, calculations, analyses, measurements, survey reports or other similar documents, these must be provided to the opposite party at the same time as the exchange of reports.

In this day and age, any expert witness can learn of his duties and responsibilities simply by referring to the Guidance for the instruction of experts in civil claims.[174] However, the Cresswell Principles were not only ground-breaking and pioneering material in a subject which had resisted both control and guidance, but are still of intrinsic value to this day and age. Not only were these principles endorsed by the Court of Appeal, but they also impressed and inspired Lord Woolf, the Presiding Officer of the Civil Division of the Court of Appeal in his own future enunciations of the duties of the expert witness.

Although not universally embraced, these principles gathered immense professional admiration and have been cited in numerous Court cases.[175] Furthermore, the version amplified by the much-respected Lord Woolf were also updated in 2000 by Toulmin J[176] as follows:

Court expert witnesses:

I. Owe a duty to exercise reasonable skill and care to those instructing.

[174] Guidance for the instruction of experts in civil claims. Civil Justice Council. June 2005.

[175] See note 173.

[176] *Ibid.*

II. Owe a duty to comply with any relevant professional code of ethics.

III. Have an overriding duty to help the court in matters within their expertise, which duty overrides any obligations to the person instructing them or paying them. This applies to experts brought forward by plaintiff or defendant.[177]

IV. Have a duty to act objectively and this does not imply acting as mediators between the parties or trespassing on the rights and duties of the Court.

V. Should confine their opinions to matters which are material to the disputes between the parties.

VI. Should provide opinions only in relation to matters which lie within their expertise and should indicate without delay where particular questions or issues fall outside their expertise.

VII. Should take into account all material facts before them at the time that they give their opinion.

VIII. Should state any literature or any other material[178] on which they have relied in forming their opinions.

IX. Should indicate if their opinion is provisional, qualified, or requires further information or even cannot be expressed finally and without qualification.

X. Should inform those instructing them without delay of any change in their opinions on any material matter and the reason for it.

XI. Should be aware that any failure by them to comply with the Civil Procedure Rules or Court orders or any excessive delay for which they are responsible may result in the parties who instructed them being penalised in costs and even, in

[177] Known as ex parte experts.

[178] Such material is technically hearsay but is admissible in helping the expert form his opinion see *R v. Abadom* 1 All ER 364: English Exporters (London) Ltd. V. Eldonwall Ltd [1973] Ch 415.

extreme cases, being debarred from placing the experts' evidence before the court.

It is worth noting that the British Court ruling in *The Ikarian Reefer* and Lord Woolf's dicta on the duties of a Court expert and their Toulmin amplification are essentially complete as they stand. Even so the subject keeps re-appearing under various new guises and enactments which unfortunately often add little or nothing new to the original foundations.

Lord Woolf's law reform-the sixty-third one following a hundred-year old gap[179] included an enlightened reshuffle of direction to the Court witness. The Lord of the Rolls sought the amendment of a civil system in which the expert would offer the Court more practical and streamlined service which required less time and hence cost less.[180] Although Lord Woolf accepted the unavoidable necessity of the Court expert, he identified the related potential associated disadvantages and their hampering instead of aiding the Court process. He specifically identified that besides being often inappropriate and excessively involved at exorbitant payments, such experts were at times also holding up the Courts through their unavailability. More worryingly they owed their allegiance to whoever paid them. Lord Woolf unearthed other even more worrying habits involving various judges' discretion of deciding the actual stages in the Court process when expert evidence was to be given and whether it was to be in an oral or written form. Furthermore, abuse and confusion ruled as to who paid experts and a there was also a worrying and increasing habit of

[179] Elliott C, Quinn F. The English Legal System. Pearson Education Limited; 2009.

[180] Peysner J, Seneviratne M. The Management of Civil Cases: A Snapshot. Civil Justice Quarterly.2006 July;25:312-326.

…claimants who generally suggested experts to defendants, often at the pre-action protocol stage, who were likely to be acceptable, so they became, in effect, joint experts by default.

Although championing the dictum that *the days of the "hired gun" are largely over*, Lord Woolf realising the difficulty of eliminating the partisan expert, sought a compromise through the creation of a single expert whose allegiance was purely to the Court.[181] While criticising certain aspects of the judiciary's behaviour, the reformer also strengthened the judiciary's arm within the tenets of the Adversarial Court system. He empowered judges in dealing with the game of ever-increasing expert supremacy, instructing them to restrict the use of expert evidence[182] and resolving unsolvable expert arguments with a single joint expert opinion.

Lord Woolf's advice and dicta were not cast in stone and one cannot say that all his advice would be faithfully followed up. However, his attempt did set a milestone in Court expert reform. Some of his express wishes never materialised, a cardinal one being his wish for the Court to diminish the use of experts. Trials involving the use of experts have not only not diminished but are clearly on the increase,[183] which is hardly surprising with the ever-increasing pace of science in all spheres. However, Lord Woolf's effort to curb abuse at both individual and institutional level did pay many dividends. Furthermore, a number of lessons originally emanating from *The Ikarian*

[181] Zander M. Cases and material on the English Legal System. Cambridge University Press, 2007.

[182] *Daniels v. Walker* (2000) 1 WLR 1382.

[183] UK Register of Expert Witnesses. Across Europe. Survey 2019.

Reefer highlighted by Cresswell and further strengthened by Woolf are now indeed set in stone and part and parcel of the UK Civil Procedure Rules. Two fundamental and crucially important principles stand out most prominently: the stressing of the expert's competence, and the closely guarded holy of holies of requisites, namely that of absolute Court allegiance.

2.4.2 On proposing local guidelines for the Court expert in the Maltese Court

The evolution of control of and direction to the Court expert, incubated for centuries and born in the twentieth century, should be one source of light directing the local expert. All necessary practical guidance is also available in the UK Civil Procedure Rules, both generally as well as regards to his competence in his specialty. Thus, while warning of the expected Court allegiance, the Rules also admonishes the expert of competence in his specialty, whatever it may be. As matters stand, in the absence of organised and official local direction, the Maltese Court expert can still, with immediate effect, seek direction from this source at his own initiative. This not only does not diminish the legislator's responsibility from such a task but, in effect, it increases the onus of responsibility pertaining to this deficiency.

There are other UK sources of guidance which the Maltese obstetric expert can refer to with great advantage while the local hiatus lasts. Thus, the already referred to GMC guidelines[184] offer invaluable advice. These range from emphasising one's duty to Court to the importance of impartiality, honesty, competence, to mundane matters such

[184] Doctors giving evidence in Court. Ethical Guidance. General Medical Council. 2019.

as punctuality and the adherence to Court timescales. The BMA's input[185] concurs with direction and advice from other sources but stresses such particular aspects as the writing of the expert's report. Furthermore, the BMA also publishes extensive on-line for any of its members who are interested in pursuing UK courses leading to work in the medico-legal field including that of Court expert witnesses. Needless to say, obstetric College guidance will focus on more medically specialized fields which are of specific concern to the obstetric expert. In the RCOG much crucially important clinical advice lies within its official green top guidelines and such advice is not necessarily labelled as medico-legal or as obstetric expert material. It forms a crucial basis of the latest officially accepted teachings related to obstetric practice in the UK as embraced by the RCOG and as such yields its own weighting in establishing the Court's SOC. College guidelines were certainly among the guiding lights in the preparing and finalising the expert's report in the *Gambina* case. The previously mentioned ACOG's guidance tends to concentrate in its handbook on general ethical principles and guidelines, while also discussing contemporary views and needs, as well as changes in laws, statutes and the wisdom of case law rulings.

There is little doubt, that the local obstetric expert will encounter challenges peculiar to the local scene. Foreign guidelines do much in the way of enlightening the way of the Maltese obstetric expert seeking guidance to perform his job conscientiously but are not tailor made for Maltese requirements. There are always local difficulties which no foreign advice may completely fathom. Indeed, there are challenges which even local awareness still fails to offer a solution for. Thus, sub-section VIII of the proposed Lex Medica (section 4.1.6.), demands as expected, complete objectivity and impartiality in

[185] British Medical Association expert witness guidance October 2007.

the expert's discharging of his Court duty. This is clear, self-explanatory and applies to universal justice. A British gynaecologist may read this guideline and move on. The sincere Maltese obstetrician may pause and reflect on the potential difficulty of imparting objective and impartial testimony in an island with a population of 433,168 souls, living in a total area of 316km.[2] The defendant obstetrician will be definitely known to the Court expert and more than likely work at MDH with him, while the plaintiff herself may easily have been a past patient with happy or sad connotations for either or both of them. Having said all this, one must be prepared to judge actions along a professionally established SOC, and like Lady Justice be blind to all else. Major specific difficulty in attaining impartiality, since we are all human, must be divulged to the Court.

There are a number of other guidelines pertaining to the obstetric expert in the Lex Medica which may be briefly reviewed at this juncture. Thus, the expert must have the knowledge and the experience concerning the matter in front of the Court. However, he must also guard against the blind faith which the Maltese Court tends to show in its chosen experts. The expert must make clear to the Maltese Court his limitations where this is called for. In countries such as the UK where the GMC recognizes various obstetric sub-specialisations, the argument is easier to drive home. A UK Court case involving allegations of ultra-sound negligence in an obstetric case is likely to have as a Court expert a qualified obstetric ultra-sonographer. These sub-specialisations do not exist in Malta as is evident from the perusal of the annual medical register. There may be local obstetricians with a particular interest in a sub-speciality such as feto-maternal medicine, infertility, and so on. Such interests may lead to a greater experience in the subject, but this is not synonymous with being a sub-specialist which in the UK and

elsewhere, demands an officially structured training course leading to a formal recognition as a sub-specialist. The Maltese Medical Council does not currently, as yet, recognise the existence of obstetric sub-specialisation.

This reasoning brings us to square one and the local meaning of the word *requisite knowledge.* As matters stand, only the appointed expert knows if the specific knowledge and experience demanded by a specific Court case falls within his province of knowledge and experience. Only he knows if he has the requisite knowledge to advise Court on technical matters involving say intra-partum CTG monitoring, doppler values or ultra-sound scanning. This places further importance on forwarding clear information in the initial letter appointing the obstetrician as an expert to a particular case, as discussed in section 2.10.

It is also important to crystallise the essential hallmark of the desired knowledge, namely that which is evidence-based and updated along the latest published knowledge as directed by such professional authorities as the RCOG or equivalent European bodies. The habit of using such subjective terms as 'secundum artem' must be avoided or used only in limited, precise and clearly defined fashion e.g. *"the use of forceps traction along the pelvic axis secundum arterm*". Otherwise, such terms may mean all things to all men and may end up reflecting anyone's subjective concepts. With the use of updated evidence-based obstetric knowledge, the expert is hardly likely to veer outside the correct path in establishing the correct and justified SOC. Even in the present state of local deficiency in SOC direction, the individual expert by meticulous adherence to such evidence-based science, may, as but one cog in a whole machinery, help justice move in the right and updated direction.

By contrast, the expert must also be wise enough to remember and, where necessary, stress to the Court that obstetric practice which does not follow official guidelines is not necessarily and automatically in breach of the SOC. Guideline breach and a resultant inadvertent clinical outcome does not necessarily spell malpractice causality. This is intimately linked to the exhortation to the expert that he is obliged to examine all the facts pertaining to the case at hand not excluding the defendant's own reasoning at the time of action or omission. And having examined all the available facts, including the defendant obstetrician's evidence pertaining to his clinical reasoning at the time, the expert may conclude that an official guideline was not followed for a most justifiable reason. The expert is also obliged to distinguish between malpractice and maloccurrence, which may result, for example, from a complication which the defendant took all measures to prevent and may have even possibly warned the patient about.

2.5 Ensuring a well updated obstetric Court expert

The need for the expert obstetrician to be well-updated has been repeatedly made, and it attains a much graver responsibility in Malta where no established system ensures such academic preparedness. In the present local scenario, it is far from impossible for the Court to appoint an obstetrician who may be well known to society but has not kept himself updated. Even if an obstetrician is generally sufficiently well informed as to the progress of his profession, he will always be duty bound to leave no stone unturned to ascertain the latest official views pertaining to the case he is assisting the Court with. He must also remember that it was the state of knowledge pertaining to the period of

occurrence of the case that he must apply to formulate the necessary SOC and not the time of the Court hearing. The current lack of need for Continuing Medical Education as a requisite for yearly registration in one's specialty requires greater self-discipline efforts for the expert to update himself as required. The following are all beneficial in such updating.

Books

These are often maligned as being out of date by the time they are in print.[186] Generally speaking, aspects such as biochemistry and physiology may have undergone substantial changes even within a few years, but, generally most books published within the last five years may have valuable material to offer especially if updated by relevant journals and professional guidelines where necessary. One notes here that such guidelines may not be necessarily issued by Colleges but also by relevant professional bodies.

Journals

It is probably not incorrect to state that an obstetric expert cannot conscientiously finalise his opinion without an intensive search of peer-reviewed articles on the subject. Journals publishing articles for or against interventions as based on randomised controlled trials (ideally meta-analysis of such trials)- are the ideal journals to refer to. It is wise to download or photocopy such articles and categorise them carefully in case the source of the quoted information is challenged in Court.

[186]Talaulikar V, Nagarsekar U..Evidence-Based Medicine: An Obstetrician and Gynaecologist's Perspective. The Journal of Obstetrics and Gynaecology of India. 2012 April; 62(2):146-153.

Official guidelines

These include those published by the RCOG, ACOG, NICE, BMA, UK Civil Procedural Rules. In this aspect, where obstetric (medical) guidelines are concerned, the Maltese expert must keep an open mind and not be limited to guidelines necessarily issued by Colleges or those employed solely by the UK. Guidelines from relevant associations and bodies such as WHO may be much more relevant than any nationally issued directives.

Internet searches

This must be limited to official sites especially academic databases such as PubMed (www.ncbi.nlm.nih.gov/pubmed), Ovid (ovidsp.ovid.com), Cochrane (www.cochrane.org or www.thecochranelibrary.com), CDC (www.cdc.gov), WHO (www.who.int), ACP Journal club (www.acpjc.org), NHS Evidence (www. evidence.nhs.uk), Google scholar (scholar.google.com), and Web of Science/Knowledge (wok.mimas.ac.uk).

2.6 Conflict of interest

Conflict of interest, particularly undeclared and unknown to the Court, is a potential universal problem in obtaining an impartial opinion from a Court expert. On the other hand, it is not rare for the losing party at Court to assume conflict of interest where none exists. In *Toth v. Jarma,*[187] decided by the UK Court of Appeal, the appellant's

[187] *Toth v. Jarman* (2006) EWCA Civ 1028.

complaint centred on the fact that the medical expert was a member of the Cases Committee of the Medical Defence Union. Although the Court rejected this argument, it issued useful guidance for future cases declaring that:

The expert should not leave undisclosed any conflict of interest which might bring into question the suitability of his evidence as the basis for the court's decision. The conflict of interest could be of any kind, including a financial interest, a personal connection, or an obligation, for example, as a member or officer of some other body. But ultimately, the question of what conflicts of interest fall within this description is a question for the court, taking into account all the circumstances of the case. Without wishing to be over-prescriptive or to limit consideration by the Civil Procedure Rules Committee, we are of the view that consideration should be given to requiring an expert to make a statement at the end of his report on the following lines:

(a) that he has no conflict of interest of any kind, other than any which he has disclosed in his report;

(b) that he does not consider that any interest which he has disclosed affects his suitability as an expert witness on any issue on which he has given evidence;

(c) that he will advise the party by whom he is instructed if, between the date of his report and the trial, there is any change in circumstances which affects his answers to (a) or (b) above.

Such a declaration regarding conflict of interest should be strongly considered to be included in the relevant part of the Maltese Code of Organisation and Civil Procedure dealing with Court experts and has been included in the proposed Lex Medica.

2.7 Court admissibility of the obstetric expert's evidence: the Frye Test

The Maltese Court, as stated repeatedly in many cases, will not normally discard expert evidence unless its conclusions are unreasonable or illogical or are challenged along such lines. This seems to be the only hurdle which the obstetric expert evidence must navigate. As stated before, the status and respectability of the obstetric expert may render any other challenge unthinkable. In the UK and the USA, however illustrious, eminent and well qualified the expert is, his evidence must be ruled as acceptable in Court. This precedes actual testimony and if such scrutiny of admissibility fails then the evidence will never appear in Court. Such admissibility of expert Court evidence has a long and colourful history, which we shall review here in reference to the USA with the unfurling of the subject taking place in 1923. No equivalent British history of evolution exists with regards to this aspect of expert testimony.

Frye v. United States[188] was the first case testing the Court's responsibility as to what is truly scientifically acceptable and what is not. This case was an appeal case by James Alphonzo Frye convicted of second-degree murder in Washington DC. The basis of the appeal was the trial Court's refusal to let Frye introduce the 'systolic blood pressure

[188] *Frye V. United States* 293 F. 1013 (D.C. Cir 1923).

test'[189] as well as an expert witness to describe the test's scientific background. The test was based on the notion that although any man would feel stressed on interrogation and hence experience a blood pressure rise, this would settle after some time in the non-lying man but not in the lying one who retains persistent mental stress and a higher blood pressure. The Appeal Court backed the decision of the lower Court stating that:

...the systolic blood pressure deception test has not yet gained such standing and scientific recognition among physiological and psychological authorities as would justify the courts in admitting expert testimony deduced from the discovery, development, and experiments thus far made.[190]

The Frye test or the general acceptance test, therefore, became a test for the admissibility of expert evidence stating that scientific tests quoted at Court must be generally accepted as reliable in the relevant scientific community. One of the major weaknesses of this test is that it tends to smother serious and genuine and promising research if still at that period of transition between the experimental and its acceptance by the scientific community at large.

2.7.1 Enter Daubert

The Frye test held sway for seventy years between 1923 and 1993. Despite many detractors, it was a step forward in the vetting of expert testimony which is crucially

[189] The rather coarse precursor of what would eventually develop into the modern polygraph or lie detector test.

[190] Criminal Law and Procedure: Evidence: Admissibility of Lie Detector Tests in Evidence. Michigan Law Review. 1939; 37(7): 1141-143.

important and may avoid the surfacing of such flaws mid-trial with a subsequent trial crisis. Even so, the Frye test only came into its own in the 1970's, especially in criminal cases and eventually settling in its defined role in civil cases and finding a particular sub-niche in tort cases dealing with toxicity.[191] In 1993, an interesting and unusual situation would arise where the Supreme Court of the USA would pit its Federal Rules of Evidence against the Frye test, originally born out of case law but with the qualification of seven decades of Court use. The amphitheatre for the encounter would be *Daubert v. Merrell Dow Pharmaceutica,*[192] a case of great human interest.

Daubert concerned a claim against the drug firm Dow Pharmaceuticals opened by the parents of two boys born with birth defects. The plaintiffs blamed the drug Bendectin for their children's deformities. Developed in the 1950's by William S. Merrell Company of Cincinnati, Ohio, and indicated for pregnancy-induced nausea and vomiting the widely used drug had been approved by the Food and Drug Agency (FDA) in 1956.[193] The drug, a combination of doxylamine,[194] dicyclomine,[195] and pyridoxine (Vitamin B6), marketed in the USA as Bendectin and as Debendox in the UK (in 1958) was considered as the only effective drug against the nausea of pregnancy and one time was even sold as an over-the-counter (OTC) medicine. It is thought that 33 million

[191] Cappellino A. Daubert vs. Frye: Navigating the Standards of Admissibility for Expert Testimony. The Expert Institute. 2018 Jul 17.
[192] *Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 509 U.S. 579 (1993).

[193] Bendectin: The Genesis. Public website.

[194] Doxylamine is a member of the ethanolamine class of antihistamines with marked anti-allergy properties.

[195] A member of a class of medications known as anticholinergics and used widely to treat irritable bowel syndrome by removing muscle spasm.

women were exposed to the drug.[196] Many anecdotal reports, especially in USA linked the drug to congenital malformations mostly relating to cleft lip/ palate[197] and limb anomalies. In the late 1970's and early 1980's, some published studies appeared to link Bendectin to Poland's syndrome,[198] pyloric stenosis,[199] and cleft lip and palate. Dicyclomine was removed from Bendectin.[200] However, in the absence of confirmation by large epidemiological studies, the FDA retained the drug on the market.

The *Daubert* parents claimed that their children's birth defects were due to Bendectin taken by their mothers in pregnancy.[201] Jason Daubert had been born with his right hand missing three fingers and a shortened right arm, while Eric Schuller was born missing a left hand and one partially shortened leg. The case opened in the California State Court was against Merrell Dow Pharmaceuticals Inc., a subsidiary of Dow Chemical Company. Merrell Dow removed the case to federal court, and then, on the basis of lack of existence of any serious published scientific study linking Bendectin to the alleged birth defect, they moved for summary judgement. However, Daubert and Schuller countered with results from serious animal in-vivo and pharmaceutical studies. The matter ended up at the United States Supreme Court,[202] which after the summary

[196] Orme ML. The debendox saga. Br Med J (Clin Res Ed). 1958 Oct 5; 291(6500):918-919.

[197] Defects related to formation of the lip and palate, separately or in conjunction with each other.

[198] A syndrome incorporating underdeveloped chest muscles and unilateral short webbed fingers at times also including breast and nipple anomalies, short ribs and absence of fat on the same side.

[199] A condition occurring between birth and 6 months of age in which recurrent forceful vomiting results from narrowing of the stomach outlet and requiring surgical correction.

[200] See note 196.

[201] Angier N. High Court to consider rules on use of scientific evidence. The New York Times. 1993 Jan 2.

[202] Supreme Court of the United States DAUBERT et ux., individually and as guardians ad litem for Daubert, et al. *v.* Merrell Dow Pharmaceuticals, Inc. Certiori to the United States of Appeals for the ninth circuit. No. 92-102. Argued March 30, 1993 -- Decided June 28, 1993.

judgement ruled for Merrell Dow on the arguments that the plaintiff's scientific data appeared to be in preparation for the purpose of litigation and had not yet been accepted as reliable by the general scientific body as demanded by the Frye test.

The issue at hand was wider than the potential teratogenicity of Bendectin, for it now involved the admissibility of scientific evidence. As the New York Times put it:

Now the United States Supreme Court has taken up the California case, Daubert v. Merrell Dow Pharmaceuticals, not to consider whether Bendectin causes birth defects but to tackle an issue with vast legal and ethical implications.[203]

The newspaper continued putting forward arguments which could have all applied to the *Frye* situation, fifty years previously:

The debate distils down to these questions: Who should decide when a scientific claim is legitimate enough to put before a jury in a civil or criminal case? Should a judge be able to exclude scientific testimony that the judge deems unorthodox, say, because the theory has not been published in a scientific journal? Or should any expert who holds so much as a master's degree in a specialty be able to testify on a theory that mainstream scientists would dismiss as wild speculation?

Technically, the answer lay in whether the Frye test would hold its own when put to the challenge.

[203] See note 201.

2.7.1.1 Out with the old, in with the new

The Supreme Court case of *Daubert* appeared before Judge Blackmun in 1993, eighteen years after Congress had adopted the Federal Rules of Evidence (FRE) in 1975. The FRE constitute a body of law comprising six rules specifically regulating the admissibility of expert witness into Federal Court.[204] Of cardinal importance for *Daubert* was rule 702 [205] (shortened to FRE 702) which states that:

(a) the expert's scientific, technical, or other specialized knowledge will help the trier of fact to understand the evidence or to determine a fact in issue;

(b) the testimony is based on sufficient facts or data;

(c) the testimony is the product of reliable principles and methods;

(d) the expert has reliably applied the principles and methods to the facts of the case.

The establishment of FRE 702 in 1975 heralded the death of the Frye test as the golden standard of defining what scientific evidence would be admissible in Court. In establishing FRE 702, Congress had smoothened Judge Blackmun's path in *Daubert.* The judge stressed that in a Federal Court, it was FRE and not Frye which determined scientific evidence admissibility. FRE 702 excluded Frye's criterion of "general acceptance" by the scientific community. Nonetheless FRE 702 still demanded a valid

[204] See note 192.

[205] Rule 702. Testimony by Expert Witnesses. Federal Rules of Evidence. Legal Information Institute. Cornell Law School.

connection of the evidence to the inquiry at hand if it were to be admissible after the Court accepted the scientific evidence following due assessment. This assessment included several criteria including its acceptance in the scientific community, the scientific validation of the underlying reasoning, its testing, whether subjected to peer review and publication, etc. Blackmun stressed the avoidance of Frye's rigid and uncompromising "general acceptance" and the substitution with a challenge to scientific concepts on valid principles. In 1983, Merrell Dow Pharmaceuticals settled out of court maintaining that this was cheaper than proceeding with the case. Although Bendectin production was stopped in 1983, several case-control studies performed since have found no association with fetal abnormalities,[206] However, although, while a high teratogenic risk was excluded, a low-grade risk was not.

Daubert replaced *Frye*'s general supremacy but the latter was not dead and buried. Seven states including California, New York, Illinois and Florida still apply Frye[207] itself or its extensions.[208] Some other states employ combinations of it and Daubert while others have also devised their own derivatives of both principles. The existence of so many derivatives, combinations and combinations of derivatives, likely implies that no ideal rules of admissibility of scientific evidence have as yet been established. Frye must be given due recognition as opening the door to the scrutiny of scientific evidence regarding suitability for Court admissibility. It instilled a defining of basic premises where previously there were one, but it does have many points against it. It

[206] See note 196.

[207] Frye as the principle in contrast to *Frye* referring to the Court case.

[208] *State v. Quattrochi*, No. 95-343, Slip op. at n.2 (R.I. July 31, 1996).

does not even offer that most basic of requirements, namely a functional definition of the term "relevant scientific community".[209] In its fervour to embrace what is recognized and accepted by this undefined "relevant scientific community", it may formally choke valid emerging research. And its "cut to the chase" way of accepting admissibility on what has already been accepted or rejected by the scientific community, provides a rigid and impenetrable shield which may leave much ground lacking the chance of justified challenge.

However, one must also add that Blackmun's criticism of Frye's rigidity was not particularly compensated for or even substituted by much laxity, for Daubert's criteria as based on FRE 702 may offer a more specific request for proof instead of a generalised "acceptance" but are by no means lacking rigidity of criteria themselves. Blackmun widened the criteria and specified them but by no means did he *lower* their expectations. Furthermore, one may challenge Blackmun's stressing that nothing in the Federal Rules establishes 'general acceptance' as an absolute prerequisite to admissibility.[210] For in reality, FRE 702 *is* inclusive of Frye's spirit without its appellation and clearly without its exclusivity. Daubert also set the burden of proof a notch or two higher than that in Frye.

2.7.2 Seeking the truth in scientific evidence

It is beyond question that the obstetrician, serving as a Court expert, when delivering an opinion dealing with science must deliver what science accepts and teaches and not

[209] Giannelli PC. The Admissibility of Novel Scientific Evidence: Frye *v.* United States, a Half Century Later. Colum L. Rev. October 1980; 80(6):1197-1250.

[210] See note 208.

his own's opinion on the subject. If we apply Daubert's principles as delivered by Judge Blackmun, such evidence must fulfil two criteria. The first refers to the reliability of the scientific evidence which must be

derived by the scientific method..... supported by appropriate validation—i.e., 'good grounds,' based on what is known.[211]

The science delivered by the obstetrician to the Court must be *based on what is known.* And one stresses here, *what is known* and not *what is known to him.*

The second criterion demanded by Daubert is that the evidence presented by the expert must be *relevant* to the case facing the Court. In fact, the word originally used was 'fit' and this implies even more than 'relevant'. Whereas the latter may simply shed more light by the describing of scientific facts related to the case, the word 'fit' is taken by the Daubert Court as assisting the Court by making the facts under review as more probable or less probable. Such 'fitness' implies a higher standard than simple bare relevance.[212] Here, in line with science, 'fitness' is being loaded with quasi mathematical weighting.

This brings to the fore Daubert's almost obsessive precision in delineating and defining both the main actors in the Daubert Court as well as the terms of use in such a Court. Thus, it speaks of the Judge as the gatekeeper which under FRE702 ensures that the

[211] See note 192.

[212] In N RE: Paoli Railroad Yard Pcb Litigation. Mabel Brown, Individually and on behalf of all others similarly situated *v.*, 35 F.3d 7 17, 745 (3d Cir.1994).

evidence proceeds from true scientific knowledge. In addition to other details, Daubert also demands scrutiny along scientific methodology, namely:

I. Whether the theory or technique employed by the expert is generally accepted in the scientific community;
II. Whether it has been subjected to peer review and publication;
III. Whether it can be and has been tested;
IV. Whether the known or potential rate of error is acceptable; and
V. Whether the research was conducted independent of the particular litigation or dependent on an intention to provide the proposed testimony.

This commitment of scientific precision laid on the judiciary is both central to Daubert's interpretation of FRE 702 as well as immediately presents an Achilles heel. It makes unique and possibly over-demanding expectations from the average member of the judiciary. Yet, one *is* dealing with evidence pertaining to science and it is science which can gauge science. Daubert even seeks to guide and assist the judiciary almost to the point of mathematical spoon-feeding, by stating that:

If epidemiological studies reveal a relative risk factor greater than 2.0, a jury can reliably conclude that the exposure caused the injury under the preponderance of the evidence standard.[213]

[213] *Daubert II*, 43 F.3d at 1321: *For an epidemiological study to show causation under a preponderance standard, the study must show that children whose mothers took Bendectin are more than twice as likely to develop limb reduction birth defects as children whose mothers did not.*

Such a standard has been applied, for example, in *Theofanis v. Sarrafi*,[214] where Daubert is quoted essentially verbatim:

Where the risk with the negligent act is at least twice as great as the risk in the absence of negligence, the evidence supports a finding that, more likely than not, the negligence in fact caused the harm.

Although Frye did make the scientific community its gatekeeper, Daubert places the judiciary in the same role. How acceptable this is, is highly debatable because the placing of the judiciary in the metaphorical laboratory has and still evokes much criticism. One argument holds this as fundamentally flawed and almost an abrogation of the system's responsibility, because the judge's repertoire does not normally comprise the ability to deal with the responsibility laid on him.[215]

This evolution of complex obsessive American demand of scientific scrutiny lies unparalleled in the UK. Nor do the USA conclusions of Frye and Daubert seem to have impressed the British world to any noticeable effect. In fact, in England and Wales, one finds a surprising lack of equivalent stringency. For example, in the case of forensic evidence, inadmissibility is only met with in the presence of gross inadequacy.[216] In contrast to the USA's Frye and Daubert and their combinations, derivations and combined derivations, the UK lacks a specific reference name in the subject although

[214] *Theofanis v. Sarrafi*, 791 N.E.2d 38 (Ill. App. Ct. 2003).

[215] O'Brien É, Daeid NN, Black S. Science in the court: pitfalls, challenges and solutions. Philos Trans R Soc Lond B Biol Sci.. 2015 Aug 15; 370(1674): 20150062.

[216] The Law Commission. (Law Com. No 325). Expert evidence in criminal proceedings in England and Wales. Printed 21 March 2011. London: The Stationery Office.

it obviously does have its own approach to the problem. The British Court aims at establishing that the basis of the scientific evidence forwarded by the Court expert is not a personal belief or hypothesis but one which truly reflects the views held by the science of the day. There are no named gatekeepers and no scientific or mathematical formulae involved. The UK situation admits to much greater fluidity in a subject which is multi-faceted and difficult to be guided by the inflexibility inherent in both Frye and Daubert. It is as if the British legal system is still searching for the ideal solution, which in truth, may not even exist at all.

There are no Daubert judiciary gatekeepers in the UK. Making a Daubert gatekeeper of the judiciary is after all not too far removed from expecting the judge to be somewhat on par with his appointed expert, in which case one wonders why the expert is required at all. Yet, scientific experts *are* indispensable, and their level of expertise cannot be taken on by the judiciary whose competence lies in a different direction. There is also the attitude that disagrees with general rigid principles applied as a blanket formula to a specific case:

Generic principles for admission may, taken in isolation, be more inclined to mislead than assist. Instead, it is preferable to consider each case on an individual basis. Judges may benefit from guidance provided by working parties outside the courtroom. A middle path is suggested charting a path between laissez-faire admission, on the one hand, and a call for pervasive principles of admission, on the other.[217]

[217] Wilson A. Expert Opinion Evidence: The Middle Way. Journal of Criminal Law. 2009; 73(430):430-450.

Incidentally, one also notes that whereas the Frye and Daubert cases emanated from criminal and civil law, most published argumentation in UK literature more often than not concerns criminal and forensic cases. While this is understandable on considering the volume of criminal work demanding the admissibility of raw scientific evidence as compared to cases of a civil nature, one notes that it was an American civil case which gave birth to Daubert. Neither can one discount glaring examples which suggest that that tighter rules of admissibility of scientific evidence in UK civil jurisprudence have a burning need to be evaluated. One example would be a decision of the role of FBS and other confirmatory tests in cases of alleged obstetric negligence leading to fetal distress and subsequent damage, as discussed in appendix two section A2.6. One may also reflect on the fact that cases with wrong and misleading science such as that found in the Meadow case, as discussed in section 2.8.1, are likely not to have caused the human suffering therein caused had more stringent laws of scientific acceptability existed in the UK.

It is worth noting that the Lord Chief Justice of England and Wales, aware of the present problems associated with the admissibility of expert scientific evidence in Court has expressed willingness to implement much of the Law Commission's 2011 report by means of a Practice Direction.[218] The fact that the UK has resisted adopting Frye and/or Daubert in a wholesale rigid form is probably a wise and calculated move. The matter is almost certainly insolvable by the simple expedient of adopting either or both principles, although one must respect them in the effort represented by the initial tottering steps in a difficult problem. It may also well be that a two-tiered solution may

[218] Ward T. 'A new and more rigorous approach' to expert evidence in England and Wales? The International Journal of Evidence & Proof. 2015 Oct 1; 19(4):228-245.

be more appropriate than a rigid guideline. Such a solution may comprise broad general acceptance guidelines which apply across the board such as those related to general criteria of the expert's qualifications and experience as well as the relevance of applicability of his evidence, and more specific guidelines involving an out-of-Court working group dealing with the intricacies of the specific science involved.

In spite of the fact that this subject may or may not be tackled in the future by the Maltese Civil Code, it is not felt that at this juncture, it should be included in the proposed Lex Medica. Although the importance of the subject is unquestioned, it is felt that a future medical law may always incorporate whatever optimal conclusions are reached by future revisions and amendments of the Lex Medica. The relevant groundwork would ideally fall within the remit of responsibilities of the Maltese Institute of Medico-Legal Studies as proposed in section 5.3.

2.8 Expert Witness Immunity

Witnesses, be they expert or not, have traditionally enjoyed immunity in a number of jurisdictions, including the UK and the USA, with regard to all that concerns their statements made as evidence to Court. This was specifically aimed at removing the inhibition caused by fear of repercussions arising out of prosecution. Thus, immunity was considered a way of ensuring honest, free and unencumbered facts pertaining to the truth. Having stated this, all witnesses be they expert or not, have at all times, been liable to prosecution for the crime of perjury or if they admit to crimes for which the government has not granted them immunity for testimony. In these circumstances, the action would not be initiated by a party injured by the divulged evidence, but the

prosecution and the action would pertain to the Criminal Courts and not the Civil Courts.

Obstetric experts were thus protected by such immunity in giving their specialised type of witness for which they were also compensated either by the Government if Court appointed or by individuals if acting as partisan experts. UK expert immunity which dated back a good four centuries was re-affirmed as recently as 2000 in the case *Stanton v. Callaghan.*[219] In this case, the Court of Appeal emphasized that expert witnesses are protected from being sued in civil proceedings *even where they have clearly acted negligently*. Until then, both the UK and the USA Courts had defended this position most strongly, reasoning that the advantages of serenity of mind for the great majority of experts who give good, frank and unfettered opinions outweighed the disadvantages incurred by the minority who delivered (purposefully or negligently) defective evidence. In the USA, for example in *Briscoe v. LaHue*,[220] the Supreme Court emphasized that common law provides *complete* immunity from lawsuits against expert witnesses.

Such a position of partial or complete immunity has never been provided for by the Maltese Court which has always treated the expert witness as any other witness with regard to the responsibility of what is stated in Court and its potential liability. If the Maltese expert witness gives any evidence which can be interpreted as false, he can be prosecuted in a criminal Court. If he makes defamatory statements, he is liable to any civil Court action which the injured party may wish to institute. Neither is there any

[219] *Stanton v. Callaghan* [2000] QB 75.

[220] *Briscoe v. LaHue*, 460 U.S. 325 (1983).

instituted protection for an ex parte expert who is considered to have failed his client in the evidence submitted from being sought in a civil action by the party who commissioned him, although the situation does not present any precedents. These facts apply to any written report or to any oral evidence which the obstetric or other expert presents in Court. The twentieth century developments of the subject in the USA and the UK render the Maltese position as being by default on par with the latest views. The circle had completed itself! However, while the Maltese outlook had not changed its stance , the UK and USA position on immunity had undergone much evolution.

2.8.1 A Challenged Immunity

The late twentieth and the present century brought strong winds of change regarding UK expert immunity. Such changes are in themselves signs of a healthy dynamicity, however slowly manifested, of the jurisdictions under review. A recent clear example was the 2015 case of *Montgomery* and its effect on the replacement of the Bolam test by the Prudent Patient Principle as regards disclosure. The change in old attitude of the UK Courts with regard to the subject of expert witness immunity had been another, albeit perhaps less well known, evolutionary step. These changes seem to be following an unspoken universal tenet of bringing all men to the same level while demolishing all demi-gods. In *Montgomery*, we see the disappearance of medical paternalism in deciding what the patient ought or ought not to know about his own treatment. In the present discussion we see the expert's immunity being brought down from its own pedestal.

To be historically correct, the main waves of attack on the special status of the Court expert's immunity had been preceded by a one-off isolated and localised tremor in 1973 with the USA case *Brousseau v. Jarrett.*[221] In reality that episode resulted in a self-healing crack with no permanent or precedential effect to speak of. In *Brousseau,* the Court did uphold a patient's claim against an expert medical doctor whose Court evidence adversely affected the patient's benefits from a car insurance policy. It was technically questionable ruling in the climate of the day, but it passed, more or less unchallenged and left no ripples influencing other cases. However, twenty-five years later, the UK would be rocked by a number of circumstances which proved shocking to the legal world for two reasons. One was the uncovering of the frightening truth of how unjust the system of justice can be in its deliberations and conclusions. The other would be the merited questioning of the concept of the justice of untouchability of the Court expert. Unlike the 1973 American *Brousseau,* this would prove to be no self-healing crack.

The circumstances of the case, commenced in 1998 when the world-renowned paediatrician Professor Sir Samuel Roy Meadow, was first called in for his professional opinion by the Cheshire Constabulary. The matter was a confusing one and involved the cot deaths of two children of Sally Clark, an English solicitor from Wilmslow in Cheshire. Clark had lost her first son in December 1996, when he died within a few weeks of his birth. In January 1998, she lost her second son in similar circumstances, the established diagnosis once again being Sudden Infant Death Syndrome (SIDS). Sally Clark was arrested in February 1998 and charged with the murder of her two sons on the basis of the statistical evidence presented by Professor Meadow.

[221] *Brousseau v. Jarrett* 73 Cal.App.3d 864.

It was a fact that the world listened when Meadow spoke. Now, in his evidence, the statistical evidence was taken at complete face value for the term ipse dixit could have been coined with the man in mind. No equivalent of Frye or Daubert put Meadow's stated facts through any scrutiny. The man had spoken! Purely on Meadow's statistical evidence, Sally Clark was convicted in November 1999. And this was upheld at Appeal in October 2000 but overturned in a second Appeal in January 2003. On the latter occasion the forensic pathologist Dr Alan Williams, was found guilty of failing to disclose microbiological evidence that suggested a natural cause of death for Clark's second son.[222] Although Sally Clark walked now away a free woman, after unjustly serving three years of her sentence, her life had been ruined. The great miscarriage of justice had taken its toll on the poor woman's health, and she died prematurely after developing serious psychiatric problems including alcoholic dependency. She was not alone to have suffered from Meadow's negligent expert opinions as three other women who had been convicted on Meadow's scientific evidence as Court expert had their sentences overturned.

The tabloids had a field day with the fall of Meadow. Obviously relishing the turning of the tables, they *now* described the most unorthodox way by which the famous professor had reached his statistical conclusion that the chances of two cot deaths happening to the same family were 1 in 73 million:

[222] Gooderham P. Have any lessons been learned from Sally Clark's case? New Law Journal E-newsletter). 2008 Jan 24.

The GMC also heard, from Sir Roy's own mouth, how he arrived at his astronomically inaccurate figure. He had read an article in The Lancet, in which a physiologist at Bristol University, Professor Peter Fleming, had claimed that there was a one-in-8,543 chance of a child in a middle-class family falling victim to a cot death. Sir Roy had then whipped out his pocket calculator and squared that figure, thinking that the answer represented the odds against two cot deaths happening in one middle-class family…… I will only observe that the kindest thing to be said about him is that he is intensely stupid…[223]

No one had queried the statistics before – a prime example of the evil of ipse dixit and an argument, if ever there was one, of the indispensable need for the rules of scientific admissibility in Court. Using Daubert's terminology, Sally Clark had been convicted by *junk science*. For Meadow, a knighted professor and an international paediatrics authority and now called an "intensely stupid" man, had wrongly calculated a 200:1[224] risk for a 73,000,000:1 risk as applied to the risk of two SIDS cases occurring in a single middle-class family. Based on his imaginary calculations, he categorically stated what became known as Meadow's Law, namely that "one in a family is a tragedy; two is suspicious; and three is murder" in reference to SIDS cases, all of which was proven wrong by the Royal Statistical Society.[225].

Throughout this saga, Meadow's position was still secure, protected as he was by full immunity. This was all being taken in and studied by Sally Clark's father, Frank

[223] Utley T. How could an expert like Roy Meadow get it so terribly wrong? The Telegraph. 2005 Jul 15.

[224] Sir Roy Meadow struck off by GMC. BBC News 2005 Jul 15.
[225] Walter G. 'Meadows' Law' is wrong. Brit Med 2004 Jan 18; 328:9.

Lockyer, a retired police officer, who was determined to seek accountability from Meadow. Finding the only possible Achilles' heel in the expert's immunity, Lockyer reported Meadow to the General Medical Council [226] for serious professional misconduct and grossly negligent and irresponsible use of medical statistics which had seriously mislead the Court. This was an intelligent move, but it was untested ground. The law did confer immunity from matters legal, be they civil or criminal, but it made no reference to disciplinary actions by regulating bodies constituted of one's peers. Lockyer was exploring the only potential chink in the armour of expert immunity to stop Meadow from doing future expert work and harm more people.

Lockyer's move paid dividends. On 15 July 2005, the GMC Disciplinary Board had no option but to strike off Meadow's name from the medical register[227]for committing grave errors, and, among other things, failing to have regard to variables which would have would have substantially changed the statistics which he was citing with serious implications and repercussions for many people, not least those working in the field of child protection.[228] However unintentional were Meadow's actions and in spite of his previous undoubted glowing contributions to medicine and his ensuing international reputation, the GMC had no other path to follow. The GMC also took up the case of Alan Williams who had performed the post-mortem examination on both the Clark babies. By failing to divulge important information which turned up from the post-

[226] Laville S. Tireless voice vows to continue speaking out. The Guardian Weekly. 2006 Feb 18.

[227] Sir Roy Meadow struck off by GMC. BBC News. BBC News. 2005 Jul 15.

[228] Freckelton I .Expert Witness Immunity and the Regulation of Experts *General Medical Council v. Meadow.* [2006] EWCA Civ 1390; [2007] 1 All ER 1.Psychiatry, Psychology and Law. April 2007; 14 (1):185 – 193.

mortem of Sally Clark's second son, Williams had hidden evidence pointing to a natural cause of death of this baby. The GMC ruled Williams guilty of serious professional misconduct. Although his case was not considered serious enough to merit being struck off, he was banned from Home Office pathology work as well as work in relation to Coroner's cases for a period of three years.[229]

However, Meadow was not prepared to let the matter lie there and took the matter to the High Court in 2006. In *Meadow v. General Medical Council*,[230] a majority decision found in his favour, and on the 17 February 2006 the Court ruled that the punishment delivered by the GMC was excessive for Meadow's misconduct did not merit being struck off the medical register. The Court ruled that the professor had acted in good faith in spite of his erroneous work and furthermore that in his capacity as Court expert, his work *was* covered by immunity. The GMC went to the Court of Appeal.[231] On the 26 October 2006 the High Court by a majority decision upheld the ruling that Meadow's misconduct was not sufficiently serious to merit the punishment which he had received. Lord Justice-Auld described Meadow's error as part of his professional service and that he had not acted in bad faith. However, regarding the previous ruling on immunity as delivered by Collins J, the High Court dismissed the "unprincipled" extension of the common law. No immunity was extended to disciplinary investigations such as those by the GMC about any doubts concerning fitness to practice procedures arising out of court expert evidence. The final word of the High Court had been delivered: expert's

[229] Dyer C. Pathologist in Sally Clark case suspended from court work. Brit Med J. 2005 Jun 11; 330(7504):1347. DOI: 10.1136/bmj.330.7504.1347.

[230] *Meadow v. General Medical Council* [2006] APP.L.R. 02.17.

[231] *Medical Council v. Meadow* [2006] EWCA Civ 1390; [2007] 1 All ER 1.

evidence was not immune from disciplinary proceedings such as those of the GMC in investigating fitness to practice.

The Court encounter between Meadow and the GMC had been an ill-fated one for Meadow, whose case attracted world-wide attention to his shocking statistical gaffe in Court. Furthermore, the case also proved the GMC‘s mettle in its disciplined approach in maintaining medical standards, in spite of Meadow’s regaining his license to practice. If the GMC would discipline a man like Meadow, it would discipline anyone. The man of international standing who had even been knighted for his work on child abuse,[232] may have regained his license, but in effect he was a finished man. The lesson for all lesser men was clearly written on the wall for all to see. The first serious crack in the armour of the Court expert’s immunity was clear as daylight and would be ruthlessly followed by others still.

2.8.1.1 Trans-Atlantic Immunity challenges

It is interesting to note how certain concepts seem to mature and flower into existence in a strange synchronism which may be partly due to mutual influence but seems to be more the result of parallel pari passu cerebration. Although many examples exist, reference is made here to the concept of Court expert immunity. After solidly withstanding any possible assault for hundreds of years expert immunity was successfully challenged in both the UK and the USA approximately within the same two-decades.

[232] Meadow coined the term *Munchausen Syndrome by Proxy* and in his textbook ABC of Child Abuse.

The UK High Court's ruling stressing that medical expert testimony was not immune to disciplinary procedures by medical regulators was not far removed in time from other not dissimilar challenges to expert immunity preceding it across the Atlantic. Although not of the same calibre or resulting furore as the UK Meadow case, the Supreme Court of Washington in the 1997 case *Deatherage v. State of Washington Examining Board of Psychology*[233] had clearly stated that professional disciplinary hearings regarding expert evidence did not fall under the umbrella of expert immunity. Another case, *Austin v. American Association of Neurological Surgeons*,[234] preceding the Meadow case by five years had witnessed the USA seventh Circuit of Appeals deliver a similar ruling stating that a professional society *could* discipline one of its members for improper expert testimony in a Court case.

An interesting and extremely important argument antedated these cases which were setting a precedent of enforcing professional disciplinary bodies' jurisdiction over matters arising out of Court expert medical evidence.[235] This centred around the query of whether expert medical testimony constituted part of medical practice or not. This was no vague philosophical argument for its conclusion had many serious ramifications. The American Medical Association (AMA) knew full well that the implications of its conclusion. After much argumentation, in the late 1990's, the AMA gave its final ruling by the AMA House of Delegates through resolutions 121 and 216,

[233] *Deatherage v. State of Washington Examining Board of Psychology*, 948 P2d 828 (Sup Ct of Washington 1997).

[234] *Austin v. American Association of Neurological Surgeons*, 253 F 3d 967 (7th Circuit, 2001).
[235] Gomez JCB. Silencing the Hired Guns. Journal of Legal Medicine. 2005 Sep;26(3):385-399.

holding that such expert medical testimony was indeed to be considered as part of medical practice; that it was subject to peer review and that moreover, false testimony by physicians would be intolerable and require disciplining by state licensing authorities.[236]

A different attack on expert immunity would affect the partisan expert and the standard of his work. From about the 1990's, the USA would witness a number of judicial rulings which attacked the efficiency of the expert's testimony when hired to give "partisan" expert evidence in a Court suit. The Court was not averse to this argument and from the 1990's accepted such claims ruling in favour of the plaintiff when his argument had sufficiently solid foundations. However, the Court did stress that such arguments must be based on factuality of sub-standard work and not simply be the outcome of discontent from a lost Court case. The 1999 case *LLMD of Michigan Inc. v. Jackson-Cross Co*[237] was one such early and successful Court claim where expert witness immunity was laid aside. Strangely enough it strikes feelings of a déjà vu for as in the Meadow case it involved sub-standard work involving the relying on other people's mathematical work and moving from thereon to serious errors on a basis of a mathematical nature.

Three years later in *Davis v. Wallace*[238] the Court, in addition to stating that immunity did not preclude expert witness testimony liability to negligence, made a very serious statement in relation to this immunity in general and not related to action resulting from

[236] Weintraub M. Medical expert witness. Brit Med J. 1999 Jun 12; 353(9169):P2076.

[237] *LLMD of Michigan, Inc. v. Jackson-Cross Co*., 559 Pa. 297, 740 A.2d 186 (Pa. 1999).

[238] *Donald Ray Wallace, Jr., Petitioner-Appellant, v. Cecil Davis, Respondent-Appellee*. United States Court of Appeals, Seventh Circuit. No.02-4262. March 26, 2004.

sub-standard performance. In a realistic and what would prove prophetic way, the Court stated that the expert witness' absolute immunity was being questioned by an emerging body of case law and scholarly work. The prophesy would find its fulfilment seven years later in the UK Supreme Court case *Jones v. Kaney*.[239]

Jones would result in a UK landmark ruling which would deliver the death blow to expert immunity as defined in the preceding four centuries. The claimant, Jones had undergone injuries from a road traffic accident and had asked a female psychologist, Dr Kaney to make a report confirming Jones' post-traumatic stress disorder, which report was then used in the Court case where Jones was claiming damages. The opposing expert refuted the diagnosis stating that Jones was playing up his symptoms and therefore, the Judge asked for a joint statement from the two experts. Having agreed as to the final statement by telephone, the two experts met and signed a joint statement stating that the claimant did not have any resultant psychiatric disorder. The unexpected move by the psychologist Dr Kaney was questioned in Court by her own client's solicitors and Kaney stated that she had signed, not out of conviction but out of pressure. Needless to say, Jones was hardly appreciative of this manoeuvre which resulted in his claiming much less than he had originally hoped for.

This led to Jones opening a Court case against his expert psychologist Dr Kaney and the Court while rejected the claim on the basis of the defendant's immunity as Court expert the plaintiff's case by allowing him to by-pass the Court of Appeal which would have inevitably stated that the joint statement was also covered by immunity. It was

[239] *Jones v. Kaney* (2011) UK SC 13.

clear that the Court, while knowing that the Court of Appeal would have had to tow the official line and throw the case out, desired further deliberation by a Court which was senior enough to amend the law regarding expert immunity, if the justice of the case demanded it. One may reason further, that the wise judge was fully aware of the signs of the times and, as had been quoted in *Davis v. Wallace,*[240]*:*

the expert witness' absolute immunity was being questioned by an emerging body of case law and scholarly work.

Whatever the lower Court's reasoning, the Supreme Court's reasoning ran true to expected course. It stated, by a majority by five to two, that expert witnesses were not immune in the law of England and Wales from claims in tort or contract for matters connected with their participation in legal proceedings. The evidence given by the expert obstetric or other medical witness in Court was now not only liable to disciplinary action by peer review bodies such as the GMC, but furthermore were also under the potential threat of legal challenge under the law of tort or contract.

It is clear that the signs of the times weigh heavily against expert immunity. In Malta, where such protection was never in existence, it would be wise to let matters be as they stand, certainly for the next decades while the effect of such eroding of overseas immunity is established through long-term evaluation. In the unlikely event, that time will re-influence the overseas status of the Court expert, there is always the possibility for the Maltese lawmakers to think again.

[240] *Donald Ray Wallace, Jr., Petitioner-Appellant, v. Cecil Davis, Respondent-Appellee*. United States Court of Appeals, Seventh Circuit. No.02-4262. Argued Oct. 22, 2003. March 26, 2004.

2.9 Diminishing the liability of the Maltese obstetric Court expert

Malta stands right in contemporary times because the circle has turned a full round spanning 400 years of expert immunity evolution. Be it as it may, the Maltese obstetric Court expert is liable to a number of prosecutions, which he ought to be dutifully warned about when he is appointed. No such warning reached the Court appointed expert in the *Gambina* case. However conscientious and well-intentioned such an expert may be, it should be his sacrosanct right to be know the potential dangers ahead.

The best attitude to inculcate the risk of liability in the obstetric expert's mind is to remind him that he is acting within his official medical capacity and duty when he gives expert evidence in a Court of law. This means that he is both liable to peer review and discipline by the Malta Medical Council (MMC) as well as liable to criminal prosecution if found guilty of perjury and to civil prosecution if he for example is accused of slander. The prudent and well-intentioned expert should transgress no law, and while not becoming subject to paranoia, he must still take steps to guard himself. The optimal self-protection of the expert lies in being properly schooled as a Court expert. This is a currently unavailable option and if effected say, through the Malta Institute of Medico-Legal Studies would ensure the expert's knowledge of Court systems, the relevant section of both the Civil and the Criminal Law and other basic information to ensure efficacy of evidence as well as self-protection.

The unfortunate local attitude that the Court appointed expert needs to know all about his specialty but not the law is as rampant as it is potentially dangerous. The ease with which such an expert may put himself in harm's way, blinded by a false sense of

security "because he is there as an expert" is worrying. Referring to *Brandt v. Medical Defence Associates*,[241] Bal[242] describes how two specialists who had treated the plaintiff for Crohn's disease were called to testify in a case where the plaintiff was suing his physician for alleged negligence in the treatment of his condition. The two specialists had separately discussed aspects of the plaintiff's medical condition in ex parte talks with the defendant's medical malpractice insurer. Once the original trial had been concluded, the plaintiff sued both specialists for breach of fiduciary duty. The Supreme Court of Missouri ruled that the patient's waiver to the expert(s) does not cover ex parte discussions with the opposing defence team and such discussions carry the risk of tort liability unless specifically authorised by the patient.

2.10 Selecting the obstetric expert: The need for change

The status quo process of selecting an obstetric Court expert follows no organized system. Presently, a name of an obstetrician may be put forward by the magistrate or judge or is even suggested by the legal team of the plaintiff or the defendant and if no objections arise, the chosen obstetrician is appointed. The decision is formally noted by the Court and a letter of appointment is forwarded to the individual. Any name may be put forward and selected, as long as no objections arise, as is stipulated by the Code of Organisation and Civil Procedure. For example, in the *Gambina* case, the name of the author of this thesis was put forward by the plaintiff's advocate.[243] Such a system is hardly likely to select the optimal obstetric expert and the argument that, once chosen,

[241] *Brandt v. Medical Defence Associates*, 856 S.W.2d 667 (1993).

[242] See note 33.

[243] Although totally irrelevant to the argument, the expert's opinion favoured the defendant.

the expert will rise to the occasion, makes poor argument indeed. The system needs the *optimal* person rising to the occasion, for although any expert opinion may assist the Court reach a conclusion, this conclusion may not be the best one for justice to be truly served.

Although such matters are unlikely to have ruffled local legal feathers, there have been at least two cases which stand out as discovered on reviewing the small profile of existent obstetric Court cases. These two separate cases involved claims pertaining to alleged obstetric negligence with very senior consultants as defendants. In spite of this, the Court appointed junior[244] obstetricians as Court experts. In one case the expert was appointed alone and in the other case the junior expert was accompanied by a senior one. Such a situation should never arise in any circumstances but particularly in a small Island with one government hospital dealing with all cases of obstetrics and gynaecology. Most probably not knowing the hospital hierarchal system, the Court seems to think of a medical specialist is a medical specialist, irrespective of experience and hospital hierarchal status.

There is an obvious and serious hiatus in the method of selecting a Court expert, which seems to ring no alarm bells. In the very great bulk of cases where experts are required, the Court often tends to repeatedly appoint the same people as experts. Admittedly there seems to be a serious shortage of such experts but the matter cannot be left at that. A seeming 'closed shop' status is not healthy. It is time to make the position attractive to would-be experts who are genuinely interested, and this may be kick started by

[244] This refers to all sub-consultant grades. Both junior obstetricians referred to here, have since then, reached consultant status.

elevating the position of Court expert to the status it merits by organising courses for properly qualified people in the different scientific disciplines and the different medical specialties.

2.10.1 A proposed system for selecting the obstetric Court expert

The scope and duties of a Court expert have been very sensibly stated by Justice Dickson in *R v. Abbey*:[245]

With respect to matters calling for special knowledge, an expert in the field may draw inferences and state his opinion. An expert's function is precisely this: to provide the judge and jury with a ready-made inference which the judge and jury, due to the technical nature of the facts, are unable to formulate.

In *R v. Mohan,*[246] the Court put forward four qualities or caveats relating to the employment of a Court expert, which may be of value to the Maltese scenario. The case centred on the use of Court expert evidence on the subject of human behaviour in criminal activity. This topic had appeared on at least five occasions between 1990 and 1994 in front of the same Supreme Court of Canada. The subject had been of great on-going challenge to the Canadian courts for the previous fifteen years. Hence the Court was quite au fait with the concept in front of it when it declared its caveats regarding the subject of Court expert testimony, namely:

[245] *R. v. Abbey*, [1982] 2 S.C.R. 24.

[246] *R. v. Mohan*, [1994] 2 S.C.R. 9.

(a) The relevance of an expert;

(b)The necessity in assisting the trier of fact;

(c) The absence of any exclusionary rule; and

(d) The proper qualification of such an expert.

Caveat (a) is self-explanatory. Caveat (b) reminds the expert that, however heavy the final judgement leans on his report, it is the judiciary who is the trier of the fact. This issue been of longstanding concern. Once the member of the judiciary, as the trier-of-the fact, receives the report then it is his prerogative whether to reject or accept it and the degree of acceptance and use in the final deliberation. Caveat (c) has a very limited application in Maltese jurisprudence as no rules of exclusion exist as yet although there are obvious cut-off points where a Court expert may not act, for example in a trial where one of the parties is a relative up to the third degree.

Caveat (d) requires much reflection in the local scene and is closely related to the system proposed by this thesis regarding the creation of a database /register of eligible obstetricians from which the judiciary may chose its expert. The system as proposed in the Lex Medica enables the Court to have at its disposal a register of obstetricians from which it can chose an expert with complete serenity as to the reliability of the selection criteria. The database does not simply include anyone who has qualified as an obstetrician and gynaecologist and is on the obstetric specialist register of the Malta Medical Council, as the present, clearly inadequate system situation allows. Such a

system might have partial defensibility had Malta operated a system of assessing CME participation to retain one's registration. Even then, using the medical register would still be equating the Court expert's role with simple specialisation status. Whether the point is seriously appreciated by *some* members of the judiciary or not, qualifying as an Obstetrician/Gynaecologist is far from being a sufficient criterion to render one an ideal Court expert in the subject. It is also important to bear in mind that certifying as a specialist is not only dependant on obtaining the RCOG membership or the European (EBCOG) fellowship, but also requires the attendance of a defined training program.

Even as far back as 1983,[247] qualifying as an Obstetrician/Gynaecologist, in this case by attaining MRCOG status was, at least in the UK, considered as no more than the neophyte specialist's formalised entry into the world of obstetrics and gynaecology (OBGYN), at which he still had much to toil, day and night and for several years.[248] Such post-MRCOG training was and is meant to be undertaken under a recognised hospital's supervision, while the young obstetrician advances slowly in the path of knowledge, technique, discernment and maturity as guided by his consultant. Pari passu with this, he should strive to publish articles in peer reviewed journals and complement his practical work with ever enriching his theoretical knowledge and contributing actively to it. This is the planned course of the *still maturing* obstetrician.

During the requisite period of training, the junior obstetrician would normally, climb the promotional ladder under the guidance and supervision of a senior obstetrician.

[247] The author's qualifying year as an MRCOG.

[248] The blue and black fields of the shield in the RCOG's coat-of-arms indicate day and night. This conveys the idea that the obstetrician's duties often comprise work throughout the day and the night.

Eventually, and in most cases, after much trial and tribulation and peer-reviewed publications, one hopefully reaches the "promised" land and achieves consultant status.

In Malta as in many other places obtaining the position of consultant often involves the "dead man's boots" situation. Having achieved this position and with a minimum of 12 years post-membership, such a specialist may be recommended for a fellowship (FRCOG) of the RCOG. [249] In view of the increasing local interest in European qualifications, asking for FRCOG standing would be prejudicial, but the 12 year post-qualification criterion in an obstetrician of consultant status would be a wise one.

Therefore, this thesis proposes that an obstetric Court expert, besides being a man of integrity and holding a clean police conduct, with 12 years experience, and of active or retired consultant status. There is only one local qualified authority which has the discernment and the authority to form a database and an accompanying register of such eligible obstetricians, and that is the Malta College of Obstetricians and Gynaecologists (MCOG).[250] Such a register must be updated annually, and together with registers from all other medical specialty colleges. Would be ideally forwarded to the Malta Medical Council for its scrutiny. Once the MMC has confirmed or proposed otherwise, the registers, as revised, can be published as an appendix to the annual medical register issued by the same Council. The MMC vetting is important as the Council may have information on the proposed candidate, which may be privy to the Council and may render the candidate as inappropriate for availability as a Court expert, e.g., a pending

[249] Such a candidate must also have no pending Court or medical council disciplinary hearings.

[250] Founded on 3 July 1993. The author was one of the founding members. The MCOG retains official connections with its parent RCOG and has a representative committee at the RCOG.

disciplinary case against such a candidate. Once confirmed by the MMC, the register/database is made available to the Court for use at its discretion.

The register/database should be made public hence the proposal to have it published as an appendix to the annual medical register published by the MMC. This makes the choice of the named candidates available to any person or lawyer who wishes the services of an ex parte obstetric expert for any Court case. This right is generally universally acceptable by most jurisdictions. The universal right to an expert's assistance in Court has been long and well established, as firmly illustrated by many cases such as *Scott v. Spanjer Bros.Inc*[251] and *Danville Tobacco Assn. v. Bryant-Buckner Associates Inc*.,[252] In Malta, the choice of ex parte expert witnesses is also *allowed* by Article 563 A of the Maltese Code of Organisation and Civil Procedure, but it is solely the Court's prerogative to appoint a *Court* expert or referee. The appointment of an ex parte experts is not a *legal right* in Malta; hence expenses are not carried by the Court. The permitting of such a witness in the UK is in line with UK Civil Procedure Rules:

There is, however, nothing in the Civil Procedure Rules that prevents expert evidence being called on any factual issue in dispute that is deemed to be outside the knowledge or experience of either judge or jury – providing, that is, that the court deems it admissible.[253]

[251] *Scott v. Spanjer Bros., Inc.,* 298 F.2d 928 (2d Cir. 1962).

[252] *Danville Tobacco Assn. v. Bryant-Buckner Associates, Inc*., 333 F.2d 202 (4th Cir. 1964).

[253] See note 183.

2.11 Summoning the local obstetrician to Court expert duty

The present local system of informing a particular obstetrician that he is being summoned to act as Court expert is often the arrival of a *komunika* (communication) informing him of his chosen services as a *perit mediku* (medical expert) in such and such a case, with the Court designation, hall number, location, date and time of the next Court session. The *komunika* usually reflects the relevant minutes of the previous sitting in which the obstetrician's name would have been proposed by the judge or one of the involved lawyers. Such a request may be for an expert opinion in a case where no other expert opinions had been expressed before, or, as in the *Gambina* case, the summons may follow the removal of a previous expert/experts for whatever reason.[254] In the author's case, no information was given as to why the previous expert's services were terminated and a new expert sought. The author was not asked for a curriculum vitae, nor for any particular details of experience and qualification, as one would expect with reference to article 563A(1) of the Code of Organisation and Civil Procedure which states that.

Where a person is called as a witness, his opinion on any relevant matter on which he is qualified to give expert evidence shall be admissible in evidence only if, in the opinion of the court, he is suitably qualified in the relevant matter.

One must add that the pattern of events as described so far and in the following sections case was and is the norm and is being described here, as in fact, representing the norm.

[254] Common reasons include repeated absences from Court sessions and lack of respect of the time frame allotted by the Court for the handing in of the report.

Presumably, all that was known to the Court about the expert in the *Gambina* case was known to the public namely that the person to be approached was a consultant obstetrician and gynaecologist at the government's hospital. Any reputation, good or bad, of this obstetrician entertained by the Court was based on pure hearsay. Neither was the nature of the case or any other details disclosed to the appointed expert. This contrasts strongly with the UK system of summoning the Court expert, which, among *many* other aspects of information includes:

- The nature and extent of the expertise which is called for;

- The purpose of requesting the advice or report, a description of the matter(s) to be investigated, the principally known issues and the identity of all parties.

The UK Civil Procedure Rules make it a strong point to clearly advise refusal of appointment unless *all* the necessary information is provided with the letter of appointment. It is clear that although such details are not supplied in Malta as a default position, a wise obstetrician must take the initiative of learning what the case is all about, lest once he has confirmed his acceptance, he discovers that he is swimming in unchartered waters and may have to abandon his position in mid- trial. However, this should not be a matter of arbitrary decision of the expert but must become firmly established praxis and delineated as such within the Code of Organization and Civil Procedure. It is in the Court's best interest to ensure that the approached obstetrician knows for a fact that he is competent to truly and honestly assist the Court.

2.12 Disciplining and sanctioning

The concept of disciplining and sanctioning a local Court expert is likely to be immediately shot down in view of the present dearth of available local Court experts. If the system finds the status quo a desirable one, then perhaps one should let sleeping dogs lie. Furthermore, the idea of introducing a disciplining body for Court experts must be seen as part of the already discussed outlines of elevating the present status of the expert, including by the establishment of courses, qualifications and eventual licensing for all who may be suitable qualified and interested. All ideal material to fall under the aegis of the MIMLS. In such a context, a disciplining body is only part of a spectrum which embraces wide schooling and training, assessment, qualification, refresher courses and maintenance of standards and discipline. The whole vista is more than likely to attract new blood and produce experts who in addition to their original medical calling, perform their duties at a far superior level than previously. This does not imply that the present experts are mediocre, but in any system, one expects a range of performances. The very situation of non-availability of Court experts may be improved by making such an important position an onerous and prestigious adjunct to Court procedure and the studied target of improvement, training, education, assessment and discipline.

It has already been pointed out that, as matters stand, the Maltese expert has absolutely no protection from immunity. Hence whether the concept of discipline and sanction is made known or not to the expert, he is in a default position of legal liability. In the case of the medical person, such as an obstetrician, any peer disciplinary procedures for such liability also includes disciplinary measures by the Malta Medical Council.

In serious jurisdictions, the role of the Court expert does not come without possible sanction, and this does not scare off those who are serious and professional in their work. The discipline and sanctioning being referred to here, requires elucidation to the Maltese expert if he is to be made to truly understand and appreciate the relevance and the gravity of his role. No local precedence of such Court or Medical Council sanctioning is known, and the latter is highly unlikely to ensue as it requires a person to report and under oath to the Medical Council. This requires strong motivation. As a result, it is not difficult to surmise that a number of ethical breaches may indeed occur and be allowed to go by. An independent disciplining body is a necessity. The role may be entrusted to the authority which organises the schooling and qualifying for such experts, for such a body will always hold the final sanctioning card of withdrawing an expert's licence to practice. As the adage goes, justice must be done and must be seen to be done. Likewise, the integrity of the Court witness must be bereft of any possible mudslinging which might raise any kind of doubt in who is assisting the Court in reaching its conclusions. It is disconcerting to read that:

*The Sunday Times of Malta has been informed that although **** has been acting as a court expert for a long period of time, it is only two years ago that official court documents from the London court were obtained and presented to the court's administration as proof of his convictions. Yet it has since taken no action.*[255]

[255] Camilleri I. Lawyer found guilty of theft and fraud still serving as court expert. Times of Malta. 2016 February 29.

Regarding this case, one may further note that in spite of a Court decree stating that this person could not be appointed owing to his record, his position remained unchallenged as a number of judges kept appointing him to the position.

In an international climate which encourages challenges by all men to all systems, Court transparency must extend to the Maltese expert. Just as medical paternalism has become a by-word for an ethical sacrilege, the legal system must bear in mind that even if what is not up to European standard, is not yet openly challenged, it must not let be, until the day of reckoning. The lore of the Court expert must regularise itself and be reborn as a modern, transparent efficient corps which requires serious training and even qualifying or licensing by an established entity. Even if we just consider cases of alleged obstetric and other medical negligence, the ever-increasing technology with its corresponding ethical dilemmas demand such a re-adjustment both regarding the individual expert's preparation but also in the whole concept of the Court expert. Furthermore, in addition to such ever evolving technological, scientific and moral challenges, one must bear in mind that not all experts respect reliability, objectivity and truth.[256] The system must weed out whatever is not up to standard in the obtaining of expert assistance to the Maltese Court.

[256] Slovenko R. Expert testimony: use and abuse. *Med Law*.1993;12:627-641.

2.13 Planning the case evaluation

The obstetric expert must set off from the premise that the obstetrician has a duty to practice his art and science with the degree of attentiveness, caution and prudence shown by a reasonably prudent obstetrician in the same circumstances encountered by the defendant. This constitutes the duty of care as applied to disclosure, diagnosis and treatment and the SOC demanded by such a duty and which must be determined by the ethics and the science of contemporary obstetrics and gynaecology. The obstetric expert also has the undisputed requirements to determine the *clinical* aspect of confirming or rejecting causality, as the case may be.

The obstetric expert must bear well in mind the fact that the requisite SOC is not that of some mythical, omniscient and super dextrous obstetrician. The role model would be an ordinarily prudent obstetrician, practising secundum artem[257] and reasonably updated as regards matters concerning his daily practice. Neither can the expert not compare like with like. Thus, a general practitioner struggling with an undiagnosed and emergency breech delivery or shoulder dystocia, in a patient with no antenatal care, cannot be submitted to the same measuring stick as a consultant obstetrician in similar circumstances. It may also be noted here that the nature of the act under scrutiny is statistically more likely to revolve around some aspect of birth, as was the *Gambina* case which involved shoulder dystocia. Another example would be that of *John u Mary Cachia pro et noe v. Tabib Tancred Busuttil et noe.* [258] which involved alleged

[257] Here defined as practising along orthodox and contemporary principles of the art, science and ethics of obstetrics as regulated by legitimate authorities such as the RCOG.

[258] *John Cachia pro et noe et v. Tabib Dottor Tancred Busuttil et noe,* Qorti Ċivili, Prim' Awla, Onor. Imħ. Lino Farrugia Sacco, Ċitazz. Nru. 983/1987, deċ. 27/11/2012.

negligence at birth leading to cerebral palsy. Once local medico-legal statistics will (hopefully) be collected and published, the actual Maltese obstetric litigation profile can be correctly defined and clinical stock of the situation evaluated accordingly.

It is at this core stage of the expert's evaluation that the obstetric expert comes into his own. It is also the time when he must apply all the admonitions and guidelines which have formed his expert persona and the outcome of which may in the future be reviewed by a peritus peritorum.[259] The direction, level and ethos taken by the expert will guide the main direction of the Court's deliberation. As an example, in the *Gambina* case, the evaluation could have essentially confined itself to labour management since the alleged negligence involved shoulder dystocia. In fact, had the patient's blue card remained unavailable, the report would have had little choice but to solely objectively evaluate labour management as the only clinical notes available where those of St Philips' Hospital pertaining to Mrs Gambina's labour management.[260] The logic of the previous expert(s)' review[261] of the case remained unknown to the author. It was clear that evaluation of obstetric correct management in this case demanded full knowledge of the defendant's *antenatal* management including consideration of the plaintiff's obstetric history, scrutiny of any indication of maternal diabetes, evaluation of clinical and ultra-sound evidence of fetal macrosomia,[262] and so on.

[259] An expert appointed to review the original expert's work on appeal by the plaintiff or the defendant.

[260] Local private antenatal care often involves limits *written* information pertaining to such care as to what is available in the patient's blue card as separate notes are often not kept.

[261] The author has never enquired about *any* information pertaining to the previous expert obstetrician or obstetricians' reports. Indeed, it is not known to the author, if one or more than one expert had been involved. It would have been extremely interesting to know the previous expert(s) line of evaluation.

[262] Exceeding 4000 grams at birth, regardless of gestational age.

2.13.1 The obstetric Standard of Care

One may define the obstetric SOC as that degree of care which is expected from an ordinarily obstetrician of the same experience and essential qualifications as the defendant in dealing with an obstetric situation involving similar circumstances as those under Court evaluation. In Maltese jurisprudence, lacking the relevant measuring stick afforded to other jurisdictions such as the UK, an immediate difficulty is encountered. As fully evaluated in section 4.3, it is far from practical or even possible in any practical sense to apply the laws of general negligence to establish a functional SOC for use in cases of alleged medical negligence. However, an opportunity arises for the expert to truly assist the Court in the direction, level and ethos taken in its deliberation.

The expert cannot amend the law, but since he is allowed to set his own level and direction of SOC, he can, without fanfare or statement, gently nudge the local Court's deliberation along reasoning which is resonant with modern medico-legal principles if his report is in keeping with such principles.

The first step of the expert obstetrician is to review the requisites of the updated, evidence-based orthodox obstetric teaching, with regard to the prevention and management of the case at hand. In the *Gambina* case, this was shoulder dystocia. There is no doubt that such review must be based on official, evidence-based teaching emanating from sources such as the RCOG or equivalent European body. The expert must also study all pertinent peer-reviewed publications related to the subject of shoulder dystocia, and if he is medico-legally inclined, also review the subject from this angle from appropriate journals of the specialty. Justice demands that the local status

quo be kept in mind where it is necessary. For example, the RCOG has long advised the establishment of shoulder dystocia drills which, incidentally, is recommended to the MOS in section 3.3.2.1.6.1.1.5. Had this report been written in the UK, the question as to the defendant's certified attendance of such drills would have definitely figured, but not in the local situation as it stands. The ordinarily safe and prudent Maltese obstetrician unfortunately did not have current access to such local shoulder dystocia drills at the time of occurrence of the case in question.

The retrospective analysis of the defendant's management must be based on all potential sources of such information, the reliability of which must be evaluated. The primary sources include all potentially available written or digitally stored records. These may be used to enable the expert to draw his own notes comprising timelines and other details and which may be used as framework to which other information is appended as the Court process proceeds. Next comes all evidence emanating from the Court process including the evidence given by plaintiff(s), defendant, midwives, and any other attendants. Regarding the defendant's evidence, one must metaphorically try to enter the defendant's shoes at the time of the incident. Although this did not apply in this case, for example, if an official guideline has not respected, the defendant must explain his logic, for not doing so and if the information is not volunteered, the defendant must be specifically asked and the question and answer entered as such in the expert's final report.

Whatever is recorded in the official Court transcript concerning any aspect of management must be noted and evaluated by the expert. Even hearsay, once it is mentioned in Court, as long as it is so noted, needs to be considered, evaluated and

ideally included in the final report. Since Malta operates the Adversarial Court system, it is the plaintiff who bears the burden of proof and by presenting such evidence must convince the Court that the damage suffered was the result of the breach of duty by the defendant. Hence special attention must be paid to the Court statements of the plaintiff(s), in this case the patient and her husband. Also, comments made or written by other professionals such as midwives present at birth or even antenatally must also be singled out and incorporated at some point in the report. If such comments are ignored in the expert's report, the impression will be given, justly or unjustly, that the expert avoided answering or commenting on them.

2.13.2 Evidence-based benchmark to establish the obstetric standard of care

Foreign jurisdictions with an established medical law, still allow a certain latitude of interpretation of such law. This is to some extent inevitable and one might even argue, desirable from the point of view of the Court's discretion. The purist might argue for the rigidity of observance as instilled by Daubert, but such confines are rarely ever imposed on Courts unless in the USA and as applied to admissibility of scientific evidence. Such latitude may, on the other hand, allow the possibility of controversy of interpretation. Let us take Bolam's law as an example:

A doctor is not guilty of negligence if he has acted in accordance with a practice accepted as proper by a responsible body of medical men skilled in that particular art.

The argument here centres on Bolam's criterion of negating negligence if the practice under review is *accepted as proper by a responsible body of medical men skilled in that*

particular art. In most cases the view upheld by such a responsible body of medical men is likely to concur with that held by the great majority of peers. While this probably applies to the great majority of cases, there may arise a situation where the established SOC does not reflect peer practice generally. One can be more specific and ask:

what if peer practice based on the latest science opposes official traditional guidelines? What if evidence-based medicine (EBM) clashes with official, and well-established guidelines?[263]

This situation, though not common, contemplates a position where equally respectable sources provide diametrically opposed advice. As a practical example we can return to the argument on FBS as discussed in appendix two, section A2.6. which presents a serious and most serious challenge. For, while official guidelines still recommend the use of FBS and Court still holds it in high respect as regards confirming or negating fetal distress, there is now (and has been for a substantial amount of time) ample evidence challenging its scientific reliability.[264] Chandraharan,[265] takes the situation a step further when he states that:

[263] Buttigieg GG. Submitting medico-legal intra-partum CTG (I-P CTG) monitoring to the Bolam and Bolitho principles. Medico Legal Journal.2017; 85(2)93-96.

[264] Wiberg-Itzel E, Pettersson H, S Cnattingius S, Nordström L. Association between lactate concentration in amniotic fluid and dysfunctional labour. Acta Obstetricia et Gynecologica 2008 Sep;87(9):924-928.

[265] Chandraharan E. Fetal scalp blood sampling during labour: is it a useful diagnostic test or a historical test that no longer has a place in modern clinical obstetrics? BJOG. 2014; 121:1056 – 1062.
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Continuing to perform FSBS without scientific evidence may result in risks associated with the procedure without any potential benefit, which may lead to adverse clinical and medico-legal consequences.

In spite of the example of FBS, official guidelines remain as a rule the best source of evidence-based advice in contemporary obstetrics. The above discussion stresses the point that in establishing the SOC, the expert may employ a yard stick which may satisfy a seeming objectivity of balance but, in fact, is not the best available, truly objective assessor of contemporary obstetrics. Such criteria, at the present time and in the foreseeable future, should embrace evidence-based obstetrics, and this is what, in the great majority of instances, the professional colleges simplify, crystallise and publish in their guidelines. And it is such methodology which is ideally employed by the Court expert in establishing the SOC as based on formal evidence-based medicine (EBM)[266] which demands the robust evidence of systematic reviews, meta-analyses and randomized controlled trials of medical practice, including obstetric practice. In the case of an adverse clinical outcome, where FBS had been employed, the expert must fully explain to the Court the present *in-between* medico-legal situation where Court and official obstetric guidelines still recommend FBS, while new EBM points to the potential existence of more reliable methods of confirmation of intra-partum fetal hypoxia but that these are still being evaluated.

Gaining ground since the early 1900's, EBM took off in 1922 when first applied to general medicine, but subsequently spread to all health professions. When correctly

[266] Evidence-based medicine is the official recognised term and is thus used here although the subject in this discussion remains obstetrics.

applied, EBM may offer views which necessarily concur with traditional views However, it replaces habit and hearsay with ruthless observation and subjection to analysis, all of which must be meticulously recorded and made available for future retrieval.[267] EBM may displace the ritual of unchallenged habit, but it does *not* diminish the art and the humanity of obstetrics. EBM enriches the scientific aspect[268] and puts true objectivity at the centre of practice and at the core of retrospective evaluation. It was the yardstick of use in formulating the SOC in the case discussed here.

The proposed establishment of the medico-legal principles, by which the Court is empowered to formulate the specific SOC, is fully evaluated in section 4.3.4.

2.13.3 The *Gambina* case: Gathering the data and writing the expert's report

In the report, special care was taken to ensure that:

I. It is evidence-based, wherever such evaluation is called for.

II. Although the complaint presenting to the Court concerns shoulder dystocia and hence labour management, the report objectively evaluates the *whole* of pregnancy care from all available documentation and from all official evidence

[267] Peile, E. Reflections from medical practice: balancing evidence-based practice with practice based evidence. In: Pring R, Gary T, editors. Evidence-based Practice in Education. U.K. McGraw-Hill Education; 2004.

[268] Practice based on clinical consensus opinions and expert opinions are level C recommendations, whereas level B recommendations are derived from limited or inconsistent scientific evidence while level A recommendations are based on consistent and scientific evidence. Ideally all college recommendations should be of level A evidence.

given. No stone was left unturned. Thus, regarding antenatal management, the crucial aspects primarily considered antenatally are those which the standard of obstetric care would involve in the *prevention* of shoulder dystocia.

III. The scrutiny of the labour ward management also involves the scrutiny of any possible breach of the SOC concerned with the detection of signs of shoulder dystocia which could have averted the occurrence by the timely performance of a caesarean section, and also those late signs of impending shoulder dystocia which although too late for a caesarean delivery could have shortened the time of dystocia by preparing for optimal management.

IV. The scrutiny of the second stage of labour was in large part, as expected, devoted to the management of the shoulder dystocia itself, but the general management was not omitted.

V. The conclusions and the reasoning leading to it are presented to Court with minimal reference to technicalities and jargon.[269] No reference to medico-legal principles was made as such to avoid patronising pontification but the discussion purely limited to the remit of assessing whether the defendant's obstetric management fell short of the expected standard of procedure by omission or commission.

[269] The Court unofficially complimented the report on its thoroughness, clarity and simplicity of explanation.

VI. Since the subject is a technical one, use was made of diagrams and pictorial representation wherever possible.

The approach of analysing the defendant's management entailed an analysis of the management along the following lines:

Analysis of the antenatal management

Analysis of the management of labour:

(i) Analysis of Stage I management.

(ii) Analysis of Stage 2 management.

The information regarding the defendant's management was based on the traditional sources of clinical information, normally obtained in such cases. These included:

(i) Handwritten notes

Antenatally the only source of written information was obtained from the patient's blue/co-operation obstetric card. Carried by the patient in case of an emergency hospital admission, the blue card contains all the relevant details pertaining to the patient's obstetric history and current care. The information within it is divisible into two: details which are "fixed" such as the age, past obstetric history etc. and details which are entered during every antenatal visit.

Kept and carried by the patient, the blue card contains the serial recording of the maternal weight and blood pressure, the clinical size of the uterus, presence of the fetal heart sounds, maternal urinalysis and any symptoms the patient may describe.

Mrs Gambina's blue card was the only source of recorded information of antenatal care as no other separate medical records had been kept, or made available, except for the ultra-sound reports. Although this habit is not ideal it is a common local phenomenon in private antenatal private care where the blue card serves this purpose. In Mater Dei Hospital, entries must be made in both the blue card as well as the hospital's file of the patient. This thesis strongly recommends that all details entered in the blue card are precisely replicated in the clinical file.

Notes pertaining to labour management were available and complete. They were presented in the patient's St Philips' Hospital file and included the partogram and an intra-partum cardio-tocographic tracing. The partogram,[270] is indispensable for analysing the course of labour and any deviation from normal duration. It has particular contributory value in cases of shoulder dystocia in pin-pointing any premonitory deviations from normal in the rate of cervical dilatation and fetal head progress in the maternal passages, in terms of flexion, rotation and descent.

[270] A graphical representation in labour of the relevant changes cervical dilatation, fetal heart rate, maternal pulse, blood pressure, and temperature as well as urine output and the volume and details of any intravenous infusions. At a glance such a chart identifies important deviations from the normal.

Notes relating to a consultation with a chest physician in labour due to the patient's asthma were available, although this was a precautionary visit rather due to any worrying issues. The paediatric notes were also available.

(ii) Electronically recorded information.

This may include:

a. All details pertaining to given appointments.

b. Obstetric health data.

c. Medical health data – current and past.

d. Surgical history.

e. Medications – current and past.

f. Investigations/tests.

No electronic data was supplied or asked for in this case.

(iii) Witness testimony including from the obstetrician herself, the plaintiffs (Mr and Mrs. Gambina) and the midwife were available from Court transcripts.

The rationale of reviewing the defendant's management:

Analysis of the Antenatal management

Analysis of the Labour Management:

Analysis of the Antenatal management

The rationale of contrasting defendant management with the established SOC was reconstructed from the answers to a prepared set of questions. While the answers could only be obtained from the material obtained from the Court case (notes made available plus oral evidence), the questions were arbitrarily drawn purely as a guiding framework for the report. The report itself was not bound in any way by these questions, which assisted rather than limited. Some questions overlap, but this tends to be inevitable in such questionnaires. The objective is to obtain information relevant to antenatal care management, such as:

The adequacy of such antenatal care:

- Was antenatal care commenced at a judicious time? Were the patient's details, height, weight, BMI, social, medical, obstetric and family history duly noted and entered in the file/blue card?

- Were the antenatal visits spaced out as per accepted norm? Is there evidence of the correct management of each visit? Were such results recorded at least in the blue card since a separate antenatal case file was not kept?

- Was there difficulty in establishing the date of last menstrual period expected and date of delivery (EDD)? Was this EDD confirmed by ultra-sound prior to 20 weeks gestation? Establishing the exact maturity of the pregnancy is crucial for many aspects, including that of correctly interpreting any future ultra-sound fetal weight estimations and corelating it to the fetal maturity as well as for accurately calculating/confirming the expected date of delivery. After 20 weeks gestation, the ultra-sound accuracy for establishing maturity may be impaired.

- Was the uterine size clinically assessed regularly per visit?

Evidence of a clinically large for dates fetus as detected in the antenatal visits would have incurred the responsibility of focusing on the possibility of development of macrosomia and if this is suspected, the obligation of full disclosure to the patient kicks in, on its own right.

- Was maternal weight checked at every visit and the weight gain profile scrutinized regularly to ensure progress along a normal range? Was there excessive weight gain, and if so, was there a semester preferential distribution? Excessive maternal weight gain may be relevant, both as a cause of impaired glucose metabolism as well as a potentially indicative of pari passu excessive fetal weight gain.

- Was urinalysis performed at every antenatal visit? Was it indicative of a need for further investigations such as the need for fasting blood

glucose/glycosylated haemoglobin HBA_1C, necessitated by heavy or repeated glycosuria?

- Was there evidence of antenatal risk factors suggestive of an increased incidence of shoulder dystocia in birth? These include:

    I. Medical and family history including any history along these lines of diabetes/large babies/actual shoulder dystocia/unexplained upper limb paralysis.

    II. Where parameters such as age, weight, BMI, height, pelvic anatomy as noted above, evaluated?

    III. Details of the patient's obstetric history including history of large babies, gestational diabetes, any aspect of first and second/or stage problems, including prolonged first and second stages, secondary arrest or, any difficulty in delivery including difficulty with the shoulders or actual dystocia, the use of instruments to assist delivery, etc.

    IV. Pointers to potential/occult pelvic problems such as previous maternal upper femoral/ pelvic fractures.

- Was there evidence of fetal macrosomia, which was missed misdiagnosed, misinterpreted? This question is sub-divided into a number of others:

I. Was there clinical (physical assessment, presence of gestational diabetes, maternal/fetal weight gain profile) evidence suggesting the presence or suspicion of fetal macrosomia?

II. Was there ultra-sound evidence of the fetal weight estimate approaching the 4-4.5kg range?[271]

III. Were any ultra-sound abnormalities noted, especially pertaining to fetal size/weight? A small deviation here may be used to give one example of the use of EBM pertaining to ultra-sound evaluation regarding fetal weight estimate. This concerns the fact that the detection of macrosomia by ultra-sound has sensitivity as low as 60% with a margin of error of at least 10%. The positive predictive value of a birthweight greater than 4.5 kg for predicting shoulder dystocia is only 3.3%. Clinically translated this means that it may be extremely difficult to diagnose macrosomia by ultra-sound scanning. This point is itself *very significant*, and to it, was the added fact that while reviewing the ultra-sound scan results, it became clear that, six days prior to delivery, the defendant had been misled by about 20% in the scan's assessment of the presumed fetal weight.

[271] Although 4 kg establishes the definition of macrosomia, 4.5kg establishes the "red zone" where clinical complications from macrosomia are much increased.

- Was there evidence that antenatal management could have diminished the chance of shoulder dystocia occurring for example by effecting changes in the maternal diet and diminishing fetal weight gain?

  This considers the possibility that dietary control could have affected the final fetal weight, if excessive. Such reasoning may apply if for example gestational/true diabetes had been present and particularly (but not exclusively) if accompanied by the wrong diet.

- Was there evidence that metabolic condition(s) particularly associated with shoulder dystocia was/were missed? This basically refers to true diabetes or gestational diabetes no evidence of which existed.

Analysis of the Labour Management:

Evaluation of Stage I.

- Was labour induced or was it spontaneous?

  Labour, which is induced, be it surgically or medically, may be associated with some degree of increased risk of shoulder dystocia.

- Was Syntocinon (oxytocin) used for augmentation of labour?

The use of Syntocinon in both induction and augmentation may be associated with an increased risk of shoulder dystocia. In this case, Syntocinon was only called for when shoulder dystocia supervened, but never used.

- Was the partogram correctly filled in?

- Was there evidence of any partogram abnormality regarding progress, fetal head descent, rotation or flexion?

- Was there any partogram evidence of abnormality in the rate of cervical dilatation abnormality?

- Was there any partogram evidence of secondary arrest?

- Was there any evidence of fetal distress?

- Was there a need for I-P CTG monitoring and if so, was it satisfactory?

Evaluation of Stage II of labour.

- Was there any abnormality of the second stage of labour prior to delivery of the fetal head?

- Was there any difficulty in delivering the head?

- Was there evidence of the classical signs indicating impending shoulder dystocia once the head was born? If the answer to this question is positive, where any positive management steps taken to curtail the period of dystocia, such as the uplifting of maternal legs onto stirrups?

- When was shoulder dystocia precisely diagnosed?

- What management was adopted when shoulder dystocia was diagnosed?

- What precisely were the manoeuvres employed in this management?

- What was the final manoeuvre which effected the liberation of the shoulders?

- What was the time interval between birth of the fetal head and the full birth of the child?

- Was there any evidence noted in the scrutiny of any deviation from normal practice or any other abnormality even if not considered relevant to the eventual occurrence of shoulder dystocia.

- Was there any evidence of a breach of the SOC from the aspect of disclosure?

The analysis of the methodology employed in the drawing up of the export report in the *Gambina* case, is but an illustration of the effort of a local obstetrician who sought evidence-based direction in seeking objective, fair, and impartial conclusions. Much reflection and study preceded the drawing up of the report, including the consideration of adopting an approach which is both logical, systematic, as well as intelligible to a non-medical reader. Despite the details of the report, which was apparently atypical of expert reports in its unusual length, an attempt was made to keep arguments as concise and lucid as possible taking care to avoid over-complex reasoning which is considered both off-putting as well tends to make the judiciary suspicious of ulterior motives.[272] Since the subject of shoulder dystocia involves mechanical principles which are best appreciated through pictures, these were liberally used and two examples are reproduced here.

A short declaration, albeit not requested, accompanied the report stating that while writing the report, the expert considered himself still under the oath taken in Court, that the report was based on the author's own obstetric experience and that no one had influenced or tried to influence the outcome of the report. Unlike the UK situation, no reference could be made to the fulfilment of requirements regarding the familiarisation with any code or protocol of expert witness practice for none exists locally.[273]

This is not senseless ritual for such reports may not be accurate, honest, or informed,[274] and once the requisite code or protocol has been made available and is studied, one can

[272] *Lewis v Daily Telegraph Ltd* [1964] AC 234 (HL).

[273] In the UK, the witness must state in writing that he is aware of the requirements of Practice Direction 35, of the expert witness protocol and of the statement on pre-action conduct.

claim no excuse for failing to fulfil the requisite obligations. It is time for Malta to take a leaf or two out of the UK's Protocol for the Instruction of Experts[275] including, among other things, guidance instructions for the writing and submitting of the expert's report.

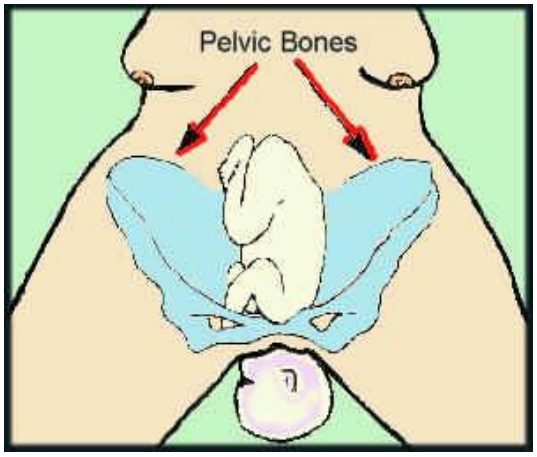

Figure 2 Anterior view of shoulder dystocia

The report carried no reference to underlying research or medico-legal references to avoid the least suggestion of a patronizing attitude. Furthermore, while a minimal number of references were included, the massive bibliography employed was not included but were downloaded and kept available for use at the Court's discretion.

[274] Feld AD, Carey WD. Expert witness malfeasance: how should specialty societies respond? Am J Gastroenterol. May 2005; 100(5):991–995.

[275] See note 162.

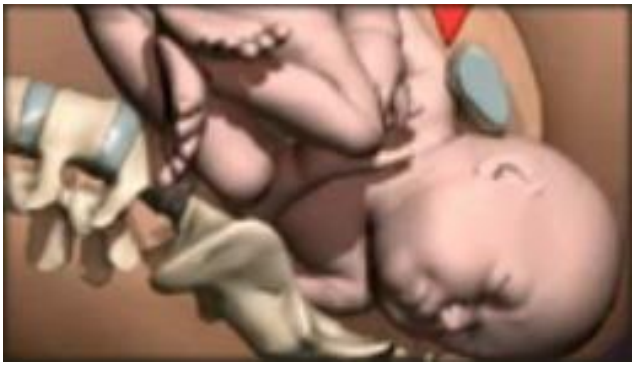

Figure 3 Side view of the right fetal shoulder impinging on the pubic ramus

2.14 The need to effect change

There *is* occasional fleeting evidence pointing to a local awareness of the need to effect changes in the general climate related to Court experts. Thus in 2001, the government of the day set up a specific commission to review the situation regarding the appointment of such witnesses. The concept was commendable but the actual mechanism of action left much to be desired. The commission set up by the Minister of Justice and Local Government by letter dated 28 August 2001, regarding the appointment of Court experts[276] was composed of a judge, a magistrate, a police superintendent, six lawyers, and a lay secretary. The commission held consultations with various professional bodies as recorded in part two of the report. We find consultations with the Malta Union of Professional Psychologists, the Department of Correctional Services, the Association of Social Workers, the Chamber of Architects, the Malta National Laboratory Co. Ltd, the Maltese Psychological Association, the Institute of Forensic Studies and even the Mortuary Services. The secretary of the Medical Association of Malta was one of the persons simply listed as 'expressing an

[276] Set up by the Minister of Justice and Local Government, Dr Austin Gatt with the project brief relating to the appointment of Court experts. 2001. Appendix V. Report on the appointment of Court experts.

interest'. The seeming lack of medical and particularly obstetric consultation is further evidenced in Document A, in the listing entitled 'Specialities and Areas of Expertise that may be required in Civil and Criminal Cases'. Among the listed eighteen specialities,[277] we do find gynaecology but not obstetrics, possibly out of lack of discernment between the two specialities.

At present, just as the Maltese judiciary is deprived of appropriate direction by an appropriate medico-legal framework, so is the obstetric and any other Court expert, deprived of much that foreign jurisdictions consider as essential for the professional to correctly and prudently discharge his Court duties. This chapter has referred to and evaluated to many such necessities. Change is required both from the system and from those acting as experts. However, it is the government's duty to set the benchmark. Setting up a Commission of investigation is certainly a step in the right direction as long as it commences by seriously and critically evaluating the Court expert scenario. The needs for change are extremely vast and widespread and cannot be accommodated by a one-off Commission unless such a Commission's remit is to assess the present deficiencies and outline the complex and multi-faceted way forward.

It is crucial for the Maltese legislator to consider a serious revision of articles 644-692 in the Code of Organization and Civil Procedure. As matters stand, it is hardly surprising that a local modus vivendi has arisen which is not compatible with optimal output and results while simultaneously ignoring the occasional symptom of the malady which erupts from time to time. Systems adapt and the need for change is hardly perceived from within.

[277] Including veterinary services.

2.14.1 Revising articles 644-692 in the Code of Organization and Civil Procedure

Although one may assume that a *simple* revision of articles 644-692 of the Code of Organization and Civil Procedure may remedy all, this could not be further from the truth. Such a revision, like one piece of a large mosaic depends on and reciprocally impinges on a number of changes, ranging from to the simplest to the most complex.

Firstly, it may be advisable for any amendments to the Code of Organization and Civil Procedure to be part of a much larger upheaval including the introduction of the proposed Lex Medica as discussed in section 5.3. It may be that some sections from Article XVI of the Lex Medica may be more appropriately located among article 644 – 692 of the Code. Some parts may require cross-referencing. Thus, while the Lex Medica's Article XVI section IV makes reference to a code of ethics, such a code of ethics would be more fittingly suited within the Code of Organization and Civil Procedure.

Secondly, the required revision of the articles referred to may involve such extensive revision as to probably benefit from a total substitution rather an extensive amendment. The proposed amendments include:

I. The elevation of the Court expert's role to specialty requiring qualification or licensing, which in turn demands the organization of relevant courses which can be at university level or preferably under the aegis of the newly created MIMLS. The latter would be more amenable to ensure that this is not a one-off course

but will be followed by regular in-house refresher courses. Furthermore, it will be MILM's responsibility to gauge the degree and nature of the courses within the evolving nature of medico-legal principles as well as the introduction of relatively new materia medica in the Maltese Islands. One example of the latter would be the subject of assisted reproduction including in-vitro fertilization and other aspects of artificial reproductive techniques, as recently locally introduced.

II. The establishment of a serious and efficient system of assisting Court in selecting a suitable expert. The role of the local Malta Medical Council and the specialty colleges, in this case the MCOG has been evaluated in section 2.91.

III. A radical modification of the methods of appointing the expert and his summons to Court to ones which are consonant with the gravity of such an undertaking.

IV. The establishment of clear procedural guidelines to the expert who must confirm his familiarity with them.

V. The establishment of clear ethical guidelines and the confirmation by the expert of his familiarity with them.

VI. The specifications of the report to be submitted by the expert, both in terms of discussion parameters as well as manuscript format. The expert must also be informed that his report may, in due time, be reviewed by a peritus peritorum..

The effects of code amendments or substitution need to be regularly reviewed and amended as required. The Malta Institute of Medico-Legal Studies may provide an ideal role working with any |Government commissions to discuss, review and improve amendments as necessary.

CHAPTER 3

The medico-legal vulnerability of the current Maltese obstetric service and proposed corrective amendments

3.1 Introduction

Sir Harry Talbot Gibbs, Australia's Chief Justice (1981-1987), often referred to a deep seated concern that the law of negligence was exhibiting a rapid need of reform.[278] In Malta, where *Maltese law ... lacks a legislative framework specifically applicable to juridical relationships, and rights and obligations arising in the sphere of healthcare,*[279] the situation is significantly worse as regards medical law than Sir Harry's deepest concerns for the law of negligence. The lack of a legislative medical framework has been repeatedly and rightly stressed by a number of Doctor of Laws' theses submitted to the University of Malta, including those by Zarb Adami (1999).[280] Bernard (2008),[281] and Lia (2009).

[278] Sir Harry Gibbs. Chief Justice of Australia (1981-1987) Living with Risk in our Society, 14 May 2002. As quoted in Bernard R. Medical Malpractice- The need for local legislation. Unpublished thesis submitted for the degree of Doctor of Laws, University of Malta. May 2008.

[279] Lia A. The nature and consequences of contractual relationships involving patients, medical practitioners, and health institutions. Unpublished thesis. Faculty of Laws. University of Malta, May 2009., submitted for the degree of Doctor of Laws.

[280] Zarb Adami K. The consequences of negligence in the medical profession. -a comparative study and proposals for reform. Unpublished thesis. Faculty of Laws, University of Malta, June 1999, submitted for the degree of Doctor of Laws.

[281] Bernard R. Medical Malpractice- The need for local legislation. Unpublished thesis, Faculty of Laws, University of Malta, May 2008, submitted for the degree of Doctor of Laws.

A proposal for the creation of such a legislative framework within the Lex Medica, in a body of laws is put forward in section 5.3. In keeping with the subject of this thesis, the proposed body of laws is mostly directed at obstetric care, but this can be amended to apply to general medicine or all other specialties with minimal effort.

The institution of a Lex Medica within the corpus of the Laws of Malta requires a pari passu evaluation of other local medico-legal short-comings both within the legal sphere as well as within the medical service. An example of the former would be the collection of serious shortcomings in the Maltese Court expert scenario as evaluated in chapter two. The Local obstetric shortcomings vis-à-vis legal vulnerability are dealt with in this chapter which proposes corrective amendments to be considered by the MOS. This thesis firmly believes in such a dual and concurrent medico-legal approach if genuine progress is to be achieved.

3.2 The Maltese Obstetric Service

The Maltese obstetric service (MOS), referred to in this thesis does not exist as an entity per se but arbitrarily comprises a functional conglomerate embracing the OBGYN Department at Mater Dei Hospital, the obstetric contingent within the Radiology Department, the general MDH administrative umbrella and the Ministry of Health. Under no circumstances is MOS simply directed at the local OBGYN department which, on its own responsibility, could not even begin to consider most of the proposed changes in this chapter. Introducing concepts which ought to be present, such as the tightening of what grade of personnel may perform a congenital anomaly scan may be within departmental remit, but major changes will require immediate administrative

clearance and more than likely will require clearance at ministerial level. In most cases, administrative clearance of anything beyond minor changes often implies ministerial clearance without which, little indeed is achieved in the Maltese Islands.

The entity implied by the term MOS is a complex inter-functioning one with multi-level multiplier effects on the functional, structural, financial, political and social connotations. Admittedly, to some extent, similar mechanisms operate in any system. However, unlike what happens say in the UK with its system of National Health Service (NHS) Trusts, it would be unthinkable for MDH administration to set up a local VBAC clinic[282] on its own initiative. Such a paternalistic system of running affairs in the UK would be equivalent to requiring the direct permission of the Secretary of State for, say, Mid-Essex Hospital NHS Trust to organise such a clinic! Administrative heads of the OBGYN Department maintain constant, direct, open-line communication with the Health Ministry (governments change but local habits do not). This option of direct ministerial access is a privilege enjoyed by a number of local citizens and this applies to all the various ministries. Such links, often forged at election times, may secure many advantages which may affect work dynamics. Thus, a disenchanted receptionist/clerk/nurse/midwife who has been shifted from morning to afternoon clinics may easily use her personal contact telephone to attempt to block the move. Whether this succeeds or not is another matter, but such is the frequent local mentality and its available options and circumstances. It must be seen as part of a very particular socio-cultural milieu found in the island and applies to whoever is in government. All

[282] A clinic, presently unavailable locally, specifically dealing with patients who had a previous caesarean section and are now planning a normal birth.

this and more is implied in the generic but highly functionally significant term the Maltese Obstetric Service as coined by this thesis.

3.2.1 How efficient is the local obstetric service?

Establishing the efficiency and international standing of the local obstetric service is the first requisite before contemplating any proposals for amendment. The statistics published by the local National Obstetric Information System (NOIS)[283] for 2016,[284] speak well of the efficiency of the local service. In 2016, the Maltese Islands registered 4465 total births with o maternal deaths.[285] For fetal weights of 500g and over, the fetal mortality[286] rate was 3.7/1000 total births. Neonatal mortality[287] rate stood at 4.9/1000 live births, with the early neonatal mortality[288] rate being 3.7/1000 live births and the late neonatal mortality[289] rate holding at 1.1/1000 live births. The perinatal mortality[290] rate stood at 7.5/1000 total births, and this includes those deaths associated with serious anomalies which in other countries would have led to an early termination of pregnancy. These results speak for themselves in placing the Maltese obstetric results

[283] The National Obstetric Information System (NOIS) is an internationally recognised hospital information system, monitoring and publishing all Maltese obstetric activity, originally launched in collaboration with the WHO-OBSQID project at the beginning of 1999.

[284] The NOIS Annual Report 2016. Directorate for health information and research.

[285] The death of a woman while pregnant or within 42 days of termination of pregnancy, from any cause related to or aggravated by the pregnancy or its management but not from accidental or incidental causes.

[286] Fetal death at any stage prior to birth.

[287] Death within the first twenty-eight days of life.

[288] Death between zero and seven days after birth.

[289] Death between seven and twenty-seven days after birth.

[290] Fetal deaths after twenty-four weeks of gestation up to seven days after birth and includes stillbirths.

well within satisfactory European levels of performance. In fact, Malta's good standard of health management had been internationally recognised even before the country joined the European Union (EU) in 2004. Thus in 2000, out of 191 member states the World Health Organisation (WHO) placed Malta in the fifth place on matters of health management and second in *over-all* health system performance.[291]

3.3 Lack of obstetric medico-legal statistics

The amply stressed lack of medico-legal awareness in Malta has many implications one of which is the registering, maintaining and publication of any statistics related to any such activity. This is not a rare finding in a significant number of EU countries, particularly in the Mediterranean region, which share this lackadaisical attitude to medico-legal affairs. These countries also share an astonishing apparent lack of realisation of the effects of litigation on daily clinical practice.[292] This sharply contrasts with countries such as the USA, UK, Canada, Germany, Italy and others which have been down the bitter road and publish meticulous statistics. This often leads or should lead to a concomitant improvement in the very clinical practices which had led to the original litigation.

The non-availability of gathered and published medical data is often heralded by an absence of systemised referral and collection of the relevant information. In Greece, for example, a 2017 WHO report[293] revealed the non-existence of a central authority to

[291] The World Health Report 2000. Health Systems: Improving Performance. World Health Organization.

[292] Hammond CB. The decline of the profession of medicine. Obstet Gynaecol. August 2002; 100(2):221-225.

[293] Economou C, Kaitelidou D, Karanikolos M, Maresso A. Greece Health System Review. Health Systems in Transition. The European Observatory on Health Systems and Policies 2017; 19(5):1-192.

which one could revert and report relevant cases resulting in an obvious and significant lack of litigation data. In Portugal, no studies on obstetric medical liability had been done prior to 2007,[294] although about half of the local obstetricians had faced Court and 25% of them even admitted to practising a negative type of defensive medicine.[295]

Malta dwells in this category, along with other facts attesting to an uncultivated medico-legal consciousness. For example, it was only on 14 March 2014 that medical indemnification insurance became legally[296] required for Maltese Medical Council registration. Yet, the fact that such subsidiary legislation *was* finally enacted also reflects a sudden realistic, yet compartmentalised concern based on increasing litigation. As for litigation statistics, however, these remain non-existent both at government level as well as, surprisingly enough, even at medical indemnity insurance companies. This surprising absence of concern with official statistics extends to other aspects of medical practice such as the registering of new cases of cerebral palsy which only commenced in 2016.[297] We speak here of the commonest childhood motor disability disorder and one where litigation pay-outs in proven obstetric negligence often far outstrip all other conditions.

3.3.1 Establishing a local arbitrary reference point

[294] Moreira H, Magalhães T, Dinis-Oliveira RJ, Taveira-Gomes A. Forensic evaluation of medical liability cases in general surgery. Med Sci Law. 2014; 54 (4):193-202.

[295] See note 294.

[296] See note 1.

[297] Information supplied by the Maltese Department of Health on the 16 August 2016.

The basis of proposing amendments to diminish obstetric liability must be guided by a framework of practicality including the statistical basis of known litigation frequency. It was felt that the statistics published by Britain's NHS Litigation Authority (NHSLA)[298] ought to be used for two main reasons:

- The roots of the Maltese school of medicine at both under- and post-graduate levels are steeply immersed in British tradition. Thus, the Maltese obstetrician generally but not invariably, considers his official grand entry into the world of obstetrics and gynaecology on attaining his membership of the UK's Royal College of Obstetricians and Gynaecologists (RCOG). This statement must now be partially qualified by the increasing interest in European qualifications.

- In spite of all challenges and self-criticism, the UK's system of NHS litigation has been finely honed to a transparent and exemplary one which lends itself to much academic dissection and application.

One may raise objection to the use of another country's medical litigation profile. However, the UK's obstetric medico-legal profile as reported by the NHSLA seems to be generally replicated in countries which publish such statistics. The pattern shows a universal heavy leaning towards obstetrics rather than gynaecology with the OBGYN specialty often leading or close to leading in such liability figures. Within obstetrics, labour management is essentially and universally the principal cause of obstetric litigation, and in turn, with labour taking pride of place. Within labour management

[298] The operative arm of the NHSLA has been called the NHS Resolution, since April 2017. It manages negligence and other claims against the NHS in England on behalf of its member organisations.

itself the predominating issues tend to be related to intra-partum hypoxia and fetal trauma. Thus, in looking at Coimbra in Portugal, one finds a not dissimilar similar pattern of litigation to that in the UK with OBGYN among the front runners in the litigation race and with obstetrics contributing to the great bulk of cases within OBGYN itself. Looking within the obstetric specialty, the management of labour clearly predominates with antenatal care issues being only limited to 19%. The labour management issues comprise 50% of cases being related to perinatal asphyxia and 24.4% to traumatic injuries of the new-born, with the rest presenting a number of mixed elements.[299]

Hence, it was felt justified to apply the well assimilated results of the NHSLA's report covering the decade 2000-2010 to the local scene utterly bereft of statistical guidance as it stands. The report entitled *Ten Years of Maternity Claims: An Analysis of NHS Litigation Authority 2000-2010*[300] has been thoroughly dissected and expanded upon by various relevant bodies including the RCOG.[301] In this context it is worth quoting the following RCOG's comments on the report:

The NHSLA report is staggering in its stark facts and the reality of the enormous costs of maternity litigation. Hidden behind the financial burden are countless stories of tragedy to individuals and families, which are not included in this report. This is a serious wake-up call to all with responsibilities in providing maternity care, whether

[299] Domingues AP, Moura P, Vieira DN. Lessons from a decade of technical–scientific opinions in obstetrical litigation. Journal of Forensic and Legal Medicine. July 2014; 25:91-94.

[300] See note 39.

[301] RCOG statement on the NHSLA report '10 Years of Maternity Claims'. RCOG. 26.10.12.

as providers, commissioners or regulators. Urgent action is needed to further improve the safety of clinical services for women and their babies.

This is an illuminating statement and one worthy of the spirit of any mission statement for any country seeking to elevate medico-legal consciousness milieu to the twenty-first century The RCOG's appeal for urgent action in this sphere applies to all European obstetric services, not least of which is that offered by the MOS. In proposing the local amendments found in this chapter, some of the many NHSLA recommendations were also taken on board when they could be applied locally. The NHSLA report at times makes reference to guidelines from various bodies such as the UK's National Institute for Health and Care Excellence (NICE)[302] as well as the RCOG's guidelines including 'green top' publications. The original information from these sources, as referred to by the NHSLA report and some others which were not, have also been used as a basis for a number of local proposals for amendments. All case law referred to has been originally researched and is not related to the NHSLA report, which quotes no direct cases although it does refer to a few cases without however publishing Court or individual details.

[302] National Institute for Health and Care Excellence.

3.3.2 Using the NHSLA Report for a systemic review and proposed amendments to clinical practice

According to the NHSLA report, maternity claims constituted the second highest number of UK medical global claims. However, financially, they outstripped all other specialties. The three most frequent categories of obstetric claims were those relating to:

- Management of labour (14.05%)
- Caesarean section (13.24%) and
- Cerebral palsy (10.65%).

Cerebral palsy and management of labour along with cardiotocographic (CTG) interpretation accounted for 70% of the total *value* of all maternity compensation. One should note that cerebral palsy is the only *medical condition* being singled out in the NHSLA litigation profile when considering groupage of conditions such as labour management or topics with a wide litigation umbrella potential such as caesarean section litigation. This is due to the unequalled medico-legal importance of cerebral palsy, which is also unique in the sheer magnitude of its compensatory pay-outs. These are also some of the reasons justifying the creation of appendix three which specifically deals with the medico-legal aspects of cerebral palsy.

In addition to the main report covering the 2000-2010 decade, the NHSLA report on a secondary tier singles out for further discussion four important topics, namely:

- Antenatal ultrasound investigations.
- CTG interpretation.
- Perineal trauma.
- Uterine rupture.

These entities also carry significant importance in the marked legal vulnerabilities of the Maltese obstetric service. Hence, they have been individually discussed and applied to the local scenario. Some degree of overlap is inevitable in these discussions as exemplified by the ubiquitous presence of CTG and caesarean section with its multi-faceted medico-legal vulnerability.

3.3.2.1 Labour management

In the UK, compensation pay-outs for labour malpractice constituted about 70% of the total figure of £3.1 billion paid out in the period 2000-2010 confirming its lead in the pecking order of the litigation profile. In reviewing the vulnerabilities of the local management of labour and their proposed correction, this section is divided into six major sections, namely:

- Documentation pertaining to labour management

- Labour ward staff deployment

- Prostaglandin cervical ‘ripening’ and Syntocinon stimulation

- Intra-partum ctg. (I-PCTG) monitoring

- Caesarean section

- Cerebral palsy

3.3.2.1.1 Documentation

Labour management related documentation including the patient’s clinical file, the antenatal co-operation card (blue card), the partogram and intra-partum CTG tracings are crucial Court evidence. The blue card, already referred to in section 2.13, contains information which should be copied into the clinical file, in case of future litigation. Alternatively, the blue card should be photocopied in its entirety and legally certified as a true copy. The blue colour dates back to its introduction in 1978 and has no clinical relevance.

The partogram is medico-legally most crucial as it sheds objective light on the timed progress of labour allowing accurate assessments of management within the requisite SOC or otherwise. The partogram should also have all the details pertaining to the use

of any prostaglandins for cervical ripening as well as the indications, dose, infusion rate and time of administration of any Syntocinon used to induce or augment labour. The partogram will also have a summary of all relevant labour details up to the birth as well as the neonate's initial clinical observations.

The I-P CTG tracing itself, has been the frequent basis of alleged obstetric negligence resulting in fetal death or damage through mismanagement of I-P CTG abnormalities. Hence, it should be carefully stored in a plastic cover and carefully *secured* in the file's side compartment. This applies to both normal and abnormal tracings. At MDH, at the end of labour such tracings are simply folded and without any protective covering unceremoniously slid unsecured into the MDH hospital file side pouch. Displacement, spontaneous or otherwise, is easy and it is not unknown for such tracings to be irretrievably "lost". In cases where labour had an adverse clinical outcome, future legal challenge must immediately be prepared for including scanning and electronic storage. In such cases, copies of the relevant notes, antenatal co-operation card, partogram and I-P CTG tracing should be safely stored away in the MDH legal office. Such tracings should always be stored electronically and it must be remembered that due to the thermo-sensitive nature of the paper, CTG tracings may fade away with time.

One must bear in mind continuously the great medico-legal relevance of all labour related medical records in all their forms including digital ones. Court cases are not rarely indefensible because of poor documentation[303] and, in a 2015 Medscape malpractice report,[304] poor documentation was itself directly responsible for 4% of

[303] Thomas J. Medical records and issues in negligence Indian J Urol. Jul-Sep 2009; 25(3): 384–388.

[304] Peckham C. Medscape Malpractice Report 2015: Why Ob/Gyns Get Sued. Medscape. 30 April 2019.

litigation. Details from the patient's recorded documentation are often the most important of Court influencing evidence.[305] In *Baynham v. Royal Wolverhampton Hospitals NHS Trust*[306] a cerebral palsy case, the availability of extremely accurate and well-kept clinical records convinced the Court that no medical negligence was responsible in the causation of the brain damage resulting from an abruptio placentae.

In acute conditions such as pre-eclampsia, accurate and detailed documentation, fluid charts and neurological assessments attain tremendous importance especially if the conditions deteriorate. It is disconcerting to be chastised by the Court on bad record keeping as in the case of *R v. Inner London North Coroner*[307] where, admittedly, the atrocious/non-existent record keeping was a reflection of the apparently equally atrocious clinical mismanagement leading to the death of the mother of twins from pre-eclampsia/eclampsia.

The *timed* details in labour management documentation may make or break a case especially in issues such as intra partum hypoxia (IPH), where minutes can make a difference to life or death. In *Popple (a child by his litigation friend, Stephen Popple) v. Birmingham Women's NHS Foundation Trust,*[308] an avoidable interval of twelve to seventeen minutes was deemed as having seriously contributed to the circumstances leading to severe dyskinetic or athetoid cerebral palsy. Similarly, in *L v. West Midlands*

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[305] See note 304.

[306] *Baynham v. Royal Wolverhampton Hospitals NHS Trust* [2014] EWHC3780GB.

[307] *R v. Inner London North Coroner* (2001) EWCA Civ 383.

[308] *Popple (a child by his litigation friend, Stephen Popple) v. Birmingham Women's NHS Foundation Trust* [2012] All ER.

Strategic Health Authority,[309] the Court ruled for negligence in a case of cerebral palsy and declared a loss of six avoidable minutes with a tight double cord (nuchal cord) around the infant's neck as responsible for the bulk of the cerebral insult.

Clinical records should be safely stored and made available whenever recalled. Safe storage and recall of the notes are an administrative responsibility which, however, can impinge on the defendant obstetrician's fate. Especially in cases involving cerebral palsy, the Court often looks with understandable sympathy on the victim and it is far from unknown for the statute of limitations to be waived. The plaintiff may now be in his twenties and less commonly in his thirties. In *Davis v. City and Hackney Health Authority*,[310] for example, a cerebral palsy patient born in 1963 sought Court redress in 1985 with a writ being issued on 1 April 1987. The Court understood that it was only then that the plaintiff realised, or was made to realise, that his condition may be the result of obstetric mismanagement.

Such instances provide a challenge not only to memory and witness availability, but also to the hopefully safe storage of the case file with all its contents in a well nurtured environment. Even with the most conscientious of storage of such notes, there may still be problems of availability or even of deterioration. For example, thermal CTG paper is known to deteriorate with age and hence the earlier advice to scan relevant tracings

The non-availability at Court of any relevant notes pertaining to any aspect of labour management constitutes one aspect of s*poliation.* This is defined as the intentional,

[309] *L v. West Midlands Strategic Health Authority* [2009] EWHC 259 (QB).

[310] *Davis v. City and Hackney Health Authority* 2 Med LR 366 (1991).

reckless, or negligent withholding, hiding, altering, fabricating, or destroying of evidence relevant to a legal proceeding. However genuine the reason for such spoliation, the matter, as expected, tends to reflect badly on the defendant. Spoliation of the I-P CTG tracing, for example was viewed very negatively by the Court in *London Strategic Health Authority v. Whiston*[311] where:

The judge put in the scales the prejudice that the defendant would suffer by reason of the loss of the CTG.

Since it is clear that all labour management related notes carry tremendous legal weight, such notes must not be tampered with, corrected, modified or in any way altered. In fact, once any official complaint is received by the hospital administration about alleged negligence and even more so if formal Court procedures have been instituted, the clinical notes should be under lock and key awaiting further instructions. As soon as notice of litigation is received by the administration, the clinical notes should be electronically stored in their entirety and the copy safely stored away separately from the original notes.

Since written clinical entries carry tremendous legal weight, they should be clearly written in indelible blue or black ink, dated, timed and signed. Corrections done at the time of original writing should be done by a single clear strike which still allows the original to be legible.

[311] *London Strategic Health Authority v. Whiston* 3 All ER 452(2010).

Proposed amendments to the MOS regarding the labour ward notes include the following:

I. The patients' labour ward notes, including the partogram, I-P CTG and all labour related drug sheets, drug administration sheets and other pertinent material must be safely stored but remain accessible whenever required, up to a minimum of twenty- five years duration.

II. In cases where labour was complicated by an adverse clinical outcome affecting the new-born's well-being, the I-P CTG tracing must be electronically saved in its entirety and in one continuous piece and the original appended safely in the patient's file.

III. The thermal paper used in the CTG tracing must be of an optimal level to ensure its preservation as much as it is possible. Optimal storage conditions must also be ensured.

IV. Once litigation has commenced, all of the patient's related records must be photocopied or preferably electronically scanned with the original ones stored at the legal office.

3.3.2.1.2 Labour ward staff deployment

The duties of both obstetric and midwifery staff at the MDH labour ward are guided by weekly rosters. The obstetric roster is usually drawn by a secretary, who basically slots

in the name of the consultant according to his turn in covering labour ward but allots junior (sub-consultant) duties partly by firm (team) duty and partly by exigencies of the department. However, these exigencies are usually solved at the secretary's discretion which essentially cannot be too discerning as to the legal implications of allotting staff responsibilities. This firm[312] split up has become habitual, and at times to the point that the concept of a working team is defeated. It may lead both to disruption of patient care and follow-up as well as the firm members' academic progress and assessment.

The firm covers labour ward from 08.00hrs of one day to 08.00hrs of the following day completing a twenty-four hour shift. During this shift, the firm carries out its elective deliveries, be they inductions of labour or caesarean sections, and also provides continuous emergency obstetric and gynaecological emergencies. The consultant officially leaves MDH at 14.30 hrs but remains on call from home for the remaining period of the twenty-four hour shift. The resident specialist, who is normally recently certified is therefore the most senior person in charge of labour ward and all other emergency admissions within the OBGYN Department. In grave matters, he communicates with the consultant who may choose to be physically present if the matter is sufficiently serious.

The NHSLA report stresses the necessity of an increasing consultant presence in the labour ward.

[312] The firm is composed of a consultant, resident specialist, higher or basic specialist trainee, first year foundation doctor and at times a second-year foundation doctor.

"In the future, there will be an increase in obstetric consultant cover out of hours in the largest maternity units"[313]

This has two points of local application. The first is that in the present system, it is important for the consultant to *make his presence felt* from 08.00hrs to 14.30hrs. This helps lead by example, maintains the necessary discipline and adherence to protocol and allows consultant review of high-risk cases as well as of dubious I-P CTG tracings. By 14.30 hrs, unless the labour was atypically busy, most of the days early inductions should have delivered.

Wise midwifery deployment is no less crucial and demands reflecting on by the MOS. The more experienced midwives should be allotted to the higher-risk patients. This demands an adequate shift complement, a sense of staff co-operation and an established system of serious accountability. Allocating the right midwife to the right patient may avoid catastrophes such as that encountered in *Jill Clark (A.P) Pursuer and Reclaimer against Greater Glasgow Health Board Defenders and Respondents.*[314]:where Syntocinon over-stimulation led to a ruptured uterus and severe IPH leading tosevere cerebral palsy. The Court pin-pointed the crux of the problem:

The midwife in charge had failed to allocate a qualified midwife to supervise the student midwife. The midwives, like the registrar, knew or ought to have known of the risks caused by the use of Syntocinon and that the labour was to be undertaken with care.

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[313] See note 39.
[314] *Jill Clark (A.P) Pursuer and Reclaimer against Greater Glasgow Health Board Defenders and Respondents.* 2017 CSIH 17.

They ought to have stopped or reduced the Syntocinon and sought review by a more senior midwife, or a member of the medical staff, at or around 3.05am.

Midwifery staff shortage is a universal, long established common denominator in many labour ward disasters. Often the result of an end-point of conglomerate factors, some of these catastrophes may have had a different outcome had an experienced and practical midwife been orchestrating the immediate situation. Labour ward midwifery shortages have drawn the clear and distinct warning to the British government by the RCOG.

The difficulties in securing staffing in obstetric units is particularly worrying. Moving forward, it is anticipated that rota gaps will persist and worsen in most units. The pressures on maternity services are growing which could compromise the experience for women and their families. Stretched and understaffed services also affect the quality of care provided to both mothers and babies. If the UK governments are serious about improving the safety of maternity services, these staffing and capacity issues must be addressed as a matter of urgency.[315]

This argument, as it stands, can be forwarded to the MOS with the full consciousness that responding to such a request involves many administrative chess board moves, not the least of which are budgetary ones. However, the MOS's role does not start and finish with an effort at increasing the midwifery complement, which incidentally includes attractively advertising the midwife's role to attract potential young

[315] RCOG comment by Professor Lesley Regan, RCOG President, in response to the National Maternity and Perinatal Audit (NMPA) Organisational Report 11 August 2017.

newcomers. It should also be the MOS' mission statement to ensure the optimal deployment of midwives within the labour ward and smashing long established seniority-based decisions of which midwife looks after which patient, the fostering of healthy obstetrician-midwife relations, and a number of other issues. The latter include the ensuring of adequate communication and hand-over, assessment and education of I-P CTG management, and a number of mundane "small" things which have potentially major repercussions. One must also bear in mind the unfortunate aspect of obstetrician-midwife inter-professional rivalry which locally has significant potential medico-legal repercussions.

The NHSLA report's emphasis on the legal vulnerabilities of labour management provides myriad lessons to the MDH scenario where, in the absence, as yet, of serious Court challenge, the need has not arisen to take stock of the potentially dangerous practices which bedevil daily labour ward work. The NHSLA report is a golden opportunity to reflect on the need for self-assessment before the need to clean one's house is painfully imposed as a result of medico-legal litigation.

Proposed amendments to the MOS on labour ward staff deployment, include:

I. The drawing up of the obstetric labour ward staff roster should be the sole responsibility of the head of department or his immediate delegate and who should be well aware of the professional status of each member of the department.

II. Firm splitting is to be avoided, except in rare instances. By employing 2 or 3 extra doctors, enough laxity will allow the maintenance of the intact firm. Such extra doctors may rotate 6-monthly so as to also participate in firm duties.

III. The increased presence of the consultant in labour ward between 08.00 – 14.30hr (His official in-hospital hours of duty).

IV. The consideration for a call of a consultant mostly covering labour ward duties or at least such duties as limited to 'after-hours'.

V. Increasing the advertising attractiveness of the profession of midwifery. In the meantime, the employment of overseas midwifery advertising and recruitment, should be considered. This involves discussions with the Malta Union of Midwives and Nurses.

VI. Re-visiting the midwife's code of ethics and clinical duties and legally defining the border between normal and abnormal obstetrics.

VII. Re-visiting the logistics, scopes, risks of labour management and their avoidance by in-house joint obstetric/midwifery symposia.

VIII. The regular reviewal of labour ward problems, adverse outcomes and near misses, while avoiding witch-hunting. The institution of a formal and enforced handover system.

IX. The instilling of a sense of consciousness of the significant medico-legal implications of labour ward duties, demanding clinically correct management, the precise recording of such management, as well as remembering the potential retrospective scrutiny of such management in any future allegation of mismanagement. This can be achieved by a senior person attuned to medico-legal issues who randomly assesses the local situation and regularly reviewing the clinical notes as to their legal standing.

3.3.2.1.3 Prostaglandin cervical 'ripening' and Syntocinon stimulation

The agents known as prostaglandins (PG) and Syntocinon (oxytocin) play indispensable roles in the modern management of labour. PG renders the unripe cervix inducible when a decision has been decided to deliver the child as in a case of post-maturity. Judiciously employed, PG and Syntocinon, singly or in sequence though never simultaneously, may generate a labour which perfectly mimics a spontaneous one. However, either agent, may lead to a number of complications often as a result of uterine hyper-stimulation, both in terms of over frequent contractions or else excessively strong even tetanic ones.[316] Hyper-stimulation will increase the period of fetal de-oxygenation which may easily tip the fetus into fetal distress. The outcome may range from the extreme of still-birth to any form of hypoxic induced damage, including HIE which may progress to cerebral palsy. Artificially induced/augmented contractions, even if not excessive, as indeed may also happen even in spontaneous labour, may also lead to a ruptured uterus in the patient with a scarred uterus from previous surgery such as a CS, which risk is increased with hyper-stimulation.

[316] Lasting two minutes or more, instead of thirty to ninety seconds.

Both PG and Syntocinon are in constant and daily use in essentially all labour wards, including MDH's. They are an indispensable part of the modern obstetrician's armamentarium. PG is most often inserted high vaginally on the eve of the planned delivery usually in the antenatal ward and if labour supervenes the patient is transferred to the labour ward. Otherwise, in the morning, hopefully, with a ripened cervix, she can be transferred to labour ward for induction. The overnight period in the antenatal ward may be a dangerous one, especially with an unmonitored patient. In a patient with the least suggestion of fetal compromise, PG is best avoided or else with the risks firmly in mind, is only administered in labour ward with the necessary monitoring and supervision.

Syntocinon should not be administered before a minimum time gap of six hours after PG administration. Once administered, PG is technically irretrievable[317] unlike Syntocinon, which can be immediately switched off. Hence PG is officially contra-indicated in the presence of a previous caesarean section scar. Such use has been discouraged[318] by the American College of Obstetricians and Gynaecologists (ACOG),[319] as well as by the RCOG which refers to the PG manufacturers' formally stated contra-indication:

[317] Technically some brands of PG such as Propess have a knitted polyester retrieval system to allow removal if necessary. However, official advice about PG use in the presence of a scarred uterus remains what it is.

[318] Committee on Obstetric Practice. ACOG committee opinion Induction of labour for vaginal birth after caesarean delivery. International J of Obs and Gynae. June 2002; 77(3):303-304.

[319] National Library of Medicine. ACOG Practice Bulletin No. 107: Induction of labour. Obstetrics and gynaecology. 2009 August; 114(1Pt 1):386-397.

women with a previous caesarean section is listed as a contraindication to use in the manufacturer's guidelines of both products.[320]

To the College's official warnings, one must add the simple unadorned fact that the use of a drug 'off license'[321] implies that full legal liability is assumed by the obstetrician.

Even with Syntocinon, the presence of a uterine scar demands great judicious use and its rate should not exceed 12 mu/min.[322] There are also obstetricians who refuse to use *any* amount of Syntocinon in the presence of a uterine scar, most commonly from a previous CS. The phenomenon of ruptured uterus is well documented in UK Court litigation often presenting as a claim based on maternal damage and risk to life or else as resultant cerebral palsy of the new-born from intra-partum hypoxia.

In *J v. Birmingham Women's Hospital NHS,*[323] the administration of PG led to uterine hyper-stimulation and the rupture of a previous CS. The Court ruled for the plaintiff, declaring clinical negligence in a case where:

The Claimant was severely brain-damaged, as a result of oxygen deprivation during the last 20 minutes of her mother's labour. Her labour was artificially induced using Prostin which resulted in over-stimulation of the uterus, which then ruptured, leading to anoxia until the Claimant cold be delivered by Caesarean section. As a consequence

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[320] See note 318.

[321] The use of a medicine not as officially prescribed by the manufacturers.

[322] Arulkumaran S, Symonds M. Intrapartum Fetal Monitoring-Medico-Legal Implications. The Obstetrician and Gynaecologist. October 1999; 1(2): 23-26.

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[323] Oxygen deprivation following uterine rupture at birth causing cerebral palsy J v. Birmingham Women's Hospital NHS Trust. Medicine and Public Health. Clinical Risk 1 November 2008;14 6 (246).

of her injury, the Claimant had cerebral palsy affecting all four limbs, a marked development of delay and microcephaly. She will never walk and will be dependent on others for 24-hour care throughout her life. She has a significantly reduced life expectancy.

The plaintiff was awarded £4,200,000.00 to compensate for care, loss of earnings, the cost of accommodation, assistive technology, therapies and equipment including occupational therapy, physiotherapy, speech and language therapy and music therapy. This clinical and medico-legal threat involving uterine rupture is expected to increase with the essentially universal increase of caesarean sections. The NHSLA 2000-2010 report devotes much space to discussing the legal liability of both PG and Syntocinon in the causation of ruptured uterus in situations involving a trial of labour after a previous caesarean section (TOLAC).

PG administration may also lull one into a false sense of security when the agent may seem to have been ineffective. In *Ogwang v. Redbridge Healthcare NHS Trust*,[324] a patient with pre-eclamptic toxaemia who had been administered prostaglandins for two consecutive days was discharged after ten days. She was re-admitted the following day with an abruptio placentae, the child incurring severe cerebral palsy. Liability was confirmed on the ground that delivery by CS rather than discharge should have been carried out.

In the case of Syntocinon, the correct dosage must be administered intra-venously via a variable-speed infusion pump as per standard practice. This implies that the correct

[324] *Ogwang v. Redbridge Healthcare NHS Trust* [2003] All ER (D) 82 July.

dose of Syntocinon is prescribed, then mixed with a physiological electrolyte solution (in normal circumstances) and administered by an infusion pump which any midwife ought to be able to prime and operate without the least hesitation. Whatever the *ordered* infusion regime, contractions which are excessively strong, too frequent or are accompanied by any I-P CTG disturbances [325] are an indication for immediate cessation of the infusion and review of the management including a full evaluation of the facts so as to decide on the appropriate mode of delivery.

It is also useful to remind that the only *objective* evidence of the rate of uterine contractions, although not the strength[326] lies in the lower 'toco' compartment of the I-P CTG tracing. This is worth keeping in mind as this constitutes objective and Court acceptable evidence. Uterine activity must reveal at least a clear 60-90 second inter-contraction interval and any stimulation encroaching on this is dangerous. Such I-P CTG evidence may work in favour of either plaintiff or defendant.

Syntocinon mismanagement is a frequent occurrence in litigation where unphysiological contractions lead to uterine rupture or IPH. The management of some of these cases, as it unfolds in Court transcripts, at times challenge the most basic of logical thinking. For example, in *Lummis v. Barking, Havering & Brentwood Health Authority*,[327] a case concerning a girl suffering from severe quadriplegic dystonic cerebral palsy, we find a rather disturbing birth management:

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[325] Such disturbances may not be due to genuine fetal distress, but all stimulation must cease until the aetiology of the I-P CTG disturbances are clarified.

[326] To record the actual strength or pressure of the contraction, a special intra-uterine catheter must be employed. This is only used for research purposes.

Syntocinon (a drug used to stimulate uterine contractions) was commenced at about 18:45 hours, some 15 hours after admission. As a result of the introduction of Syntocinon, the fetal condition deteriorated as evidenced on the CTG trace. The Syntocinon was correctly turned off at 19:35 hours. Full dilatation occurred at about 20:15 hours and shortly afterwards the CTG trace again began to deteriorate. Notwithstanding this, the midwife restarted the Syntocinon which increased the fetal distress and the baby was born at 21:20 hours by forceps delivery. The midwife thought that it was appropriate to use Syntocinon to expedite delivery even though there was fetal distress. The correct action at 20:30 hours was to wait and see and not to introduce Syntocinon. If these steps had been taken, then it was likely that the baby would have been born at about 21:15 hours without damage.

Again, part of the plaintiff' claim in *Evans v. Birmingham and The Black Country Strategic Health Authority*[328]concerned the injudicious use of excessive amounts of Syntocinon leading to HIE and cerebral palsy. In *Pauline McKenzie Pursuer against Fife Acute Hospitals NHS Trust Defenders,*[329] another case of cerebral palsy, the Court declared that:

Accordingly, if the obstetric registrar, who was the defenders' employee, had acted with reasonable care by stopping the Syntocinon infusion and arranging the prompt delivery

[327] Syntocinon usage, obstetrics, birth asphyxia, cerebral palsy. in Lummis v. Barking, Havering & Brentwood Health Authority. Medicine and Public Health. Clinical Risk. 1997 Jan;3(1):17.

[328] *Evans v. Birmingham and The Black Country Strategic Health Authority* [2007] EWCA Civ 1300.

[329] *Pauline McKenzie Pursuer against Fife Acute Hospitals NHS Trust Defenders* [2006] CSOH 63.

of Kyle by 21.40 hours on that date, I consider that Kyle would not have suffered the brain damage which has given rise to this action. I conclude therefore that the admitted negligence of that employee caused that damage.

The NHSLA report also accentuates the need for pre-induction disclosure in high risk cases such as a uterus scarred by a previous CS. This is crucially important for the MOS to bear in mind and take immediate steps to amend in the local scenario, regarding disclosure, be it oral or written. The NHSLA report quotes one particular case where a VBAC patient suffering a uterine rupture and was eventually awarded £6.1 million. Both PG and subsequently Syntocinon had been employed, but:

…it was accepted that there had been a failure to consult the claimant's mother about the increased risk of uterine rupture with induction of labour in a VBAC case.

Proposed amendments to the MOS include:

I. The need for greater senior supervision in the selection of cases for the use of PG to ensure adherence to indications, contra-indications and precautions in use. This includes antenatal CTG monitoring before and at identified intervals after administration.

II. In the higher risk situation, if PG administration is still to be used, its insertion should only be allowed in labour ward and with appropriate monitoring including I-P CTG monitoring.

III. The prevention of patient discharge from hospital after PG administration until delivery has been effected.

IV. The complete banning of PG in the presence of a scarred uterus.

V. The signing by the obstetrician on a register when PG is used. This reminds of the potential danger of what is being administered and registers the amounts of PG used.

VI. The introduction of disclosure and oral consent before the use of PG and Syntocinon and in cases with an increased degree of risk the consent should be a signed one clearly stating the disclosed risks.

VII. The ensuring of full knowledge of the preparation of a Syntocinon infusion and full operative knowledge of the infusion pumps, their potential malfunctions and dangers by all labour ward personnel.

VIII. The introduction of a strict labour ward regime for the use of Syntocinon in patients with a history of a uterine scar and those at known risk of fetal distress.

3.3.2.1.4 Intra-partum CTG (I-P CTG) monitoring

CTG has been evaluated in detail in appendix two and here it is reviewed from the medico-legal aspect along the NHSLA report conclusions as applied to the Maltese

scenario. Although it is incorrect to state that the antepartum CTG has no medico-legal role to play, the very great majority of liability centres on I-P CTG.

3.3.2.1.4.1 I-P CTG mismanagement and legal implications

The NHSLA report states that I-P CTG litigation along with cerebral palsy and labour management issues account for a staggering 70% of the total monetary value of maternity claims between 2000 – 2010. Hence, we speak of a parameter of great and well-established medico-legal vulnerability. In the quoted period of time, there were 300 claims (5.89%) based on alleged I-P CTG related negligence with a total estimated compensation value of £466,393,771, or 14.95 % of the *global* money awarded in UK NHS litigation for the decade.

According to the NHSLA report, the biggest group involved in I-P CTG negligence is that of midwifery. However, when it comes to obstetricians, no grade including consultant level is immune. Any of these entities may be involved with I-P CTG mismanagement, itself divisible under a number of issues (see figure 4) namely:

- Failure to recognise an abnormal CTG.
- Failure to act on an abnormal CTG.
- Failure to refer an abnormal CTG.
- Failure to monitor the fetal heart in labour adequately and effectively.

- Inappropriate use of Syntocinon in the presence of an abnormal CTG.

I-P CTG mismanagement may be quoted as part of any claim involved in any aspect of a case alleging labour mismanagement. This is to be expected since I-P CTG is the only existing practical investigation to-date by which intra-partum well-being may be assessed. Most of the litigation concerning I-P CTG mismanagement is considered preventable starting with the surprisingly and persistently high misinterpretation rate. The latter even earned a specific delineation in the NHSLA report:

…the most effective way to reduce the financial and human cost of maternity claims is to continue to improve the management of risks associated with maternity care, focusing on preventing incidents involving the management of women in labour, including the interpretation of CTG traces.

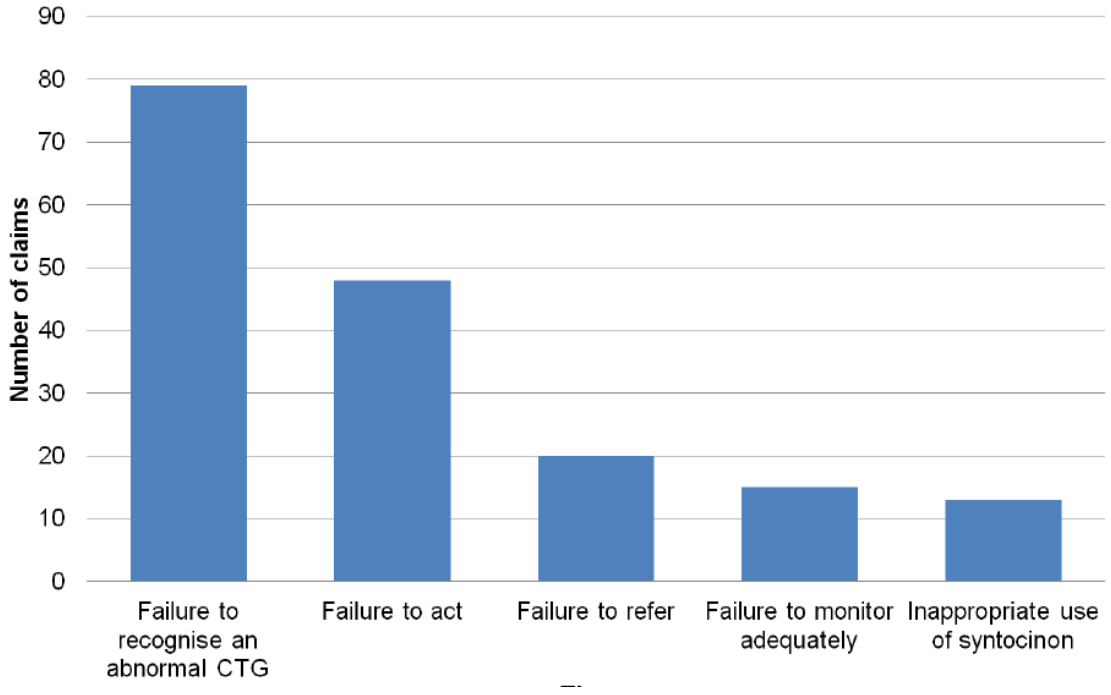

Figure 4 Sub-division of CTG litigation cases (NHSLA 2000-2010 Report)

The NHSLA report points out that 60% of cases occurred "after hours" with the great bulk of cases involving an initial contact with the attending midwife who failed to alert medical staff.

If the British experience is worrying, the Maltese scenario with its unknown facts is even more. Undoubtedly the deficiencies and their legal vulnerability are here, but unchallenged so far, they trouble but few people. The extent of such likely deficient CTG interpretative skill may only be appreciated by actual systematic testing at all levels of midwifery and obstetric personnel. Until then, a challenge will not emerge until the first medico-legal case involving I-P CTG mismanagement hits the local Courts.

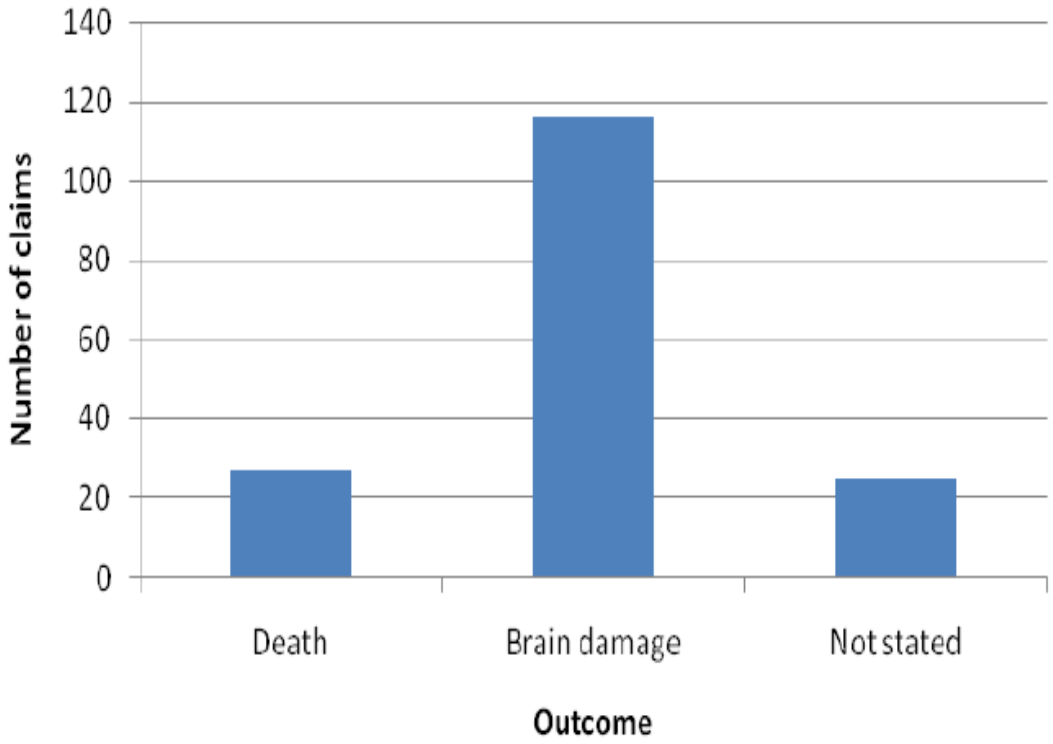

Figure 5 Clinical outcome of CTG mismanagement (NHSLA 2000-2010 Report)

Furthermore, ensuring I-PCTG competency of interpretation and management is doubly important locally in view of the unfortunate habit/policy of resorting to CS simply on abnormal I-P CTG readings.[330]

It is worth noting that the NHSLA report comes up with one extremely unexpected conclusion which actually goes diametrically against established official guidelines on the subject. On reviewing the I-P CTG liability cases, it states:

[330] Zammit D, Buttigieg SM, Caruana M. Caesarean sections at Mater Dei Hospital, Malta. Abstracts / European Journal of Obstetrics & Gynaecology and Reproductive Biology 206 (2016) e128–e193.

Only 35 cases (21%) involved high risk pregnancies, indicating the importance of the effective monitoring of all women.[331]

This is the polar opposite of other current guidelines issued by NICE and the RCOG advising that CTG monitoring be limited to high risk cases, although effective monitoring is not limited to CTG. Thus, under the section *When to offer continuous cardiotocography and telemetry*, the 2019 NICE guidelines commence with the statement: *Do not offer cardiotocography to women at low risk of complications in established labour*.[332]

The issues raised by the NHSLA on I-P CTG monitoring have direct local relevance with clinical, logistical, financial and medico-legal I-P CTG monitoring implications. Although the local practical knowledge of the subject remains unknown until it is investigated, there is no doubt that extrapolating from the NHSLA report, the situation must be perturbing. Equally perturbing, from many angles but particularly from the aspect of unnecessary caesarean sections, is the unofficially established albeit *de rigueur* practice of diagnosing fetal distress simply on an abnormal I-P CTG. The habit combined with the absence of disclosure of the basis on which such an abdominal delivery is being offered is the basis of a ticking medico-legal bomb. This would be further compounded by the potential situation of such a CS being complicated by surgical or anaesthetic adverse events.

[331] See note 39.

[332] Intrapartum Care. Fetal monitoring during labour. NICE 2019.

The illogicity of this unchallenged practice of allowing CS for presumed fetal distress as diagnosed on I-P CTG abnormalities in the absence of corroborative investigation of fetal acidosis may be summarised by the well-known fact that even in a bad case CTG scenario, with a fetal baseline tachycardia, with reduced variability, no accelerations and late decelerations, the incidence of fetal hypoxaemia and acidosis can be confirmed in only 40–60% of cases.[333] Zammit et al.[334] have advised the introduction of FBS to help diminish the high Maltese CS rate. Besides the inherent medico-legal vulnerability, the present system is responsible for much unnecessary increased morbidity, potential mortality, and massive national health budgetary drain.

It must be clearly stressed that the present MDH use of a computerised CTG monitoring system is not synonymous with formal confirmation of hypoxia in the presence of an abnormal I-P CTG tracing. It does help eliminate the unacceptably large intra- and inter-observer errors associated with conventional visual assessment, and there is some improvement in predicting umbilical artery pH.[335] Such computerised CTG monitoring has the *potential* to improve clinical management but whether it will actually reduce the incidence of adverse neonatal outcomes has never been established in randomised controlled trials.[336] One may obviously debate which would be the ideal investigation to ensure that an abnormal I-P CTG *is* indeed caused by genuine fetal distress.

Proposed amendments to the MOS include:

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[333] Beard RW, Filshie CA, Roberts GM. The Significance of the changes in the continuous fetal heart rate in the first stage of labour. BJOG. Oct 1971; 78(10):865-881.

[334] See note 330.

[335] Costa A, Santos C, Ayres-de-Campos, Costa C, Bernardes J. Access to computerised analysis of intrapartum cardiotocographs improves clinicians' prediction of newborn umbilical artery blood pH. 2010 September; 117(10):1288-12931.

[336] See note 335.

I. The fostering of awareness of the great medico-legal vulnerability associated with I-P CTG interpretation and management. The recognition that related interpretation and management issues are amenable to improvement.

II. The installation of an immediate compulsory programme of CTG evaluation and education both for obstetricians and midwives with regular in-house follow up-and assessment.

III. The identification of a group of consultant obstetricians specialising in CTG and its medico-legal implications. These will be responsible for organising all teaching and assessments within the OBGYN and midwifery departments and may, if interested, be the lynchpins in any ventures to assist the Court in related problems concerning I-P CTG interpretation.

IV. Regular obstetric departmental review of specific case managements of CTG interpretation which are purely cased and never doctor- based, including cases of adverse clinical outcome as well as all known ‘near misses’.

V. The implementation of dated and precisely timed entries of noted I-P CTG monitoring and noted abnormalities in the patient’s file.

VI. Ensuring the ability to effect adequate monitoring, including basic knowledge of monitor function and the uses and implication of different speeds of CTG recording.

VII. The safe storage of I-P CTG strip tracings and, especially in potentially contentious cases, the scanning of the tracing *in toto.* Such tracings and relevant notes must be safely kept for a minimum of 25 years. Electronic archiving is long overdue and this is probably the result of lack of legal challenge.

VIII. The reminding that it is the patient who should be the centre of attention in labour and not the I-PCTG, and that management changes must be disclosed, discussed and accepted by the patient. This also applies to the introduction of an oral consent following adequate disclosure prior to commencement of CTG monitoring.

IX. The introduction of a test for confirmation/ exclusion of IPH in the presence of I-P CTG abnormalities. If FBS is introduced this should ideally be complemented with one of the newer tests such as ST waveform Analysis (STAN). The present system of assuming hypoxia in the presence of a pathological I-P CTG is neither clinically nor legally tenable, is not cost effective and is heavily contributing to a future population of women with a scarred uterus.

3.3.2.1.5 Caesarean Section

The NHSLA report states that for the period 2000 – 2010, there were 674 claims related to a wide variety of complaints associated with caesarean sections with compensations amounting to £216,167.223. Standing as the second most frequent cause for litigation

(13.24%) in UK obstetrics, CS litigation also offers multiple facets of serious concern to the Maltese situation considering Malta's high CS rate. Although not standing alone in its high CS rate (see Figure 6), Malta, should not feel particularly reassured. In 2006 it had an alarmingly high rate at 35%, which had more or less stabilised around 30.7%. (Figure 7) in 2016. The WHO's recommended CS rate is 10-15%,[337] A 2015 study[338] concluded that there is a:

…persistent high rate of caesarean delivery at Mater Dei Hospital with a large number of electives and emergencies being done for previous sections and fetal distress, respectively. More trials of vaginal births after caesarean sections and the introduction of fetal blood sampling can help reduce our caesarean delivery rate.

The higher the present CS rate, the higher the likelihood of repeat CS's in the future and the higher the chance of complications, litigation and health national budget drain.

Besides the increased maternal and neonatal morbidity,[339] there is also the ever-increasing number of patients with a scarred uterus and a liability of future uterine rupture. Economically, the astronomical unnecessary wastage may be gleaned from the fact that in 2016 the UK NHS figures showed that the cost of a health service vaginal

[337] Caesarean sections should only be performed when medically necessary. Media Centre. World Health Organization. 2015 April 10.

[338] See note 330.

[339] Souza JP, Gulmezoglu A, Lumbiganon P, Laopaiboon M, Carroli G,Fawole B, Ruyan P. Caesarean Section without medical indications is associated with an increased risk of adverse short-term maternal outcomes: the 2004-2008 WHO Global Survey on Maternal and Perinatal Health. BMC Medicine.2010; 8: 71.

delivery was £1,985 while that for a CS, section was £3,781.[340] Comparative statistics are likely to show a similar ratio in Malta.

Many other important aspects concerning the subject of caesarean section are discussed under other topics such as that of uterine rupture in section 3.3.2.1.6.1.1.4.

Proposed amendments to the MOS include:

I. Evaluation of the present Maltese CS rate.

II. Emphasizing the need for a full pre-consent disclosure.

The need to temper and complement the junior staff's eagerness to master the technique of performing a caesarean section with an understanding of its role within the spectrum of a woman's obstetric history, its relationship to I-P CTG interpretation in a general context and within the Maltese scenario, and its personal and wider economical significance.

[340] Donnelly L, (Health editor), NHS is rationing caesarean births to save money, coroner warns. The Telegraph. 15 April 2016.

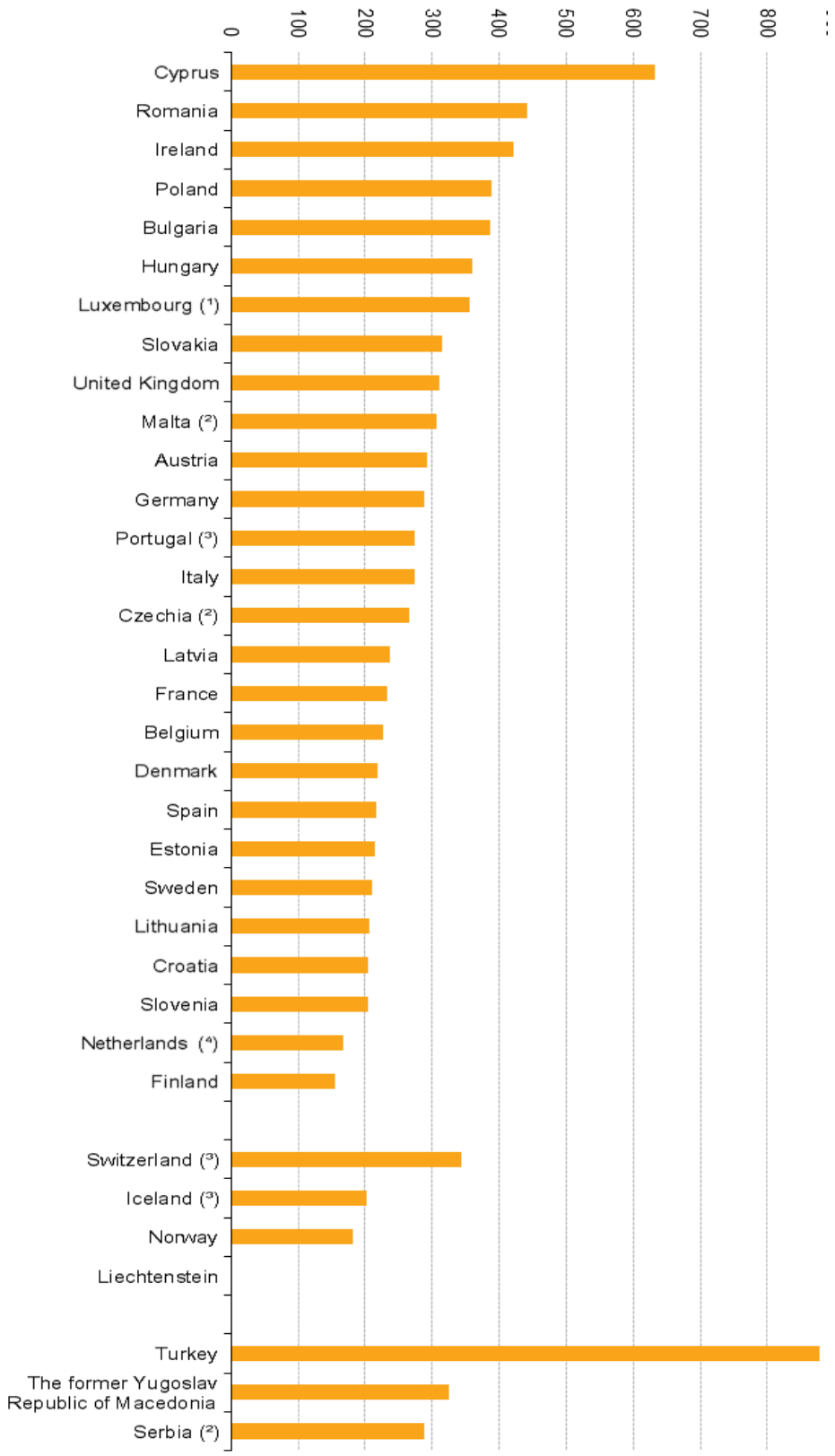

Figure 6 Comparative European CS Rates per 1000 live births (Eurostat 2016)

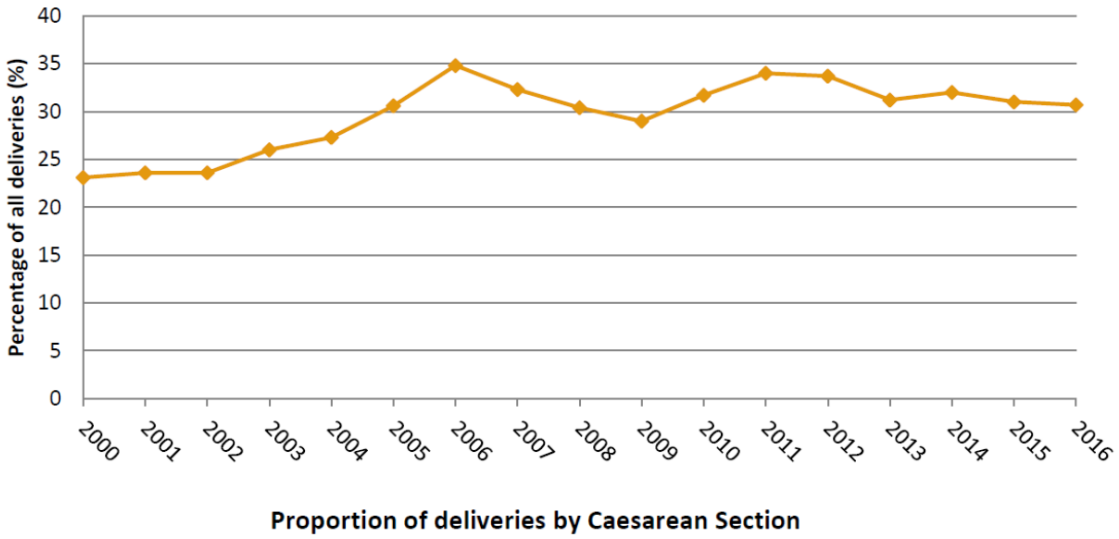

Figure 7 Caesarean section deliveries in Malta for the period 2000 – 2016 (NOIS Report 2016)

3.3.2.1.5.1 Disclosure and Consent in CS

In the post-*Montgomery* climate, CS related disclosure and consent ought to be critically reviewed in Malta where a strong element of medical paternalism still thrives and raises no eyebrows among the local patients. One often meets the cavalier attitude among patients of not even *wanting* to be informed of risks or potential complications because "I leave it all up to you, doctor!" In fact, the Maltese situation in obstetrics tends to *foster* medical paternalism in an age where such medical behaviour is frowned upon by all principles of medical autonomy. Yet the Maltese obstetrician must also keep well in mind the changing profile of patients attending the MDH obstetric unit as discussed in section1.**5.** Non-Maltese residents in Malta come from a completely different background and may expect completely different attitudes. In fact, although by the same rules of autonomy a patient has a right to refuse disclosure of complications and risks, the Maltese patient's laissez-faire attitude must be corrected whenever

possible. For one often senses that it is born out of an archetypal deference to the medical profession in which one must not question the healer. Furthermore, although no litigation precedence exists one wonders at what the attitude would be in the presence of a negative clinical outcome which has reached Court.

The still rife local medical mentality of obtaining a signature on a consent form is diametrically opposed to the suggested spirit of disclosure emanating from *Montgomery.* The disclosure pendulum is swinging away from Bolam-backed medical paternalism to the other extreme of oft-misinterpreted post-Montgomery deification of patient autonomy.[341]Although both extremes are wrong, *Montgomery* has engendered a new spirit of disclosure which goes far beyond a token rattling off of major complications and a scribbled signature on a consent form. It challenges the obstetrician to mentally engage the patient and not only inform her of relevant facts but to discuss these with her in a clear and understandable way. The patient must truly learn the facts of what will happen to her obstetrically, the need for it, its risks and complications, whether the operation is avoidable or not, whether other options exist, and what may be expected if the operation is not effected.

The timing of a CS may be one of great urgency or else it may be elective and may have even been planned from the beginning of the pregnancy. Whatever the nature of the indication, a written consent for a CS is inevitable. In the emergency CS, disclosure must be dictated by the gravity of the emergency but some form of disclosure is a *must* with, say, a 'crash CS' having to make do with the barest of explanations

[341] Buttigieg G G. *Montgomery and its impact on current medical practice – good or bad?* Medico-Legal Journal. 2019 May 8; 87(2):80-83.

before proceeding. Neither is the ‘general consent form’ signed on being admitted to labour ward sufficient to cover CS unless the patient is collapsed or actually unconscious. This general consent lies in a watershed of debate as to what it refers to and legally covers. Presumably if the roof collapses, one may say that the patient was there on her own free will but other than that, one queries what precise procedures are covered.

In the case of an elective CS long planned by the consultant and awaited by the patient, not only should disclosure be complete and adequate, but it should be delivered well before the CS date. Allowing a maturation of thought and queries will allow the patient to genuinely express any concerns or reservations before agreeing and signing the consent form. Disclosure must never be a talking down to, especially when time is not at a premium, but one allowing a frank discussion to evolve. The obstetrician must be aware his concerns are not necessarily the patient’s. Such aspects of the operation as skin incision may be preying heavily on the patient’s mind. Tattoos in the line of the likely incision must be discussed pre-operatively. Such discussions must never be left until the last minute and definitely not with the patient under pre-operative or other sedation.

Proposed amendment to the MOS:

The immediate realisation of the medico-legal importance of both disclosure and consent. The clinical and medico-legal importance of disclosure and consent for CS must be brought fully home immediately, and without waiting for future Court precedence to initiate the process.

3.3.2.1.5.2 Caesarean Section as a patient's choice of delivery

Modern concepts of the patient's rights and autonomy of care, wisely or not, make the patient's choice of delivery by CS completely possible even in the absence of any obstetric indication for it. Accepting such a request does bring with it the need of a thorough disclosure of all potential risks and complications including the possible effect on the patient's future reproductive career. All such disclosed information must be carefully documented by date and time, as indeed is the patient's express choice of delivery.

These requests are not common but neither are they unknown. Both the UK's NICE and RCOG's guidelines recommend compliance with the patient's wishes. What must *not* be done, and a temptation might exist locally, is to mask such a decision under a trumped-up indication. Inventing a medical reason for such a caesarean section will run the risk of definite exposure in any future legal investigation, as when a CS results in a serious complication and all including the original indication is reviewed possibly in Court.

In 2018, UK media reports[342] stated that only 26% of NHS trusts fully comply with the NICE guidelines to carry out a CS on request. 15% of the 146 trusts which shared their policies with Birthright are known to have refused such requests outright, 47 % partially complied and 12% did not express a clear position. The European scenario[343] has a

[342] Young S. Pregnant women being denied choice of caesareans at a number of UK hospitals, report finds. Independent. Independent. 2018 Aug 21.

variable attitude to the situation, ranging widely in individual compliance from 79% in the UK itself, 75% in Germany, 31% in Sweden 30% in the Netherlands, to 19% in France and 15% in Spain. The position in Malta is unknown but in the majority of cases, if one were to hazard a guess, compliance is likely to be good.

Proposed amendments to the MOS include:

I. The education of the public about the phenomenon with the recommendation that the risks of any operation should limit it to when it is medically required.

II. The direction to obstetricians that legally the patient has a right to choose her mode of delivery, however unwise the establishment considers this option. If this request is accepted, the indication should be clearly registered as complying *with the patient's wish*. No trumped-up reason or excuse should be added or substituted, and this increases not decreases medico-legal vulnerability.

3.3.2.1.6 Cerebral palsy

Cerebral palsy (CP), evaluated in some detail in appendix three, is here reviewed along the NHSLA medico-legal conclusions and statistics and vis-à-vis the local situation. The reason as to why CP is here classified in this chapter under the general umbrella of labour management is simply one of convenience of categorisation. Having placed CP under labour management, it is fitting to remind that intra-partum hypoxia is now

[343] Nilstun T, Habiba M, Lingman G, Saracci R, Da Frè M, Cuttini Mand the EUROBS study group. Caesarean delivery on maternal request: Can the ethical problem be solved by the principlist approach? BMC Medical Ethics. 2008 Jun 17; 9:11.

known to be responsible for no more than about 14.5% of cases of CP.[344]. As the illuminated Court stated in the 1992 case *De Martell v. Merton and Sutton Health* Authority:

…up to ten years ago the accepted wisdom was that cerebral palsy was more often than not caused by birth asphyxia. Now the pendulum has swung the other way. All knowledge and certainly all medical knowledge is provisional. [345]

While the suffering of the child with CP and his family dominates all considerations, the financial impact of the liability arising out of CP case due to Court proven obstetric negligence often reaches staggering amounts. The NHSLA report shows that with 542 claims, CP constituted 10.65% (third commonest) category of litigation in the 2000-2010 decade, but as regards compensation CP combined with CTG issues and management of labour accounted for a staggering 70% of the £3.1 billion pay-outs for all maternity claims. CP *alone* contributed to an impressive 40.52% of the global money awarded. Quoting from another NHS report, namely the 2017 NHS Resolution report on cerebral palsy:

Possibly the most devastating and undoubtedly the most expensive, are claims for avoidable cerebral palsy, the number of which has remained relatively static over the last ten years.

[344] Graham EM, Ruis KA, Hartman AL, Northington FJ, Fox HE. A systematic review of the role of intrapartum hypoxia-ischemia in the causation of neonatal encephalopathy. Am J Obstet Gynecol. Dec 2008; 199 6:587-95.

[345] *De Martell v. Merton and Sutton Health Authority.* [1992] 3 All ER 820.

The British multi-faceted experienced with CP contrasts sharply with the Maltese one where, as already stated, a register recording new cases was only commenced in 2016. This was not related to any medico-legal instigation and no local CP medico-legal oriented data exists or is in the offing. The newly set-up register yielded its first prevalence for CP as 1.5-2/1000 live births in 2018.[346].The register has the following stated objectives:

- Data collection and surveillance of all local diagnosed CP cases to facilitate statistical and epidemiological research in the field.

- The issue of reports and answering of queries to interested individuals including health professionals, policy makers, researchers, students and the media.

- Active collaboration with CP international organisations and networks.

- Epidemiological studies to assist management of affected children including improvement of quality of life, of diagnostic investigations and of rehabilitation, medical, surgical and psychological treatments.

- The introduction of new modalities of evidence-based treatments.

Perhaps another stated objective could have been:

[346] Malta Cerebral Palsy Register. Member of European Surveillance of Cerebral Palsy (SCPE).

The analysis of all potential remediable causes with a view to prevention of the condition in those situations where this is possible such as those related to prematurity, low birth weight, intra-partum hypoxia and treatable maternal conditions such as hypothyroidism, maternal infections and inflammations, etc.

Hopefully more local data related to the subject will emerge, including the eventual link to the medico-legal relevance.

CP jurisprudence *has* undergone a major *volte face* over the last five decades on both sides of the Atlantic. The basis is the now scientifically accepted view that birth asphyxia is a minority cause of CP, in contrast to what was taught and practiced fifty years ago. Even so, it must be borne in mind that this terrible condition is often preventable in the minority associated with intra-partum hypoxia. This is important to stress as it is easy for the pendulum to swing in the other direction and the labour causation, small as it is, to be downplayed.

This part of the thesis deals with the 14.5%[347] which is linked to labour hypoxia damage resulting from a number of conditions leading to fetal distress such as those acting acutely (labelled peri-partum causes), e.g., uterine hyper-stimulation, abruptio placentae, cord prolapse, shoulder dystocia, etc. and those operating in a somewhat sub-acute way such as the damage associated with intra-uterine growth restriction (IUGR). The sub-acute antenatal contribution may not be purely related to conditions contributing to sub-acute hypoxia, and hence the section dealing with this aspect, and

[347] See note 344.

exemplified by IUGR, is labelled as ’sub-acute contributory causes’. Only IUGR is discussed as although mediating roles of cytokines are considered as important, it is too early medico-legally speaking to establish with certainty. This section is followed by an evaluation of brain damage resulting from trauma such as that inflicted by negligently executed instrumental deliveries.

In evaluating the several causes of intra-partum hypoxia, this section on cerebral palsy itself provides a convenient groupage umbrella for these topics of causation. The only drawback was a resulting disproportionately large section for cerebral palsy, which, was felt to be symbolically appropriate in that it reflects the condition’s unique medico-legal, economical and jurisprudential relevance. The term cerebral palsy appears more than three hundred times in this thesis under various aspects including as a presenting claim in numerous Court cases discussed here to illustrate various medico-legal principles unrelated to cerebral palsy itself. Hence also the need for the creation of appendix three on the medico-legal aspects of the condition. This appendix provides for many cross references in the main chapters. It also deals with an evaluation of what this thesis repeatedly refers to as ‘the great cerebral palsy myth’ in section A3.5. This phenomenon is an unparalleled example of the gross misleading of medical jurisprudence by wrong science at the inestimable costs of uncountable defendants and plaintiffs.

3.3.2.1.6.1 Peri-partum[348] preventable causes of cerebral palsy

Where CP *is* confirmed as originating from intra-partum hypoxia leading to hypoxic ischaemic encephalopathy, modern theories of CP causation speak of a "sentinel" episode in labour. This is often the acute episode or causative moment, which may be due to any of the causes discussed here under acute hypoxia such as uterine hyper-stimulation, cord prolapse, uterine rupture, etc. Besides the medico-legal implications of the sentinel event, there may be evidence of separate but predisposing antenatal factors which may contribute to the final clinical outcome and which may therefore carry their own medico-legal liability. These provide a ripe background, so to speak, amplifying or facilitating the damaging effect of the eventual sentinel event on the fetal brain. They may include evidence of potential hypoxia of a sub-acute nature as associated with say intra-uterine growth restriction (which may not simply operate through hypoxia) and/or situations with less obvious connotations such found in prematurity and multiple pregnancy.[349] Other causes such as chorioamnionitis, previously considered as operating through hypoxia and now known to involve cytokine pathways, inflammation and coagulopathies are now attaining increasing importance in the evaluation of aetiology.[350]

[348] Comprising both intra-partum causes such as fetal distress as well as birth causes such as trauma from assisted birth delivery.

[349] MacLennan A. A template for defining a causal relation between acute intrapartum events and cerebral palsy: international consensus statement. Brit Med J. 1999 Oct 16.

[350] See note 349.

The theory involving a "fertile field for CP" on which the sentinel event is super-imposed, and collectively known as the 'two-hit theory'[351] must be kept in mind throughout the discussions of the following long list of "sentinel events" grouped here as causes of acute hypoxia.

3.3.2.1.6.1.1 Acute intra-partum hypoxia

This section concentrates on those *acute* situations where hypoxia results from such sentinel events as over-frequent or over powerful uterine contractions (as in PG/Syntocinon uterine hyper-stimulation), abruptio placentae, cord prolapse, etc. The commonest cause would be uterine hyper-stimulation, already considered in section 3.3.2.1.3, where this relatively common cause of IPH resulting from PG and Syntocinon mismanagement was exemplified by a number of British Court cases in which obstetric negligence was confirmed.

3.3.2.1.6.1.1.1 Abruptio placentae

This rare condition (prevalence 3-6/1000 pregnancies) may uncommonly be fatal to both mother and child, but more often leads to fetal brain damage. Normally, striking without warning, it involves the premature placental separation off the uterine wall. It may cause massive internal and/or external maternal haemorrhage leading to acute fetal hypoxaemia, which if protracted may lead to still birth or fetal organ damage including

[351] Yanrong Hu, Gang Chen, Hong Wan, Zhiyou Zhang, Hong Zhi, Wei Liu, Xinwei Qian, Mingzhao Chen, Linbao Wen, Feng Gao, Jianxin Li, Lihui Zhao. A rat pup model of cerebral palsy induced by prenatal inflammation and hypoxia. Neural Regen Res. 2013 Mar 25; 8(9): 817–824.

cerebral damage. This condition may well be beyond the obstetrician's control with extensive fetal morbidity resulting even from the best possible management. In *Baynham v. Royal Wolverhampton Hospitals NHS Trust*[352] for example, the obstetrician was cleared of all liability in such a case which ended up with CP. However, abruptio placentae along with a number of conditions such as severe pre-eclampsia, amniotic fluid embolism and septicaemia is also well known to be associated with complications such as disseminated intravascular coagulopathy (DIC).[353] This carries the warning of accurately dated and timed documentation and the pre-empting or at least preparation for eventual complications such as DIC. This medico-legally translates as potential liability for any harm resulting from secondary complications unless, once abruptio placentae is diagnosed, pre-emptive steps are taken to prevent or diminish such complications as DIC. It is crucial to fully document all such steps.

The term used for the ultra-urgent CS which may be required in conditions such as abruptio placentae[354]and similar acute conditions, such as uterine rupture, cord prolapse or a sudden marked and persistent fetal bradycardia, is 'crash section.' Within this context, the local MDH scenario may seriously consider a second labour ward theatre constantly prepared for a 'crash section'. This eliminates the loss of precious time waiting for a previous CS to finish or having to transfer the patient down to one of the main surgical theatres, as is the current practice. Admittedly, the setting up of a second theatre brings with it logistic changes and corresponding theatre and anaesthetic staff changes, but the advantages are likely to outweigh the disadvantages.

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[352] *Baynham v. Royal Wolverhampton Hospitals NHS Trust* [2014] EWHC3780GB.

[353] Edozien LC. The labour ward handbook. London: Hodder Arnold; 2012.

[354] Vaginal delivery may be possible in such a case, if presentation occurs at an advanced stage of labour.

Care must also be taken to eliminate the weak links in the chain of 'crash section' logistics. It would not be the first time that a CS is delayed because the resident anaesthetist cannot locate his anaesthetic nurse. Regional analgesia as a rule has no place in crash sections and is contra-indicated in abruptio placentae due to the possible development of coagulopathy. This brings us to the new midwife habit of allowing indiscriminate drinks and sometimes food, n the labouring patient, which habit should be reviewed and regulated.

While the creation of a second labour ward theatre does go a long way in preparing for 'crash sections,' another proposal is for the MOS to ensure optimal staff/bed co-ordination. There *has* been an attempt at registering and limiting the number of elective CS's as well as inductions, but it is far from rare for the outcome to be a battle of wills between the obstetric consultant and the labour ward sister. A radical labour ward policy of limiting the number of inductions, say to four and elective CS's to three (two if complicated),[355] must be firmly enforced by a senior midwife with the right personality. All elective work must also be registered by the eve of the duty day. Late added elective CS's should be allowed only if performed whenever time, space and manpower safely allow it and the problem must be sorted out personally by the respective consultant and not delegated to a junior member of the team. Enforcing a consultant presence here is likely to prevent a repetition of the situation. One must distinguish between bed availability and optimal bed functionality. Good labour ward practice involves planning, the execution of such planning and often unshakeable determination. Such crucial optimisation of labour ward resources may determine the

[355] See note 353.

outcome of a patient's fate once admitted with an acute emergency such as an abruptio placentae.

Proposed amendments to the MOS include:

I. The reminding of the principle to all labour ward staff of being forever prepared for the most challenging of cases at any time in the labour ward.

II. The constant preparation of the labouring patient for the potential administration of general anaesthesia.

III. The continuous availability of all staff including the labour ward anaesthetist and his anaesthetic nurse.

IV. The practice, even if on a yearly basis, of the 'crash section' procedure including the need to inform the paediatrician on call, the obstetric consultant at home, obtaining the patient consent, even if orally and remembering the administration of routine thromboprophylaxis.[356]

V. The consideration of setting up a second obstetric operating theatre.

VI. The establishment of a firm and enforced policy of departmental agreement limiting the number of daily elective inductions and caesarean sections and the official registering of such cases with labour ward, at the latest, by the eve of

[356] See note 353.

the labour ward day. The appointment of an obstetric consultant and a senior midwife in charge of labour ward management and in daily liaison with the senior midwife on duty in labour ward. This arrangement should also involve the Department of Anaesthesia. Breaches of such a protocol must be dealt with seriously and involve the highest administration of MDH hospital.

3.3.2.1.6.1.1.2 Cord prolapse

In spite of the low incidence of 0.1% to 0.6%, cord prolapse carries a 10% risk of fetal death.[357]Such a prolapse is preceded by membrane rupture and often declares itself with an acute drop in the fetal heart rate. This condition needs to be kept in mind in labour involving prematurity, low-birth weight babies especially under 2500g with the risk increasing substantially if under 1500g, in polyhydramnios,[358] with multiple gestation, breech presentation and a high head in labour. An unexplained fetal bradycardia needs immediate exclusion of cord prolapse.

While being transferred to the operating theatre for a 'crash section' the patient should be immediately put in the genu-pectoral position (GPP) while the cord is replaced into the vagina as cold can induce a vasospasm, or failing that, the cord should be wrapped in swabs. Failing the adoption of the GPP, an intra-vaginal hand must continuously keep the fetal head off the lower segment to relieve pressure on the cord and prevent its compression.

[357] Critchlow, CW; Leet, TL; Benedetti, TJ; Daling, JR. Risk factors and infant outcomes associated with umbilical cord prolapse: a population-based case-control study among births in Washington State. American Journal of Obstetrics and Gynaecology. 1994 Feb; 170 (2): 613–8.

[358] A condition in which the amniotic fluid is present in excessive amounts.

Proposed amendments to the MOS include:

I. All the proposed suggestions regarding the “crash section.”

II. The institution of the drill of the practising of the genu-pectoral position. This can be combined with the annual shoulder dystocia drill proposed in section 3.3.2.1.6.1.1.5.

III. The raising of awareness, especially among new labour ward staff of:

    i. The conditions likely to be associated with cord prolapse.

    ii. The establishment of the diagnosis of cord prolapse especially when prolapse is occult and limited to the vagina.

    iii. The mechanics by which cord prolapse can be relieved.

    iv. The suspicion of the condition in the presence of a sudden fetal bradycardia or marked variable decelerations on I-P CTG monitoring.

IV. Staff dealing with the urgent management of cord prolapse must be reminded that during the emergency management the patient must be informed of what is happening.

V. At birth, blood must be taken for umbilical pH.

VI. A dated and timed account of the events must be noted in the file with due prominence to the chronological aspect of events and their management.[359]

3.3.2.1.6.1.1.3 Nuchal cord

Acute fetal hypoxia may result from an interruption of the umbilical cord blood supply to the fetus when the cord wraps itself 360 degrees around the fetal neck (Type A) or else by forming a true knot within itself (Type B). While the condition may declare itself in labour through I-P CTG abnormalities through bizarre variable decelerations, antenatally it is usually impossible to diagnose. However, in both type A and B, the situation often becomes dangerous in labour as the baby's head descends in the maternal pelvis thus drawing the noose/knot tighter. In these circumstances, I-P CTG abnormalities usually become manifest or worsen and at this stage the onus of legal responsibility shifts to the correct I-P CTG disturbance management.

In view of the possibility of cord compression, not caused by Type A or B compression but for example due to cord compression from pressure by a fetal shoulder, staff should be taught/reminded to alter the position of the patient in the presence of variable decelerations, e.g., sit the patient up if she was lying down and observe any resultant I-P CTG response.

Proposed amendment to the MOS include:

[359] See note 353.

The ensuring of regularly assessed knowledge of I-P CTG interpretation, in this case, with special reference to disturbances such as variable decelerations and the potential effect of posture changes on them. In performing such posture changes, the constant reminding of the danger of the maternal supine position in labour especially if combined with epidural anaesthesia.

3.3.2.1.6.1.1.4 Ruptured Uterus

Although grouped here as one of the acute causes of IPH which may result in CP, this subject stands out in its own right as a highlighted topic of great clinical and increasing importance. It is discussed specifically in the NHSLA report as one of the four topics discussed intensively at secondary level. The report stressed that this life-threatening complication is bound to increase along with the increasing CS rate. Between 2000 and 2010, there were 85 cases (constituting 1.67% of all obstetric claims) of ruptured uterus and the NHS pay-out was of £103.264.627 (3.31% of the total).

A patient with a history of a previous CS who wishes to deliver normally in a subsequent pregnancy (the co-called VBAC patient), if this is judged as safe, must undergo a Trial of Labour (TOL) or more appropriately Trial of Labour after Caesarean Section (TOLAC). This implies the responsibility of preventing uterine rupture (UR) and its its earliest possible detection and management if it supervenes. The development of rupture may clinically signal its presence with a number of signs and symptoms,[360] namely:

[360] See note 353.

- Sudden sharp abdominal pain followed by cessation of uterine contractions.

- Abdominal tenderness.

- I-P CTG abnormality.

- Vaginal bleeding.

- Maternal collapse.

- Haematuria.

The picture may also be clinically silent. I-P CTG disturbances may be the most dependable but non-specific of signs although such abnormalities are not predictive of the condition.[361]

The increasing number of VBAC patients, as well the inherent corresponding risks in pregnancy and particularly in labour, merits the establishment of a local VBAC Clinic. The very fact of the creation of such a clinic will immediately raise the local obstetric consciousness to the collective needs, risks, responsibilities and medico-legal implications of caring for this at-risk group. The role of the previous CS in the aetiology of subsequent UR is rendered clear when considering that UR prevalence in overall

[361] Andersen MM, Thisted DLA, Amer-Wåhlin I, Krebs L. The Danish CTG Monitoring during VBAC study group. Can Intrapartum Cardiotocography Predict Uterine Rupture among Women with Prior Caesarean Delivery? A Population Based Case-Control Study. PLOS One. 2016 Feb 12; 11(2): e0146347.

pregnancies is 0.2/1,000 maternities while it rises to 2.1/1,000 maternities in those with a previous CS and trying to achieve a vaginal delivery.[362] This is another point strongly favouring the set-up of a VBAC clinic. Such a clinic offers specialised care for the VBAC patient, as well as full disclosure. It also provides a 'watch dog' with regard to labour management of these patients including the judicious use of Syntocinon, if the use of Syntocinon is unavoidable, remembering that the use of Syntocinon by itself raises the risk of UR two to three-fold.[363]

The element of disclosure in VBAC patients needs to raise its profile in local MDH management. Medico-legally, there is little doubt that TOLAC requires special disclosure to be delivered to the patient by her consultant and recorded as such in the patient's file along with the patient's expressed worries and questions. The gravity with which the NHSLA regards TOLAC disclosure can be gleaned, among other information by the following statistics published by the NHSLA's report:

- 47% of the claims carried the main allegation of the delay in diagnosing the rupture or impending rupture.

- In 24% of the claims there was lack of discussion and counselling on the method of delivery.

- In only 22% was a discussion as to the mode of delivery held in a VBAC clinic.

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[362] Fitzpatrick KE, Kurinczuk JJ, Alfirevic Z, Spark P, Brocklehurst P, Knight M (2012) Uterine Rupture by Intended Mode of Delivery in the UK: A National Case-Control Study. PLoS Med 2012; 9(3): e1001184.

[363] Uterine Rupture. Stratog e learning. RCOG 2019.

- In only 18 out of 45 clams was an approved guideline in place.

The proposed amendments to the MOS include:

I. The recognition of the complication of uterine rupture as a serious occurrence to the individual and as a likely increasing phenomenon of the high local CS rate.

II. The realisation of the practical seriousness and medico-legal liability of the condition of uterine rupture, which is certainly locally more theoretically known than practically appreciated.

III. The implementation of the previously suggested evaluation of the current local high rate of CS.

IV. The familiarisation of labour ward staff with the symptomatology of uterine rupture with special emphasis of the importance of I-P CTG abnormalities in the presence of a woman with a uterine caesarean scar in labour.

V. The exceptional importance of adequate disclosure both antenatally and particularly again at the commencement of TOLAC. These disclosures should be held by the consultant and noted in detail in the patient's medical records.

VI. The careful consultant evaluation of the VBAC patient as to whether to allow a TOLAC or not. Such evaluations require reviewing towards the end of pregnancy in case of change in the original circumstances.

VII. The establishment of VBAC and TOLAC guidelines and protocols in the antenatal ward, out-patients and in the labour ward and the explanation of such guidelines to the patient by the consultant. A suitably worded leaflet in both Maltese and English to be given to the VBAC patient.

VIII. The raising of awareness of the potential of increasing uterine rupture in labour ward staff.

IX. An established labour ward protocol for the VBAC patient including as a minimum, cross-matching of blood, continuous I-P CTG monitoring, an experienced attending midwife and regular frequent senior obstetric review in labour.

X. The outlined measures for ‘crash section.

XI. Awareness that in spite of the preponderance of uterine rupture occurring in the presence of a previous CS, *any* uterine scaring such from previous myomectomies, hysterotomies and any extensive uterine damage also puts the patient at risk.

XII. The consideration of the establishment of VBAC clinics. These have a number of scopes:

(i) The encouragement of such patients to persist with the choice of VBAC. 60-80%of such patients will achieve a normal delivery.[364] Such statistics should be discussed to further encourage the patient. Full disclosure should also include discussions on what is obstetrically acceptable or not in labour, the risks, complications and the liberty to change one's mind about the planned delivery. Such disclosure should be frank, complete, and open to *reviewed* discussion. All aspects of disclosure, including interval discussions and the handing over of printed material should be fully documented. Disclosure at the VBAC clinic is an *ongoing* exercise.

(ii) The screening as to the suitability of TOLAC and again this is an ongoing exercise where parameters may shift e.g., the development of macrosomia.

(iii) Ensuring optimal antenatal care and attendance with an ever-increasing bonding with the staff. This also helps guard against anaemia (antenatal haemoglobin to be kept, say, above 13g/dl), the gaining of excessive maternal weight with the encouragement of a healthy diet and good exercise, etc.

(iv) The establishment of a twenty-four-hour link-line with an experienced midwife.

(v) The regular updating of the VBAC clinic staff through such sources as:

[364]Patient Care and Health Information. Vaginal birth after caesarean (VBAC) Mayo Clinic. 2018 Jul 6.

i. The RCOG guidance on the care of women giving birth after previous caesrean section.[365]

ii. NICE guidelines.[366]

iii. NHS Institute for Innovation and Improvement guidelines.[367]

(vi) The constant monitoring ensuring that these patients:

i. will never be exposed to PG use.

ii. ideally are not induced, but if unavoidable, the preference should be a physical method of induction such as amniotomy. If Syntocinon must be used, its rate must not exceed 12 mu/min.[368]

iii. can change their mind, even in labour.

iv. When in labour, are immediately cross-matched, are offered continuous I-P CTG monitoring, are attended by an experienced

[365] Birth After Previous Caesarean Birth. Green-top Guideline No. 45. RCOG. October 2015.

[366] NICE guidelines. CG 132 Caesarean Section.. Published Nov 2011. Available at www.nice.org.uk.

[367] NHS Institute for Innovation and Improvement guidelines. (2007). Focus on normal birth and reducing Caesarean section rates. Coventry. www.institute.nhs.uk.

[368] See note 322.

midwife, and are closely and regularly monitored by senior obstetricians.

v. Have signed all necessary informed consent documentation after appropriate disclosure and discussion.

3.3.2.1.6.1.1.5 Shoulder dystocia

Occurring in 0.5-1% of deliveries, shoulder dystocia involves shoulder entrapment within the maternal pelvis, after the fetal head has been delivered. It is evaluated here from a number of medico-legal standpoints as well as the constructive evaluation of the related local clinical management. Shoulder dystocia may lead to damage resultant from hypoxia during the period of arrest and this is a classical cause of cerebral palsy which has been well tested in overseas Court. Naturally the mechanical aspects of the arrest may lead to physical damage such as upper limb paralysis and clavicular fracture.

The NHSLA report revealed 250 claims for 2000-2010 with an estimated total value of £103,520,832 (3.32% of total money awarded). The nature of the complaints was only known in 50 cases with 36 alleging inappropriate manoeuvring to free the shoulders while 14 claiming excessive traction.

Proposed amendments to the MOS include:

I. The emphasising of the relevance of detecting fetal macrosomia, particularly in view of the incidence of diagnosed gestational diabetes affecting 1.81% (by the

most conservative of studies) of all pregnancies in Malta.[369] Macrosomia must be diligently searched for both clinically and ultra-sonographically, particularly in gestational diabetic pregnancies, in women with a pre-pregnancy weight of 80 kgs or more, and those who gain an excessive amount of weight in pregnancy. Full disclosure of any prevalent risks, when these are present, must be respected and the patient ‘s views, once she is provided with all facts, must be listened to carefully especially regarding the mode of delivery.

II. The need for emphasising the importance of disclosure to the patient where macrosomia is suspected. Full risk disclosure must precede a discussion on the appropriate mode of delivery. If the final decision veers towards a vaginal delivery, the consultant or a senior experienced obstetrician must be available during birth.

III. An annual shoulder dystocia drill (combined with the genu-pectoral position drill) should be instituted. The RCOG in conjunction with the Royal College of Midwives lays great emphasis on the necessity of such officially organised drills held at least annually and to be attended by *all* birth attendants.[370] This has been recommended as far back as 1998 by the 5th CESDI.[371] Such training has been

[369] Savona-Ventura C, Chircop M, Ellul, A, Azzopardi J, Janulova L.The outcome of Gestational Diabetic pregnancies in the Maltese Islands Malta. Medical Journal. 2002; 16(2):33-35.

[370] Shoulder Dystocia. Green-top Guideline No. 42. 2012 Mar 1. Royal College of Obstetricians and Gynaecologists.

[371] Confidential Enquiry into Stillbirths and Deaths in Infancy. (1998). 5th Annual Report. London: Maternal and Child Health Research Consortium.

shown concretely to improve knowledge of the emergency,[372] increase confidence[373] and improve management[374] of shoulder dystocia.

IV. The ensuring of the optimal results from the Ultra-Sound Department regarding fetal weight assessments. Besides adequately trained sonographers, this implies the use of the best possible ultra-sound scan machines as well as regular maintenance and optimal use.

V. Special shoulder dystocia forms, as recommended by the RCOG should be made available and filled appropriately when required. Full documentation is crucial for medico-legal reasons. All investigations, antenatal care, any disclosures and discussions, and the clinical notes pertaining to the management labour must be checked for their availability in Court. Medico-legally, documentation in SD is extremely important. All investigations, discussions, disclosures, antenatal and labour details must be fully available to any eventual investigation or litigation.

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[372] Crofts JF, Ellis D, Draycott TJ, Winter C, Hunt LP, Akande VA. Change in knowledge of midwives and obstetricians following emergency training: a randomised controlled trial of local hospital simulation centre and teamwork training. BJOG December 2007; 114(12):153 – 41.

[373] Sørensen JL, Løkkegaard E, Johansen M, Ringsted C, Kreiner S, McAleer S. The implementation and evaluation of a mandatory multi-professional obstetric skills training program. Acta Obste Gynaecol Scand. 2009 Oct; 88(10):1107-1117.

[374] Goffman D, Heo H, Pardanani S, Merkatz IR, Bernstein PS. Improving shoulder dystocia management among resident and attending physicians using simulations. Am J. Obstet Gynaecol 2008;199:294.e1-5.

3.3.2.1.6.1.1.6 Arrest of the after-coming head of the breech

This is a rare but certainly known cause of cerebral palsy complicating a vaginal breech delivery. However, albeit very rarely, it is not unknown for such entrapment to happen even at caesarean section as in the case of *Smith v. Sheridan*[375] where liability for resulting cerebral palsy was upheld by the Court. However, the classical case of cephalic entrapment is that associated with a failed assisted vaginal breech delivery. This is more likely to occur in the case of the premature breech delivery but may be the simple result of a defective technique of breech delivery.

Proposed amendment to the MOS:

The encouragement of re-discovering and disseminating the technique of assisted breech delivery (ABD) which has been virtually lost since elective caesarean section has virtually universally displaced vaginal delivery in breech labour in the civilised world. Re-learning the technique of ABD is important and nowadays such learning must be through the use of manikins, films and other teaching material. One may also incorporate the practice of the technique of ABD with the annual shoulder dystocia drill and the practice of the genu-pectoral position for cord prolapse. All obstetricians ought to be fully conversant with the basic steps of an ABD, for irrespective of preponderance of elective deliveries by CS, any obstetrician may be faced with the odd case of emergency breech labour.

[375] *Smith v. Sheridan* [2005] All ER (D) 141 (Apr).

3.3.2.1.6.1.2 Sub-acute contributory causes

This section must be viewed in the light of the latest teaching on the aetiology of cerebral palsy including the two-hit theory', referred to in section 3.3.2.1.6.1. This theory, which is slowly gaining clinical importance, has serious medico-legal implications for it may involve shared causation responsibility between the sentinel episodes and antenatal co-factors. As discussed in appendix 3 section A3.5, up till relatively recently, CP jurisprudence commencing in the 1960's was essentially myopically focused on an intensive scrutiny of labour management in search of any factors leading to IPH. The picture is slowly changing to embrace obstetric liability for antenatal care where circumstances of care may have contributed to a 'fertile field' to which is added the *coup de grâce* of the sentinel event in the final development of suffficient IPH to cause HIE and eventual cerebral palsy.

Much remains to be elucidated scientifically but it does seem that rather than originating from a single episode, CP may develop from a sequence of interdependent adverse events rather than a single episode of challenge. [376] This will in turn potentially further widen the medico-legal vista and inadvertently compensate for the diminished liability from the 1960's and now limited to the 14.5% of cerebral cases known to result from avoidable IPH.[377] This section refers to what is termed here as sub-acute contributory events which include causes associated with what may be loosely called "sub-acute hypoxia" but comprise other factors such as infections, inflammations and other

[376] Asim K, Maja P, Stanojevic M, Salihagic-Kadic A, Miskovic B, Badreldeen A, Talic A, Zaputovic S, Honemeyer U. Intrauterine Growth Restriction and Cerebral Palsy. Acta Inform Med. 2010 Jun; 18(2): 64–82.

[377] See note 344.

undefined factors. IUGR is used as an example here in providing an antenatal ‘fertile field’ for the development of CP once a sentinel event strikes in labour.

Once IUGR is detected antenatally, full disclosure of the planned management must be instituted including the risks of the condition itself as well as those of management such as premature delivery. The options of the mode of delivery must be fully evaluated along the advantages and disadvantages of a vaginal and an abdominal delivery. Guidance along the path of least risks as evaluated by the obstetrician in the specific case must be stressed as well as the fact that the final decision is the patient’s. All points discussed and the patient’s input must be recorded in the patient’s file.

If a vaginal route is chosen, the labour ward must be alerted as to the higher risk of the labour. This implies specific preparation, namely:

I. A fully alerted labour ward staff, neonatologist and labour ward anaesthetist.

II. A haemoglobin assessment along with a cross-match for two units of blood standing by.

III. Continuous I-P CTG monitored CTG monitoring.

IV. The avoidance of PG if possible and if not its administration in labour ward with monitoring.

V. The avoidance of Syntocinon if possible, and if not, its limitation to 12 mu/min.

VI. An experienced attending midwife.

VII. A firm plan for an abdominal delivery if planned established progress objectives are not reached in time.

VIII. Regular senior obstetric review and update with disclosure and reassurance of the patient.

IX. The location of the labouring patient in the closest available room to the operating theatre.

X. If epidural anaesthesia is used, full precautions to avoid episodes of hypotension. At no stage and for no reason must the patient be allowed to lie supinely.

It may not be judicious to embark on complex vaginal operative methods such as rotational forceps, however good an exponent of the art, the obstetrician may pride himself to be. Simple ventouse extraction and low forceps deliveries may be acceptable, unless the fetus is extremely small for dates or premature.

Proposed amendments to the MOS include:

I. The departmental reminding of the need of increased awareness during antenatal care of conditions such as maternal hypothyroidism or thrombophilia in view of their potential permanent fetal neurological damage.

II. The setting up of an easily accessible high-risk management protocol in labour.

III. The re-evaluation of all patients for induction, with a view to ensuring that IUGR or other risks factors have not been missed, prior to amniotomy especially if Syntocinon infusion is to be employed.

IV. The explaining of the 'two- hit theory' with a view to reminding of the essential careful scrutiny of patients in the antenatal period.

V. The reminding of the importance of disclosure in cases, such as IUGR, where the risk of complications such as cerebral palsy may be more prevalent. Disclosure is not a carte blanche for mentioning catastrophic risks and moving on. The approach must be both practical and realistic but nonetheless humane.

3.3.2.1.6.1.3 CP related intra-partum obstetric liability of a non-hypoxic primary aetiology

In this section, which involves *trauma* as the primary insult to the fetus, the lion's share of responsibility involves breach of the obstetric SOC mostly pertaining to instrumental deliveries but one must not omit the after coming head of the breech presenting fetus,

manual rotation of the fetal head, and such even rarer manoeuvres as internal podalic version.

Trauma is the primary feature in these cases, but hypoxia may be a crucial contributor to the final fetal outcome and hypoxia may supervene before the trauma or as a complication of it. Particularly where an instrumental delivery is performed in response to an abnormal I-P CTG suggestive or confirmed as due to fetal hypoxia, the causative aetiology of the final underlying cerebral pathology may be difficult to ascertain. Multiple issues may be involved. Assessing legal liability in such instances may involve ascertaining or excluding breach of SOC involving say management of a pathological I-P CTG tracing as well as, and on a separate note, the performance of a forceps delivery or ventouse extraction.

One reminds here of the crucial importance of fetal neuro-imaging as early as possible after delivery.

3.3.2.1.6.1.3.1 Instrumental deliveries

The NHSLA report identified 160 claims over the studied 10-year period involving instrumental deliveries, 88 of which were forceps deliveries, 42 were ventouse extractions and in 30, strange as it sounds, the instrument involved was not stated. (See figure 8). The estimated total value of these claims was £94 million. In the UK instrumental deliveries constitute between 10 to 13% of all deliveries.[378]

[378] Sivashanmugarajan V, Yoong W. Instrumental delivery (Tutorial). Royal College of Obstetricians and Gynaecologists. Last updated December 2015.

The disparity between the number of claims involving the use of forceps and ventouse may lie in the fact that a ventouse extraction is likely to be less traumatic than forceps especially if the latter also involves a rotational element. However, ventouse extractions may not have their own fair share of misadventures. Edozien[379] states that a ventouse extraction is less likely to be associated with maternal perineal and vaginal trauma but more likely to fail at vaginal delivery and in causing fetal cephalhaematomas and retinal haemorrhages. The vacuum cup is often easier to introduce and apply to the fetal head then forceps blades and the instrument cannot be used to *force* rotation of the head as in vacuum extraction, rotation tends to occur spontaneously as the flexed head is pulled down in the pelvic axis. In a Kiellands rotational forceps (KRF) rotation is effected forcibly and it may, at times, also involve an element of fetal head disimpaction with its potential risks including that of cord prolapse.

Both instruments demand knowledge, mastery of technique, much practice and much common sense, but generally speaking, forceps deliveries demand a greater workable knowledge of the maternal pelvis and its relationship to the fetal head. The KRF is obviously on a class of its own, both as concerns mastery of technique as well potential maternal and fetal manage.

Wrongly used all instruments can inflict much damage, but there is an increased risk of maternal trauma with forceps, and neonatal trauma when the metal ventouse cup is

[379] Edozien L. Towards safe practice in instrumental vaginal delivery. Best Practice & Research Clinical Obstetrics and Gynaecology. 2007 Aug 21; 21(4):639-655.

used. Yet the latter is more effective in achieving delivery than the plastic cup.[380]The opportunity to inflict more damage with forceps than ventouse, is also reflected in a large Cochrane review which found that attempts at forceps delivery are associated with more Caesarean sections, maternal third or fourth degree tears, vaginal trauma, use of general anaesthesia, flatus incontinence and fetal facial injuries.[381] Fetal brain damage, especially with traumatic forceps deliveries are well recorded as causing a wide range of cerebral damage including that associated with subsequent cerebral palsy.

Although instrumental deliveries are discussed under this section, as a potential cause of cerebral palsy, the usual fetal[382] trauma inflicted is vastly more consistent with soft tissue damage ranging from facial and eye injuries to facial nerve damage. However, claims for liability of cerebral palsy involving fetal skull damage including fractures, resultant brain damage and convulsions resulting mostly from instrumental delivery are certainly not unknown in the UK Courts.

[380] O'Mahony F, Hofmey GJ, Menon V. Choice of instruments for assisted vaginal delivery. Cochrane Database of Systematic Reviews. 10 November 2010.

[381] See note 378.

[382] Maternal trauma is being excluded in this context.

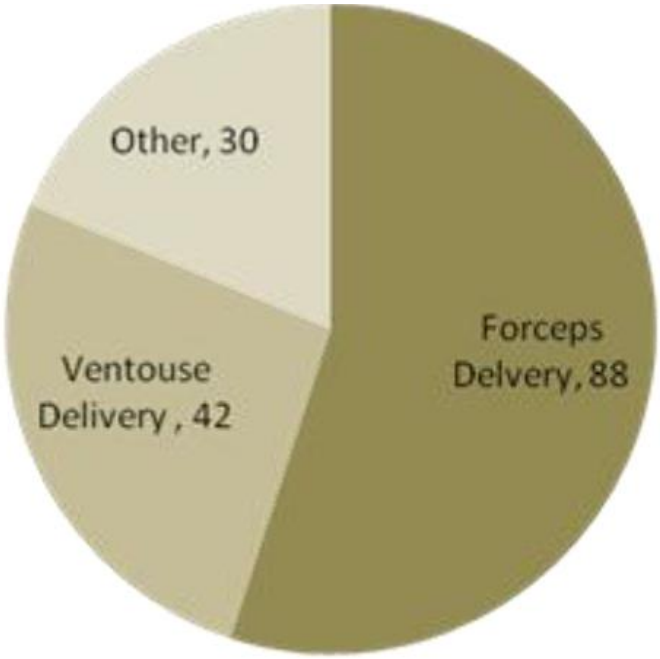

Figure 8 Litigation numbers involving instrumental deliveries (NHSLA 2000/10 Report)

Retracing some birth experiences from UK case law often reveals nightmarish scenarios of a Dickensian reality rather than that of modern obstetrics. In *Hamilton v. Fife Health Board*[383] involving a disastrous KRF delivery, the child died after 3 days from massive brain damage. In a case quoted in the lexis database, [384] a failed ventouse delivery was followed by a KRF application, accompanied by such force that the fetal skull was fractured and the child, hardly surprisingly, suffered severe asymmetric spastic quadriplegic cerebral palsy. In *D's parent and guardian v. Greater Glasgow Health Board,* a KRF led to a rare spinal cord compression-torsion damage at C1/2 resulting in total paralysis from the head down including inability to breathe spontaneously.

[383] *In Hamilton v. Fife Health Board* 1993 SC 369.

[384] Birth injury, failed attempts at vacuum extraction and Kiellands forceps, claimant suffered a fractured skull, intra-cerebral trauma and brain injury. Journal of Patient Safety and Risk Management. Case Notes.2013 May; 19(3).

However, KRF is far from being the only type of forceps involved in Court proceedings. In *Whiston v. London Strategic Health Authority,*[385] it was the use of a non-rotational forceps which inflicted the brain trauma when the circumstances actually called for the use of a rotational forceps.

An example of serious ventouse damage is found in *C (by his mother and litigation friend) v. The Avon, Gloucester and Wiltshire Strategic Health Authority (2005).*[386] The negligence here involved the contra-indicated use of ventouse extraction on a distressed *premature* child resulting in a large cephalhaematoma and failure to effect delivery. Forceps were then necessary to deliver the child who developed a massive cephalhaematoma. Unfortunately, paediatric management was not short itself of further mismanagement of the child's condition with the result that a massive bilirubinaemia was allowed to wreak further havoc on the child's brain. The final outcome was a disastrous one with marked brain damage and subsequent cerebral palsy, bilateral sensorineural hearing impairment, severe cognitive disabilities and permanent motor function impairment.

In Malta out of 3089 births in 2016, 174 were instrumental, out of which 160 were ventouse deliveries and 5 were forceps deliveries.[387] Here we see a gross reversal of the UK phenomenon of forceps delivery majority in instrumental liability litigation. The difference begs the obvious question of why should this be?

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[385] *Whiston v. London Strategic Health Authority* 113 BMLR 110.

[386] Case report: bilirubin encephalopathy following ventouse delivery. Journal of Patient Safety and Risk Management. 2006. Case Notes. July;.12(4).

[387] See note 284.

These local statistics for instrumental deliveries are a cause for serious concern. The gross disparity in the local use of ventouse and forceps certainly does raise inherent medico-legal concern in addition to clinical concern. A grand total of 5 forceps out of 165 (just > 3%) cases requiring an assisted vaginal delivery, implies a general and individual lack of exposure to sufficient numbers for anyone to be proficient in the art of forceps delivery. Even if all the forceps deliveries done in 2016 were performed by one person, which is highly unlikely though not impossible, this person is still far short of maintaining knowledge of technique and sufficient practice to acquire/maintain the required dexterity.

Although the RCOG recommends proficiency in using both ventouse *and* forceps, in the present Maltese situation, one should consider the elimination of the o*ccasional* forceps delivery for therein lies an accident waiting to happen. Furthermore, in any potential litigation alleging malpractice in a case of forceps delivery, these very statistics may provide justified ammunition for the plaintiff's claims. The local NOIS 2016 report does not specify the details of the types of instruments used in deliveries. This could have shed further important light. In fact, scrutinising the deliveries register one comes across the very rare one-off delivery effected by KRF. If one states that ordinary non-rotational forceps demand regular practice for safety and dexterity to be maintained, the argument holds without reserve with much greater exhortation with regard to KRF. The use of KRF should be reserved for the obstetrician who after much close supervision can use it safely and effectively and *is* using it regularly. Anyone using KRF *occasionally* is undoubtedly likely to be of much greater potential liability than of service to the patient, his unit and himself.

Proposed amendments to the MOS are grouped together with those from the next section.

3.3.2.1.6.1.3.1.1 Disclosure, consent and clinical note keeping in instrumental deliveries

The pre-consent disclosure at MDH, very much in resonance with the general medical, legal and jurisprudential low-key attitude, leaves much to be desired. More often than not, once a decision to assist a patient in the second stage of labour is taken by the local obstetrician, the attitude *of both patient and obstetrician* is often to "get on with it." Unless the assistance is for marked and very urgent fetal distress when the barest of simple disclosures is justifiable, disclosure should include the reason why instrumental assistance is necessary, how it will be done, the length of the procedure, the analgesia to be employed and potential complications. The discussion should also be documented in the clinical file. The RCOG recommends[388] that oral consent suffices, unless the procedure is done in theatre when written consent must be obtained. In Malta, it would probably be wise to adopt a written consent for all instrumental deliveries as this is likely to remind and accentuate the importance of such disclosure. In those cases where a previous instrumental delivery had been associated with a serious mishap, such as a maternal perineal tear extending to the anus, then the maternal consent attains much greater significance and furthermore the instrumental delivery should be undertaken by the consultant.

[388] Operative vaginal delivery. Green-top guideline No.26. January 2011. RCOG.

In this section, one may also include the failed forceps or failed ventouse. Such failure may be due to numerous reasons ranging from lack of adherence to the norms of use of the instrument, to defective instrumentation in the case of ventouse extraction, and to defective technique. Whatever the reason, one would be wise to pause, recollect oneself and reassess the clinical situation de novo. The sub-conscious urge to rush and deliver and thus correct one's initial failing should be completely thwarted. As long as fetal distress is not present, it would be wiser to obtain a senior's assessment of the situation. It may be that one is missing cephalopelvic disproportion or mis-diagnosing a mal-position. If the operator is the consultant and the "buck stops with him" then safety should be paramount. If on re-assessing he feels comfortable that changing instrument or re-applying the same is likely to effect delivery, then he should proceed, explaining and calming the patient before doing so. If a strong element of doubt persists then he should resort to an immediate caesarean section.

The Trial of Forceps delivery, where an element of uncertainty exists as to the feasibility of vaginal delivery, should be carried out in the operating theatre with all ready for an imminent CS. Disclosure must be clear on what will be done, its chances of success, the alternatives ready and available and the incurred risks. Written consent is necessary. Such trials must only be carried out by a consultant or by an experienced resident specialist who ideally is supervised by his consultant.

Immediately following an instrumental delivery, the obstetrician must complete his responsibility by filling in the operative sheet. Reasons for the intervention must be filled in. If the indication was one of fetal distress, the obstetrician would do well to gather all details including time intervals, all pertinent clinical note references as well

the I-P CTG tracing and any FBS results (if done). Careful documentation and record keeping of the fetal state before and after the delivery are important. In cases of unrelated cerebral palsy, misled or mal-intentioned parents are not unknown to commence litigation blaming the use of 'instruments' as the cause of CP.

Dates, time and signatures are important, as well as the information as to any senior supervision/assistance. TOF's and failed forceps need all details to be recorded, including precautions taken to avoid harm, e.g., pre-delivery pelvic assessment, ensuring full cephalic engagement, emptying of the maternal bladder, etc. Any misadventures must be described in great detail including the precise timing and remedial actions. References such as *forceps delivery done as per usual procedure* not only make no sense to Court but may invite dangerous conclusions as interpreted by the opposing lawyer.

Edozien[389] recommends the following details to be noted and recorded. These carry much legal protection:

- Indication for intervention;
- Consent;
- Fifths palpable (abdominal examination) of the fetal head;
- Position and station of the fetal head (vaginal examination);

[389] See note 379.

- Degree of fetal head moulding and caput;
- Adequacy of maternal pelvis;
- Fetal heart rate;
- Assessment of uterine contractions;
- Ease of application of instrument;
- Number of pulls;
- Number of detachments;
- Duration of instrumentation.

The RCOG also recommends[390] a regular obstetric unit audit regarding instrumental deliveries, indications, morbidity, consents, documentation and other aspects. Considering the relatively small number of instrumental deliveries in Malta, such meetings may be held with great advantage at three monthly intervals. Such audits should, among other factors, evaluate the quality and the contents of such clinical notes pertaining to instrumental deliveries.

[390] Operative vaginal delivery. Green-top guideline No.26. January 2011. RCOG.

Finally, in those unfortunate instances where an instrumental delivery has resulted in serious fetal trauma, the obstetrician must immediately discuss the situation with the neonatologist who must in tun immediately alert his consultant. It is important that neuro-imaging investigations are instituted as early as possible although the decision will be in paediatric hands. However, it is firstly in the child's interest but, secondarily in the obstetrician's medico-legal interest, that the extent and the *nature* of the child's cerebral damage be ascertained as early as possible.

The proposed amendments to the MOS include:

i. A review of the current situation with regard to the state of practical and safe use of ventouse and forceps deliveries. If the impression given by the NOIS 2016 report is correct, then a decision must be taken to abolish the occasional use of forceps. This is *not* an ideal solution, but it is wiser than the current no man's land situation where individuals dust off a pair of forceps and apply them to a baby's head every 10 weeks or so (5 forceps deliveries per year/365 =1 delivery per 73 days).This should apply even more forcefully to the use of KRF.

ii. Steps should be considered to implement the correct teaching of use of both instruments. Such knowledge and experience are ideal, but if the ideal cannot be achieved then the safe option wins. One solution for retaining the use of both forceps and vacuum extraction and that involves intensive, serious regular simulation programmes with continuous assessment. This will involve purchasing the right simulation models and the commitment of one or two consultants with extensive experience of both instruments.

iii. The inculcation of the importance of disclosure preceding consent which ideally should be a written one.

iv. Any instrumental delivery beyond the simplest needs consultant clearance and consultant attendance should be a must for TOF or immediately following failed forceps. The consultant should be notified when there is a failed instrumentation and *before* the next attempt at delivery is made. The resident specialist, if not involved at the first attempt, must continue the delivery himself. Explanation of what is happening to the patient and meticulous note keeping are crucial.

v. The establishment of a regular departmental review of all instrumental deliveries with a view to ascertaining disclosure, technique, outcome and documentation.

vi. The establishment of a protocol of neuro-imaging for signs of cerebral damage or evidence of HIE within the first twenty-four hours of birth. This neuro-imaging should be carried out by the most senior radiologist experienced in such imaging and ideally in sub-specialised in paediatric neuro-imaging.

3.3.2.1.7 Perineal trauma

65.4% of patients who delivered in Malta in 2016 had an episiotomy, or tear/laceration.[391] Table 2 gives further details which unfortunately do not reveal the

[391] See note 284.

actual numbers of patients with first, second, or third-degree perineal damage. Curiously, normal vaginal deliveries had an incidence of 47.4% spontaneous tears whereas instrumental deliveries were associated with the much lower incidence of 24.9%.[392] Again, these spontaneous tears are not classified. However, a perineal tear is more likely to be expected with an assisted vaginal delivery rather than a natural birth. These odd statistics might be explained by a general local midwifery reluctance to perform episiotomies, which attitude then results in an increase in natural tears and lacerations. Such undirected tears and lacerations are naturally more dangerous than ones directed through an episiotomy and carry a much higher potential medico-legal risk. *If* this is the case, one would also expect a higher than expected incidence of third and possibly fourth degree tears. This can only be confirmed if relevant and detailed statistics are kept and published. A future full statistical breakdown by the NOIS report may help clarify these serious queries.

As with other complications, no local precedent Court action on perineal trauma seems to exist, whereas the UK experience is anything but similar. The NHSLA report reveals that between 2000 and 2010, 441 claims of negligence were identified mostly involving the more serious third and fourth degree tears. The total pay-out was of £31,200,000.

[392] *Ibid*.

Damage to perineum	Normal Vaginal Delivery (n= 2908)		Assisted Vaginal Delivery** (n= 181)	
	Number	%	Number	%
No Damage	1060	*36.5*	10	*5.5*
Episiotomy* only	373	*12.8*	88	*48.6*
Tear only	1378	*47.4*	45	*24.9*
Episiotomy and tear	97	*3.3*	38	*21.0*

Table 2 Post-partum perineal trauma in Malta (NOIS 2016)

The claims were based on:

- Failure to consider a CS which would have avoided the perineal damage.

- Failure to perform or extend the episiotomy with the result that an uncontrolled tear resulted. This should be given particular imporance by the MOS in view of the above observation regarding the local statistics.

- Failure to diagnose the true extent and grade of the injury.

- Failure to perform a rectal examination (and thus miss rectal damage).

- Failure to perform the repair.

- Failure to repair adequately.

Diagnosis of the precise preineal trauma is crucial. This is the first step which will then lead on to the establishment of *who* ought to carry out the perineal epair. The MOS

needs to review the situation involving the most junior doctors especially while they lack basic experience and certainly in the first few months of employment. Cases exist where such unfairly involved doctors have commenced repair of an undiagnosed third degree tear, involuntarily inflicting further tissue damage. Establishing a sysytem of immediate classification and registration of all perineal damage *before* repair is one way of avoiding this while forwarding crucial statistics to the NOIS.

Such attention to establishing diagnosis may be remembered better if one considers that in one example quoted by the NHSLA report, a £500 000 liability pay-out was incurred, when a third degree tear was mistaken for a second degree one with the unrepaired anal damage later resulting in faecal incontinence.

Proposed amendments for this section are combined with those from the next.

3.3.2.1.7.1. Managing perineal trauma

Up to 90% of women experience a perineal tear during childbirth, with a substantial amount of such tears being small first degree ones (involving just skin and which will even heals spontaneously), or second degree ones affecting deep perineal muscles and require straightforward suturing. Severe perineal tears are only present in 0.6 – 9.0%, with the the risk of obstetrical anal sphincter damage being limited to 1% of all vaginal deliveries.[393]

[393]The Management of Third- and Fourth-Degree Perineal Tears. Green-top Guideline No. 29 June 2015. RCOG.

Disabling symptoms resulting from absent, partial or negligent repair or superimposed infections include:

- Persistent heavy vaginal discharge.
- Incontinence of faeces and/or flatus.
- Passage of faeces per vaginam from a recto-vaginal fistula.
- Irritable bowel syndrome.
- Colostomy.
- Psychiatric damage.
- Local pain with or without dyspareunia (painful intercourse).
- Local disfigurement

The fact that that 65.4% of all the patients, or 2,019 patients delivering in MDH in 2016 had repairs of some kind or other, demands the establishment of a firm policy of management regarding perineal trauma. Such a policy should include:

I. Classifying perineal damage.

II. Disclosure of information and patient consent.

III. Repairing and checking the repaired perineum.

IV. Documentation.

I Classifying perineal damage

The first and most and crucial step in effecting a safe repai, this is usually made by the delivering midwife. The NHSLA reported wrong grading in 59% of the cases, with third or fourth degree tears were misdiagnosed as first or second degree by 20 out of 23 midwives. Obstetrician review found 65% of wrong grading, with a fourth degree tear being misdiagnosed as a second degree by a consultant.

Figure 9 illustrates perineal trauma grading and this should be easily accessible in labour ward. Misdiagnosis may be due to a number of contributory factors, including:

- Lack of experience combined with lack of available supervision.

- Lack of experience combined with uncalled for supervision.

- Poor examination technique, e.g., omission of a digital rectal examination, poor lighting and incomplete limited examination.

Tear	Definition
First degree	Injury to perineal skin only.
Second degree	Injury to perineum involving perineal muscles but not involving the anal sphincter.
Third degree	Injury to perineum involving the anal sphincter complex: 3a: Less than 50% of EAS thickness torn. 3b: More than 50% of EAS thickness torn. 3c: Both EAS and IAS torn.
Fourth degree	Injury to perineum involving the anal sphincter complex (EAS and IAS) and anal epithelium.

EAS: External anal sphincter IAS: Internal anal sphincter)

Figure 9 Perineal trauma grading (NHSLA 2000-2010 report)

II Disclosure of information and patient consent

The patient's consent is tacitly expressed when the patient co-operates with the midwife by allowing her to put up her legs in stirrups. However, in simple perineal repairs up to grade two, an oral consent should best be secured after a brief and simple explanation of what needs to be repaired, the extent of the surgery required, the approximate duration and the fact that a local anaesthetic given by a local injection will render the surgery essentially painless although touch will still be felt. In the case of third or fourth degree trauma, which should be undertaken by a suitably experienced obstetrician all necessary information including that of the potential risks of non-repair *and* of the repair, should precede the obtaining of written consent. The local complication of partial or full faecal incontinence requiring more major surgical repair work should the repair not be done or if the repair fails should be clearly specified.

Unco-operative patients should not have perineal trauma repair carried out “quickly, to get it over and done with”. Such an attitude is a recipe for a potential medico-legal disaster especially if an adverse clinical outcome is combined with a nightmarish experience for the patient. The correct way involves the use of light general anaesthesia, for which full preparation is still necessary and written consent obtained after adequate disclosure. If the patient had her labour pains controlled by regional anaesthesia such as an epidural, this can be conveniently topped up and the patient administered a light sedative to relax her. These steps must be adequately explained both for legal purposes as well as for reassurance that the procedure will be essentially painless. Such patients may also be managed by an anaesthetist administrating a sedative, but as a rule, especially if the repair required is extensive, or a proper diagnosis of the extent of the damage cannot be easily achieved, it is wise for general anesthesia to be adminsitered.

III Checking the repair

A digital rectal examination must be performed to re-confirm the absence of damage to the rectal mucosa or that if a repair did involve the rectum, this has been satisfactorily repaired. Special care must be taken to exclude unwarranted sutures penetrating the rectal mucosa when this has not been originally damaged. Ignoring such simple advice may lead to the major complication of recto-vaginal fistula in the following weeks, a terrible complication which can be easily avoided.

All third and fourth degree tears require a senior and experienced obstetrician. It may be possible that the resident obstetrician available is not confident to perform the surgery. In this case the consultant himself must attend to the patient. Rarely, the worst

third and especially fourth degree repairs may even be beyond the consultant's expertise and no hesitation should be shown in calling for surgical assistance from a proctologist/bowel surgeon or other experienced surgeon. All such inter-specialist consultations should be both explained to the patient and clearly recorded in the clinical file.

IV Documentation

Full documentation is indispensable in all cases but especially so in those of third or fourth degree. The obstetrician who did the repair should write the operation notes as soon as possible after the repair. Documentation must include:

I. A clearly legible, correctly dated, timed and signed true account.

II. Any specific point of importance in the causation of the perineal tauma, e.g., shoulder dystocia, forceps delivery, etc.

III. The confirmation that discloure and consent were obtained after the trauma was properly classified and before commencing the repair.

IV. The diagnosis and the basis on which it is formed, e.g., third degree 3b as >50% of external sphincteris involved. One should note that although most cases of wrong diagnosis by an obstetrician involved a junior rank, this is not always the case.

V. Description of the repair.

VI. The post-operative reassesment including a digital rectal examination.

VII. Any post-operative instructions, e.g., type of diet in the case of repair to the anus/rectum.

VIII. Post-operative care and suggested follow up.

IX. Inclusion of names of doctors/ midwives present at the repair. If the surgeon was not a consultant but a consultant supervised, this must also be incuded in the notes.

Proposed amendments to the MOS include:

I. The NOIS reportage of perineal trauma needs to include further details including the diagnosis of the degree of the perineal damage.

II. An enquiry directed at the OBGYN drectorship as to any labour ward policy, declared or not, to allow natural tearing of the perineum and not perform an episiotomy.

III. The introduction of a serious management policy involving disclosure to consent as well as the introduction of signed consent forms for third and

fourth degree trauma repair and all repairs, irrespective of the extent, if general anaesthesis is required to effect the repair.

IV. Active certified training/retraining in diagnosing and grading of perineal trauma at both midwifery and obstetric level.

V. Active policy of who should repair what grade of perineal trauma. The present situation of “do it if you know how to” is dangerous and it is quite possible that third and fourth degree tears may be unwittingly entrusted to inexperienced hands. Furthermore, it is important to realise that knowledge of repair of the more difficult tears may not be necessarily synonymous with grade of hospital hierarchy. Lower bowel involvement should best involve a bowel surgeon.

VI. Full documentation must be insisted upon in all but the simplest of first degree tears.

VII. Patients presenting with complications such as faecal incontinence after a previous repair must be immediately seen by the patient’s consultant and full documentation instituted. Repair of such damage does not follow the normal rules of episiotomy repair and must be handled by the consultant in tandem with a surgeon experienced in such repairs and often after a number of months have elapsed from the initial repair. Such patients must have full disclosure as to what is happening and a detailed record kept in the patient’s file of what was specifically disclosed, by whom, on what date and time and

details of follow-up visits since then. Explanations as to the failed first attempt at repair should be imparted by the consultant, must be honest and must be accompanied by a firm plan as how treatment is to be effected. The period of waiting which must be allowed between the first and second repair must be explained well, lest the patient inteprets this as lack of interest or 'waiting list' time.

VIII. The fostering of increasing awareness that the mundane and the familiar perineal tear or laceration may be the cause of much suffering for the patient at a time when she should be enjoying her newborn. To this one must add the potential spectre of medico-legal litigation.

3.3.2.2 Antenatal Care

According to the NHSLA 2000-2010 report, 391 claims (7.6% of the total claims) relating to antenatal care (ANC) issues, cost the NHS the sum of £144,811,665 (4.64% of the total obstetric litigation pay-out). There is no equivalent concept of antenatal care-oriented litigation in Malta which, however desirable, is not the result of having achieved a state of antenatal care Utopia. In fact, according to a 2016 midwifery dissertation reviewing the quality of local public health antenatal care, *"all of the midwives identified that the provision of antenatal care locally, needs to better its quality".*[394]

[394] Borg C. Quality antenatal care in the local public health sector: midwives' views Unpublished dissertation. Faculty of Health Sciences. University of Malta. 2016 May; submitted for the degree of Batchelor of Science(Hons) Midwifery.

ANC is an indispensable part of any health care system providing a reliable and safe maternity service. It is a critical tool of improvement of short and long-term mortality and nutritional outcomes of children.[395] ANC opens the door for communication between the pregnant patient and her carers, instils confidence, especially in preparation for the moment of birth, and provides a golden opportunity for identifying the more vulnerable patients at risk of suffering from the various complications of pregnancy and childbirth.

Prenatal investigations ensuring the well-being of the fetus have also inevitably raised the legal liability stakes. The more advanced the service, the greater the opportunity for medico-legal comeback. Thus, the NHSLA report lays great emphasis on antenatal ultrasound anomaly scanning as a source of infrequent but very expensive Court litigation. The report cones on 92 claims purely related to such ultra-sound scanning and mostly dealing with the congenital scan. There is also another brewing reason for ANC litigation namely its potential role in cerebral palsy litigation as discussed in section 3.3.2.1.6.1.2 and in appendix three section A3.6. The ACOG's Neonatal Encephalopathy and Neurologic Outcome report[396] emphasized that conditions such as maternal thyroid dysfunction, coagulopathies, inflammations and infections, which though theoretically known as causes of CP, have so far been accorded much less obstetric emphasis then indicated. This serious admonition calling for an increase in the potential role played by antenatal care in CP prevention implies a sharing of focus in

[395] Kuhnt J, Volmer S. Antenatal care services and its implications for vital and health outcomes of children: evidence from 193 surveys in 69 low-income and middle-income countries Brit Med J.Open 2017; 7(11).

[396] Neonatal Encephalopathy and Neurologic Outcome. Second Edition. Report of the American College of Obstetricians and Gynecologists' Task Force on Neonatal Encephalopathy. Statement of Endorsement. Pediatrics. 2014 May; 133(5):e1483-1488.

CP prevention to include ANC and a potential shift to be anticipated in CP litigation. This thesis firmly stresses that ANC based liability will fill the vacuum resulting from the elimination of the 'great CP myth. The end-point of the argument stresses the increasing importance of ANC, bearing in mind that:

...the major etiological factors of spastic CP are hypoxia/ischemia (HI), occurring during the last third of pregnancy and around birth age.[397]

Under this new light, conditions such as inflammations, infections, inflammations, coagulopathies and endocrine conditions in the developing pregnancy may attain new significance. It will be most interesting to observe the evolution of the obstetric litigation profile over the next thirty years or so. This, combined with increasing litigation such as that resulting from prenatal anomaly diagnosis and disclosure challenges may well increasing the proportion of ANC litigation as compared to the present status

The proposed amendments to the MOS for this section are combined with those for the next section.

[397] Rumajogee P, Bregman T, Miller SP, Yager JY, Fehlings MG. Rodent Hypoxia-Ischemia Models for Cerebral Palsy Research: A Systematic Review. Front Neurol. 2016; 7:57.

3.3.2.2.1 The scopes of local antenatal care

As expected, there *are* difference in antenatal care between a UK and Maltese ANC, mostly resulting from Malta' commitment to the defence of unborn life. Thus, one cannot say that NICE's clinical guideline CG62[398] can be applied in its entirety to the local scene, for section 1.7. of this guideline refers to fetal anomaly screening. Although in Malta, fetal us anomaly scanning is in regular use, there is no established prenatal screening programme.

The following statement is an ideal broad mission statement for local antenatal care:

I. The management of pregnancy whether normal as in the majority of patients or that complicated by medical conditions, already existent or pregnancy induced.

II. The establishment of a healthy clinical relationship between the patient and her carers which relationship forms the basis of a future pleasant and safe childbirth experience.

III. The regular monitoring of patients with a view to ensuring healthy progress of the pregnancy, good maternal health and appropriate fetal growth and well-being.

[398] Nice Guidelines. CG62.Antenatal care for uncomplicated pregnancies. Published March 2008. Last updated: February 2019.

IV. Maternal screening for what may be asymptomatic clinical, haematological or infectious conditions, which may harmful to the mother and the fetus.

V. Congenital anomaly ultra-sound scanning offered as part of the ultra-sound service to all pregnancies. This is not held with the purpose of detecting anomalies with a view to offering a therapeutic abortion, as any form of abortion for whatever reason remains a criminal offence in Malta.

As it stands, the last point raises many queries which are discussed further on.

The current local ANC has undergone many recent challenges imposed by the needs of a rapidly increasing population of varying ethnicity, as discussed in a number of places including sections 1.5, 1.5.1 and 1.5.1.2. These challenges naturally affect the whole OBGYN Department including its logistics and administration. Partly as a response to these challenges, there has been an increase in the number of consultants and an increasing number of new afternoon clinics have been established, where previously, the afternoons were completely vacant. Such clinics tend to be more gynaecologically oriented and include such topics as colposcopy, post-menopausal problems and vulval pathology. Such positive initiatives bring their own administrative and logistical challenges. Thus, the increase of consultants has meant that the morning antenatal clinic must accommodate two obstetric firms concurrently.

One must mention that in the next years the whole department is expected to be relocated in the near future, so the proposals put forward in this section may come at an opportune time. The concept of a general change in site location as well as system

functionality in one major shift is appealing and is essential to accommodate increasing patient needs, partly due to ever increasing obstetric demographic challenges. Fulfilling the evolving needs engendered by modern obstetric care is a duty owed to all those presenting for obstetric in a modern Malta.

Proposed amendments to the MOS include:

I. An increased exploitation of afternoon clinics and the consideration of evening clinics

II. A re-iteration of the respect of the firm concept as proposed in section 3.3.2.1.2 regarding labour ward personnel deployment.

III. The ensuring of punctuality by all personnel, commencing with the consultant at the antenatal clinic

IV. The creation of internal doors allowing communication between the consulting rooms to increase efficiency in function and time management in inter-firm communication.

V. The introduction of the Assessment Based Risk Management System (ABRMS) as discussed in section 3.3.2.3.3.

VI. The creation of better functional space area in the new OBGYN unit. Much precious space is wasted especially in the reception area in the present set-up.

3.3.2.2.2 Catering for the changing profile of the patient at the antenatal clinic

Section 1.5 stressed the existence of the phenomenon of the changing patient profile using the Maltese obstetric services for both antenatal care as well as delivery and the resulting logistical, clinical and medico-legal challenges. This section seeks to propose amendments which may assist the MOS in minimising medico-legal vulnerability in handing issues relating to the care of resident foreign EU nationals as well as irregular migrants as reviewed in section 1.5.1.2.

Proposed amendments to the MOS include:

I. The call for a consultant obstetrician with interest in migrant obstetric issues. Such a consultant must open up the sub-specialty to embrace the socio-cultural and religious elements leading to obstetric issues in this group of pregnant patients. He must also aim to foster an increasing academic and clinical interest in related medical conditions.

II. The increase in female interpreters who are groomed in materia medica as concerning the interpretative aspect.

III. The strengthening of obstetric liaison through midwifery projects, with the local Maltese Islamic community to foster education of modern obstetric principles of care including the needs for and implications of a caesarean section.

IV. Liaison through seminars and clinical meetings between the OBGYN Department and physicians who are ideally specialised in tropical medicine.

V. The consideration of a yearly seminar between the OBGYN Department and the Department of Anthropology of the University of Malta directed at understanding the socio-cultural, religious and psychological background of the immigrant

VI. The identifying of a person from within the higher management sector to be the anchor person in communication of irregular migrant affairs, be they medical, social, religious, or administrative. This person must bridge between government and NGO's such as MSF as well as the corresponding departments of W.H.O and the E.U.

Policies pertaining (though not necessarily limited) to EU nationals.

I The recognition that the patient's psychology, attitude, religious beliefs, morality and expectations may be different to those of the Maltese patient. This should reflect itself in the MDH staff behaviour including the avoidance of over-familiarity and the respect of patient-staff boundary lines.

II The ensuring of good and clear communication throughout the antenatal visit but especially in matters relating to disclosure and consent. Language difficulties may be a greater issue than presently considered.

III The importance of recognising that this group of patients may have a greater expectation of patient autonomy than the local patient. This includes but is not limited to satisfactory disclosure where necessary, accountability, respect of confidentiality and access to one's own file and other recorded details about the patient.

IV Leaflets, in the main European languages, explaining Malta's position with regard to abortion and resultant effects on certain specific services such as prenatal genetic testing. This should not constitute an apology but an explanation.

3.3.2.3.3 Proposing the Assessment-Based Risk Management System

The Assessment-Based Risk Management System (ABRMS) is a system meant to functionally and efficiently streamline patients at any level of management as based on the assessment of the risks to their pregnancy. Subsequently it serves to create the optimal time/resource/manpower base at any level of care, be this at the Out-Patients Department, the antenatal ward or the labour ward. Instituted wisely and applied efficiently, it will automatically improve clinical efficiency and outcome and thus diminish the chance of litigation.

The system is based on the concept of systemising the amassed groupage of individual patients' obstetric risks. Currently, every patient's risk status becomes clear as soon as her file or antenatal co-operation card are reviewed. What information lies in the

clinical notes leading to the established risk is confidential e.g., IUGR, precious CS, previous abruptio placentae, etc. The risk status per se need not be confidential,[399] and using this risk status, a patient is placed in say a category of ascending or ascending severity, e.g., Class A (high risk), Class B (moderate risk) and Class C (low risk). Perhaps another group reflecting 'normal pregnancy' should be avoided to avoid the connotation of abnormality associated with the other classes. It is important to stress to patients that the classifying of patients into risks categories will increase efficiency all round, diminish wastage of man-hours and diminish waiting times. The system will direct the degree of required intensity in care as appropriate to risk

The ABRMS may be compared to a class 1 lever system where, by optimising distance from fulcrum a small effort will uplift a significantly larger load as illustrated in Figure 10. The systematic gathering of the necessary information includes information obtained from the patient herself, her family doctor, her family, an existent hospital file, the history taken, and the physical examination carried out at the booking visit. This information allows the classification of risk by the consultant at the booking visit.

The ABRMS patient classification may need re-classifying with, for example, the development of pregnancy complications. The patient may be moved from a classification of lower to a higher risk but obviously not vice versa. Such classifying and re classifying should be the consultant's sole prerogative. The patient's risk category would be entered into her digital registration and appear in whatever aspect of care the patient is in (see Figure 11).

[399] A patient must be consented in accepting to participate in the ABRMS. The disclosure must state clearly that the patient's risk category will be used within the OBGYN department, but never the circumstances leading to such a risk status. The advantages of the system, if explained well, are most attractive but the final choice is the patient's.

- **Antenatal clinic advantages**

The list of patients expected for the day will now translate itself into three separate classes of patients who may be designated for the requisite consulting rooms. For example, class A (high risk) patients will be designated for the consultant's and the resident specialist rooms, while Classes B and C will be distributed to the more junior firm members. Depending on the firm's policy, all class A patients may require ultra-sound, antenatal CTG and doppler flow studies before their visits.

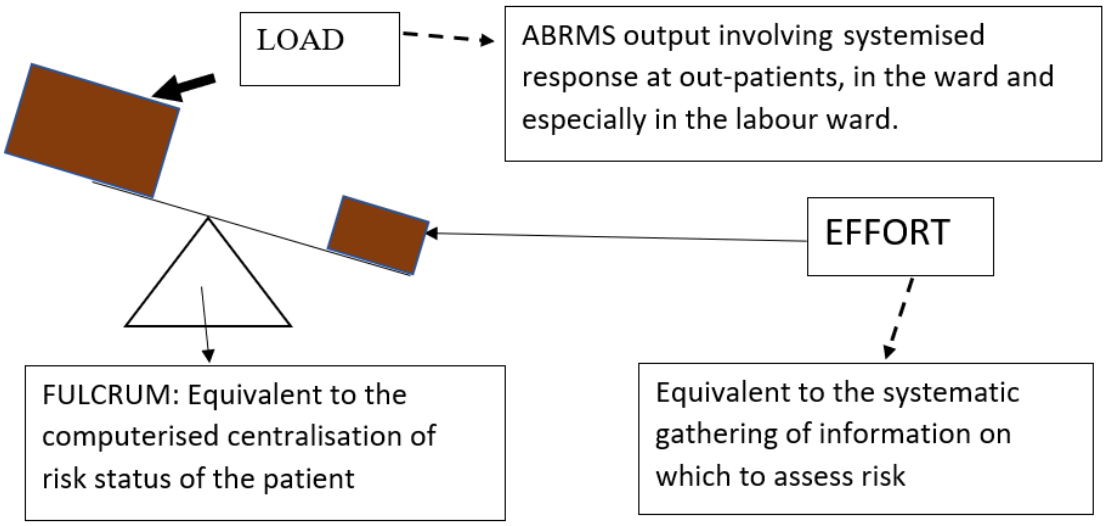

Figure 10 Pictorial analogy of the ABRMS to a class 1 lever system

Substantially less time is likely to be wasted than at present where more often than not patients are admitted willy-nilly to any member of the day's obstetric team. As a rule, as matters stand there is no groupage of patients by risk directed to the more or less experienced of the team's doctors. Using the ABRMS, where the experience of the obstetrician is now pre-matched with waiting patient risk category, less time is wasted, for example, while a more senior firm member comes to see a higher risk patient who

has been sent to a junior's room. Waiting times are also likely to be shortened, as patients will also waste less time at the desk and can simply look at the board to know behind which door they must wait.

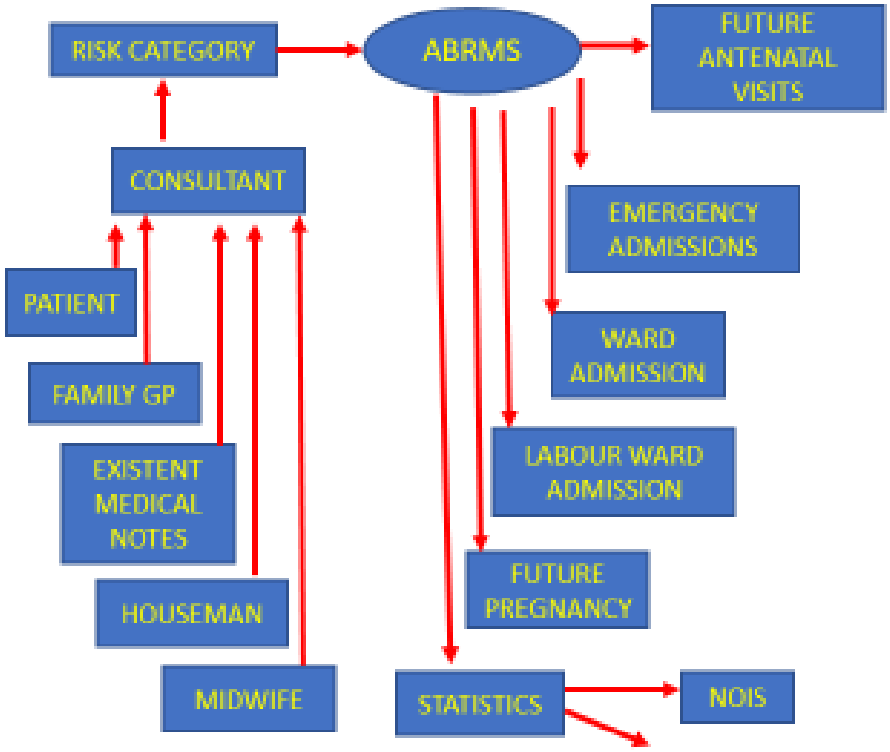

Figure 11 Chart representation of the inflow of data into the ABRMS and some of the outflow advantages

- **Antenatal Ward advantages**

As a rule, since the patients in the ward are normally not excessive in number and their risk potential is generally known, or ought to be known by all staff. However, it is not unwise to automatically instil a sense of awareness as to the patient's pecking order of risks. This may, for example, have a guiding role when labour ward is full and patients awaiting induction of labour are being trickled into labour ward. The system may also be extended to prioritising laboratory results. Risk awareness may also save the odd

situation where a high-risk category patient is absent-mindedly having her PG insertion casually like all the others in the ward instead of labour ward.

- **Labour ward advantages**

The advantages here commence from the eve of the firm's duty day by alerting the midwifery staff as what to expect on the next day and ensure a sufficiently experienced midwifery complement is available. Labour ward will be in a position to know even the minimum number of CTG monitors required for the following day as well as the number of minimum blood cross-matches, which information can be forwarded to the blood bank a day before. In the absence of the required necessities whether number of monitors or a sufficient experienced midwifery complement, high risk deliveries may be prioritised unless the labour ward situation can be remedied. Induction prioritisation may still be necessary as dictated by emergency labouring patients with its effect on bed occupancy, CTG monitoring availability and midwifery experience deployed on the day.

The higher risk patients should be placed in rooms closest to the operating theatre, have the more experienced midwives and be reviewed more frequently by senior obstetric staff during labour. Between 08.00 and 14.30hrs, the consultant himself ought to make himself active in this regard and make himself quietly visible. The use of Syntocinon for induction and augmentation should be subject to the usual safety scrutiny of management and limited to 12 mu/min.[400] Unless actively contra-indicated, epidural anaesthesia should be encouraged with stringent avoidance of potential hypotensive

[400] See note 322.

episodes and, epidural being used or not, the supine position completely avoided. Ideally, the on-call anaesthetist consultant should be involved as much as possible in the period 0.800 to 14.30 hours. Particular instructions must be issued during ward rounds commencing with the first one at 08.00 hours e.g., in cases of pre-eclampsia, detailed fluid input/output charting as well as urea and electrolyte and clotting screens monitoring. The pre-warned laboratories will tend to give priority to results of such high-risk patients.

Throughout the labour, the patient must be continuously updated and where possible reassured that all is progressing according to plan. Once delivered, the neonate should be examined immediately by the paediatrician and depending on the results, the patient reassured as early as possible. Depending on the reason for the high risk, the post-delivery period should set in motion any required new instructions of review. Thus, in cases of severe pre-eclampsia the patient must be watched for signs of developing post-partum eclampsia, the grand multipara must be watched for post-partum haemorrhage, etc.

3.3.2.3.3.1 Anticipated opposition to the ABRMS

The biggest hurdle may surprisingly originate from the patient herself who if she has an “outside” obstetrician may expect to have him review her at any ANC appointment at MDH. Furthermore, the higher risk patients may refuse the offered MDH pregnancy reviews as they are “being seen privately anyway”. The only positive way to combat this is by a strong publicity move through the Health Department’s media office stressing that co-operation is necessary if the new system is to offer better service to

pregnant mothers considered to be at risk. The junior doctors themselves must be aware of the advantages as well as the potential legal risks they incur by taking on such responsibility of high risk patients in their private capacity. They must be made to understand that the scope is not related in any way to curbing their private practice.

There will always be obstetric and midwifery members of staff who will oppose the system for the sake of opposing. However, given time and exposure to the ABRMS, they will come to realise that the little initial effort of risk assessment and subsequent streamlining is of benefit to all and not just the patient. It simply boils down to the Boy Scout motto "Be Prepared" which motto should also be adopted along with the RCOG's 'Super Ardua'[401] meaning "let us overcome our difficulties" coined in 1929 by the RCOG's first president and co-founder, the famous William Blair-Bell.

3.3.2.3.3.2 Proposed suggestions to the MOS regarding the establishment of the ABRMS

I. The first ANC assessment by the consultant is crucial as it lays the basis of classification. The parameters required involve a meticulous history taking of all aspects of the patient's health including, obstetric/medical/social/ drug/family/ and all else that is relevant. This is followed by a complete general examination by the firm's junior doctor. Factors such as age, ethnicity, weight, height, the presence or history of hypertension, diabetes, cardiac disease, severe myopia, rickets, uncontrolled asthma, hepatitis, HIV/AIDS, thalassemia, neurofibromatosis, mental disorders, suicide attempts, etc, must all be noted.

[401] The full motto actually is 'Super Ardua Consurgamus'.

Bleeding disorders such as von Willebrand disease and disorders tending to increase clotting such as Factor V deficiency are extremely important to note.

II. Obstetric history must include information as regards previous infertility, assisted reproduction, parity, caesarean sections, thrombo-embolism, still-birth, shoulder dystocia, cerebral palsy, antepartum haemorrhage, leiomyomas, pre-eclampsia/eclampsia and gestational diabetes.

III. Proper tick-lists should be available on special sheets which must allow ample space for any extra details and information.

IV. For most patients, the first visit should ideally be held not later than twelve weeks gestation. In diabetic patients, the earlier such a visit is organised, the better. This implies that *all* staff, including clerical staff/receptionists understand the simple requisites of the ABRMS with ‘simple’ not implying laxness. The Health Promotion Unit may help by frequent advertising of the importance of early antenatal registration on the frequent short media spots, adopted over the last years.

V. The MOS, once aware of the advantages of the system and if convinced of its adoption, should invite considerations of further improvements over a limited time span before its final deployment.

VI. The MOS should be conscious of the fact that if correctly operative, the ABRMS is likely to change management so as to diminish litigation, but if not effected

along the established rules, it may actually *increase* such liability. This is because, a plaintiff's defence alleging negligence may take the line of reasoning that "*your system allows you an opportunity to deal more effectively with higher risk situations, in spite of which you still failed to…".*

VII. The understandable Out-patients Department's mentality of "many hands make light work" must be replaced by a risk consciousness resource deployment as offered by a fully functional ABRMS. However, before implementation, the benefits and drawbacks of the system must be constructively discussed with all members of staff. Once it is implemented, regular reviews say on a three-monthly basis for the first year will afford valuable practical feedback to enable the necessary 'tweaking' of the system.

VIII. Once the system is up and running, administration must observe closely and compare pre and post-ABRMS audits to objectively assess the system. This will also allow all necessary 'tweaking' of the system which is inevitable with any new system of such a calibre.

3.3.2.2.4 The Maltese ultra-sound service

This is the fourth and final of the group especially highlighted by the NHSLA report for detailed review at a secondary level. Locally, the ultra-sound service technically falls under the Radiology Department although the obstetric ultra-sound unit is located within MDH's OBGYN Out-patients Department. The number of obstetric ultra-sounds carried out at the Radiology Department are negligible in number. However, in case of

staff shortage, general staff ultra-sonographers from the Radiology Department may provide the required obstetric service.

The first point of evaluation here concerns *who* performs the ultra-sound. The local position is somewhere mid-way between that of the UK and that of continental Europe.[402] In the former, it is sonographers (as distinct from doctors/obstetricians) who usually perform the scans, while in the latter it is often obstetricians themselves. Locally, we find an admixture of qualified sonographers, non-obstetrician doctors as well as obstetricians of various sub-consultant grade. The latter are assigned to ultra-sound duties by rosters which, as repeatedly mentioned, are drawn up by secretaries.

As a rule, universally speaking, non-medically qualified sonographers tend to excel at image optimisation while the obstetrician-sonographer is ideal in terms of clinical correlation. The non-medical sonographer technician usually first qualifies in general ultra-sound, and then specialises further and obtains his credentials as a diagnostic medical sonographer[403] specialised in obstetrics and gynaecological sonography. The absolutely ideal person would be an obstetrician who is formally qualified in obstetric ultra-sonography and has subsequently honed his skills over a sufficiently long period of time through exposure to heterogeneous problems and populations. In Malta, over the last few years, a number of junior obstetricians have formally qualified in the subject after attending a professionally organised local course with overseas (UK) involvement. Efforts like these are a good way forward and must be lauded, encouraged and supported.

[402] Mavroforou A, Mavrophoros D, Koumantakis E, Michalodimitrakis E. Liability in prenatal ultrasound screening. Ultrasound Obstet Gynecol. 2003; 21:525-528.
[403] Scope of Practice and Clinical Standards for the Diagnostic Medical Sonographer. April 13, 2015. The Society of Diagnostic Medical Sonography (USA). April 13, 2015.

Since this chapter has made extensive reference to the NHSLA report for 2000-2010, one should state that a great boundary separates the official formative status of the Maltese antenatal sonographer and his UK counterpart. The latter belongs to a well organised group of technicians or doctors who are fully qualified, attend regular updating and assessments, and are essentially performing such duties on a full-time basis. Their education and constant evolution have been further augmented by the NHS' clinical feedback resulting from circa half a century of medico-legal challenge which has itself reflected the science and human response of the day.

The Maltese ultra-sonographer is in *most cases* firstly disadvantaged in lacking a proper formative background. Most of the junior obstetric staff allotted roster ultra-sound duties are likely not to be qualified in the subject although they may have gathered much practical experience and, as stated, a number have *recently* formally qualified in the subject. This group of junior obstetricians recently qualified in obstetric ultra-sound should be reviewed as to their regular workload as well as to their theoretical updating and assessment. Initial qualification without the necessary structured follow-up, unfortunately, deprives much of the advantages of initial qualification. One must remember that consultant posts in a small Island like Malta are very much a case of "dead men's boots" and obtaining yet another certificate is further CV boosting for when the big job arrives. This does not by any means belittle these efforts but obtaining such credentials must be associated with a long-term training programme if this is to be significant in the local evolution of antenatal ultra-sonography.

The NHSLA report makes it clear that ethical and legal obligations of obstetric ultra-sonography demand an appropriate level of trained *qualified* competence which is subject to the standards of training and continuing education.[404] This is indispensable advice for the MOS both from the daily practical aspect demanding training, qualifications, work experience and ethical guidance but also for the future necessity of Court scrutiny. If the MOS is to aim for an efficient, reliable and European level of ultra-sound service, it first needs to understand the need to heed the relevant advice of those overseas systems which have tested the waters for decades and have optimised their service both in response to their clinical needs and their medico-legal implications.

In the challenging subject of antenatal ultra-sonography, even the very best qualified may come across insurmountable Court challenges. In *Lillywhite and another v. University College London Hospitals' NHS Trust,*[405] the defendant ultra-sonographer was a top qualified obstetrician, an international authority and a recognised teacher of teachers. However, the Court still ruled for the plaintiff and declared breach of duty by the defendant when, in his role as an obstetric sonographer, he failed to diagnose holoprosencephaly in a fetal anomaly scan. One can never assume that all medico-legal challenge can be sufficiently pre-empted to avoid litigation. However, the level of the service can always be improved, especially when that level has essentially never been tested against a modern SOC in a Court of law. The current MOS ultra-sound service is a functional one in a department which has provenly maintained a European level of obstetric care. However there is also little doubt that much remains to be done in the ultra-sound specialty if the service is to move to a next level of care both because the

[404] Chervenak FA, McCullough.LB. Ethics, an emerging subdiscipline of obstetric ultrasound, and its relevance to the routine obstetric scan. Ultrasound Obstet. Gynecol. 1991; 1:18-20.

[405] *Lillywhite and another v. University College London Hospitals'* NHS Trust [2005] EWCA Civ 1466.

discipline itself demands such progress and also because in catering for an ever increasing foreign EU population carries its own specific legal vulnerabilities.

Proposals for amendments to the MOS include:

I. The recognition of the potential gravity of medico-legal challenge resulting from antenatal ultra-sonography. Subsequently the qualifications and experience of an official MDH antenatal sonographer need to be established and adhered to. Such criteria must be such as to withstand any Court challenge. Furthermore, MDH administration must formally recognise the clinical and legal implications of the distinction between level one and level two antenatal ultra-sonography. For example, although a technician or an obstetrician qualified at level one may certainly perform routine antenatal ultrasonography, only persons qualified at level two may perform fetal anomaly scanning.

II. All duty rosters in the obstetric Out-Patients Department pertaining to antenatal ultra-sound to be the responsibility of the head of the OBGYN Department.

III. The organisation of regular Radiology-OBGYN meetings, in-house training programmes and assessments along with the encouragement of attending European courses in the subject and further specialisation.

IV. The establishment of codes of guidance for ultra-sonographers as based on well-established systems e.g., the RCOG's and the UK's national guidelines and the

the Society and College of Radiographers' Guidelines for Professional Ultra-Sound Practice.

V. The issue of such official guidelines should include, among other relevant points, direction relating to:

i. Patient communication, disclosure, consent and confidentiality.

ii. Relevant ethics

iii. Medico-legal awareness

3.3.2.2.4.1 The Maltese Anomaly Scan

The fetal anomaly ultra-sound scan is normally carried out between eighteen and twenty-one weeks of pregnancy with the scope of ruling out abnormalities in the baby's bones, heart, brain, spinal cord, face, kidneys and abdomen. It specifically seeks to rule out anencephaly, open spina bifida, cleft lip, diaphragmatic hernia, gastroschisis, exomphalos, serious cardiac abnormalities, bilateral renal agenesis, lethal skeletal dysplasia, Edward's syndrome and Patau's syndrome. While the detected abnormalities are not limited to these, some anomalies are easier to detect than others. Thus, whereas open spina bifida is correctly diagnosed in 9 out of 10 cases, only 5 out of 10 of certain heart defects[406] tend to be diagnosed.

[406] Your pregnancy and baby guide.20-week anomaly scan. NHS. 6 March 2018.

This subject needs to be given separate and individual consideration over and above daily routine obstetric ultra-sonography. The NHSLA report specifically zeroes in on this aspect of the subject as it is underlying the core of UK litigation in obstetric ultra-sonography. Although only ninety-two incidents were reported for the period 2000-2010, one must not under-estimate the problem as Court remuneration in cases of missed anomalies is normally extremely punitive. Furthermore, most of the mistakes involved were preventable. Thus, one stressed factor was that in only 60% of cases were the established protocols in use. In 72.5% of the claims, preventable human error was clearly responsible.

According to the NSLA report, ultrasound related claims amounted to 230. Only 40 questionnaires were returned out of 92 forwarded. Regarding the staff involved, 42.5% related to ultra-sonographers, 27.5% involved obstetricians and the smallest number, 25% (though still substantial) concerned ultra-sound trained midwives. In addition, the report stressed a number of factors including the need for adequate training, the use of sufficiently modern, efficient and regularly serviced equipment, proper documentation, correct disclosure the unsuppressed call for senior assistance where and when necessary. Maltese ultra-sonographer will find that all these requirements apply locally across the board. Apart from equipment efficiency which demands a co-operative administration, all the above factors are within the ken of the ultra-sonographer's ambition to improve his practice. The OBGYN Department and the Department of Radiology are duty bound to ensure such requirements are enforced. Furthermore, it is also their responsibility to remember that the performance of an anomaly scan requires

specific qualification, experience and persistent exposure to the subject, and moreover, considerable advanced skill is necessary to detect certain subtle anomalies.[407]

The obvious lack of perception of the gravity of the medico-legal responsibility of anomaly scanning is unfortunately clear in the Maltese situation. There have been in fact a recurrent number of situations where major fetal anomalies have been completely misdiagnosed, although none led to Court litigation. In the private sector, the situation is infinitely worse and can never be truly monitored unless one imposes official government regulations and guidelines, as for example has been done in India where in 2018 extremely strict laws were enacted to regulate pre-natal diagnostic techniques, including ultra-sound.[408] Although this is not recommended at this stage, one must keep in mind the local phenomenon of the plethora of private antenatal us scanning some even carried out by self-taught family physicians. There are even obstetric consultants who risk their reputations in performing anomaly scans privately when they are clearly nowhere near qualified for the job. There have been cases of patients where a diagnosis of a private anomaly was declared wrong overseas when the patient was referred for termination of pregnancy. These situations can certainly exist everywhere but they particularly flourish where doctors are not held to account. It is a salutary reminder that the NHSLA report reveals that 27.5% of cases alleging negligence due to misinterpretation concerned obstetricians as defendants.

The proposed amendments for this section are combined with those of the next section.

[407] Berlin L. Medicolegal • Malpractice and Ethical Issues in Radiology. Am.J Roentgenol. 2014 Jun; 202(6):W597.

[408] Raghavan P. Government to strengthen regulation of ultrasound, other imaging equipment. The Economic Times. 01 Mar 2018.

3.3.2.2.4.2 Disclosure, Consent, privacy and counselling in anomaly scanning

Although the NHSLA report laid no special emphasis on the lack of disclosure as a significant cause of litigation, this aspect needs to be reviewed with urgency locally. In litigation-ridden countries, lack of adequate communication is known to be a commoner cause than diagnostic errors in litigation issues.[409] Furthermore, good communication and good disclosure often go hand in hand. Unfortunately, disclosure is generally often considered of low importance in obstetric ultra-sound but potentially devastatingly in anomaly scanning. Improving the situation must start with ultrasound in general, where an oral consent should suffice after a simple explanation of the process. It takes little effort to explain the safety of a simple ultra-sound, what it may show, what it may not show and explain the actual findings to the normally eager parents.

Abnormal results are best divulged by the patient's consultant. If a vaginal ultra-sound is to be performed, it is crucial to stress that the pregnancy cannot be damaged by this and furthermore that vaginally, certain information may be more accessible than in an abdominal ultra-sound. UK Court claims of negligence based on defective disclosure in general are well known, and there have even been claims of assault based on simple lack of adequate communication and resultant misunderstandings in the performance of a vaginal ultra-sound[410]. Furthermore, the patient should be encouraged to feel free to ask any questions. It is important that the patient leaves the consulting room mentally satisfied and with no queries.

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[409] Gann R. The therapeutic partnership: legal and ethical aspects of consumer health information. *Health Libr Rev* 1995; 12:83–90.

[410] See note 409.

In the case of anomaly scanning, it may be wiser to obtain a signed consent, and this will remind the ultra-sonographer of the gravity of what may ensue and the need for adequate disclosure. The success and failure rate in detecting anomalies must be explained, as well as the fact that the scan may pick up certain anomalies better than others, but that a full guarantee of success is impossible. One must remember that the patient, more often than not, has no idea of the limitations of the anomaly scan. Furthermore, it should be explained that anomaly scanning it is not a screening test for say trisomic conditions, which seems to be a commonly held view locally It is best if a printed sheet with these limitations is explained, discussed and given to the patient.

Revealing the fetal sex may or may not be wished for and the sonographer must clearly ascertain the patient's wishes. If it is technically difficult to determine fetal sex, one should explain the difficulties of making the diagnosis.[411] All anomaly scan results should be written down and handed over to the patient along with any photographs taken. Copies should be kept in the patient's file. Specific or unusual points raised or asked about by the patient should be noted in the clinical file. Any scan features which are considered unusual or abnormal should be photographed. It should be stressed to the patient that ethics demand that the results be discussed by the referring obstetrician. This point is often flagrantly disregarded, and not only with regard to anomaly scanning, and there have been occasions where patients have been informed of what the subsequent clinical management ought to be, even before the referring consultant knows what the ultra-sound result has shown.

[411] Faden RR, Becker C, Lewis C, Freeman J, Faden Al. Disclosure of information to patients in medical care. Med Care. July 1981; 19(7):718–733.

Discretion and confidentiality must also be particularly stressed in MDH which services the whole island and where it is said that everybody knows everybody. It is not unknown for family members to learn of a congenital anomaly in a relative's pregnancy from hospital linked sources. Such data leakage is extremely serious and needless to say, can lead to legal action under a number of clauses, including that of serious breach of the Data Protection Act, Chapter 586 of the Laws of Malta as well as the medical confidentiality laws.

It is important for a formal and efficient counselling service to be set-up and be constantly available for situations where anomalies are discovered on ultra-sound. It is strictly the patient's consultant who should impart the available information, who at no point must intimate a suggestion of terminating the pregnancy unless he wants to run foul of the local criminal law. The news of such anomalies must be imparted with tact and humanity and much counselling will be needed by staff who must be *professionally* trained in this aspect of antenatal care. It should be unthinkable just to send the patient home having just informed her of the news of some major anomaly. Suitable literature, in both Maltese and English, should be prepared and given to such a patient along with a helpline contact number.

Proposed amendments to the MOS include:

I. No one below certified ultra-sound level 2 should undertake anomaly scanning, irrespective of other medical qualifications and hospital hierarchy. Moreover, such level 2 sonographers must practice their discipline regularly and be

periodically assessed and certified or otherwise have their duties limited to general level one scanning duties.

II. Ultra-sound machines should be the best compatible with a balance of quality, optimal results and cost. Such machines must be scrupulously and regularly serviced and maintained.

III. All anomaly scanning must be registered, and the results stored electronically with patient consent. This applies whether the results reveal normal findings or otherwise.

IV. All anomaly scans should follow an official set-up protocol which is regularly reviewed as necessary. Such a protocol combined with regular practice are the best ways to diminish the chance of human error in misdiagnosing fetal anomalies. This was amply highlighted in the NHSLA report.

V. A code of ethics should be made available and strictly followed.

VI. The ultra-sonographer, even if a qualified obstetrician, must remember that he is performing a service to a patient belonging to an obstetric consultant whose rights and duties should never be abrogated. Flagrant over-stepping of such ethical obligations should be disciplined, and if persistent, formally reported to the Malta Medical Council.

VII. Full disclosure to the patients must include what will be looked for and the chances of success and of a missed diagnosis. This must be followed by a signed consent.

VIII. Full and adequate documentation is imperative. Photographs of anomalies should be both suppled to the patient and stored electronically and/or in the file. Queries and statements of relevance by the patient, in response to disclosure or spontaneous, should be noted.

IX. The ultra-sonographer will occasionally come across difficult cases where he may not confidently establish a diagnosis in spite of local senior assistance. In the absence of a more experienced opinion locally, the case may either be referred for overseas assessment or else await the arrival of a feto-maternal medicine specialist who already visits Malta from the UK on a regular basis precisely for this reason.

X. The consideration of a call for the post of a consultant obstetrician sub-specialised in feto-maternal medicine with a special interest in antenatal ultra-sonography.

XI. The OBGYN/Radiology Departments, ideally in conjunction, should organise updating seminars and assessments on the subject.

XII. A counselling service specifically trained for assisting and guiding patients with a diagnosed fetal anomaly should be made immediately available. A telephone helpline number should also be made should be supplied.

XIII. All involved personnel must be reminded that that the Criminal Code in articles 241–244A safeguards human life from the moment of conception and an abortion, or advice, guidance or referral associated with such for *any* reason whatsoever will render the involved person liable to criminal prosecution.

CHAPTER 4

On proposing a general medico-legal framework of legislation with special reference to the care of the unborn and the specialty of obstetrics

4.1 Introduction

The present chapter offers a number of multi-faceted legislative proposals to address the repeatedly referred to local medico-legal framework. Although the body of laws, as proposed by this thesis makes frequent reference to the obstetric specialty in conformity with the subject of this thesis, the proposals are applicable across the board of all medical specialties with suitable adjustment. This body of proposed laws has been arbitrarily named the Lex Medica and comprises 16 articles (section 5.3) which cover many crucial aspects left unaddressed by the present statutory deficiency. The present chapter may be considered as preparatory to the Lex Medica and it evaluates many of the important aspects dealt with in the different articles of the proposed law, making frequent reference to local case law. Such aspects as the establishment of the SOC in cases of alleged medical negligence, disclosure, informed consent, selection of and guidelines to the Court appointed obstetric expert, are clearly part of the backbone of such medical law. As regards the subject of the Court expert, the bulk of evaluation was discussed in chapter two but here is the opportune occasion to bridge that chapter with the Lex Medica.

Among other aspects, the present chapter also draws attention to the similarity in stages of the medico-legal evolution between the present local statutory deficiency of specific

medical law and the pre-1957 UK position. Special relevance is given to the Bolam principle, its role in UK medical jurisprudence and as an instrument for establishing the medical SOC. The British system has much to offer to Malta, if and when the present local medico-legal system is officially recognised to be deficient in this area and serious reformation is embarked upon. Without the need of re-inventing the wheel, the local legislator can, with advantage borrow much from well-honed overseas jurisdictions, with the British one deserving pride of place. One must add that much is already borrowed in medical jurisprudence from British case law and legal principles always at the discretion of the individual members of the judiciary.

4.2 Repeated and specific jurisprudential reference to the present lack of medico-legal guidance

There are numerous cases where the local Court, in dealing with cases of alleged medical negligence, makes clear reference to the absent relevant Civil Code guidance to effect the necessary judgement. It is hardly surprising that the use of the local laws pertaining to general negligence, often need to be supported by reference to foreign medical jurisprudential principles. In the ophthalmological case *Joseph Micallef v. Dr. Ivan Vella MD et,*[412] the Court states that in the absence of any special existent legislation catering for the medical profession, legislation pertaining to general rights of responsibility (articles 1031 – 1033 of the Civil Code) must be employed:

[412] *Joseph Micallef v. Dr. Ivan Vella MD et,* Qorti Ċivili, Prim' Awla, Onor. Imħ. Dr Mark Chetcuti, Ċitazz. Nru. 1951/1997, deċ. 30/4/2013.

Il-Kodiċi Ċivili ma jipprovdi ebda norma speċjali fir-rigward tal-professjoni medika u għalhekk japplikaw in-normi generali tad-dritt ċivili fil-materja ta' responsabiltà (ara artikolu 1031 sa 1033 tal-Kap. 16).

The Civil Code provides no special direction for the medical profession and therefore what is applied are the general principles of civil rights regarding responsibility (see articles 1031 to 1033 of Chap.16).

Here we have a clear reference to the local lack of a particular standard of care by which Court can assess the responsibility expected of a medical practitioner accused of negligence.

In yet another ophthalmological case, also alleging negligence, namely *Carmen sive Charmaine Ebejer v. Dr. Ivan Vella et noe*,[413] the Court skips the frequently encountered introductory preamble concerning the local lack of specific jurisprudential guidance and law, and directly launches into what *foreign* jurisprudence has to say about medical diligence, which in practice would be the requisite SOC:

Dwar il-grad ta' diliġenza li professjonist bħat-tabib għandu juża, il-ġurisprudenza estera hija konkordi li mhux mistenni mit-tabib grad għoli ta' diliġenza, iżda dik normali li wieħed jistenna minn professjonist tal-affari tiegħu.

[413] *Carmen sive Charmaine Ebejer v. Dr. Ivan Vella et noe,* Qorti Ċivili, Prim' Awla, Onor. Imħ. Dr Mark Chetcuti, Ċitazz. Nru. 1957/1997, deċ. 30/4/2013.

Regarding the grade of diligence required of the professional as a doctor, foreign jurisprudence consistently agrees that a high degree of diligence is not required but that which is normally expected from a serious minded professional.

Again, in *L-Avukat Dottor Louis Cassar Pullicino noe et v. Id-Direttur tal-Psikjatra fl-Isptar Monte Carmeli et*,[414] the Court, had to adapt the local Civil Code as applied to general (and not medical) responsibility with the Court emphasising that *as has always been done.* It specifically explains this need as arising from the fact that, unlike in other jurisdictions, *Maltese* law does not, render a precise definition of the degree of *medical responsibility* expected from a doctor in his profession:

Peress li l-liġi tagħna ma tagħtix definizzjoni preċiża, bħal leġislazzjonijiet oħra, tal-grad ta' responsabbiltà li għandu jiġi eżerċitat minn tabib fil-professjoni tiegħu, il-Qrati tagħna dejjem imxew fuq ir-regoli ġenerali tal-Kodiċi Ċivili u adottawhom skond iċ-ċirkostanzi.

Since our law lacks a precise definition, unlike other laws, of the degree of responsibility due by a medical doctor in his profession, our Courts have always followed the general rules in the Civil Code and applied them accordingly.

In the obstetric case dealing with shoulder dystocia, *Albert Gambina noe et. v. The Golden Shepard Group Limited et,*[415] the Court seemed to assume a universal condicio

[414] *L-Avukat Dottor Louis Cassar Pullicino noe et v. Id-Direttur tal-Psikjatra fl-Isptar Monte Carmeli et,* Qorti Ċivili, Prim' Awla, Onor. Imħ. Dr Anna Felice, Ċitazz. Nru 12/1993, deċ. 25/10/2016.

[415] See note 145.

sine qua non about the paucity of local direction in such cases. Skipping the frequently met local Court archetypal explanation, it plunges business like into the deliberation of a famous 1989 Irish medico-legal case *Dunne v. National Maternity Hospital*[416]. This case had been a landmark case in Irish jurisprudence, somewhat equivalent to the milestone reached with the 1957 *Bolam v. Friern.* In fact, one discerns much influence from *Bolam,* in the *Dunne* deliberation, which dealt with alleged negligence in a case of cerebral palsy. The reference to *Dunne* in *Gambina* included the following:

Biex tabib, jew f'dan il-każ, anki l-isptar jinstab ħati ta' negliġenza u konsegwentement responsabbli għad-danni jridu jiġu sodisfatti żewġ rekwiżiti stabbiliti fil-każ Dunne v. National Maternity Hospital (1989) IR 91.

For a doctor, or in this case, even a hospital, to be found liable for negligence and subsequently responsible for the damage caused, two requisites established in the case Dunne v. National Maternity Hospital (1989) IR 9, must be fulfilled:

Principles thus laid down... can in this manner be summarized:

1. The true test for establishing negligence in diagnosis or treatment on the part of a medical practitioner is whether he has been proved to be guilty of such failure as no medical practitioner of equal specialist or general status and skill would be guilty of acting with ordinary care.

[416] *Dunne v. National Maternity Hospital* (1989) IR 91.

2. If the allegation of negligence against a medical practitioner is based on proof that he deviated from a general and approved practice, that will not establish negligence unless it is also proved that the course he did take was the one which no medical practitioner of like specialization and skill would have followed had he been taking the ordinary care required from a person of his qualification.[417]

The Maltese Court was using here, two of the well-known Dunne Principles, later established as pillars of Irish medico-legal jurisprudence. There is hardly any doubt that extending, however masterfully, the local laws of general negligence, namely Articles 1031, 1032 and 1033, would *have* hardly shed the necessary jurisprudential light in this case.

A final example comes from *Josephine Borg et v. Dr. Anthony Fiorini,*[418] a case alleging negligence in the management of a chronically sick geriatric patient. The Court clearly stated that, since Maltese law, unlike most foreign jurisdictions, lacked guidance as to the degree of the requisite medical SOC, it had to turn to Articles 1031 and 1032 of the Civil Code, whereby a person is held liable in the absence of responsibility in exerting the prudence, diligence and attention of the bonus paterfamilias. In this particular case, while admitting the lack of existent specific medico-legal direction, Court did not seek the assistance of borrowed legal principle of case law. In the Court's words:

[417] See note 416.

[418] *Josephine Borg, mart John kif minnu assistita ghal kull interess li jista' jkollu skond il-ligi, Norman Bugeja, Doreen, Anna u Antoinette xebbiet, ilkoll ahwa Bugeja, u kif ukoll missierhom Victor Bugeja zewg il-mejta Olympia Bugeja ghal kull interess li jista' jkollu fil-ligi v. Dottor Anthony Fiorini*, Qorti Ċivili,Prim' Awla, Onor. Imħ. Dr Justice Godwin Muscat Azzopardi, 18 July 1994, Kollezzjoni ta' Decizjonijiet tal-Qrati Superjuri ta' Malta, Vol. LXXVIII, 1994, Pt. III, pp. 103-116.

i) Ir-responsabbiltà tat-tabib hija l-istess responsabilità li l-qrati tagħna diversi drabi spjegawha fil-konfront tal-professjonista. Il-liġi tagħna ma tagħtix bħalma jagħtu leġislazzjonijiet oħrajn, definizzjoni preċiża tal-grad ta' responsabilità li għandu jiġi eżerċitat minn tabib qua tabib."

i) The doctor's responsibility is the same responsibility which our Courts often define in dealing with professionals. Our law does not offer, as do other Jurisprudences, a precise definition of the degree of responsibility, which is owed by a doctor, in his role as a doctor.

ii) Huma għalhekk applikabbli l-1074 u 1075 (illum artikoli 1031 u 1032) tal-Kodiċi Ċivili li jistabilixxu l-prinċipju li kull persuna għandha tirrispondi għall-ħsara li tiġri bi ħtija tagħha, u li jitqies fi ħtija kull min fl-egħmil tiegħu ma jużax il-prudenza, id-diliġenza u l-attenzjoni ta' 'bonus pater familias', iżda f'difett ta' disposizzjoni espressa fil-liġi, ħadd ma jirrispondi għall-ħsara li tiġri minħabba nuqqas ta' prudenza, diliġenza u attenzjoni fi grad akbar. (Victor Savona pro et noe v. Dr. Peter Asphar et, App. Civ., 2.4.1951).

Therefore, articles 1074 and 1075 (today articles 1031 and 1032) of the Civil Code are applicable and establish the principle that every person must answer for the harm he causes through his fault and all who do not exert the prudence, diligence and attention of the 'bonus paterfamilias' are considered at fault; no one can be held liable for damage caused by want of prudence, diligence or attention in a higher degree other

than the aforementioned unless this is expressly stated by law. (Victor Savona pro et noe v. Dr. Peter Asphar et, App. Civ., 2.4.1951).

The quoted Articles 1031 and 1032 from the law of torts and quasi-torts, merit a very close evaluation. However, before doing so, one cannot help commenting on the sheer difficulty enshrined in the persistent use of the holy lore of tradition that has been laid on the judiciary in evaluating alleged medical by the unpractical is extension of a body of laws designed for *general* negligence. Quite possibly it is the lack of volume of such medical cases which has so far not brought the situation to the fore. One also wonders if the consideration of such uncharted waters, could have inspired the Court in *Rose Gauci* to prefer an interpretation based on infraction of the law of contract rather than that of tort and quasi-tort, as is discussed further on.

4.2.1 Evaluating Article 1031 of the Civil Code

Article 1031of the Civil Code states that:

Every person shall be liable for the damage which occurs through his fault.

In considering general negligence, this article is easy to apply. A man in a car hits a pedestrian standing on the pavement or a woman cycling carelessly hits a woman pushing a pram, etc. In another hypothetical case, this same article must be made to apply say to a case where parents allege obstetric negligence in not performing a caesarean section with resultant serious brain damage to their son who now suffers from cerebral palsy.

There are however a multitude of serious differences between the medical case and the previous two. Even the very point of departure is different, for whereas the medical case commences with a relationship between the parties and has beneficence as a scope, the non-medical cases involve no relationship at all with the encounter between the parties being casual and void both of intended beneficence or maleficence (hopefully). The non-medical cases may require corroboration by a witness, whereas in the medical one the relationship has as evidence, for example, the medical notes with the name of the patient and the doctor. These are but basic minor differences, although in argument they may be made to flower into more significant ones. However, the biggest difference lies in the rationale of assessing the final damage, its causality link and its subsequent allotment of guilt and hence recompense.

Oceans separate these cases. This is already evidenced by the fact that whereas the non-medical cases often need no assistance of explanation to the Court, the cerebral palsy case is already placed in a different category by the need of a Court expert. The very nature of the jurisprudence is on distinctly separate categories. The juridical assessment of the cerebral palsy case will need extensive evaluation of the defendant's management by an experienced expert obstetrician who knows what *should* have been done and compares this to what was *actually* done. If he discovers a lowering of the expected SOC, he must see if such action was causally responsible for the final damage of the child resulting in cerebral palsy. Based on the information supplied by the expert, the Court must follow an established legal reasoning.

I. The establishment of a duty of the obstetrician to his patient.

II. The proof that this duty was breached.

III. The causal link that this breach led to the damage complained of to the Court (cerebral palsy).

IV. The quantification of this damage.

It may well be that at the end of the process the obstetrician is found liable of causation of the child's cerebral palsy. One may indeed state that *at this stage,* and in a general way, article 1031 now applies:

Every person shall be liable for the damage which occurs through his fault.

However, article 1031 does not even begin to guide the Court as how to effect any particular principles to conclude whether the obstetrician was indeed liable for the damage being claimed, or not. Neither does it shed the least light in distinguishing between the ordinary care owed by the car and the bicycle drivers (the care of the prudent man) and the care of medical responsibility, the complexity of which is such that it merits a special SOC to be defined in each and every individual case. Such a medical SOC needs to be established along medico-legal principles which are locally non-existent. Furthermore, the medical case involving claims of cerebral palsy damage entails numerous facets, each of which must be viewed professionally along its own specific parameters. Thus, Court assessment of an I-P CTG tracing in such a case, only constituting one small part of the whole management, requires expert guidance in establishing the SOC of such interpretation. As does for example obstetric analysis of

the progress or otherwise of labour, or as does for example the neuro-radiological interpretation of the new-born's MRI result at birth. The many different links in the chain are all indispensable for the Court, guided by the expert, to pass judgement as to whether the defendant did depart from the expected SOC and thus be responsible for the damage which befell the new-born and if so, as demanded by Article 1031 now pay for his damage. The show is almost over when Article 1031 enters the stage.

4.2.2 Evaluating Article 1032 of the Civil Law

Article 1032 states that:

(1) A person shall be deemed to be in fault if, in his own acts, he does not use the prudence, diligence, and attention of a bonus paterfamilias.

(2) No person shall, in the absence of an express provision of the law, be liable for any damage caused by want of prudence, diligence, or attention in a higher degree.

Article 1032(1) introduces us to the noble Roman standard of care of the bonus paterfamilias as regards prudence, diligence and attention in executing one's duty. Parker[419] equates this with the English principle of the prudent man. However, in discussing article 1031, it has already been seen that the medical standard to be evaluated in Court is far more complex and on a different plane than that of the prudent man. One must note the difference between the prudent man and the prudent doctor, for

[419] Parker W. The reasonable person: a gendered concept? Victoria University of Wellington Law Review. 1993; 23: 105 -112.

the principle of the bonus paterfamilias has no reference whatsoever to a medical situation but refers to the qualities of a wise and good father of a family. The qualities which Article 1032(1) were laid by the most respectable Roman Law and much brilliant oration can be made in Court by a gifted lawyer departing from the basic qualities of prudence, diligence, or attention. Through the spartan simplicity of three words, much can be built to sway the Court either way. However, are we to remain dangling hoping an illuminated legal orator discerns all the medical truth as it stands or should we let cold science makes its presence known along statutorily directed SOC?

The bonus paterfamilias describes qualities which are good and desirable and do not conflict with those qualities which the obstetrician or indeed any doctor must inherently possess in discharging his duty of care. The qualities of diligence, prudence and attention are condiciones sine quibus non, in the very *basic* behaviour of medical practice–indispensable ingredients of the medical persona. However, it should not be prudence, diligence and attention which should be the threshold of adjudication of alleged medical negligence. In fact, doing so is selling the patient short. These qualities should be the parting point of an inherent and basic medical philosophy in delivering medical care. This medical care should then conform to an SOC pertinent to the case to be judged and establishing this SOC requires medical law. The qualities of prudence, diligence and attention cannot be stretched into defining a medical SOC for they are part and parcel of the necessary disposition of the medical person who must perform his duties along a requisite SOC, which demands totally different criteria of assessment. A doctor who is prudent, diligent and attentive at performing a particular action may still perform his duty in sub-standard fashion for the three qualities may easily assume

a completely subjective quality. Simply put, using the qualities of the bonus paterfamilias as a yardstick for reaching the desired SOC is barking up the wrong tree.

Article 1032 (1), which builds on Article 1031, was clearly never meant for evaluation of alleged negligence in medical matters, and it baffles the mind how the venerable Maltese Court still squares the circle by quoting articles 1031 and 1032 in judging alleged medical negligence. Quoting the concept of the bonus paterfamilias and his archetypal qualities of prudence, diligence and attention, the Court seeks to ascertain that the obstetrician exhibited beneficence, absence of maleficence, great care and attention in his treatment. An obstetrician could have exhibited all these qualities in, for example, performing a forceps delivery *to the best of his ability* and still caused a disaster, because no matter how much good he wished his patient and how much he toiled as prudently as he could, his technique could have been wrong. It is the comparison of the obstetrician's performance of a forceps delivery to one performed secundum artem [420]which will yield the answer. This SOC is not implied in the qualities expected to be based on the bonus paterfamilias.

One can take the bonus paterfamilias analogy further. Let us apply the good father principle to the UK Court case, *Pearce v. United Bristol Health Care NHS Trust,*[421] where the claim concerned defective disclosure when the defendant failed to inform the patient of the 0.1 – 0.2 % risk of stillbirth at 2 weeks beyond term and unfortunately a stillbirth did actually supervene. What would the *bonus paterfamilias* have done, using

[420] Although criticised in situations where evidence-based practice should be used, in this context the expression holds correctly.

[421] *Pearce v. United Bristol Healthcare NHS Trust* [1999] P.I.Q.R. P53.

all his prudence, diligence and attention? Would he have worried his daughter by divulging and discussing the minimal risk if nature was left to take its course in letting labour commence when it will? Or, would he have informed her to consider artificially inducing labour with its own potential risks? Or would he, like a good father, carry the worries himself and being wiser and more knowledgeable decide the course of action himself? Quite possibly, the latter course would be chosen, and this would constitute the very course of action – medical paternalism – to be condemned on the basis of the modern principles of medical autonomy. In the landmark case *Montgomery v. Lanarkshire Health Board*[422], which officially replaced Bolam by the Prudent Patient Principle as regards disclosure, the UK Supreme High Court declared:

The social and legal developments which we have mentioned point away from a model of the relationship between the doctor and the patient based upon medical paternalism.

These social and legal developments had been accruing for a good five decades, set in motion by the 1972 case from the Columbia Court Circuit, *Canterbury v. Spence*[423] which ushered in the Prudent Patient Principle, initially ridiculed in the UK but subsequently championed in *Montgomery*. Even before *Montgomery* the Patient Prudent Principle had long as been making its *de facto* presence felt in the U.K. Courts.

European laws and directives in particular, Article 5 of the Convention for the Protection of Human Rights and Dignity of the Human Being, makes it clear in spirit if

[422] See note 103.

[423] *Canterbury v. Spence*, 464 F. 2d 772 (DC. Cir 1972).

not in words, that medical paternalism and patient autonomy are polar opposites. Neither is such paternalism consonant with the declared patients' rights as declared in the Maltese Patient's Charter[424] published in 2016.

The concept of the bonus paterfamilia*s* reveals good and admirable qualities, appreciated by the ancient Romans as well as modern man. However, whichever way the engendered qualities are looked at, they may become a hindrance to medico-legal justice if employed in setting the bar at a lower level and a different plane. It altogether distracts from the true and necessary discernment of weighing the problem on a different weighing scales where one pan is labelled SOC. The concept of the bonus paterfamilias, when used in medical cases, usurps the place of the medical SOC, and by its application in waters too deep for it, deviates from the requisite path.

In Article 1032(2) of the Civil Code, we have an intimation that the Court is admitting to the fact that there *could* exist damage of a *higher degree.* To return to the original analogy, the case of the car and the bicycle accidents were not on par with that of cerebral palsy which conforms to the requirements of a *higher degree* of damage and subsequently liability. The article states that:

No person shall, in the absence of an express provision of the law, be liable for any damage caused by want of prudence, diligence, or attention in a higher degree.

Here, the Civil Code makes it clear that although every person shall be liable for the damage which occurs through his fault, no one can be held liable for damage caused by

[424] Patient's Charter. Parliamentary Secretariat for Health. Malta. 2016.

want of prudence, diligence or attention *in a higher degree other than the aforementioned unless this is expressly stated by law*. Medical negligence would be one to appertain to such a higher degree of negligence. Yet, as pointed out by Alessandro Lia[425] there is *"no such thing as a law regulating the responsibility of medical practitioners and health institutions."* It simply does not exist. It is as if the local lawmaker, meant to institute such a law to regulate the *higher degrees* of negligence, but never actually did so.

This leaves the Maltese Court, unguided by law, as the final arbiter of what constitutes the SOC (obstetric or of any other medical specialty). The local judiciary must make do, and have indeed done so, using their venerable wisdom as directed by the concept of prudence, diligence and attention of the bonus paterfamilias. This, to some extent, places greater dependence of the Court on the obstetric expert, the choice and guidance of whom one would have thought would have subsequently received major local consideration at law. This, unfortunately, did not prove to be the case. To some extent, the Court's dependence on assistance in technical matters may be considered as an incursion into its independence and to some extent this is so. Interestingly enough, the introduction of the 1997 Bolitho 'reining in' of Bolam did restore back some of the Court's autonomy in the matter of accepting or rejecting Bolam on logical analysis. This rendered the Court and not the medical fraternity as the final arbiter of malpractice or its absence[426]. This is a good example of *medical jurisprudential evolution* which is only possible once medical jurisprudential principles are instituted and established at

[425] Lia A. The Nature and consequences of contractual relationships involving patients, medical practitioners and health institutions LL.D. Thesis. May 2009. Here quoting from *Rose Gauci et v. Mr Donald Felice et*, Court of Appeal, 31st October 2008.

[426] Mulheron R. Trumping ''Bolam'': a critical legal analysis of Bolitho ''gloss". Camb Law J. 2010 Nov; 69(3): 609–638.

law. Locally, we still have to reach that very early departure stage. However, an illuminated Court may rise over considerations of incursions into its own autonomy, and may consider that, while the present statutory medico-legal deficiency lasts, a well-schooled Court expert may tacitly assist the Court if he views the case along correctly established guidelines in formulating an SOC. This assistance stretches beyond the simple explaining of obstetric facts to the Court.

Article 1032(2), by its referral to *damage caused by want of prudence, diligence, or attention in a higher degree* is making it amply clear that there is a need, among others, for the establishment of a law to deal with those issues of a *higher degree* such as those emanating from medical cases. If the need to consider a *higher degree* of negligence was felt in the nineteenth century, for Maltese Civil Law has been enacted in stages since Ordinance number VII of 1868, how much stronger should the need be decried an odd century and a half later?

4.3 The legal instruments for establishing a standard of obstetric care

Little progress can be made until the Maltese legislator recognises that the principle of the bonus paterfamilias, however admirably extrapolated by the judiciary, is not only inept at guiding the jurisprudence of medical negligence, but also actually misguiding and sets a much lower standard of expected medical care owed by the doctor to the patient. Once this position is fully accepted, the next question would be to enquire as to what criteria ought to be used. And this, inevitably, leads to a consideration of the existent principles which may be used to establish a modern, reliable and functional SOC.

The SOC creates the yardstick by which the allegedly negligent obstetric or other medical management must be scrutinised. If this shows that the defendant's actions or omissions breached the required SOC, this *may* establish malpractice. However, such malpractice, which once uncovered may be the subject of say, a medical council disciplinary review is not necessarily the cause of the damage with which the plaintiff approached the Court in the first instance. An example of this comes from *De Martell v. Merton and Sutton Health Authority*,[427] where the Court stated:

.. the plaintiff…… succeeded on negligence but he has failed, I am afraid, on causation.[428]

An obstetric example would be the finding of I-P CTG mismanagement in a case of brain damage associated with say, Angelman syndrome.[429] If the breach of the SOC can be specifically linked to the presenting complaint, then liability *may* be legally established. For the Maltese legislator in search of the ideal SOC, it may be most instructive to review the evolution of the British SOC.

4.3.1 The UK evolution of standard of care: from *Donoghue* to *Bolam* to *Montgomery*

[427] *De Martell v. Merton and Sutton Health Authority.* [1992] 3 All ER 820.

[428] Such failure of linking what may be medical negligence to the presenting complaint of the plaintiff is a relatively common cause of failure to establish medical malpractice.

[429] A genetic disorder mostly affecting the nervous but also associated with certain physical features, intellectual impairment, developmental issues, language and balance problems as well as sleep pattern disturbances.

The UK medical SOC made its appearance in the 1950's, but it is essential to ante-date this and consider the non-medical duty of care which was established in the UK case *Donoghue v. Stevenson*, [430] The concept of the duty of care as established in tort law, is that legal obligation which imposes a reasonable standard in the exercising of duties which may foreseeably result in harm to others. In the previously quoted examples, the man with the car accident was obliged to drive carefully, as was the lady driving her bicycle. This was a principle emanating from Donoghue which shed much light in the jurisprudence of general negligence.

Twenty-five years after *Donoghue*, in the 1957 case *Bolam v. Friern*,[431] a landmark Court pronouncement now established judicial guidance of a *medical* nature:

a doctor is not negligent, if in his actions or omissions is acting along a practice accepted as proper by a responsible body of medical opinion even if other practitioners adopt a different practice.

However much criticised over the years, Bolam, must be seen as a great link between the *general* principles of tort and those more *specifically* centred around the needs of the medical world. Whether the ruling that the Friern team was not guilty of negligence, would have been concordant with the very *Donoghue* qualities of justifiable, fair and reasonable care[432] is, like many Court rulings, potentially debatable. For example, one

[430]*Donoghue v. Stevenson* [1932] UKHL 100.

[431] Discussed in some detail in section 4.3.

[432]Lee A. 'Bolam' to'Montgomery' is result of evolutionary change of medical practice towards 'patient-centred care'. Postgrad Med J 2017 Jan;93(1095):46–50.

might question the very logic of taking no precautions in preventing a fall when a patient is going to be jolted by electric shocks, simply because such a practice is similarly performed by other doctors. One might even be bold enough to state that one could draw the argument that the very case which generated Bolam's test could have failed a logicalness standard had Bolitho existed!

The crucial point was that the UK Court was now in possession of a specific measuring stick to establish an SOC in cases of medical negligence. And, rather than ask if prudence, diligence and attention were applied in the execution of the medical intervention performed, the judiciary was asking questions like did the method under review enjoy peer acceptance? By the late 1950's, the British judiciary had the necessary instruments to ascend from the mundaneness evaluated by *Donoghue* to a level which did not demolish the common-sense qualities demanded by *Donoghue* but rather to one demanding a *different* set of values.

Bolam has guided UK jurisprudence with regard to medical negligence since its conception in 1957. While suffering much attack, both justified and unjustified, it has shed light on what a reasonable obstetrician would do, in the light of the practice as carried out by a responsible body of medical opinion of specialists in the same line and facing the same circumstances. For Bolam made it clear that if no such concordant practice existed, then one *can s*peak of negligence – irrespective of the amount of diligence, prudence and attention poured into the intervention, as in the quoted example of the forceps delivery not performed secundum artem.

In spite of repeated and serious attacks, Bolam has not only survived, but actually thrived and flowered. It was established by the House of Lords as regards treatment in 1981,[433] and in 1985, both as regards diagnosis,[434] and, albeit with some caveats, as regards disclosure.[435] It was not until 1996 that it was 'reined' in by the Bolitho principle,[436] which did not displace it, but qualified it, such that the Court had the right to reject Bolam if the responsible body of medical opinion expressed an opinion which did not make logical sense to the Court.

One of the heavily criticised direct effects of Bolam, was the fact that the Court was essentially rendered completely dependent on medical opinion for the establishment of the SOC. This was and is true for Bolam demands that it is medical peers who must set the standard of care. However, with the guardianship of Bolitho, such a peer opinion can only establish standards which must make sense to the Court. In spite of whatever attacks are levelled at Bolam, and they are many, it is still the standard-bearer of the British medical SOC except for disclosure. It was Bolam which provided the creation of a special post-1957 umbrella for medical cases, as carved out of the general field of tort and quasi-tort. Since then British jurisprudence has never looked back.

That the gatepost keepers of the law, were, however slowly and quietly, still keeping a finger on the pulse of the jurisprudential needs and wants of society, became manifest in 2015 with the landmark case of *Montgomery v. Lanarkshire Health Board*[437] where

[433] *Whitehouse v. Jordan* [1981] 1 All ER 267.

[434] *Maynard v. West Midlands* Regional Health Authority [1985] 1 All ER 635.

[435] *Sidaway v. Board of Governors of the Bethlem Royal Hospital* [1985] AC 871.

[436] See note 154.

[437] See note 103.

Bolam now officially lost all the ascendancy it had gained in 1985, relating to matters dealing with disclosure. It is interesting to reflect that it was an obstetric case which narrowed Bolam's hegemony to diagnosis and treatment. *Montgomery* concerned an obstetrician, who felt she must "protect" her patient from choosing a caesarean section as a mode of delivery. Part of the claim entered by the plaintiff, herself a molecular geneticist, was that the obstetrician failed to disclose the high risks of shoulder dystocia associated with a vaginal delivery, which complication did occur. The result was that baby Montgomery developed severe cerebral palsy resulting from the delay of delivery from the birth passages. The obstetrician readily admitted that she did not suggest a caesarean section in spite of the risk factors. The first Court accepted the defendant's reasoning based on Bolam, as supported by other peers, that the obstetrician acted in the best interests of the patient and the defendant was cleared of medical negligence. However, the UK Supreme Court, at Appeal, reversed the lower Scottish Court ruling, holding that rather than the obstetrician deciding what should be told to the patient, the reasoning should be that all relevant information should be entirely disclosed to the patient, who then, once fully informed, decides what she wants done to her.

The case was an ideal one to give the final blow to medical paternalism as the information withheld by the obstetrician was of such over-riding importance. For, while Mrs Montgomery, was a woman of short stature, an insulin diabetic and was carrying a fetus known to be larger than expected. The whole situation was assessed at a risk of 9–10% of shoulder dystocia should vaginal delivery be embarked upon. This was never revealed to the patient, in spite of her repeated and expressed worries to the obstetrician about the feasibility of a vaginal birth. Unfortunately, the dreaded complication of shoulder dystocia did supervene with the child suffering massive brain damage from

the severe episode of prolonged intra-partum hypoxia, resulting in hypoxic ischaemic encephalopathy and severe cerebral palsy.

4.3.2 The evolution of the standard of care in the jurisprudence of disclosure

Prior to 2015, there had been a number of instances where Bolam had been rejected in cases relating to complaints about disclosure. The 1992 case *Rogers v. Whitaker*[438] was one such case from the Australian High Court. Although not given much particular importance in the UK, the effect in Australia rendered the ruling essentially equivalent to the UK's 2015 *Montgomery.* In *Rogers,* the Australian High Court rejected doctor-based Bolam reasoning substituting it with a patient-oriented perspective that a 1/14,000 risk of sympathetic ophthalmia neonatorum in a patient with one functioning eye may be rare but *was* sufficiently important to divulge pre-operatively. The Court rejected the argumentation of *what was expected from a reasonable doctor* in favour of what were *the expectations of a reasonable patient*. By this ruling, Australia, in its landmark 1992 case on disclosure, replaced Bolam by the Prudent Patient Principle.

In the 1999 case *Pearce v. United Bristol Health Care NHS Trust,*[439] one of the cases actually quoted by the Court to support its deliberation of *Montgom*ery, the UK Court reached a conclusion which would only find its full official vindication sixteen years later in the *Montgomery* ruling. The case concerned a still birth occurring in a woman who was still undelivered 2 weeks past her expected date of delivery. The Court argument revolved around whether or not a 0.1 – 0.2 % risk of stillbirth in such a

[438] *Rogers v. Whitaker* [1992] HCA 58.

[439] *Pearce v. United Bristol Healthcare NHS Trust* [1998] EWCA Civ 865, [1999] PIQR P53.

situation should have been disclosed to the patient. Defendant support from a respectable body of medical opinion maintained that the risk was not significant, and hence, applying Bolam, one would have expected the defendant to be cleared. However, possibly at a level of discussion higher than of the Australian case *Rogers,* the Appeals Courts in *Pearce* reaffirmed the principle that complications which seriously affect a patient's life, irrespective of rarity of incidence, must be disclosed so as to allow the patient to make up her own mind. This would be the crucial essence of the reasoning in *Montgomery* in 2015, by which time the concept of the prudent patient (as well that of informed consent) had evolved and matured since its *first* enunciation in the 1972 ruling of the Columbia case, *Canterbury v. Spence,* [440]a concept much ridiculed initially in the UK as another American invention to facilitate litigation.

Montgomery was the final culmination of a number of cases, which were directly referred to in the ruling, including the 2004 *Chester v. Afshar*,[441]which although it dealt with causation and not disclosure, contained very relevant observations in relation to the duty of a doctor in advising patients of risks involved in a proposed treatment. In addition to quoting other cases, the Court stretched its consideration to case law from the European Court of Human Rights, such as *Glass v. United Kingdom*[442] and *Tysiac v. Poland*,[443] as well as, in particular, Article 5 of the Convention for the Protection of Human Rights and Dignity of the Human Being with regard to the Application of

[440] See note 423.

[441] *Chester v. Afshar* [2004] UKHL 41; [2005] 1 A.C. 134; [2004] 3 W.L.R. 927; [2004] 4 All E.R. 587.

[442] *Glass v. United Kingdom* (2004) E.C.H.R. 61827/00.

[443] *Tysiac v. Poland,* [2007] ECtHR 219; (2007) 45 E.H.R.R. 947.

Biology and Medicine: Convention on Human Rights and Biomedicine,[444] concluded by the Member States of the Council of Europe and the European Community at Oviedo on 4 April 1997.

The Court in *Montgomery*, combined all, making a long and admirable review and exposition of the inadequacy of Bolam as applied to disclosure both based on UK case law and within the enclave of the European enclave of the protection of human rights. It was time for the law regarding disclosure to change from the evaluation of the SOC as considered by 1957 established peer medical practice to that which listens to and considers the wants and needs of the prudent patient. The circle had been completed. The 1972 ruling of the principle of what a reasonable person would want to know, emanating from *Canterbury.*[445] in the Court of Appeal in Columbia, USA, in 1972, had now also been fully endorsed in contrast to the 1970's British Court ridicule, Bolam had lost out to the increasingly powerful ethical principles defending the patient's medical autonomy.

4.3.3 Two principles for establishing the standard of care

The evolution of jurisprudence and its resultant emergence of the Prudent Patient Principle for guiding disclosure, as emanating from *Montgomery*, created a second principle guiding the general obstetric and medical SOC in the UK. Bolam still held firm regarding matters pertaining to diagnosis and treatment. Hence, regarding

[444] Convention for the Protection of Human Rights and Dignity of the Human Being with regard to the Application of Biology and Medicine: Convention on Human Rights and Biomedicine. Oviedo, 4.IV.1997.

[445] See note 423.

obstetrics and all other medical specialties, law and jurisprudence now had *two* tenets, guiding every day clinical life and illuminating Court decisions in cases of alleged medical negligence.

The clinical practice of obstetrics in Malta is, to a large extent, not aware of the existence of *Montgomery*, and much less of its clinical implications. Individual obstetricians and other doctors are aware, in a general, often non-specific way however, of the ever increasing clinical and legal relevance of disclosure in daily practice. However, specific awareness such as to what should constitute disclosure to effect a non-contrived consent is disturbingly low although no surveys or studies have been carried out yet. Such awareness in the present climate can hardly reach that of the UK, where the shadow of the legal Damoclean sword pervades NHS consciousness both individually and even more so institutionally. *Montgomery even* seems to have induced a sense of panic in certain quarters:

The claimant's damage award of £5.25 million as a result of the defendant's obstetrician's failure to provide full disclosure seems to have induced clinicians to over-watch their step, at times to a ridiculous extent. On the one hand, many clinicians' anxiety may result in a defensive/protective approach.[446]

The seemingly low level of medical consciousness of the gravity entailed by the demands of the modern principles of patient autonomy such as that of disclosure, also seems to somewhat pervade the Maltese Courts. Although medical cases of *any* genre

[446] See note 341.

are not exactly brimming over in the Maltese Courts, cases relating to diagnosis and treatment do make an uncommon appearance. However, disclosure-related cases are virtually non-existent. Nor are the Maltese public's expectations anywhere near particularly high in this context, for the general attitude tends to remain rather entrenched in tending to view medical paternalism as a reassuring and traditional quality.

The existence of two principles underlying the desired obstetric SOC for managing diagnosis and treatment on one hand and disclosure on the other hand, should generate neither new effort nor confusion for any obstetrician. While diagnosis and treatment are guided by the expectations of Bolam, where disclosure is concerned, the obstetrician must disclose all that is necessary to allow the patient to make her own choice on an informed basis. Badenoch nicely summarises the situation as the separate judgements required to practice professionally on one hand and of how one explains it to the patient on the other. [447] There will always be debate on the extent of what should be divulged. Mallia[448] for example argues that what a reasonable person would want to know varies from culture to culture.

Philosophically, one might even reason that with the introduction of the Prudent Patient Principle replacing Bolam as regards disclosure, UK medical jurisprudence has returned to the fold of the pre-1957 general law of tort and quasi-tort stripped of all Bolam medical parochialism and paternalism. Although facts are indeed so, one may

[447] Badenoch J. Montgomery and patient consent: perceived problems addressed. Journal of Patient Safety and Risk Management. 2016; 22(1–2): 12–15.

[448]Mallia P. Consent: Informed. Ten Have H. (Ed.) Encyclopedia of Global Bioethics: Springer-Verlag Berlin Heidelberg, 2014; 1:754-761.

not correctly extrapolate the argument to state that as regards disclosure, British jurisprudence might as well never have moved from its pre-1957 position which was not dissimilar to the current Maltese one. The situation may be compared to that where an aeroplane pilot returns to earth after an extensive air flight charting land topography. He does return to earth from where he started off, but now he is much enriched with knowledge otherwise never gained. Likewise, the returning to the British Courts to the original fold of general tort and quasi-tort, after sixty-two years of Bolam-guided jurisprudence, is certainly not a return to square one but to a remarkably higher evolved plane of jurisprudential consciousness. Figure 12 summarises these evolutionary steps.

Moreover, these changes are themselves a testament of the dynamicity of British legal discernment and evolution of principles which recognise the need of changing with the times. Modern ethics demand that patient's needs displace the past authoritarian approach of the medical cadre. The historical and legal circumambulation, from general tort laws to Bolam, back to general tort laws, still makes for a richer and quintessentially more humane jurisprudence than one which had never left the zone of general principles of negligence.

Not only is a Lex Medica *not* to be discouraged by this evolutionary cycle of events as outlined in figure 12, but these evolutionary steps are inescapable proof of the need of a Lex Medica which, once established, will allow similar dynamic evolution to likewise grace Maltese law and jurisprudence.

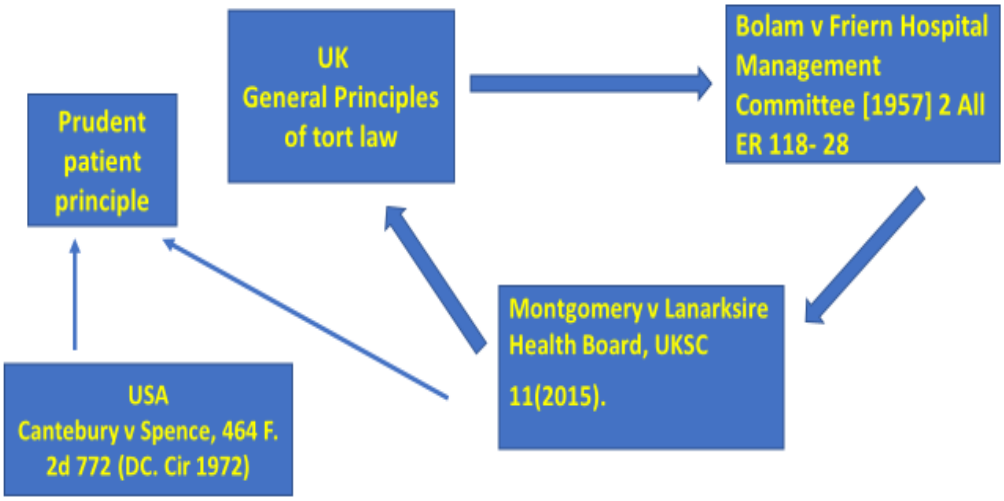

Figure 12 The evolution of UK jurisprudence of disclosure from the long-ignored USA Canterbury v. Spence (1972) ruling to the UK's Montgomery (2015)

4.3.4 A potential third principle for establishing the standard of care?

The existence of an evolutionary process determining the nature of the instruments used to establish the SOC is reassuring rather than worrying. In fact, if anything, the healthy evaluation of such positive changes may be encapsulated by a query as to the excessively long march taken by the British Courts, in displacing Bolam by Prudent Patient Principle, as regards disclosure.

The Prudent Patient Principle only saw the *official* light of day in the UK with *Montgomery*. One rhetorically asks here if the whether the UK Supreme Court could not have moved earlier than 2015. And this raises another important query: has the evolution of the jurisprudential standard reached its contemporary endpoint? This is also a rhetorical question which needs asking here and its answer is that while man's needs evolve so will the moral and legal tenets of society along with jurisprudential standards. An end point to jurisprudential standards can never be reached. Furthermore,

there may be discernible signs even now which do raise a remote possibility about further contemporary British SOC evolution, which may involve evidence-based medicine (EBM) as a remote but possible substitute to Bolam's law.

EBM has been slowly growing and gaining quiet momentum in the formulation of official guidelines emanating from official bodies such as the UK's National Institute for Health and Care Excellence, the Royal College of Obstetricians and Gynaecologists, etc. Any factor which has serious impact on established medical practice, especially when its voice speaks out with resonant truth and subsequent acceptance by official bodies, will potentially sooner or later make its mark on contemporary SOC. How extensive that mark may become is another issue. These facts are extremely important especially for a jurisdiction such as Malta's, in the search of the optimal tenets on which to build its guiding principles for establishing the SOC in cases involving medical jurisprudence.

The strength of EBM lies in the very philosophy of its apt name – it deals with any aspect of science, and medicine is one such, as proved, disproved or undecided in the light of hard scientific scrutiny. Neither tradition nor ipse dixit are sacred to EBM. All must pass through the grinding mill of scientific analysis. All practice must be submitted to the graded levels of a rigorous process which will state what level of evidence backs it or not, and on the strength of this, its subsequent recommendation. One may counter with the fact that obstetrics as part of medicine, is both an art and a science, and its practice cannot turn one into a robotic practice based on statistics. The truth is that EBM as applied to obstetrics takes away none of the art but improves the science, does not seek to undermine the benefit of experience but to enrich it and is,

without doubt, the only way forward for any science-based subject, which obstetrics most definitely is.

A true grasp of EBM principles renders the obstetrician far richer in the final care he offers his patients. He remains the final arbiter of what is best for his patients and his role as master of the art and science of obstetrics is far from threatened. EBM does not make a robot out of the traditional healer, but it does ensure the traditional healer's practice does not slide into witchcraft. The obstetrician, who knows his patient's needs may still, after disclosing all scientific facts, tender a specific opinion of a particular treatment which may not agree with the dictats of EBM. Thus, in a situation where EBM statistically favours a vaginal delivery, an experienced obstetrician may still offer a caesarean delivery, having discerned valid psychological needs. As long as he has weighed all risks and disclosed all to the patient, it is his opinion based on valid justification which he should advise for the obstetrician tenders to the needs of a woman and her unborn child and not those of a pregnant uterus. It is for the obstetrician how to apply EBM and not vice-versa, as long as the obstetrician knows the value of guidelines and goes against them for a valid reason. This is one reason why non-adherence to official guidelines should not automatically be considered as constituting negligence or malpractice as discussed in section 2.4.2.

EBM's silent evolution has been progressing pari passu, albeit independently, with the influence of patient autonomy on jurisprudence. Embracing a combination of the best currently available research, optimal clinical expertise and the patient's preferences and values, EBM now forms the basis of the official guidelines of the UK's NICE and RCOG. In Section 2.12.2, EBM was briefly alluded to as a potential contender for the

drawing up of the SOC. Furthermore, one may unequivocally state, that, albeit often not referred to by name, EBM is already behind most of the Court's accepted obstetric explanations, if these are based, as they are likely to be, on NICE and RCOG's guidelines. EBM is silently serving without glare and fanfare, in the form of guidelines which hit the limelight, while their scientific progenitor is neither heard nor mentioned. The 2015 shift of Bolam off disclosure and its replacement by the Prudent Patient Principle in *Montgomery* has possibly slightly raised the stakes in favour of EBM becoming a contender in the SOC race. For EBM has a multitude of advantages to offer. As an example, one may consider the disclosure concerning the mode of delivery in a breech presentation. RCOG EBM-based information reveals a perinatal mortality risk of approximately 0.5/1000 with caesarean section after 39+0 weeks of gestation; and approximately 2.0/1000 with planned vaginal breech birth.[449] The disclosure to the patient must explain the fourfold increased risk to the neonate. Failing to disclose such scientifically proven evidence, may lead to a situation analogous to *Montgomery*, although the risk of the discussed complication (shoulder dystocia) in that case was much higher.

However, seeing EBM as a sui generis principle underlying the SOC *instead* of Bolam, is a picture which appeals to much cold logic but little practicality in the light of day. EBM is not likely to displace Bolam in the form of an EBM-based SOC any time soon. Firstly, the British Court moves with slowness as well as caution, as illustrated by the adoption of the Patient Prudent Principle. However, this reticence is an admirable quality in view of the 1960's debacle involving CP jurisprudence and originating in the

[449] Management of Breech Presentation. Green-top Guideline No. 20b. March 2017.RCOG.

USA. Secondly, it is a major leap indeed to see EBM, which essentially has up until now only materialised in Court in clinically expressed guidelines, suddenly turn into an entity on which the SOC will be solely based. Especially when the outward manifestations of EBM in Court as guidelines, are themselves not even legally enforceable, in spite of the 88% clinical acceptance of specialty guidelines.[450] Thirdly, there has been no evidence of EBM per se influencing jurisprudence, except in the form of guidelines and under the umbrella of Bolam, where the scientific opinion declared, may or rather should be evidence based. All evidence seems to point to EBM likely to be kept in its present position as supporting actor but never the star. Its scientific dictates will become increasingly meaningful in Court but stark science is highly unlikely to take the main podium in Court.

In the wake of *Montgomery*, legal luminaries like Badenoch have predicted the close demise of what remains of Bolam. Badenoch states that *the writing is on the wall.* [451] This may well be true. However, with EBM as an unlikely contender in the foreseeable future, one wonders what principle would replace Bolam in diagnosis and treatment were Bolam to be side-lined. It is quite understandable for exponents of the law to long for the fall of Bolam with its SOC set by doctors for doctors. On the other hand, one must have a solid replacement waiting in the wings. While disclosure is likely to be more safely safeguarded by the Prudent Patient Principle then by Bolam, the latter may still yet have long years of survival. This thesis would consider EBM as a reasonable

[450] Grilli R, Magrini N, Penna A, Mura G, Liberti A. Practice guidelines developed by specialty societies: the need for a critical appraisal. Lancet 2000 Jan 8; 355(9198):103-106.

[451] Badenoch J. A doctor's duty of disclosure and the decline of 'The Bolam Test': a dramatic change in the law on patient consent. Med Leg J.2016; 84(1):5–17.

contender, and even a superior substitute, but in view of all the signs of the times, does not subscribe to the notion that the writing is yet on the wall for Bolam.

4.3.5 Proposing the dual principles for the local establishment of the standard of obstetric care

In a medico-legal conference, held in Malta on 10 October 2004, the General Secretary of the Medical Association of Malta called for the adoption of the Bolam rule.[452] This official calling on the legislator for a formal guide by which the SOC is to be evaluated in Court, was a *cri de coeur,* long harboured by many medical practitioners and discerning lawyers. This was and is but one of the many burning issues, needing over-due attention and comprising but one major part in an extremely complex medico-legal jig-saw puzzle. In searching for the ideal instruments to establish the SOC, the Maltese legislator may view with benefit the British system, with long common historical, jurisprudential, legislative and medical roots. Furthermore, present jurisprudential references to British legal principles as well as specific case law, render the justification even more significant.[453] The Accusatorial Court system is also operative in both the UK and Malta, in contrast to the Italian Inquisitorial system. Furthermore, the Italian language is also somewhat losing its magical attraction to the great majority of the younger (and relatively less generally cultured) lawyers.

The Lex Medica proposes the introduction of the current dual principled British system comprising the Bolam principle for cases involving diagnosis and treatment and the

[452] MAM organises seminar on Medicolegal issues - 3/10/2004. The Medical Association of Malta.

[453] Italian principles are also often referred to but caselaw referred to, is normally British.

Prudent Patient system for matters concerning disclosure. If this proposal is adopted, Maltese jurisprudence need no longer depend on Articles 1031 and 1032 as evaluated in sections 4.2.1. and 4.2.2. respectively. One may criticize the choice of Bolam for diagnosis and treatment when it has been discarded by the UK in 2015 as regards disclosure. However, in truth, Bolam was *displaced* by the Prudent Patient Principle, waiting in the wings since its birth in *Canterbury* in 1972, along the acute needs of a greatly increased patient autonomy. One could be cavalier and propose EBM on a clean sheet of a new jurisprudence. In spite of an ardent desire to concur with such a proposal, this thesis considers this as a fatal mistake. The introduction of medical law for the first time will not be devoid of teething problems. And it is here, where the British experience will be of assistance. While the introduction of EBM would throw the Maltese judiciary in the deep end of the pool, with other jurisdictions waiting agog for the outcome of such a brave step, adopting Bolam brings with it six decades of solid British experience available for referral and guidance. With the choice of Bolam, also come six decades of supporting case law, countless publications, theses, analyses and a host of learned discussions and deliberations from the humblest Court to the UK Supreme Court and the House of Lords.

With Bolam must come the equivalent ‘reining in’ of the Bolitho principle. The Lex Medica not only does not omit the basic spirit of Bolitho but proposes it, unnamed and in a modified form, so as to include EBM as a named principle. Thus, whereas Bolitho essentially qualifies Bolam as being accepted only as long the opinion of the responsible supporting peer view makes logical sense, the Maltese version seeks a different weighting. Without referring directly to Bolitho, the Lex Medica in Article XIV qualifies the acceptance of Bolam’s law by two caveats, the first of which is of present

interest. The first caveat limits the acceptance of the Bolam peer opinion, as needing to make logical sense and in scientific matters, *to be based on evidence-based medicine*. No such caveat binds Bolam in the UK. The Maltese version, through a modified Bolitho derivative, brings Bolam indirectly aligned to EBM. This also serves to introduce EBM in the first Maltese medical law of its kind and give it a sporting chance for a possibly bigger destiny in future amendments.

4.3.6 Comparing Maltese with British attitudes regarding disclosure

No modern body of medical law worthy of its name can afford not to vigorously protect the autonomy of the pregnant patient in the twenty-first century. The Lex Medica deals with disclosure in article IX. However, as repeatedly stated in many sections of this thesis, the relevance of disclosure is often locally under-stated both medically and legally. It is interesting to note that when in cases of alleged medical negligence disclosure does somehow raise its head in Court, it is often of low profile and secondary to a main claim, as discussed further on in this section in reference to case of *Frankie u Sonja Zerafa*.[454]

In medico-legal matters, disclosure presents a number of facets each of which may carry much legal weighting. This is somewhat reminiscent of the ubiquitous presence of I-P CTG, the mismanagement of which may raise grounds of liability per se or else as part of a claim say that of claiming damages in a case uterine rupture. So, it is with disclosure. Absent or defective disclosure may appear as a claim in front of the Court, where damage is claimed as resulting from such lack of disclosure or else the disclosure

[454] See note 151.

issue may be a secondary aspect from a claim say related to an invalid consent, where adequate disclosure is indispensable. The latter situation is discussed in section 4.5.1.1 dealing with the indispensability of disclosure as part of valid consent. Disclosure issues may also appear as one part of a bigger claim e.g., a claim for damages resulting from defective surgical technique *and* absent/defective disclosure

Clinically, the local scene reveals a certain lackadaisical attitude to disclosure especially as compared to British standards. In spite of an obsessive and rigid mentality to secure written consent where this is required, there is an element of maintaining the legal potential threat of defective disclosure on a mental back-burner. This is understandable in a country where no such precedent litigation case exists whereas taking one example from VBAC patient disclosure, the NHSLA report reveals that 24% of UK case litigation was based on defective disclosure of information. While in Malta, such claims are possible but essentially unknown, UK claims are increasing and one must keep in mind that statistics often leave out claims which fail such as *Duce v. Worcestershire Acute Hospitals NHS Trust.*[455]

The present local medico-legal disclosure climate may be *very widely* compared to the UK's between 1985 and 2015, where the doctor's opinion tended to rule the day. In 1985, UK disclosure related jurisprudence was formally accepted as guided by Bolam in the case *Sidaway v. Board of Governors of the Bethlem Royal Hospital.* [456] The case concerned the claim of a patient who claimed serious neurological damage resulting from defective disclosure by not being informed about the 1% risk of paralysis

[455] *Duce v. Worcestershire Acute Hospitals NHS Trust* [2018] EWCA Civ 1307.

[456] See note 435.

following disc surgery, which complication left the patient paraplegic. Quoting Bolam, the Court rejected the claim in and confirmed that it is the doctor, along similar peer practice, who has the right to evaluate what potential complications ought to be divulged or not. The ruling led to the House of Lords giving its blessing to the application of Bolam to jurisprudence dealing with disclosure related medical negligence. Only in 2015, would *Montgomery* elicit a revocation of this by the same House of Lords, and Bolam would be ousted by the Prudent Patient Principle. Before then in daily practice and in the absence of present-day patient autonomy, this often led to doctors divulging to patients whatever information doctors considered suitable. The Maltese situation is not quite at that level, but neither can one say that disclosure is afforded the importance it merits. Although Bolam does not and never held any official local sway, the attitude that the doctor will do and choose what's best for the patient is probably commoner than thought. This is likely to remain an inevitable consequence as long as legal challenge remains essentially non-existent.

The same low-key attitude to medical disclosure can be discerned in the local legal world. One example comes from *Frankie u Sonja Zerafa*[457], concerning failed sterilisation during caesarean section. The Court, in what seems to be a most surprising statement, seems to downplay the importance of disclosure in the circumstances.

ma hux daqshekk ammess li t-tabib għandu obbligu jagħti wkoll din it-tip ta' informazzjoni.

it is not all that recognised that the doctor is obliged to give this kind of information.

[457] See note 151.

This statement, discussed further in section 4.4**,** seems to enigmatically dismiss the relevance of disclosure to a woman undergoing surgical sterilisation during caesarean section.

4.4 Disclosure: evaluating its local *de jure* and de facto weighting

Act No. XI of 2013, also known as the Health Act, which replaced the Department of Health (Constitution) Ordinance Chapter 94 of the Laws of Malta, in Part VIII, refers to the information the patient should receive about the state of his health, any offered treatment as well as on treatment options available, apart from being involved in discussions and decisions about the treatment to be given. The topic of disclosure is accorded much more space and emphasis in the Maltese Patient's Charter[458] published in 2016 and which stresses the right to information about one's condition, asking questions, pain control, etc. Although the Charter is not legally binding, it is a step in the right direction although familiarity of its contents by MDH doctors has never been assessed.

In spite of the fact that therefore, there does exist a reasonably solid general theoretical basis of the appreciation of disclosure, there also seems to be a difference between the *de jure* and the *de facto* situation. This applies both to the clinical obstetrical (medical) side as well as to the legal and jurisprudential. The former has been examined under specific clinical topics in chapter three, such as caesarean section (Section 3.3.2.1.5.1), the VBAC patient (Section 3.3.2.1.6.1.1.4), instrumental deliveries (section

[458] See note 424.

3.3.2.1.6.1.3.1.1), etc. The present section discusses the disclosure situation from the point of legal and jurisprudential evaluation.

Possibly, one reason why disclosure deficiencies are less represented in Court than other medical claims such as those relating to diagnosis and treatment, may be due to the less demonstrably obvious and frequent outcome of such claims. The patient and his lawyer may wrongly equate a claim based on disclosure deficiency with one claiming moral and psychological damage. Although the two groups are oceans apart, one must stress the fact that the Maltese Court completely dismisses emotional pain and suffering, unless they lead to actual psychological harm. This is exemplified by the gynaecological case of *Rossi v. Dr. Joseph sive Josie Muscat pro et noe et*[459] involving complications following the operation known as LLETZ.[460] In this case, the patient's *preokkupazzjoni u ansjeta (worry and anxiety)* induced in the aftermath of alleged post-operative complications including alleged cervical damage resulting from the surgery, was interpreted as purely psychological damage, which the Maltese Court does not recognise as grounds for compensation.

The case of *Frankie u Sonja Zerafa*[461] also serves as an example of what seems a certain lack of faith in the legal mind of the clout of a claim of disclosure in front of the Maltese Courts. For part of the plaintiff's claim stated that stated that the sterilisation was performed negligently*, or if it were performed correctly, they (the plaintiffs) had not been informed that it could still fail.* Firstly, one notes here, an element of weakness in

[459] *Sue Rossi v. It-Tabib Dr. Joseph sive Josie Muscat pro et noe et,* Qorti Ċivili, Prim' Awla, Onor. Imħ. Dr Lino Farrugia Sacco, Ċitazz. Nru. 1492/1994, deċ. 25/6/2008.

[460] Large loop excision of the cervical transformation zone.

[461] See note 151.

the very claim regarding the gravity of disclosure. The reference to lack of disclosure gives the impression of being added as an afterthought and its placing at the end of the sentence reflects a psychological under-valuing of the weighting of disclosure. The placing of the disclosure claim after the conjunction 'or,' automatically weakens its claim by mentioning it almost as if in case the previous part of the claim fails. This is important to note, as it reflects the *general* lack of appreciation of the seriousness of disclosure to obtain consent as demanded by the modern notions of patient autonomy. Had the crucial and over-riding importance of disclosure along modern principles of patient autonomy been kept in mind, deficient or absent disclosure would have been used as a primary complaint in the Court claim, *in addition,* to that of alleged technical or operative negligence. The claim itself downplayed the disclosure, which the Court then correspondingly threw out. The Court stated that there *are* certain operations, such as aesthetic ones, where full disclosure is necessary, implying that the present case of failed sterilisation, was not such a case. The Court further stated that in the case at hand, due to the rarity (presumably of sterilisation failure), it was not *that recognised* for the doctor to be obliged to deliver such information.

ma hux daqshekk ammess li t-tabib għandu obbligu jagħti wkoll din it-tip ta' informazzjoni.

It is not all that recognised that the doctor has a duty to disclose such information.

Such reasoning would hardly find any sympathetic resonance in the UK Courts, where proof of deficient disclosure per se has led to massive compensatory pay-outs. In the landmark case, *Montgomery*, it was a case of defective disclosure which served to oust

Bolam and introduce the Prudent Patient Principle. Furthermore, sterilisation, is one operation, which, in NICE and RCOG guidelines is marked for specific and meticulous disclosure. In fact, most local NHS authorities require *printed* disclosure to be supplied to the patient, in addition to a complete discussion, which must include emphasis on three major points, namely:

- The irreversible nature of sterilisation.

- The existence of a variable rate of failure of the operation.

- The non-mutual exclusivity of these two factors.

Furthermore,

A number of studies have reported that the incidence of regret and dissatisfaction is increased when sterilisation has been performed concomitantly with caesarean section. Tubal occlusion should ideally be performed at an appropriate interval after pregnancy wherever possible. Should tubal occlusion be requested postpartum, women should be made aware of the increased rate of regret and the possible increased failure rate.[462]

In fact, the RCOG specifically singles out sterilisation during caesarean section, as was the case here, for special disclosure and discussion before a consent is obtained.[463]

[462] Female Sterilisation Consent Advice. RCOG, 2016 Feb 3.

[463] See note 462.

However, one must not convey the wrong impression that disclosure issues are entirely absent in the Maltese Court, however rare they may be. In the dental surgery case *Vanessa Sammut v. Dr. Charles Fenech*[464], reference is made to the practical importance of disclosure prior to consent. Quoting from *Smith v. Auckland Hospital Board,* [465] the Court made reference to some, albeit not all, of the basic requirements of disclosure:

the gravity of the condition to be treated, the importance of the benefits to be expected to flow from the treatment or procedure … the relative significance of its inherent risks, the intellectual and emotional capacity of the patient to accept the information without such distortion as to prevent any rational decision at all, and the extent to which the patient may seem to have placed himself in his doctor's hands with the invitation that the latter accept on his behalf the responsibility for intricate or technical decisions.

In this case, the local Court ruled that the dentist was obliged to clearly explain the advantages of a surgical procedure carried out on a previous one. In such a case the doctor should

Ifiehem u juri b'mod ċar il-vantaġġi ta' proċedura fuq oħra speċjalment il-vantaġġi ta' waħda fuq l-oħrai

Explain and clearly show the advantages of one procedure over another especially as regards the benefits of one on another.

[464]*Vanessa Sammut v. Dr. Charles Fenech,* Qorti tal-Appell, Onor. Imħ. Dr Vincent De Gaetano, Onor. Imħ. Dr Alberto J. Magri, Onor. Imħ. Dr Tonio Mallia, Ċitazz. Nru. 289/1998, deċ. 1/12/2006.

[465] *Smith v. Auckland Hospital Board.*[1964] NZLR 241.

Although, this is definitely a healthy step towards recognition of the cardinal importance of disclosure, such a case would ideally also have recommended the other requisites of a complete disclosure, namely,

- A clear reason as to the need of the intervention and its benefits and possible complications.

- A brief description of the intervention in layman's terms and its likely duration.

- The chances of success of the proposed intervention.

- The likely outcome if the intervention is not performed.

- Possible alternatives with their advantages and risks.

Finally, the Court would ideally have concluded with a reminder that the signed consent is but the final manifestation of a freely made and informed decision of a patient who has been made fully cognizant as to what is being undertaken. Stressing this point is of utmost importance locally, where, as stated ad nauseam, the signed consent is often the beginning and end of the great chapter in the book of autonomy entitled "Informed Consent." There is no doubt that the present local attitude is partly the result of a lack of disclosure-based Court challenge. The 'burnt finger phenomenon' would soon shake the system into a swift realisation of how easily one may end up facing Court. While

such litigation is far from desired, the local obstetricians need to reflect well and run a much tighter ship where disclosure is concerned and while there is still time.

4.4.1 Disclosure of error

The ubiquitous disclosure also makes its appearance in yet another aspect of care, which is often either forgotten or ignored. Reference here is made to the occurrence of an error, in any area of obstetric management. In accordance with modern views of autonomy, the obstetrician must disclose any and all errors performed in the execution of a patient's management, irrespective of the outcome. Such a statement should include an admission of error, its description and significance, the circumstances leading up to it and whether reparative process were necessary, were performed or will need to be performed.

The rather common attitude of failing to disclose errors especially when no obvious lasting harm resulted, or where the damage was rectified at the time, is a potentially dangerous one. Firstly, any potential future complication arising as a consequence, is likely to uncover the truth. Secondly, any future review of the clinical notes such as the operation sheet may also lead to an innocent "spilling of the beans" by any future obstetrician. Unless, of course, the unethical non-disclosure of events, has been further compounded by omission of recording in the clinical notes. In obstetrics, as in life, honesty tends to be the best policy. There is also a clear ethical and legal obligation of full disclosure, breaches of which may complicate possible litigation.

A rather unpleasant situation may involve the awareness of management errors by a colleague who refuses to disclose the truth to the patient. Unfortunately, knowing of such facts, places a responsibility on the second obstetrician, who should, first prudently and privately draw the colleague's attention. If the word of advice is ignored, an obligation does exist on the second obstetrician of alerting a higher authority in the hospital.

Although not in a category of errors, the opportunity is ideal here to mention the fact that all happenings regarding the patient who is under anaesthesia, including blood transfusions, must be divulged to the patient when fully conscious. It is by no means rare to meet situations where such occurrences remain unknown to the patient, who may be extremely surprised and upset that in a first caesarean section, for example, she had never been informed about the administration of a blood transfusion. It is quite possible that such occurrences are either forgotten by the obstetrician or he divulges them too early post-anaesthesia with resultant complete amnesia. A good habit is to go through the operation notes with the patient, ideally, the day following surgery, so that the patient may also be assessed post-operatively. Fully conscious, she may clear away any doubts and queries and in so doing, also strengthen the doctor-patient bond, in itself a precious ingredient in the formula for mitigating or eliminating future litigation.

4.4.2 Disclosure leading to the obstetrician's withdrawal of his care

There is the remote possibility that the *discussion* which must be part of true disclosure may generate a clinically challenging outcome. Although most patients tend to choose managements along lines which one may consider as logical and safe, this may not

always so. Thus, a patient may still opt for an assisted vaginal delivery after being informed that an abdominal delivery is safer. The hypothetical obstetrician, happy with his dexterity at performing caesarean sections, but totally inexperienced in assisted breech deliveries, would have hoped and expected that the RCOG based disclosed information of the perinatal mortality risk of approximately 0.5/1000 with caesarean section and approximately 2.0/1000 with a vaginal breech was going to effect the obvious choice of abdominal delivery. This may place the obstetrician in a quandary in that he is asked to embark on a management which is not in the patient's best interest. He has not only a right but a duty to direct the patient to an obstetrician who can offer a safer delivery within the right of the patient's choice. In *Mr Leslie Burke v. GMC,* [466] the principle was well established that when the treatment chosen by a patient is not considered in her best interest, the doctor should be under no legal or ethical obligation to agree, although, admittedly, the case was different to the obstetrician's with a limited repertoire. Incidentally, the hypothetical obstetrician owes an honest explanation to the patient as to why he must direct her to another obstetrician.

Maltese law makes no official provision for an obstetrician to withdraw his care for a valid reason. This should be included in a Lex Medica, as long as the law also includes the *proviso quod* that he facilitates the care to another obstetrician and that the patient is in a position to accept such a transfer and has no objections to it. Not only does the present law not cater for this situation but in *Rose Gauci,* a comment was made by the Court, which gives rise to some degree of anxiety. For the Court, clearly stated that:

tabib impjegat mal-Gvern ma jistax jirrifjuta li jaqdi pazjent.

[466] *Mr Leslie Burke v. GMC* [2005] EWCA Civ 1003.

A Government-employed doctor cannot refuse to serve a patient.

Admittedly, the Court did not speak of the situation where the patient requests a management which may not be in the patient's interests, particularly in a particular doctor's hands. Article IV the Lex Medica, without distinguishing between private and public service, clearly states that the obstetrician is under no legal or ethical obligation to effect any treatment he genuinely considers not to be in the best interest of his patient or against his better judgement or his moral or religious convictions

4.5 The Informed Consent

The evaluation of disclosure inevitably leads to that of the informed consent, where disclosure, along with the capacity to understand and free will in choosing, is one of the three requisites to render validity to any medical consent. By informed consent, one here refers to the free expression of acceptance or refusal of a proposed obstetric intervention or other form of treatment, after being fully informed of the implications of such a management and of the surrounding circumstances. It must never be contrived so as to simply guard the doctor but genuinely to inform the patient.

Maltese Law is rather frugal with informed consent. In the Public Health Act, Chapter 465 of the Laws of Malta, Article 2, *consent* is defined as *approval given by an individual without any force, fraud or threat.* And the Civil Code, in Article 974, provides that, where

consent has been given by error, or extorted by violence, or procured by fraud, it shall not be valid.

The modern view of consent is that it must be an informed consent for it is the patient, who informed well of what is being offered, its implications and possible avoidance, must effect her own choice. Once educated as to what is involved, as long as the patient has the mental capacity to understand the information disclosed and the implications of her actions, and acting freely along her will, the patient can give her informed consent. She must then externalise this accepted informed consent by an oral or written acceptance. The simplest of managements may not even require an oral consent as the patient's volition may be clearly implied, e.g., a patient presenting for an antenatal visit or a patient rolling up her sleeve to have her blood taken. Dubious situations should be cleared. Thus, a patient attending for ultra-sound, may not be conscious that a vaginal approach will be used. In such dubious situations, one should assume that the patient, who after all is a lay person, does *not* know what is involved and the procedure should be explained *before it is commenced.* In such situations, the patient must be clearly and expressly asked as to whether the proposed examination, as explained, is acceptable or not, without challenge or patronisation. Ignoring such simple rules, may result in medico-legal tenuous situations, arising even out of the simplest of procedures.

A written consent should be obtained in any case where the management involves any degree of complexity or potential complexity. Infertility cases, a genre of care well known for its legal propensity, certainly qualify for written consent. Also, cases where there is an increased degree of risk. For example, although an episiotomy repair is a simple procedure with little risk, any repair of damage exceeding second-degree should

require a written consent. All cases requiring anaesthesia or regional analgesia such as an epidural or a spinal must be covered by a written consent. Written consent should also be obtained in all cases where the proposed treatment may have potential consequences on the patient's employment, personal and social life. Those cases where the medical involvement does not have a primary therapeutic aim, as for example, insurance purposes must all be covered by written consent as does any treatment or medical management within a research programme.

4.5.1 Examining the qualities of the requisites of a valid consent

The requisites of a valid consent will now be examined in some detail. At this stage one may emphasise a number of points. The obtaining of a signed consent form without due disclosure renders it legally invalid as has been stated. However, there are other common habits which may also invalidate such a consent such as obtaining consent from a sedated and pre-anaesthetised patient just before surgery. There are cases where consent has been obtained with the patient on the operating table. Even if not sedated, the element of fear induced by the immediate surroundings and the impending surgery will tend to limit both the understanding and the memory of what is being disclosed.[467]Not only should disclosure and consent be planned at a convenient time, but since elective obstetric surgery such as elective caesarean sections are often planned weeks and even months ahead, disclosure should ideally be held early and the patient allowed days or weeks to ruminate and ask whatever she would like in subsequent visits.

[467] See note 121.

Another aspect which needs legal examining and defining is the concept of the "umbrella consent," where, for example, the patient signs a consent of admission to the labour ward. This is often taken as a consent for proceeding with doing what may be necessary, although caesarean sections *are* then consented for separately. It is far from unusual to hear the reply that the patient signed the general consent, when one queries, even in terms of hypothetical arguments, the need for consent of subsequent individual procedures. One may challenge the significance of this "umbrella consent" by querying the need for consent in cases of emergency caesarean sections. As matters stand, if it is decided that intra-partum CTG monitoring should be specifically consented for, then almost certainly, as in the case of caesarean sections, patients will still be asked to sign a separate informed consent. Hence, one must specify what is being covered exactly by the general consent and have this information specified and explained to the labour ward personnel.

4.5.1.1 Disclosure as requisite of valid consent

Here, we return to disclosure, this time as a crucial requisite of valid informed consent. Many examples come to mind where the legal office of the MDH may pre-emptively turn its attention with advantage as regards the disclosure aspect of obtaining such informed consent. The patient with a history of a previous caesarean section about to be induced with Syntocinon is one example. In fact, even the ordinary patient about to be exposed to the mundane practice of having an amniotomy and a Syntocinon infusion needs to be considered. How often are these patients warned of the potential risks they are about to undergo? The VBAC patient naturally runs a totally different set of risks,

and by the modern tenets of patient autonomy, these need to be specified to the patient and if she consents, she must do so in writing.

One must specify here that disclosing risks is not synonymous with inducing fear and worry. Withholding risks to protect the patient psychologically, however well meant, smacks of medical paternalism at its rawest. In any resulting Court litigation, such an obstetrician will cut a rather pathetic figure if he quotes such arguments in his defence. Letting patients live in a fool's paradise is not particularly respectful of any patient.

Here, one must also apply oneself to the legal consequences involving disclosure resulting from the local phenomenon of private ante-natal care with delivery taking place at MDH. Such cases must be evaluated carefully, and a policy of management arrived at. A complicating medico-legal factor may be the fact that the obstetrician carrying out the private antenatal care may be part of an MDH obstetric firm, but not its consultant. A common enough situation, for example, involves the junior obstetrician in his private practice offering some kind of unsupervised pre-caesarean disclosure to a VBAC patient. The private junior doctor effects a disclosure the legal responsibility for which lies with the consultant once the patient steps into MDH. This is a hypothetical but by no means a rare situation.

The situation involving private care and subsequent MDH surgery is another common scenario. Even situations involving consultants may incur problems as was the case of *Rose Gauci* [468] which concerned a Court claim alleging surgical negligence resulting in a serious surgical complication. The patient who underwent surgery at the Government

[468] See note 34.

public hospital had been referred for surgery by a consultant gynaecologist who had been treating her privately before reaching the point where a surgical form of treatment was unavoidable. Having been booked in MDH by the consultant who had cared for her privately up until then, Rose Gauci expected the consultant to perform the surgery himself and never even asked. In fact, the patient was operated on by the consultant's assistant. This lack of disclosure in itself, could have been a basis for serious litigation as patients have a fundamental right to know, to whom they are entrusting their bodies to, especially at such a vulnerable time as major gynaecological surgery under general anaesthesia. However, although it was not raised as an issue, as the claim concerned the loss of a kidney as a result of an allegedly negligent hysterectomy, still, the lack of disclosure was so overt that it led to the wrong gynaecologist being sued as the patient remained under the impression her original consultant had performed the surgery. Once the facts became known, and this was not before the Court case had commenced, the necessary Court modifications had to be instituted. Thus, we read:

Billi lill-atturi ma ngħatax tagħrif dwar min kien tassew li opera fuq l-attriċi, tant illi l-atturi baqgħu jaħsbu illi kien il-Kirurgu Felice u l-kawża fetħuha kontra dan u mhux kontra l-Kirurgu Abramov, u kien biss fit-2 ta' Ġunju 2000 meta l-konvenut esebixxa l-operation report sheet 12 —dokument li kellu aċċess għalih il-konvenut iżda mhux l -atturi, tant illi fuq barra tal-file ta' l-isptar ta' l-attriċi hemm miktub "CONFIDENTIAL – NOT TO BE HANDLED BY THE PATIENT

— illi l-atturi saru jafu li l-kirurgu li għamlet l-intervent kienet l-imsejħa fil-kawża, ma kien b'ebda nuqqas ta' l-atturi li dawn ma mexxewx qabel kontra l-imsejħa fil-kawża.

Since the plaintiffs where not informed about who truly performed the surgery on the plaintiff, so much so, that they still believed that it was surgeon Felice, they opened a case, against him and not against surgeon Avramov and this was only discovered on the 2 June 2000 when the defendant exhibited the operation report sheet 12. This document was only accessible to the defendant but not to the plaintiffs, so much so that on the outer part of the hospital file there is written "CONFIDENTIAL – NOT TO BE HANDLED BY THE PATIENT". It was then that the plaintiffs became aware that the surgeon who performed the operation was the doctor now summoned before Court and it was not due to any fault of the plaintiffs that they did not act against this surgeon in their original claim.

This situation presents two elephants in the room both labelled defective disclosure and both of which are decidedly ignored as potential basis for a strong separate claim by the plaintiff's legal defence. The patient had a distinct right to know the identity of the surgeon if it was to be one different to whom she was led to believe would perform the operation. Such a fact should have been disclosed *before* she was asked for her consent. This information was not even disclosed *after* the surgery. Secondly, at all stages of her care, she had a right to know the contents of her clinical file. Whatever information is held within the clinical file concerns the patient and it is the patient's right to know the information therein stored. MDH management ought to reflect well on this in their labelling such files as CONFIDENTIAL – NOT TO BE HANDLED BY THE PATIENT. This statement is a medico-legal suicide. For the confidentiality of the patient's file should reflect the legal responsibility of safeguarding the patient's confidentiality but not *from the patient herself.* Furthermore, the fact that the matter of the two aspects of defective/absent disclosure were ignored, tends to point that the

plaintiff's lawyers may have sensed that it would receive scant importance in the local Court, and possibly even detract from the original claim.

The phenomenon of an admixture of private and public hospital care, as demonstrated in the *Rose Gauci* case may pose a number of legal challenges including that relating to disclosure. The phenomenon is part and parcel of Maltese society and applies to all specialties. Obstetrically, most patients can afford private antenatal visits but not a private delivery with all its financial unknowns especially if a caesarean section is required. However, the unwritten rule universally assumed the local patients is that who cares for the patient privately will then be involved in the MDH delivery.

The private-public practice situation also has other potential medico-legal connotations, especially when the obstetrician involved is not the consultant of a firm but is a junior member of it. The Maltese public, in its majority, does not distinguish and differentiate between the hospital ranks and hierarchy, and appreciates much less the subtle difference in their grade of responsibility in MDH management. Having become the patient of an MDH specialist gives the patient an anchor or contact person and all is well with her world. That specialist becomes the patient's point of referral, her alpha and omega. This attitude may be compromising to the consultant who may find himself not only psychologically side-stepped but committed to a management the patient has been promised by one of the firm's members. Such legal implications may become more complex still if the trend to veer towards contract law and away from tort and quasi-tort as commenced in *Rose Gauci*, continues, as it seems to be doing. although the reasons for doing so were not specified. This change in jurisprudential direction is discussed in section 4.13. The Lex Medica seeks to lay guidance to assuage the present

dangerous situation resulting from the present private-public hospital practice phenomenon and this is discussed in section 4.9.

4.5.1.2 The capacity to understand

It is possible to under-estimate this essential element of a valid informed consent, especially when the obstetrician does fulfil his end of the obligation of delivering a full and frank consent. That obligation comes heavily linked to the obligation to ensure that disclosed information is truly absorbed by the patient. True capacity may be impossible to confirm regarding all that has been disclosed, but the responsibility does exist to exclude certain features which are likely to diminish such understanding.

Disclosing in a language which the patient does not understand is obvious but in the case of using an interpreter, serious distortions are beyond the obstetrician's control.

The diminution of this risk lies in the administrative powers in employing capable and reliable interpreters. The language aspect should not be ignored in European patients who speaking very limited English. They may face an obstetrician whose foreign language proficiency is limited to English. This is an element which can be under-played as the patient may speak a few words of English when more than a smattering of English may be required to convey pre-consent information. Incidentally, all cases employing an interpreter should also include the interpreter's signature on the consent form.

Besides the language barrier and hearing difficulties, psychological aspects involving the cognitive faculties must be watched out for. In cases of doubt, a relative or a close friend if acceptable to the patient, may assist but must be warned not to coerce the patient in a decision. A patient under the effects of alcohol, drugs of abuse and strong sedatives or centrally acting analgesics should not be asked to consent, unless in an emergency. Some degrees of dementia may also impair validity and in such a situation, the opinion of the caring physician must be sought *in writing.* A very low level of education and socio-cultural stratum may require a greater effort at disclosure. Psychiatric conditions may also require expert evaluation and a signed psychiatric opinion. It is important to remember however, that a diminished capacity to understand may not be synonymous with legal incompetence to give consent.

The best gauge of a reassuring response to pre-consent disclosure lies in questions being asked by the patient who must be made to feel at ease to eliminate shyness and possible feelings of inadequacy. Furthermore, the method of disclosing the necessary information may be much aided by slow clear language, while the use of diagrams, charts or photos may go a long way in aiding such an explanation. Where time is available and the patient has been allowed days or weeks to reflect, she should be advised to choose the persons she should consult for advice. Her husband and her family physician are obvious first choices. The involvement of relatives or close friends in aiding with capacity, demands prudence and the drawing of clear and strict boundary lines, to avoid incursion onto the third requisite – that of free will. This also brings the crucial point that not even the closest relative may give consent for a patient, unless he or she have been legally authorised to do so, or the situation is a life-threatening

emergency. In the UK case *Samira Kohli v. Prabha Manchanda and Another,*[469] breach of consent led to a ruling of assault and battery when, at a private laparoscopy, the operating gynaecologist proceeded to an unconsented hysterectomy and bilateral salpingo-oophorectomy after obtaining a consent from the patient's mother while the patient herself was under anaesthesia. The lesson had not been learnt from the classical 1914 case of *Schloendorff v. Society of New York Hospital*[470] where the anaesthetised patient undergoing what should have been a simple examination ended up with major surgery for uterine fibroids, with the New York Court of Appeals ruling that:

Every human being of adult years and sound mind has a right to determine what shall be done with his own body; and a surgeon who performs an operation without his patient's consent commits an assault for which he is liable in damages. This is true except in cases of emergency where the patient is unconscious and where it is necessary to operate before consent can be obtained.

4.5.1.2.1 The effect of age on the capacity to understand

This is of particular importance to the obstetrician facing occasions of pregnant children presenting for antenatal care and subsequent childbirth. In 2017, at MDH, there were three deliveries occurring in the youngest age group of less than fifteen years, with the minimum age at delivery of the mothers being fifteen years.[471] The lower age limit for the capacity of consent in Malta is set at sixteen years, below which a patient would fall

[469] *Samira Kohli v. Prabha Manchanda and Another* [2008] INSC 42.

[470] *Schloendorff v. Society of New York Hospital* 105 N.E. 92 (N.Y. 1914).

[471] See note 106.

under that category of a …. *person who has not the use of reason.* And, it was only in 2017, that a law was passed to enable sixteen and seventeen-year olds to be seen medically without parental permission. The law, before then, would allow a sixteen-year old girl the right to marry but not have sex until she was eighteen years old, and if she required medical care, she still needed parental consent!

But, what of the mature pregnant fourteen-year old,[472] who presents herself at MDH's obstetric unit for antenatal care? According to article 131 of the Maltese Civil Code, parental consent is still required. If there is disagreement between the parents over some issue or other, then with the backing of one parent the Court may step in. In cases of some degree of emergency such as permission to proceed with an urgent caesarean section, consent of one parent suffices.

Although the under-age obstetric patient should be encouraged to involve her parents, the Lex Medica in referring to children below the age of official consent, if mature and showing evidence of understanding their circumstances, while refusing parental involvement, may still be treated, particularly in the case of pregnancy. However, the proposed law draws a line at twelve years of age, below which, immaterial of individual maturity, treatment may not be administered without parental, guardian or Court authorisation.

4.5.1.2.2 The psychiatric element and the capacity to understand

[472] A frequent cause of the eternal debate between respecting the law and refusing to allow an antenatal visit and the medical obligation of caring for the patient and her unborn child especially when parents cannot attend, will not attend, or cannot be contacted.

Situations may arise, where mental health issues, require specific regulation regarding the obtaining of obstetric consent, when such issues endanger the capacity of understanding. In such situations, formal psychiatric certification is necessary. However, one should borrow guideline direction along the lines suggested by the relevant UK's General Medical Council's advice:

(1) A patient is assumed to have mental capacity to enact a decision about treatment unless the contrary is established.

(2) A person is not to be treated as unable to make a decision unless all practicable steps to help her do so have been taken without success.

(3) A person is not to be treated as unable to make a decision merely because she makes an unwise decision.

(4) In a situation where capacity is lacking a legal representative may effect such a choice, along the patient's best interests, after receiving the normal full disclosure owed to the patient by the obstetrician.

(5) Any decision, made for the person who lacks capacity, must be done in the patient's best interests alone.

4.5.1.3 The requisite of free will

Free will may be overtly influenced for whatever reason by friends or family or more subtly by a manipulative person. When suspected, the patient should be spoken to in confidence, although even then, especially where an element of fear exists, the truth may never surface. Pressure from within the family, particularly within certain culturally closed groups, may be difficult to detect or prove but if such facts do surface, the patient's previous consent must be considered null and void.

The right to obtaining advice from family or indeed, anyone else the patient wishes to discuss or consult with, is an inalienable right of the patient. There is, however, a fine line where such advice may merge, and render the final decision not valid at law, through an element of coercion. In one of its examples, the GMC quotes the case of *Re T (Adult)* [473] where the Court ruled that a decision by a pregnant woman, who only decided against blood transfusion after talking to her mother, a Jehovah's witness, had been one obtained through coercion as the patient had not initially expressed any such sentiment. In view of this, the Court ordered the blood transfusion to proceed.

There have been a number of cases involving irregular migrants, where the husband did not agree to the obstetric management offered accepted by his wife. It is the free will of the patient and no one else that matters and irrespective of any arguments, including religious ones, it is the law of the country of residence that must be respected. In such situations, even if the pregnant patient's well-being or her unborn child's life are not at stake, Court assistance may be invoked, and where necessary, it may be more a case for police intervention directed against a partner, a husband or a family member.

[473] *Re T (Adult)* [1992] 4 All ER 649.

4.5.2 The Maltese fetal locus standi versus the patient's autonomy

The right to decide one's fate in pregnancy has been repeatedly exemplified by case law in both UK and USA as well as the great majority of EU countries, particularly where the legal right of the child in utero is not recognised. This right of refusal of treatment, based on maternal autonomy, holds even in the presence of the risk of the patient harming herself or her fetus, even to the point of death of either or both. Such cases, as when a needed caesarean section is refused, exact their own price of resultant morbidity and mortality, as evidenced by resulting lower Apgar scores and higher rates of perinatal mortality and even maternal intra-partum deaths.[474] However, the principle of the right of refusal has been well tested. One UK example is that of *St George's Healthcare NHS Trust v. S; R v. Collins and others, ex parte S.* [475] In this case the Court ruled in favour of the patient who opened her Court case after having been detained in hospital for assessment under the Mental Health Act and then the opportunity was taken to proceed with a caesarean section, an action which was condemned by the Court.

In Malta in view of the Criminal Code articles 241 – 244A, abortion remains a criminal offence and this may clash with the patient's autonomy. An unsurmountable legal objection arises for example in the maternal refusal of an offered caesarean section in a situation of acute fetal distress. This aspect of the patient's autonomy may be interpreted as an infringing threat to the Maltese abortion laws. It is difficult to imagine a Maltese Court backing the patient's autonomy and right of refusal of treatment versus

[474] Ohel I, Levy A, Mazor M, Wiznitzer A, Sheiner E. Refusal of treatment in obstetrics - A maternal-fetal conflict. J Matern Fetal Neonatal Med. 2009; 22: 612-615.

[475] *St George's Healthcare NHSTrust v. S; R v. Collins and others, ex parte* S [1998]3 All ER 673.

articles 241 – 244A of the Criminal Code, although the reasoning may be completely reversed at the European Court of Human Rights.

The phenomenon of Court ordered caesarean section (COCS) has appeared in Malta only since the arrival of the irregular migrants. In the typical case, the patient refuses the offer of an emergency caesarean section even in a situation of serious fetal compromise, often with time being crucial. The underlying reasons for such refusal may be many. The patient is likely to have been minimally exposed to the idea of a CS in her country where, if it is the sub-Sahara, the CS rate is only 1-2%,[476] partly due to the lack of safe surgery. Globally, unsafe surgery contributes heavily to the estimated 350,000[477] annual maternal deaths, 90%[478] of which occurs in under-resourced countries. In spite of any reassurances, invariably conveyed through an interpreter, the patient may experience deep anxiety and fear of surgery, anaesthesia, pain and even harm and death to herself or her baby. [479] Furthermore, the incorrect but universal belief that "once a section, always a section" may also contribute to the patient's fear and confusion for the migrant patient's future whereabouts are likely to be unknown.

It was as far back as 1914, when Justice Cardozo had stated that:

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[476] Chu K, Cortier H, Maldonado F, Mashant T, Ford N, Trelles M. Caesarean section rates and indications in sub-Saharan Africa: A multi-country study from Médecins Sans Frontières. PLOS One 2012; 7: e44484.

[477]. Hogan MC, Foreman KJ, Naghavi M, Ahn SY, Wang M, Makela SM, Lopez AD, Lozano R, Murray CJL Maternal mortality for 181 countries, 1980–2008: A systematic analysis of progress towards Millennium Development Goal 5. Lancet 2001;375: 1609–1623.

[478] World Health Organization. Trends in maternal mortality: 1990 to 2008. Geneva: 2010.Report of estimates developed by WHO, UNICEF, UNFPA and The World Bank.

[479] Lyng K, Syse A, Børdahl PE. Can caesarean section be performed without the woman's consent? Acta Obstet Gynecol Scand. 2005; 84: 39–42.

Every human being of adult years and sound mind, has a right to determine what shall be done with his own body; and a surgeon who performs an operation without his patient's consent commits an assault...[480]

A number of crucially relevant Court cases may be quoted with perhaps the Carder case being one which achieved world-wide popularity. The case involved a forced caesarean section at twenty-six weeks gestation on a patient suffering from Ewing's sarcoma. Although the decision was declared after the forced caesarean section had been performed (with fatal results), the District of Columbia Court of Appeals, in re A.C.[481] enunciated against forced caesarean sections.

Much universal resistance marked the increasing autonomy by which not only is COCS considered an infringement of a basic human right, but by which the patient has carte blanche as to choose her own mode of delivery. However, a definite shift of mentality has slowly evolved. Although most obstetricians are likely not to favour COCS, this does not automatically imply acceptance of the patient's right to choose her own mode of delivery. However, in one study, a radical shift in favour of the patient's autonomy was noted between the years 1987 and 2003.[482] The current emphasis is ever increasing on the rights of the patient's autonomy, as long as the patient is of sound mind and irrespective of whether she is pregnant or not. The Maltese situation does not accept

[480] Deshpande NA, Oxford CM. Management of pregnant patients who refuse medically indicated caesarean delivery. Rev Obstet Gynecol. 2012; 5(3-4)e144-e50.
[481] In Re AC 533 A.2d 611 (1987).

[482] Dalton KJD. Refusal of interventions to protect the life of the viable fetus -A case-based transatlantic overview. Medico-Legal Journal. 2006; 74(1):16-24.

such autonomy when the patient's choice to refuse a caesarean section which puts the fetal life at risk. Subsequently, if the patient cannot be convinced of the acute need of abdominal delivery when there is substantial evidence of danger to the unborn, then the praxis involves obtaining a Court order and proceeding as deemed necessary. So far, the situation has only occasionally and has been limited to irregular migrants, who tend to appreciate what was done once they hold a living and healthy baby. If a strong-willed EU national were to be involved, the ensuing medico-legal repercussions situation are unpredictable. If the matter were to reach Court litigation, such a claim is likely to find little support locally. However, the European Court of Human Rights has repeatedly shown no recognition of the rights of the unborn, while strongly championing both the patient's autonomy and the tenets and rights of feminism.

4.6 The Court appointed obstetric expert

This extremely important subject has been extensively evaluated in Chapter 2. The Lex Medica in Article XVI puts forward an exhaustive number of proposals which reflect the importance of the Court of rendering clear and understandable those aspects of science that need explaining. The Lex Medica, cognizant of other potential advantages of local expert testimony, attaches much importance to the subject. Among these advantages is the correct establishment of an SOC along modern principles and this may be of assistance in Court deliberation in the current deficiency of medical law.

It is extremely important for the proposals in article XVI of the Lex Medica to be evaluated in conjunction with the proposal of the Maltese Institute of Medico-Legal Studies, which is seen as playing a central role in many aspects pertaining to the

schooling, qualifying and further guidance to a modern Court expert, operating along medico-legal principles as demanded by most modern jurisdictions.

4.7 Privacy and confidentiality

Confidentiality, a legal and ethical duty, is the basis of medical trust and must be firmly defended in a milieu which poses ever increasing multi-faceted challenges, while the laws of autonomy demand an ever-increasing respect for the individual's privacy. Medical issues concerning sexuality, reproduction, contraception, sexually transmitted disease (including HIV/AIDS) are daily issues facing the obstetrician and are but the tip of an iceberg which is ever threatened by new and more complex challenges. Ethics and the law have had to embark on a continuous evolutionary process to evaluate new principles demanded by society in an ever-evolving and ever-demanding society aimed at attaining a balance of functionality with confidentiality.

Even record keeping, in its new form of electronic storage and transmission, may pose new dangers of rupturing the precious bond of confidentiality. Indeed, this is an important aspect of the new world which has required the now well-established data protection laws. Besides understanding and respecting the newly evolving ethical and legal principles of confidentiality, the obstetrician must also remember not only the laws of the country which are inclusive of such data protection laws, but also any statutes and directions which may be issued with time by the institution directly employing him, which in this instance, is MDH.

The obligation of professional secrecy is well guarded by the Medical and Kindred Professions Ordinance in Chapter 31 of the Laws of Malta, and such secrecy is also highlighted under various other binding different laws and ordinances, namely:

- Data Protection Act in Chapter 586 of the Laws of Malta.

- The Department of Health (Constitution) Ordinance, Chapter 94 of the Laws of Malta.

- The Health Care Professions Act, Chapter 464 of the Laws of Malta.

- Public Health Act, Chapter 465 of the Laws of Malta.

- Mental Health Act, Chapter 525 of the Laws of Malta.

Furthermore, reference to the subject is also made in the Criminal Code in chapter 9 of the Laws of Malta, article 257 which warns against the breaking of professional secrecy. While providing for certain disclosures under certain circumstances, the Criminal Code stresses that these are not applicable to *a person who is a member of the legal or the medical profession*. Here we find a worrying equivocity, for professional secrecy may indeed be breached lawfully in cases allowed by law, such as when giving evidence in Court or when one's duty of reporting a criminal act supersedes the laws of confidentiality. Hence the Criminal Code needs revision and updating with the inclusion of such lawful breaches.

It is interesting to note that while all Maltese legislation stresses the absolute confidentiality of medical information, the first sentence in the UK's GMC's site on confidentiality[483] states that *Confidentiality is an important legal and ethical duty, but it is not absolute.* In view of the quasi-regimental discipline of the GMC known to have suspended registrations of doctors even of eminent doctors such as Sir Roy Meadow, as discussed in section 2.81, one can rest one's mind as to the legal and ethical justification of such a statement. There is no escaping from the fact that situations do arise, where, however regretfully, confidentiality must be lawfully breached, as when the greater good demands it, as gauged by the needs of society at a specific point in time. One example comes from *W v. Egdell,*[484] in which a newspaper argued that it was in the public interest to publish the names of local HIV positive doctors while the local Health Authority argued successfully for confidentiality. However, the Court of Appeal ruled for public interest and sanctioned the public disclosure, declaring that:

…the law recognises an important public interest in maintaining professional duties of confidence, but [that] the law treats such duties not as absolute but as liable to be overridden where there is held to be a stronger public interest in disclosure.

And yet, one must be discriminating in accepting published advice on breach of confidentiality. Thus, this thesis queries Ashcroft's advice that it may be permissible to reveal an HIV infection to a partner of the patient when the patient refuses to disclose it.[485] A likely ethically safer solution would be to for the obstetrician to alert the health

[483] General Medical Council. Confidentiality: good practice in handling patient information. Jan 2017.

[484] *W v. Egdell* [1990] 1 All ER 835.

[485] Ashcroft RE. From public interest to political justice. Cambridge Quarterly of Healthcare Ethics: CQ: The International Journal of Healthcare Ethics Committees. 2004; 13(1):20-27.

officer in charge of the contact tracing unit and direct him to the patient's partner, rather than the obstetrician directly contacting the partner to inform him.

The occasions where confidentiality may be lawfully encroached are listed in Article VII of the Lex Medica. The cases are exceptional, and the divulging of the relevant information should be strictly limited to the person required to have access to such information. All further unnecessary divulging must be scrupulously avoided as should any discussions about the subject, save where it is strictly necessary. Furthermore, this aspect of the Lex Medica requires a concomitant and corresponding amendment to Chapter 9, Title VIII regarding 'Crimes Against the Person' to avoid the possibility of subsequent criminal action against the divulging obstetrician. The divulging of information in these exceptional cases should be guardedly limited and directed only at other professional care workers or the involved authorities. Non-essential requests for information should be denied and any discussion relevant to management or legal obligations should be strictly avoided.

Article VIII of the Lex Medica provides much legal protection to the vulnerability of confidentiality by providing extensive legislation pertaining to the stored patient information in medical records. This is one area which, however seriously it is taken by the MDH management, will always require further scrutiny and tightening.

4.8 Documentation

It is crucially important that all medical and obstetric material concerning the patient is systematically recorded in the clinical file, dated, timed and signed. Information which

is obtained through telephone calls and text messages, should be accurately recorded, and text messages saved. E-mails, letters, etc. must be carefully stored in the side folder of the file. All decisions about management inter-disciplinary consultations, etc. must all be recorded.

The patient's file is quintessentially confidential and must only be handled in the interests of the patient and by health-workers directly involved in the patient's care. In the case of the obstetric patient, the stored information includes:

(i) The normal pages on which are hand-written management decisions, points referring to disclosure of information and subsequent decisions, treatment administered, complications arising, etc.

(ii) Investigations and their results pertaining to the general medical condition, such as routine blood tests e.g., haemoglobin, blood sugar and creatinine values, etc.

(iii) Obstetric investigations such as CTG strip tracings obtained antenatally or in labour, ultra-sound results, doppler flow studies.

(iv) Notes pertaining to labour with the partogram being the most important document relating to the process of childbirth.

(v) Other, more specialised tests, not performed on a routine basis e.g., MRI C/T scans, etc.

(vi) Photographs. These usually pertain to ultra-sound. Very unusually they may pertain to surgery e.g., laparoscopic photos or to other conditions e.g., a skin condition.

(vii) Electronically stored information.

Among the most sensitive stored information we find:

- Name, age and address.
- Contact telephone numbers.
- Marital status and contact details of husband/partner.
- Health conditions.
- Treatments and medicines.
- Allergies and past reactions to medications.
- Lifestyle information, regarding smoking, alcohol consumption, substance abuse and sexual history information.

- Intimate details, including HIV/AIDS status and other information about sexually transmitted diseases, mental health problems, previous terminations of pregnancy, etc.

- Details about previous hospital admissions and discharge information.

The devastating risk of confidentiality leakage from such clinical notes is clear and obvious. It is with this in mind, that the Lex Medica devotes a substantial amount of space to the subject of medical records seeking to strike a balance between functionality and confidentiality, aiming to cover all aspects of use and storage with the aim of preserving confidentiality and safeguarding the notes and their contents.

4.9 On obstetric hierarchy, rights and responsibilities

The already quoted local phenomenon of the intertwining of private practice and public hospital care, discussed in Section 4.5.1.1 in connection with the *Rose Gauci* case as well as in Section 3.3.2.3.3.1 in connection with envisioned potential difficulties of introducing the ABRMS system. These are some of the inherent difficulties of this local custom which has operated since time immemorial.

The situation is not easy to remedy. The patient has a right to choose who looks after her and her pregnancy in the private sector. He may be a junior in his first year or two or he may be a consultant. Technically he should be on the specialist list, but in reality, reporting such a doctor to the Medical Council, which is a gross undertaking generally unthinkable within Maltese culture, though not necessarily so to a foreign patient. The

patient also has a right to use the public hospital, if she is a Maltese citizen or fulfilling the conditions demanded of EU citizens or other locally residing foreigners. Hence, a Lex Medica, must tread extremely carefully as to scope and expression.

The Lex Medica has two articles in conjunction with this situation. Article II refers to who can use the title of consultant and specialist. The difference is defined but, in truth, it does not make much of a difference to the public. However, it is rendered clear that legally, a certified specialist may certainly call himself a specialist but not a consultant. The term consultant is reserved to those who have been appointed as such in the Maltese Civil Service, a title which is retained on retirement.

Article III is more direct in its scope. It specifically distinguishes between consultant and sub-consultant grades, their responsibilities and legal implications. It specifically distinguishes between private practice and management within MDH. It also specifically directs that all private practice decisions taken at sub-consultant level require the consultant's endorsement before being enacted with the public hospital.

The Lex Medica cannot enter into the puerile details of the discipline the consultant must maintain within his MDH firm and the responsibility for which, he fully carries himself. If the consultant seeks an easy existence and allows the members of his firm to do as they please, he must not complain when the odd serious case of litigation resulting from such lackadaisical behaviour does surface. It is also his responsibility to ensure that the law if enacted is respected. Such discipline is not aimed at curbing the juniors' private practice but at increasing discipline with a view to diminishing medico-legal vulnerability. Infractions of Article II and III should demand initial reprimand and

if persistent, reporting to the higher hospital authorities as well as the MDH legal office. If all fails and the law remains being flagrantly abused, then the matter should be resolved legally.

4.10 Ethical behaviour of obstetricians

In article V, the Lex Medica clearly discusses those qualities of basic ethics, that the obstetrician must respect, such as beneficence, non-maleficence, etc. While clinical aloofness is not desirable, neither is over-familiarity and intimacy and sexual liaisons are naturally completely forbidden. The obstetrician must never take advantage of his professional position to act as sexual predator, however willing or even inviting the patient is. Infringement of such guidance may lead to much pain all round as well as to embarrassing disciplinary and/or legal repercussions.

The obstetrician must also abstain from harbouring or expressing social, ethnic, religious or any other form of discrimination levelled at patients or colleague health professionals. A request for a second opinion should elicit an honest and sincere evaluation simply aimed at gaining the full clinical picture and concluded by an honest appraisal and independent opinion. It should ideally include no comments about the obstetrician who expressed the first opinion. Whatever the second obstetrician states may well come back to haunt him, including the situation, where he may be required to re-state his words in a Court of law. This article also includes advice regarding conflict of interest, on receiving unlawful payment and the respect of the patient’s autonomy.

4.11 Female Genital Mutilation

The subject has been discussed briefly in section 1.5.1.1.The Lex Medica also endorses UN General Assembly Resolution A/RES/67/146. Adopted on the 20 December 2012, this resolution seeks the world-wide banning of female genital mutilation (FGM). The Lex Medica in Article XI strengthens and broadens some aspects of the 2014 Maltese legislation dealing with this subject.

4.12 Pre-natal testing and ultra-sound anomaly scanning

The Lex Medica cannot concern itself with the MOS' decision as to whether to maintain anomaly ultra-sound scanning remains as the only form of pre-natal testing or whether to add to this the full available complement of prenatal genetic tests commonly available in many European countries. Article XIII of the Lex Medica, however, does stress the guarding of Chapter 9 sub-title VII Articles 241 – 244A of the Laws of Malta regarding abortion, in those cases where major anomalies are diagnosed. It also stresses the immediate need of instituting professional counselling for such situations.

4.13 The law of tort and quasi-tort *v.* the law of contract

Several references to the law of tort and quasi-tort as well as to contract law and other forms of law such human rights Law have been referred to in this thesis. At this point, it is opportune to state, that it is beyond the scope and the facility of this thesis to delve into the perennial debate of whether medical negligence should be judged along the laws of tort and quasi-tort or those pertaining to contract. The decision is legal, albeit

with serious medical implications, but its in-depth evaluation does not conform to this thesis' objective. However, some observations are in order.

It is interesting to note the recent evidence of local evolutionary activity (or is it simple metamorphosis?) regarding the choice of law to be applied. Traditionally local cases of alleged negligence have been judged along the laws of tort and quasi-tort as is the case in the UK regarding NHS practice. In the Court deliberation of *Rose Gauci*, the normal use of the traditional jurisprudence based on tort and quasi-tort was referred to but rejected in favour of contract law. While stating that the doctor-patient relationship is more amenable to a contractual relationship, no specific reasons were given to explain this change. It is, of course, the Court's discretion what type of law it decides to base its reasoning on. Having stated its decision to examine the doctor-patient relationship under contract law, the Court then emphasised the fact that the law of contract demands consent to be tacit or implicit. This is rather confusing in discussing a case of a major surgery where consent must be completely and clearly expressed and furthermore expressed in writing rather than be implicit or tacit:

Għalkemm, kif ingħad, il-posizzjoni hawn Malta ġiet eżaminata fil-kuntest tar-regoli ta' kważi delitt, din il-Qorti hija tal-fehma li jkun aktar loġiku li r-relazzjoni bejn pazjent u tabib tiġi eżaminata fil-kuntest ta' kuntratt. Hu veru li kuntratt jeħtieġ il-kunsens ta' żewġ partijiet, iżda hu veru wkoll li dan il-kunsens jista' jkun taċitu, u anki impliċitu, basta tkun tezisti l-volontà fil-partijiet li jassumu l-obbligazzjonijiet fil-konfront ta' xulxin.

Although, as has been stated, in Malta, the situation has been subjected to the laws of quasi-contract, this Court holds that it is more logical to view the patient-doctor relationship as a contractual one. It is true that a contract requires consent from both parties, but it is also true that this consent can be tacit and even implicit, as long as both parties are willing to undertake their respective obligations.

However, there *was* a point in bringing up the concept of consent, for here we find the Court stressing that medically results cannot be guaranteed even while undertaking a contractual obligation to treat the patient. Having declared its position on adopting the law of contract, the Court then made an unexpected reference to Court deliberation in the UK's *Dunne v. National Maternity Hospital and Jackson*[486] which was an obstetric case involving serious brain damage of the new-born with its jurisprudence based on the law of tort as are all NHS Court cases. The case deliberation, at Appeal, had led to the illuminating Dunne principles. The plaintiff's defence in *Rose Gauci* was quick on the uptake when the verdict had been delivered in favour of the defendant gynaecologist and asked for a re-trial citing the use of foreign jurisprudence referring to tort law instead of the conclusions emanating from the interpretation of local contract law, as the Court had intimated at the beginning of the hearing. In its answer, the Court, replied that in this case, the obligations engendered by the bonus paterfamilias in article 1032 dealing with tort and quasi-tort, were the same as those required by the law of contract. If this was the case, a respectful but justifiable reply would enquire as to the need to veer away from local tradition and choose contract law only to end up applying the laws of tort and quasi-tort.

[486] See note 416.

In spite of these queries, *Rose Gauci* created a precedent. Its inexplicable challenge to tradition, with unclear benefits, would neither go unnoticed nor uninvoked in future case law. Some of these cases, following suit, were appeal ones, among which we find *Tessie Ellul et v. Dr Astrid Camilleri,*[487] where the Court declared that:

Kif qalet din il-Qorti fil-każ Gauci v. Felice, deċiża fil-31 ta' Ottubru 2008, ir-relazzjoni bejn tabib u pazjent tixbaħ aktar in-natura ta' kuntratt, b'dan, però, li mit-tabib mhux mistenni dejjem riżultat pożittiv, għax l-obbligazzjoni tiegħu mhux dik di risultato iżda di mezzi, fis-sens li l-obbligu tat-tabib huwa deskritt bħala li "egli e` tenuto ad usare la diligenza che la natura dell'attività esercitata esige" (Corte di Cassazione d'Italia, 21 ta' Lulju 1989; każ Numru 3476). Dan ifisser li filwaqt li t-tabib ikun irid jipprova li hu aġixxa kif il-professjoni tistenna minnu, li i-pazjent irid juri, fl-ewwel lok, li gara xi ħaġa ħażina waqt l-intervent kirurġiku, xi ħaġa, jiġifieri, mhux mistennija li sseħħ f'operazzjoni ta' dik ix-xorta.

As stated by this Court in the case Gauci v. Felice on the 31 October 2008, the doctor-patient relationship is closer in resemblance to the nature of a contract, in spite of which positive results are not always expected from the doctor. The doctor's obligation is not of guaranteeing results from his work, in which he is described that he is obliged to use the diligence that his work demands (Corte di Cassazione d'Italia, 21 July 1989; case number 3476). This means that while the doctor must prove that he acted as his profession demands, the patient must first show, that something went wrong in his

[487] *Tessie Ellul et v. Dr. Astrid Camilleri,* Qorti tal-Appell, Onor. Imħ. Dr Vincent De Gaetano, Onor. Imħ. Dr Alberto J. Magri, Onor. Imħ. Dr Tonio Mallia, Ċitazz. Nru. 2653/1999, deċ. 28/5/2010.

intervention, that is something which is not expected to happen in the type of intervention which he underwent.

The ruling in *Tessie Ellul* was in turn quoted in *Joseph Micallef v. Dr. Ivan Vella MD et noe*.[488] Even the same example from the Italian Corte di Cassazione, was quoted. In this case, the Court further added

… d-distinzjoni hi aktar waħda dwar l-effetti milli waħda dwar il-ħtija per se għax id-dannu jibqa' wieħed u huma l-konsegwenzi naxxenti mid-dannu li jinfluixxu fuq ir-rapport bejn il-partijiet.

…the distinction is one pertaining to the effects rather than guilt per se as the damage remains one and it is the consequences born of damage which influence the relationship between the parties.

Hence, the Court seems to be stressing the point of the importance of the damaging effects rather than the guilt, presumably of not effecting one's end of the agreed contract. This elicits some degree of confusion in the sense that if one is stressing the resultant harm, the law of tort and quasi-tort is likely to be more suitable than that of contract law, which generally speaking is primarily concerned with the guilt resulting from the breakage of contract. One seems to gather the impression that the local Courts are searching for solid arguments to follow in the wake of *Rose Gauci*, but, seem as yet, not to have hit on the more convincing ones.

[488] See note 412.

Essentially all cases dealing with alleged medical negligence from *Rose Gauci* onwards have assumed the same stance regarding contract law, all repeating the same proviso quod that such contractual obligations do not bind the doctor to always produce positive results:

ir-relazzjoni bejn tabib u pazjent tixbaħ aktar in-natura ta' kuntratt, b'dan, però, li mit-tabib mhux mistenni dejjem riżultat possittiv.

The patient-doctor relationship resembles more the nature of contract, but this does not bind the doctor to always obtain positive results.

In *Venere Falzon v. Marcello Stella,*[489] the contract position is now stated with a particularly strong element of affirmation, which unlike other cases makes no reference to the traditional use of tort and quasi-tort:

Jibda biex jingħad illi fil-kura medika anki dik li għandha x-taqsam mal-kirurġija estetika r-rapport tat-tabib u l-pazjent hu wieħed primarjament kontrattwali.

We start off by stating that in medical treatment, even that related to aesthetic surgery, the relationship between doctor and patient is primarily a contractual one.

Similar Court reasoning, now preferring the law of contract is found in several other post 2008 cases. Further examples include *Anthony sive Tony Jones v. It-Tabib Francis*

[489] *Venere Falzon v. Marcello Stella,* Qorti Ċivili, Prim' Awla, Onor. Imħ. Dr Mark Chetcuti, Rikors Ġuramentat Nru. 1201/2010, deċ. 9/7/2015.

Pullicino pro et noe et,[490] *Joseph Micallef v. Dr. Ivan Vella (PA 30/04/2013); Linda Busuttil v. Dr. Josie Muscat et (App 27/06/2014).*

Making reference to the Lex Medica, the question of whether to employ tort and quasi-tort or contract law principles in installing the Lex Medica would serve as a bone of contention. The legal framework for medical law, long desired and much needed should not serve as an opportunity for this never-ending discussion, nor is it the proper forum for it. The trend set up by *Rose Gauci* must be noted where it matters and although the discretion of the venerable Court is supreme, no convincing advantage in making such a choice has been elaborated upon, even if by way of legal education and instruction. Some cases lend themselves better than others, and possibly *Rose Gauci* was not the ideal case to effect the first challenge to jurisprudential tradition. This was possibly evidenced by the need, in *Rose Gauci* itself, to refer to deliberations from a UK case judged along tort and quasi-tort. And, one might hazard and state, it was possibly evidenced even more by the Court's answer to the request for a re-trial by the statement that the obligations engendered by the bonus paterfamilias in article 1032 dealing with tort and quasi-tort were the same as those required by the law of contract.

One must here, also make reference to what has repeatedly been stressed regarding the local need to borrow general principles of law and juridical deliberations and case law from foreign jurisdictions, mostly Italian and British. Whereas the former tends to employ contract law for the adjudication of medical negligence, the latter uses an admixture of tort law for NHS cases and contract law being generally preferred for

[490] *Anthony sive Tony Jones v. It-Tabib Francis Pullicino pro et noe et*, Qorti Ċivili, Prim' Awla, Onor. Imħ. Dr Giannino Caruana Demajo, Ċitazz. Nru. 1287/1991, deċ. 27/6/2008.

private practice cases. Hence, one may possibly justifiably query the universal statement that until *Rose Gauci,* tort and quasi-tort principles were applied, in that if one analysed in detail such cases, one would probably find reference to an admixture of tort and contract principles inspiring final deliberation. This admixture of borrowed principles may even at times lead to the use of both Italian and English principles/case law quoted in the same Court case. One example would be *Tessie Ellul et v. Dr. Astrid Camilleri,*[491] where the Court, first quotes from *Hucks v. Cole* [492]*:*

A charge of professional negligence against a medical man was serious. It stood on different footing to a charge of negligence against the driver of a motor car. The consequences were far more serious. It affected his professional status and reputation. The burden of proof was correspondingly greater. As the charge was so grave, so should the proof be clear.

Further on, the same Court quotes from the Corte di Cassazione of Italia[493]:

ir-relazzjoni bejn tabib u pazjent tixbaħ aktar in-natura ta' kuntratt, b'dan, però, li mit-tabib mhux mistenni dejjem riżultat pożittiv, għax l-obbligazzjoni tiegħu mhux dik di risultato iżda di mezzi, fis-sens li l-obbligu tat-tabib huwa deskritt bħala li "egli è tenuto ad usare la diligenza che la natura dell'attività esercitata esige.

The patient-doctor relationship resembles more the nature of a contract, although this does not impose always positive results from the doctor as his obligation is not one of

[491] See note 487.

[492] *Hucks v. Cole* (1968) [1993] 4 Med LR 393.
[493] Corte di Cassazione d'Italia, 21 Lulju 1989; kaz Numru 3476.

results but of method in the sense that his duty is defined by the diligence that the nature of his work demands.

One may surmise that in *Rose Gauci* and the subsequent cases, the Court, which had been repeatedly challenged to stretch the limited and inappropriate principle of the bonus paterfamilias, sought the new direction offered by contract law. This would make sense particularly if searching for a diminution or cessation of assistance from foreign jurisprudential deliberations. However, these references did not cease nor diminish and in the *Rose Gauci* prototype itself, reference is strongly made to the *Dunne* case, which raised sufficient contention from the plaintiff's defence that it called for a mistrial.

4.14 Pre-Trial Hearing

Although evaluation of different methods offering Alternative Dispute Resolution

(ADR) is of immense importance to discussions pertaining to medical negligence, these are beyond the remit of this thesis. Neither is the subject alluded to in the Lex Medica The evaluation of this important aspect is however considered as one of the future most opportune objectives of the Maltese Institute of Medico-Legal Studies. However, closely linked to the subject is the so-called pre-trial hearing (PTH), which is briefly referred to in appendix four, in section A3.4 in relation to cerebral palsy adjudication and is discussed in some detail here.

The PTH should be considered by the Maltese Court system and not only within the realm of alleged medical negligence for it has many proven benefits, including the

saving of precious Court time and much expense. The process allows the weeding out of frivolous cases and also has other advantages, including an opportunity for the Court expert obstetrician to test the waters of the medical evidence available and assure his competence and confidence. If the expert conscientiously feels that he is out of his depth at this stage, he may withdraw at an optimal time, thus allowing a second expert to replace him before the commencement of the actual trial. However, the main advantage in a case of alleged medical negligence is that full scrutiny and evaluation at Court expert level of all available scientific evidence may be carried out before the main hearing, thus ensuring that clear scientific proof is available to allow a decision to be reached. An example is discussed below, involving cerebral palsy.

A PTH of a cerebral palsy case must respect many principles which are inherently important in the full trial itself. This includes an awareness of how CP jurisprudence has been grossly and inadvertently misdirected by science in the 'great cerebral palsy myth, which is briefly revisited here.

The original scientific position in the 1960's was based on two serious scientific misconceptions namely that:

- The great bulk of cerebral palsy cases were due to birth hypoxia. Unfortunately, the facts would show much later that only 14.5% of cerebral palsy cases were due to intra-partum hypoxia.[494]

[494] See note 344.

- Such birth hypoxia was likely to be detectable by the then newly developed cardiotocographic monitoring. This thinking had a basis of truth, as long as an abnormal I-P CTG was confirmed as associated with fetal acidosis and as long as the now known CTG deficiencies are kept in mind, for even in the worst-case scenario of CTG disturbances, fetal hypoxaemia can only be confirmed in 50-60% of cases.[495] The expected diminution in cases of cerebral palsy with the use of CTG never materialised.

Not long after the initial CTG induced euphoria, warning lights were appearing challenging both concepts. In 1976, Scott[496] published that *"time and time again, it has been shown that very few cases of cerebral palsy can be explained on the basis of birth asphyxia."* In spite of the mounting scientific evidence advising prudence, the jurisprudential application of the original mistakes was becoming ever more entrenched both in the USA as well as the UK, especially fanned by birth litigation lawyers. Not even the turn of the century would witness significant annihilation of the false creed particularly with regard to the role of I-P CTG in cerebral palsy prediction. By the 1990's science had been proclaiming that *the positive predictive value of a non-reassuring pattern to predict Cerebral Palsy among singleton new-borns with birth weights of 2,500 g or more, is 0.14%, meaning that out of 1,000 fetuses with a non-reassuring FHR pattern, only one or two will develop cerebral palsy.*[497] The 21st

[495] See note 333.

[496] Scott H. Outcome of very severe birth asphyxia. Arch Dis Child. 1976 Sep; 51(9):712–716.

[497] Nelson K B, Dambrosia JM, Ting T, Grether JK. Uncertain value of electronic fetal monitoring in predicting cerebral palsy. The New England Journal of Medicine. 1996 Mar 7; 334(10):613-619.

century, would witness more damning evidence, such as Macones[498] stressing that t*he false positive rate of External Fetal Monitoring for predicting cerebral palsy > 99%.*

However, not all judges where blind to the truth. As relatively early as 1989, judge Simpson QC, in *De Martell v. Merton and Sutton Health Authority,*[499] uttered illuminated words in his deliberation:

…up to ten years ago the accepted wisdom was that cerebral palsy was more often than not caused by birth asphyxia. Now the pendulum has swung the other way. All knowledge and certainly all medical knowledge is provisional.

Review of CP jurisprudence tends to suggest that such views being rather few and far between even by the turn of the twentieth century. A great step in the right direction lay with the scientific establishment that hypoxia-induced infantile cerebral palsy was *inevitably* preceded by Hypoxic Ischaemic Encephalopathy. HIE did not necessarily lead to the establishment of cerebral palsy but for cerebral palsy to occur, HIE was a pre-requisite. Absence of HIE essentially ruled out cerebral palsy resulting from IPH, which type of cerebral palsy was widely known to be no more than 14.5%.[500] This was a crucial fact in that liability for CP striking the new-born could be eliminated if HIE was absent after birth. This naturally referred only to liability related to IPH and not to some other factor, such as trauma. Furthermore, this meant that even in the presence of

[498] Macones GA, Hankins GDV, Sponge CY, Hauth J, Moore T. The 2008 National Institute of Child Health and Human Development Workshop Report on Electronic Fetal Monitoring: Update on Definitions, Interpretation, and Research Guidelines. Journal of Obstetric, Gynaecologic and Neonatal Nursing. 2008 Sep/Oct; 37(5):510-515.

[499] *De Martell v. Merton and Sutton Health Authority.* [1992] 3 All ER 820.

[500] See note 344.

I-P CTG mismanagement and hence negligence, the causal link to obstetric malpractice leading to CP could not be clinched. This could mean that CP was not hypoxic induced, irrespective what the I-P CTG showed, especially if unconfirmed by fetal blood pH and acid base studies. Review of numerous cases will reveal liability for CP incurred solely on the basis of I-P CTG abnormalities.

A further turning point would come with the publication of firm criteria for diagnosing HIE. Such criteria were in fact published by the American College of Obstetricians and Gynaecologists (ACOG) in conjunction with the American Academy of Paediatrics (AAP) in 2003. A second report in 2014, enriched the first with further views on the subject.

PRIMARY CRITERIA: ESTABLISHING THE SENTINEL EPISODE	**SECONDARY CRITERIA: ESTABLISHING THE TIMING OF THE SENTINEL EPISODE (Non-specific for asphyxia insult)**
METABOLIC ACIDOSIS (pH <7; BASE DEFICIT ≥ 12 mmol/L	THE PRESENCE OF A RECOGNISED SENTINEL EVENT
EARLY ONSET SEVERE/MODERATE ENCEPHALOPATHY IN INFANT OF ≥34 WEEKS MATIRUTY	CTG: SUDDEN SUSTAINABLE BRADYCARDIA/ABSENT VARIABIITY WITH PERSISTENT LATE OR VARIABLE DECELERATIONS
SPASTIC QUADRIPLEGIA/ DYSKINETIC CEREBRAL PALSY	APGAR SCORES: 0-3 AFTER 5 MINUTES
EXCLUSION OF IDENTIFIABLE CAUSES: TRAUMA, COAGULOPATHY, INFECTIONS, GENETIC, ETC.	ONSET OF MUTLTI-SYSTEM INVOLVEMENT WITHIN 72 HOURS OF BIRTH
	EARLY NEURO-IMAGING SHOWS ACUTE, NON-FOCAL CEREBRAL ABNORMALITY

Table 3 2003 ACOG -AAP CRITERIA FOR ESTABLISHING HIE

These ACOG-AAP criteria provided a list of core criteria to establish the presence of HIE and a list of secondary and non – specific criteria which helped in

establishing the timing of the insult leading to asphyxia which is referred to as the sentinel episode. Establishing the timing of the sentinel event or the main event of causation has great practical importance both therapeutically as well as medico-legally.

Table 3 makes it clear that HIE is essentially based on factors which, while ruling out other causes, seek to confirm the new-born's blood pH and base deficit, seek signs of an early onset encephalopathy and later on, classify the type of cerebral palsy which gradually manifests itself. The classification of CP as being one of a spastic quadriplegic/dyskinetic/tardive type is crucial as is its linkage to specific MRI changes.

One notes that I-P CTG abnormalities are not even included in the core criteria, but only play a role in establishing the *timing* of the sentinel episode. This is perfectly logical for whereas I-PCTG is but a screening test for hypoxia, here we deal with *established* hypoxia, confirmed by blood evidence as well as its specific type of cerebral damage. One must bear in mind that the critically crucial ACOG-AAP criteria depend on the availability of various investigations performed on the neonate such as FBS, Apgar scores, early fetal neuro-cerebral imaging, etc. This point is specifically included in the Lex Medica Article XVI (g) II, the section entitled *Clinical direction in cases alleging negligence in specific clinical conditions.* Furthermore, these investigations must be performed and in view of the not uncommon situation of late commencement of CP litigation, must be stored for a minimum of twenty-five years.

The importance of this review is of direct significance to a PTH in a case of CP, bearing in mind a number of points:

I. CP is only caused by IPH in 14.5% of cases[501].

II. A grossly abnormal CTG has no causal connection to CP which has been shown *not* to be due to IPH.

III. Obstetric negligence e.g., I-P CTG mismanagement may be present, but in the absence of HIE, may not amount to obstetric liability for the causation of the damage presenting to Court.

IV. HIE must precede CP resulting from IPH.

V. HIE demands pH and base deficit evidence. Yet one must also remember that both may be misleadingly normal say in blood taken proximal to an obstruction in the cord if this is the cause of the hypoxia.

VI. CP resulting from IPH must be of the quadriplegic/tardive dyskinetic type.

VII. HIE may only be confirmed retrospectively if the core investigations *had* been carried out. Absence of investigations however does not rule out HIE. corroborative evidence may be obtained from the type of CP presenting to the Court.

[501] See note 344.

VIII. Confirmation of absence of HIE does not rule out other obstetric liability which may be contributory to the cerebral damage e.g., trauma which may still amount to obstetric negligence.

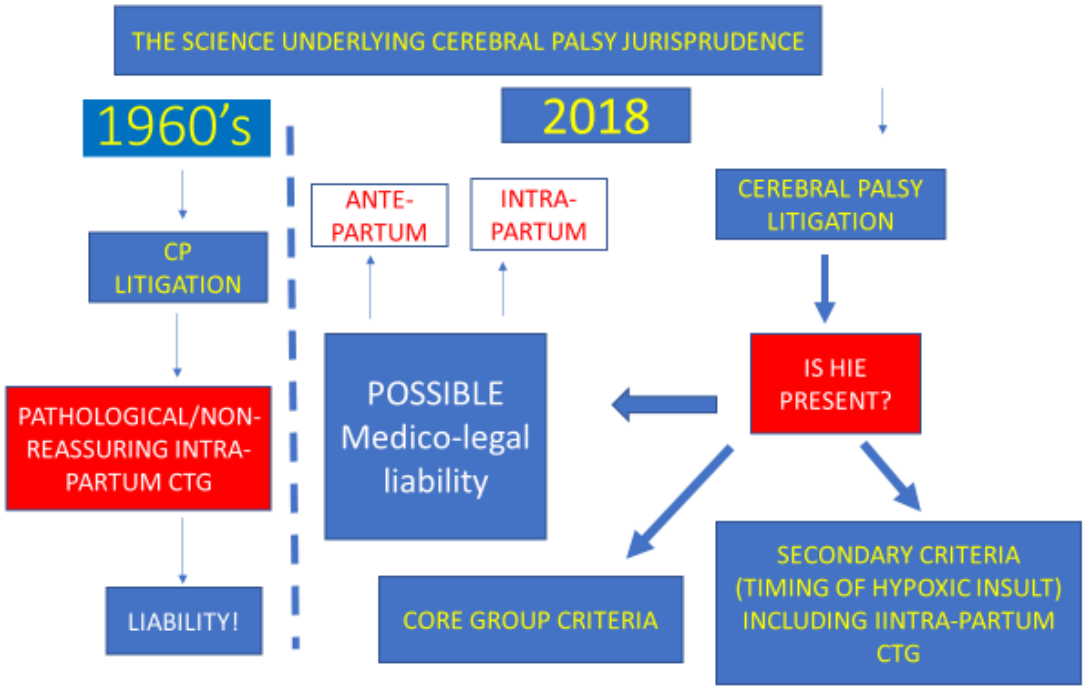

Figure 13 Chart highlighting the comparative underlying science of cerebral palsy as reflected in the USA/UK jurisprudence of the 1960's and 2018 (contemporary period)

The reasoning linking these points to a PTH now becomes increasingly clear. If the presenting CP does not show the necessary criteria of being caused by oxygen deprivation, then liability from negligence leading to such IPH cannot hold. In cases where the needed investigations on the neonate had not been performed, the inability to make a retrospective diagnosis of HIE does not exclude CP due to IPH, if it is of the quadriplegic/dyskinetic type. One notes that the difference in the scientific principles guiding modern cerebral palsy jurisprudence as compared to that in the 1960's and 1970's and in some cases dragging to the present century, is as different as night is from

day. Figure 13 simplifies the situation with regard to the science underlying the two jurisprudences. One case, discussed in appendix three, section, namely *AW Pursuer against Greater Glasgow Health Board Defenders,*[502] is a good example of the application of modern principles in establishing just CP jurisprudence.

With this background information, one can now give some concrete examples of science aiding a PTH., by visiting a number of hypothetical scenarios as applied to the results of a PTH:

- Full availability of the necessary criteria but which do not support a diagnosis of HIE. This excludes all claims of cerebral palsy purely based on claims of obstetric mismanagement leading to peri-partum hypoxia.[503] In this case, proceeding to trial will never achieve causality and therefore the case should not proceed to trial or full Court hearing.

- Insufficient clinical information to establish HIE. In such a situation, a state of doubt exists, and this demands that the plaintiff be given a chance of a full Court evaluation, if the CP is of the quadriplegic/dyskinetic type.

- A claim of cerebral palsy resulting from obstetric negligence not associated with hypoxia e.g., a traumatic instrumental delivery, is not to be subjected to a PTH based on the criteria discussed here.

[502] *AW Pursuer against Greater Glasgow Health Board Defenders* [2015] CSOH 99.

[503] Peri-partum hypoxia includes intra-partum hypoxia and hypoxia during the birth period.

- A claim not specifying cerebral palsy causation from intra or peri-partum hypoxia but simply obstetric negligence in labour will only partially benefit from this type of PTH which can only apply to mismanagement leading to IPH and subsequent cerebral damage. Since the claim is based on general negligence, other elements such as trauma may be involved. If the PTH determines hypoxia as one of the contributory causative elements, the trial or full Court hearing should proceed. If a hypoxic cause is not proved but the possibility of another element involving potential obstetric negligence is deemed present, the trial or full Court hearing should proceed. If hypoxia is not confirmed despite the full availability of all necessary criteria and no elements of trauma or other potential elements of obstetric negligence are present, a full Court hearing is not justified. In doubtful situations, the plaintiff should always be allowed to proceed to a trial or full Court hearing.

5: CONCLUSION

5.1 The challenge ahead and the gathering of the Clans

Many aspects pertaining to the legal liability of caring for the unborn in the Maltese Islands have been evaluated in the preceding chapters and several proposals have been put forward with the scope of diminishing legal vulnerability in local current obstetric practice. Likewise, many suggestions have been proposed for the attention of the Maltese legislator with regard to numerous contemporary deficiencies dealing with alleged obstetric negligence. Improving the legal situation will ensure greater guidance to the judiciary, to lawyers and also aid the obstetrician along both ethically and along the modern principles of medical law. It is fitting that this thesis concludes with two further final proposals, which unite in fact and/or principle most of amendments put forward. These are the proposed body of Law entitled the Lex Medica, and the proosed formation of the Maltese Institute of Medico-Legal Studies. It is the latter which must precede the former and be a crucial part in its enactment.

5.2 The Establishment of a Maltese Institute of Medico-Legal Studies.

The Institute is considered as indispensable in the eventual establishment of the Lex Medica. One of the initial primary aims is planned to be the preparation, co-ordination and general spearheading of the herculean task of turning the Lex Medica from paper concept to cold factual reality. There is no illusion that the groundwork entailed by this body of law will challenge the massed effort of many willing and able men and women in single minded effort and dogged perseverance. It is time to gather the clans. The

arduous task of commencing serious medico-legal statistics collection with respect to the data protection laws to build a convincing case substantiating the ned for the new law would also be an immediate and pari passu first objective of the Institute. Such data comparatively combined with overseas statistics would provide crucial scientific argumentation to lay before the Maltese Parliament. Numerous, constructive and repeated liaisons with the Health and Law Ministry and their shadow counterparts, the Judiciary, the Malta Medical Council, the Chamber of Advocates, the Medical Association of Malta, the Malta College of Obstetricians and Gynaecologists (and all other medical specialty colleges), the Malta Union of Midwives and nurses, representatives of Health Insurances and other bodies are but a fraction of the initial toils of the proposed MIMLS.

The institute must not at all be conceived as limited to purely facilitating the enactment of the Lex Medica, although this, along with the collection, collation and publication of the relevant statistics, should certainly take priority of action. However, the full scope of such an Institute is vastly wider, commencing with the challenge of raising the profile of medico-legal studies in Malta from essentially non-existent to one of European standing. No modern health system or legal jurisdiction can accept such a specialty to be anything less than fully established and playing a most crucial and dynamic role in bridging Law and Medicine in a practical and indispensable fashion. This will entail the establishment of many long-term, multi-faceted and inter-disciplinary projects uniting the relevant the legal, medical, ethical and forensic worlds at both academic and practical cross-roads. Its objectives would include:

I. The required motivation, dynamism and persistence for the implementation of the Lex Medica to substitute the application of the general laws of negligence by a specific, functional and practical medico-legal legislation.

II. The periodic review of the effects of such legislation with a view to propose necessary future amendments as demanded by local needs and along with the evolution of scientific and medical advances.

III. The issuing of an updated national code of medical ethics, in conjunction with the Malta Medical Council for all registered doctors.

IV. A sub-committee to deal with and advise on specific medico-legal/ethical queries.

V. The gathering and publication of all suitable medico-legal related statistics on an annual basis along the lines of the UK NHS Litigation Authority. This information is also to be available to all official requests, e.g., for research. The MILM would also liaise with other data-collecting bodies and may contribute to such publications as the annual Natural Obstetric Information System (NOIS) report.

VI. The liaison with similar bodies at EU and international level and the participation in EU and international fora, seminars and meetings of a medico-legal nature.

VII. The publication of an international peer reviewed journal.

VIII. The establishment of related academic courses which can be co-ordinated with forensic teaching at the University of Malta and the Police Academy. Among such courses one would also include the establishment of a diploma or degree course for Court experts including follow-up courses and assessments.

IX. The direction to the local established specialty Colleges to publish an annually updated register of suitably senior and experienced members of consultant status who are willing to act as Court experts for their specialty. This register will then be vetted by the Malta Medical Council and published as an appendix to its annual register. This register will be used by the Court at its discretion in appointing Court witnesses. The register will also be available to all who require an ex parte obstetric expert.

X. The encouragement to the local specialty Colleges to plan and publish regular guidelines for their members as well as a specialty-oriented code of ethics.

XI. The organisation of inter-disciplinary conferences/workshops in conjunction with the Chamber of Advocates, Medical Association of Malta, University of Malta and the local specialty colleges.

XII. The organisation of fostering of joint academia in subject of medico-legal specialisation in tandem with the University of Malta with an ultimate scope of the establishment of a University Department of Medico-Legal Studies.

XII The creation of an appropriate think tank evaluating the various known systems of Alternative Dispute Resolution (ADR) that are in existence overseas and may apply with benefit to the Maltese Islands. In section 4.14 the concept of a Pre-Trial Hearing with regard to Court cerebral palsy litigation is one example of ADR. The field is a most extensive one and although not evaluated in this thesis, is one of crucial importance especially in the throes of a proposed local general medico-legal 'overhaul'.

XII The liaison of the MIMLS with the MOS and responsible bodies such as the speciality Colleges for creating a long term working relationship which includes monitoring and assessing medical practice. Improved clinical practiced equates with diminished legal vulnerability. A similar relationship is crucial with the Chamber of Advocates.

The creation of the National Institute of Legal Medicine and Forensic Sciences in 2001 in Portugal can provide much motivation for the establishment of a MIMLS. The *Instituto Nacional de Medicina Legal*[504] as a government institution under the

Portuguese Ministry of Justice with general branches in Coimbra, Lisbon and Porto has yielded most impressive results since its establishment. It is also linked with the Legal Medicine Departments at the University of Coimbra, University of Lisbon, and the University of Porto. Its centralisation of medico-legal statistics has revolutionised this

[504] Official site: http://www.inmlcf.mj.pt/.

aspect in a country where no reliable statistics existed prior to 2007.[505] Furthermore, it has collected many aspects of related services under one umbrella, including forensic studies and police laboratory work.

The possibility of the MIMLS embracing the various aspects of Legal Medicine in addition to those of Medical Law would be a long term second tier of objectives. Furthermore such objectives will face great difficulties such as those generated by people fighting for their turf, which is fully understandable. Whether such a second tier of achievement comes to pass or is even desired, it would be beneficial for a strong liaison to be nurtured with the Police Academy and its facilities as regards forensic science including toxicology.

The Institute as envisaged would be domiciled in Malta and be government funded although it should be allowed to generate funding where appropriate from its courses for doctors and lawyers interesting in qualifying as Court experts and their diploma examinations. Its liaison with such entities as the MCOG and the other medical specialty colleges will generate a much-needed boost for further practical evolution of the MCOG and other medical specialty Colleges. This stimulation of the MCOG, may bring a breath of fresh air to the motivation and raison d'être to a College which has much untapped potential.

It is more than likely that the first months, possibly more, will comprise a comprehensive assimilation of the objectives, a realisation of the potential and the

[505] See note 504.

building of functional bridges of the Institute with the bodies that will constitute future stakeholders in all ventures referred to and others. The essentially bi-partisan nature of Maltese politics cannot be left out of the planning of the executive power of the Institute and this should be a matter for parliament rather than cabinet. If the Institute is allowed to become a political toy, then objectives might be reached but political contention would seriously jeopardise those objectives. The government of the day must realise that although it holds the purse strings, this institution must run its own affairs, along its proposed motto of 'Veritas Praevalebit' or 'Truth will Prevail'. No positions of trust should play any role in the appointment of staff at any level and strict meritocracy must apply to all promotions.

The first objective of the Institute which is the immediate centralisation and publication of all pertinent statistics pari passu with the groundwork for the Lex Medica are likely to prove an excellent exercise and undeclared test of the Institute. The task will enable MIMLS to establish functional dialogues with the Colleges, the Medical Council, Medical and Nursing Unions as well as the Government itself, with specific initial reference to any Commission the latter appoints to study the proposed Lex Medica. In this crucial initial phase, the MIMLS will learn its boundaries but also increasingly learn to flex its muscles, with much diplomacy and resilience but also with determination of achieving its allotted purposes.

Once the involved machinations have taken off, the other objectives can come into action. It is clear that objectives be commenced in practice with a clear and realistic final view of the difficulties to be faced. Toes will be inevitably thread upon, but this must be minimal and only when necessary. As an example, the difficult question of

rectifying the current Court expert situation should not be commenced by proposing any laws as to who can and cannot act as expert, for the choice is extremely limited as it stands. It can commence with the establishment of serious courses with extensive curricula, open to the suitably medically/legally qualified and leading to a European recognised diploma. Again, this will entail the Institute attuning itself to the ideal curricula after reviewing the European scene. Once such a diploma has been locally awarded, standards will automatically rise and the chaff will be separated from the wheat in a much easier fashion. The requisite of such a diploma would soon speak for itself regarding the need for future legislation. Pari-passu with this work, the establishment of suggested obstetricians (or other specialists) in an obstetric register must commence and this will not be achieved overnight. The first hurdle is the motivation of the MCOG and other local specialty Colleges to realise their potential and appoint their own body which will liaise with MIMLS. The criteria suggested by this thesis may be accepted as they stand or be modified in discussions between College and MIMLS. The College executives are essentially all working clinicians and must rise to their new tasks at some self-sacrifice, but like MIMLS, their new responsibilities will in turn open new vision, new objectives and new self-motivation.

5.3 The Proposed Lex Medica

In keeping with the nature of this thesis, the legal orientation of the Lex Medica as described here is related to the specialisation of obstetrics. However, the intention is for a finalised version which accommodates all specialties, hence the thesis ambitiously refers to a Lex Medica and not a Lex Obstetrica. Furthermore, laws relating to Artificial Reproductive Technology (ART) must also be included in the Lex Medica. As regards

the rights and responsibilities of the patients good work has already been achieved by the local Patient's Charter published in 2016 and which may be easily absorbed in the Lex Medica.

This thesis is under no illusion as to the magnitude of the task proposed, to the difficulties facing it as well as the vision and persistence required if proposal is to become enactment. The task requires much planning and its driving and co-ordinating force should be the MIMLS, which is most likely to have its resources fully stretched in the process. Furthermore, a government appointed Commission working with MIMLS should consider the enactment of the Lex Medica in phases of priority and achievability. Most of the sixteen articles proposed here for example may constitute the first phase of enactment. Laws pertaining to ART no doubt will, yet again, stir the usual broiling religio-socio-political pot and would ideally be finalised in a second phase after the consideration and input of all stakeholders' views, which will be no easy task, nor one of short duration. A successful enactment of the first phase would encourage the completion of a second phase.

Legislation, which is divided in primary legislation and subsidiary legislation, should be the main source for the Lex Medica. This is because statutes provide for legal certainty when the provisions contained therein are written in clear and unambiguous language and set out the required detail to the reader to comprehend better what is the wish of Parliament. This notwithstanding, case law will inevitably have to be referred to because there will always be instances where the general principles or the detailed provisions set out in the Lex Medica would not provide a crystal clear solution to a medico-legal dispute, as where changes in society, technology, knowledge, etc. would

require a revised interpretation of the law or where the law cannot be easily applied to the facts of the case such that judicial interpretation is inevitably needed. Naturally, legislation remains the primary source and case law the secondary source. Should there be a conflict between both sources, it is the former that should prevail over the latter.

The following is an index of the sixteen articles of the proposed Lex Medica:

Article I: Who can practise obstetrics and gynaecology

Article II: The use of the titles of consultant and specialist

Article III: On private practice and government employment

Article IV: The Rights and Obligations of Treating

Article V: On respecting ethical principles

Article VI: On guarding the life and well-being of the unborn

Article VII: Privacy and Confidentiality

Article VIII: Medical Records

Article IX: Disclosure

Article X: The Informed consent

Article XI: Female Genital Mutilation

Article XII: The Patient's Rights

Article XIII: Prenatal anomaly and genetic testing

Article XIV: Malpractice and medical negligence

Article XV: Statute of limitations

Article XVI: The Court appointed obstetric expert

5.3.1 Article I: On who can practise obstetrics and gynaecology

To practice obstetrics and gynaecology in the Maltese Islands one must be:

i. Registered with the Medical Council of Malta.

ii. Registered as an obstetrician and gynaecologist in the Malta Medical Council's register of specialists.

5.3.2 Article II: The use of the titles of consultant and specialist

(a) A consultant obstetrician and gynaecologist is one who has been appointed to this position in the government service by the Maltese Public Services Commission, or who has been employed in a similar position overseas. Such a title may not be used by any other, nor the impression given or encouraged that one is of such a grade, be this while in government service or in private practice. Consultants who are retired from government service retain the title.

(b) The title 'specialist obstetrician and gynaecologist' refers to a doctor who is on the specialist register of the Malta Medical Council. He may use the title 'specialist', but not 'consultant', unless he is one.

5.3.3 Article III: On private practice and hospital employment

(a) Right to Practice

Anyone, whose name appears in the Malta Medical Council's Register of obstetricians and gynaecologists has a right to practice his speciality which includes private practice. Such private practice may be lawfully excluded by other contracts, such as certain Government categories of employment.

(b) On Private Practice and Government Employment

A doctor, who is in Government employment and can also legally practice privately, must not abuse his Government employment position. He may continue the care of such private patients *under consultant supervision* within Mater Dei Hospital or other

Government clinics. The legal responsibility of care within MDH is the consultant's alone and hence no disclosure of management may be discussed privately without the consultant's consent. Furthermore, such patients are not to be treated differently to any others within MDH.

5.3.4 Article IV: The Rights and Obligations of Treating

(a) Emergency Treatment

The obstetrician is obliged to practice his speciality on anyone who requires it as an emergency where failure to do so, endangers life.

(b) Right of refusal

The obstetrician has a right to refuse treatment to any patient under circumstances not of an urgent or emergency nature. He also has a right to terminate an ongoing long-term medical relationship for a valid reason, as long as the:

i. Patient or her legal representative is informed.

ii. Patient has the ability to seek another obstetrician.

iii. The original obstetrician respects his duty in facilitating such a transfer.

(c) Safeguarding the best Interests of the Patient

The obstetrician is under no legal or ethical obligation to give or participate in any treatment he genuinely considers not to be in the best interest of his patient or against his better judgement or his moral or religious convictions.

5.3.5 Article V: On respecting ethical principles

The obstetrician has an obligation to respect the rules of ethics, always and in all circumstances, and where necessary, even beyond stated principles. The law draws particular attention to a number of these principles, but does not exclude others, including those which are intrinsic to the obstetrician's duty.

(i) The obstetrician must act in the best interest of the patient and her unborn child, respecting both and safeguarding both. In the rare instances, where such interests may not be aligned, the law of the land must be respected and where further guidance is required the Court must issue such guidance.

(ii) The obstetrician must never harm, allow or cause unnecessary suffering to the patient and her unborn child.

(iii) The obstetrician must act justly and equitably with his patients. The obstetrician has a right to just payment when treating a patient privately. When employed in the public sector, such payment is limited to his government issued salary and any direct payment from patients in those circumstances shall be deemed unlawful.

(iv) The obstetrician is not to entertain conflicts of interest when such interests directly or indirectly lead to an infringement of the patient's care and well-being. Where such potential conflicts of interest are permissible by law, e.g., owning a hospital or having shares in a laboratory, such conflicts must be clearly disclosed to the patient who may then decide how to proceed knowing the facts as they stand.

(v) The obstetrician must respect the autonomy of his patient in all of its manifestations, unless this transgresses the law of the land.

(vi) The obstetrician must always respect his colleagues at all levels and at all times, including situations where the patient is exposed to two or more differing clinical opinions.

(vii) The obstetrician must always rise above the prejudices of race, colour and religion.

Legal action for infringement of ethical principles is not prejudicial to further disciplinary action by the Malta Medical Council or other disciplinary peer constituted bodies to which the obstetrician belongs.

5.3.6 Article VI: On guarding the life and well-being of the unborn

The obstetrician, in accordance with the spirit of medicine and obstetrics in particular, shall serve as guardian of patient and her unborn life in all circumstances in accordance with his ability and knowledge of science. This precludes any action which damages or

destroys unborn life from the moment of conception along the principles contained in articles 241 – 244A of the Criminal Code. The spirit of that law also involves the obstetric responsibility of guarding life which may be harmed by the obstetrician's passive action or omission when a patient's action or refusal of necessary medical treatment shall pose such a threat.

5.3.7 Article VII: Privacy and Confidentiality

Privacy defines the right of an individual to maintain inherently special or sensitive information to himself or share with others at his own will. Confidentiality refers to the sharing of private information with another or with other individuals, usually for medical or legal reasons, on the premise that such an individual or individuals is/are professionally bound to maintain secret this information.

Thus, the obstetrician is bound, both ethically and legally, to guard such confidential information as may be revealed to him or as becomes known to him through the patient-doctor relationship. While the law here re-affirms the legal binding nature of such confidentiality, it draws attention to the existence of other laws of Malta which legally define this confidentiality, and which laws are in no way prejudiced by the Lex Medica. These laws are:

i. The Medical and Kindred Professions Ordinance, Chapter 31.

ii. The Health Care Professions Act Chapter 464.

iii. The Department of Health (Constitution) Ordinance. Chapter 94.

iv. Data Protection Act in Chapter 586 of the Laws of Malta.

v. The Public Health Act, Chapter 465.

vi. Mental Health Act, Chapter 525.

vii. The Criminal Code, Chapter 9.

There are rare circumstances when such confidentiality may be broken without incursion into neither ethical principles nor the law. These include:

i. The patient herself directly requests the physician to share the information with another party (e.g., a family member or for insurance purposes).

ii. In the case of a serious sexually transmissible disease, after exhorting the patient to warn any third parties of such a disease, the obstetrician may take steps himself to disclose. Such action precludes the direct communication of the obstetrician with third parties but permits the obstetrician to alert such health officers as are in charge of the contact-tracing facilities, normally specifically employed in such circumstances to establish contact with third parties who may have been exposed and are therefore at risk. No further divulging of information is lawful.

iii. The patient poses a danger to others (e.g., impaired driver, homicidal tendencies). Here the obstetrician may notify the police.

iv. The patient poses a threat to herself and/or to her unborn child.

v. The patient has admitted to abuse of the elderly or to child abuse or maltreatment.

vi. The patient has suffered penetrating trauma from assault (e.g., a gunshot wound, stab wound).

vii. The disclosure is permitted or has been approved under a statutory process that supervenes the law of confidentiality.

Relatives should never be party to any patient information, irrespective of their good intentions unless specifically permitted by the patient. The obstetrician must never discuss a patient, publicly or privately, unless as part of the medical care and then with the utmost discretion. The divulging of information at Court, should be most carefully limited to the information requested and no further reference may be lawfully made to this information outside the specific Court session.

5.3.8 Article VIII: Medical Records

(a) Confidentiality of Medical Records

The laws of confidentiality extend to the patient's records which include all handwritten, typed and electronically stored information inclusive of clinical dossiers, photographs, videos, and other visual records, investigations and their results, and letters and e-mails pertaining to any aspect of the patient.

(b) The Handling and Storage of Medical Records

Medical records must be handled only by personnel directly involved with the care of the patient or the care, maintenance and storage of the file or the medical data itself. When stored in the central records section, medical records shall not be accessible to anyone who is not authorised, but still be easily retrievably and accessible when lawfully requested.

(c) Further Direction concerning Medical Records

Medical records:

i. Must be stored in a place which protects their confidentiality as well as their safekeeping. Such a location is to ensure security of access as well as satisfactory control of ambient conditions to prevent physical deterioration of the records. Such a storage and processing is to be in accordance with article 257 of the Criminal Code as well as the Data Protection Act in Chapter 586 of the Laws of Malta. As soon as possible a system of CTG filming using micro-fish techniques and/or electronic storage (preferable) should be instituted.

ii. May not be removed out of Mater Dei Hospital or other government hospitals unless such transfer is official, trackable and related to the care of the patient.

iii. Must be fully trackable if accessed by any person within or outside the central records office.

iv. Shall be fully accessible to the patient along with all information related to her care as long as such requests are directed along any rules of protocol set by the hospital authorities.

v. Cannot be used in part or in whole for teaching purposes, research or publications if such teaching identifies the patient. This includes the use of photographs, videos and any visual representation of the patient. If material from the records is of a non-identifiable nature and is cleared by the hospital authorities, it may be so used. Any use which identifies the patient requires written consent from the patient.

vi. Must conform to specifications which render them as useful legal evidence, if so required. Thus, hand-written notes must be in indelible ink, clearly legible, unambiguous, concise, accurate and must be signed and accurately timed and dated. Corrections must be initialled and allow legibility of the corrected parts. They must also be able to be photocopied and ideally are written in black.

vii. Must be used and filled in as per hospital usage and in respect of established practice. Thus, operation notes must be filled in where indicated and discharge

letters issued to family physicians as directed, with a copy kept in the patient's file, etc.

viii. Must not be in any way tampered with, have pages removed, replaced, torn or defaced. After use, the notes, unmodified in any way, must be returned to their original location and in their original condition.

ix. Must be stored separately in a locked and secured place within the legal office if any process of complaint or litigation has commenced. Access then becomes limited to the administrator, the legal office and any legal parties therein involved in the process of complaint or litigation. In the case of serious litigation, including that at Court level, the clinical file shall be photocopied entirely, and this photocopy stored separately and safely in the legal office. CTG tracings, be they antenatal or intra-partum may not be scanned in separate parts but in toto. The copy thus obtained shall be certified as a true copy of the original. Separate electronic storage is permissible if available.

x. Must contain all information pertaining to management, discussions, diagnosis, treatment, complications, etc. Disclosures pertaining to any aspect of management, including diagnosis, interventions, modes of delivery, including specific points of discussion e.g., pre-operatively, should be recorded clearly, completely and as concisely as possible. All correspondence and other forms of communication such as by e-mail, text message, etc., yielding any information about the patient must be preserved and stored within the patient's records.

xi. Must contain specific operation sheets for any surgical interventions performed. The operation sheet must include the name, address, age and ID number of the patient (usually available on special patient stickers), date and time of operation, and in the case of a caesarean section, the actual time of delivery of the infant, the names of the surgeon/assistants/anaesthetist/ theatre sister/indication for the surgery/ a concise account of the surgery, and any unusual circumstances, e.g., complications and any corrective repairs and the final state of the patient. The sheet must be signed.

xii. Must be compliant with race relations laws, disability legislation and must be free of all prejudice and discrimination.

xiii. Must be updated accurately and consistently as soon as possible once new information becomes available.

xiv. While the physical file of the patient, inclusive of all childbirth related records, shall be maintained and protected indefinitely, intra-partum CTG tracings must be maintained for a minimum of 25 years in view of the possibility of lateness of commencement of legal proceedings particularly in cases of brain damage, such as cerebral palsy. This is irrespective of the Statute of Limitations, which statute may be enforced or waived at the Court's discretion.

xv. Must contain a copy of the discharge letter to the family physician. Such letters must be given to the patient on discharge or in exceptional circumstances be

posted within 48 hours of discharge. In cases where patients need continued care at home, such discharge letters must be given to the patient at the time of

xvi. discharge without exception and in cases of a particularly serious nature, the family physician should be contacted directly and a note referring to this must be entered into the patient's record along with a note as to the management requested from the family physician.

xvii. Must be stored safely and protected from casual access while in the ward. Such access must be limited to medical, nursing and midwifery staff as part of their duty of care towards the patient.

xviii. May not be released or accessed by any authority however high, but below that of the Court. This includes requests by other Government departments and any agency or authority, including any such which favours the patient herself. Such release may only be acceded to, once a signed clearance has been obtained from the patient herself.

xix. Are always and everywhere legally safeguarded by the confidentiality and privacy laws.

xx. Are used solely with the aim of providing information for improving healthcare. Medical notes enjoy the extension of the principles of beneficence and non-maleficence and thus can never be lawfully accessed and used to effect harm.

xxi. Conform to an established standard of writing or electronic recording.

xxii. Are to be governed by indices which are regularly monitored. These must take into consideration the European Personal confidentiality laws and/or its extension.

5.3.9 Article IX: Disclosure

(a) Duty of Disclosure

The Obstetrician has a duty to:

I. Disclose all known facts to the patient about her condition, including prognosis.

II. Disclose in full, all relevant information about any proposed treatment so as to enable the patient to give a truly valid and informed consent. This applies to all treatment especially major treatment or any intervention involving surgery.

Such disclosure must include the following information:

I. The diagnosis and natural course of the disease without any treatment and how it is likely to be influenced by the proposed management.

II. Nature of the proposed medical or surgical treatment

III. Benefits.

IV. Known complications.

V. Alternative treatments available, their advantages and risks.

VI. Provisions of information to the patient about the possibility of intraoperative findings that may require more intervention than originally planned.

VII. The physician is obliged to brief the patient about the measures necessary for assuring treatment success, e.g., the stipulated period of rest after surgery, the avoidance of certain activities such as heavy lifting or driving in the early weeks after a caesarean section.

VIII. In the case of surgical interventions, disclosure must contain:

i. Information on the reason necessitating the proposed surgery.

ii. The likely success of the operation.

iii. A brief description of what will be done in layman's language.

iv. Any alternatives involving possible medical, instead of surgical, treatment and any other alternative operations, their advantages and disadvantages over the proposed intervention.

v. Possible risks and complications including all such risks and complications, however rare, that may impinge on any aspect of the patient's life and health, work and social life.

vi. The presence or absence of pain during and after the operation, its control and whether general anaesthesia or other forms of anaesthesia will be used.

vii. Any instructions involving specific pre-operative and/or post-operative care such as requisite period of abstaining from work, etc.

viii. Respect for the patient's right to accept or refuse information.

The obstetrician must lay all available facts in front of the patient and ensure her understanding by using slow and simple language, aided where necessary by pictorial means. Where the nature of the choice is not urgent, such discussions may need to progress along a period of time and in accordance with the patient's wishes and intellect and if the patient so chooses she may obtain further advice any person/persons she chooses.

Although the patient is normally at complete liberty to accept or refute treatment, this does not include situations where a pregnant patient may affect the health and life of her unborn child through such refusal. In cases of refusal of such treatment, the obstetrician must explain the significance of the legal status in the Maltese Islands.

Further persistent refusal of treatment after all explanations and reasonable argumentation, may leave no option but to resort to Court permission for the treatment or surgical intervention to proceed.

(b) Withholding disclosure

Disclosure of treatment may be withheld from the patient only under the following conditions:

- The patient herself, requests that such information be withheld from her, even when warned that such a gesture may be seriously disadvantageous to her own interests.

- As a therapeutic privilege of the obstetrician, when, based on reasonable reasons, the obstetrician feels that a strong possibility exists that full disclosure may cause severe psychological harm to the patient.

The patient's family does not have a right to ask for withholding of disclosure of information from the patient by the obstetrician. However, they may put forward information to the obstetrician, which upon his professional evaluation, may provide grounds for considering therapeutic privilege.

(c) Disclosure of Error

Regardless of the outcome of treatment, an obstetrician must inform the patient immediately if an error has occurred and also disclose the nature of that error. He is obliged to:

I. Clearly admit that an error has occurred.

II. State the course of events leading to and during the error.

III. Explain the immediate and long-term consequences of the error.

IV. Describe corrective steps and whether already commenced/completed or yet to be implemented.

V. Express personal regret and apology.

VI. Allow ample time for questions and continued dialogue as is necessary.

If an obstetrician is aware of an error committed by a colleague, he should discreetly attract his attention but if this is ignored, in view of the patient's well-being, the matter should be reported to the hospital authorities.

a) Disclosure of Research

The obstetrician must fully explain the scope of the research and any possible benefits or risks undertaken by the patient's participation, if consent is granted. The patient should be under no duress to participate in such trials and need not specify a reason for refusing. Furthermore, she shall not be patronised or in any way coerced into such acceptance.

5.3.10 Article X: The Informed Consent

(a) It is the obstetrician's duty to elicit an informed and valid consent for any treatment proposed, by ensuring that such an informed consent comprises the three essential and indispensable qualities for validity:

I. Disclosure. It is the obstetrician's duty to make all necessary information available to the patient for her to make a wise and *informed choice.*

II. Capacity. The patient must have the mental capacity as legally recognised to be able to assimilate the disclosed information and subsequently make a decision of acceptance or refusal of the treatment.

III. Freedom of will: The choice must be free from coercion, or fear of coercion or any more subtle method of influencing the patient.

Informed consent for major interventions should allow enough time after disclosure for the patient to reflect, gather more information and ask further questions, when the indication is not one of an urgent nature.

The final expression of consent must truly symbolise a mature and intelligent decision which has weighed all the information disclosed. The genuine consent is never contrived to seek legal protection for the obstetrician.

Informed consent must be expressed in written form in situations involving:

i. All surgical interventions except the most simple and superficial ones.

ii. All interventions involving general anaesthesia or regional analgesia, e.g., spinal, epidural.

iii. Cases of infertility treatment.

iv. Any case involving complex management.

v. Any case involving higher risk than normally expected, e.g. an episiotomy repair diagnosed as third or fourth degree.

vi. Cases where the proposed management may have significant consequences for the patient's employment, social or personal life.

vii. Cases where the treatment is part of a research programme.

There are uncommon situations where a necessary medical or surgical intervention may proceed without such a valid consent, and even against it, in some circumstances. These include:

I. Where the Courts have ruled that for reasons considered valid the maternal refusal of treatment puts at risk the unborn child's life or even the maternal life itself with a subsequent inevitable risk to the unborn child's life.

II. Life-threatening emergencies, e.g., an unconscious pregnant patient who is bleeding profusely from an abruptio placentae.

III. A patient lacking decision-making capacity, but whose guardian has authorized the intervention, e.g., a fourteen -year old girl requiring a caesarean section.

IV. A patient lacking both decision-making capacity and a guardian's opinion when the treatment is in the best interest of the patient or her unborn child.

V. If the patient's decision to refuse treatment poses a safety risk to her and/or her unborn child's life or well-being as well as to the life and well-being of other people, e.g., in the event of severe psychosis, patient with active TB.

Excepting these specific situations, if an obstetrician administers any form of treatment without the patient's oral or written consent, he may be open to the charge of assault

and/or battery. If doubt exists in the aforementioned circumstances, the hospital's legal office should offer guidance as to whether a Court order would be advisable.

(b) Informed consent in minors

In patients, below the age of 16 years, the consent of parents or a legal guardian should precede medical treatment but this law admits to a number of exceptions:

i. The patient who is mature enough to understand her situation and cannot be persuaded to inform her parents. This has particular application to matters involving pregnancy care. However, this does not apply to a child with any level of maturity who is below 12 years of age.

ii. The treatment is required urgently and is lifesaving.

iii. The minor is seeking care involving sexual practice or pregnancy or the treatment of sexually transmissible diseases.

iv. If the parents themselves are minors, grandparents should be first substituted before the law is superseded.

v. If parents adamantly refuse life-saving treatment for whatever reason including religious ones. If the treatment is urgently needed, treatment may be administered. If it is non-urgent, then treatment should follow a Court order.

5.3.11 Article XI: Female Genital Mutilation

(a) Such surgery is illegal, unless it is a surgical operation on a girl rendered necessary:

I. For her physical or mental health.

II. Fur purposes connected with childbirth.

(b) It is illegal to arrange or assist in arranging for a resident of Malta to be taken overseas for the purpose of carrying out such surgery.

(c) It is mandatory to report to the police any case of such surgery, if confirmed, in a girl under 18 years. The detection of such mutilation must be entered into the patient's medical records. If detected antenatally, reparative steps to avoid childbirth complications shall be taken, wherever medically and surgically possible. If the patient is of mature age and it is her free will that such surgery is not undertaken, then this shall be respected as long as a caesarean section is a safe option. If the girl is not of the age of consent, the parents or the legal guardian's wish is to be considered, but always within the patient's best interests. If discordance exists with regard to the obstetric opinion, a Court order may be wisely resorted to.

(d) It is illegal to re-infibulate or in any way restore the effects of the original mutilation, after childbirth.

(e) The management of such a case, shall be conducted with prudence, respect, confidentiality and without manifestations of racial or religious prejudice.

5.3.12 Article XII: The Patient's Rights and Responsibilities

This section can conveniently absorb the Patient's Charter as published by the Maltese Secretariat for health in 2016 after suitably editing those parts which may be repeated in the Lex Medica.

5.3.13 Article XIII: Prenatal anomaly and genetic testing

Pre-natal investigations aimed at detecting fetal anomalies must be intrinsically guarded in protecting all life, including that shown to be affected by any detectable defects. The law takes cognizance that such testing in the form of ultra-sound anomaly scanning, is already established. Neither such anomaly testing, nor any future introduction of invasive or non-invasive prenatal investigations can be used to provide information with a scope to aborting any malformed fetus. Reference is here made to Articles 241-241A of the Criminal Code. The law protecting life from conception is operative and enforceable in Malta. In the presence of fetal anomalies, counselling and similar assistance shall be made available to the parents as to how such life may be embraced within the spirit and care of family life. Any assistance, direction, direct or indirect help in procuring an abortion of such life, shall be considered as an infringement of the aforementioned Articles, in the Criminal Code.

5.3.14 Article XIV: Malpractice and medical negligence

(a) Obstetric negligence may be defined as the commission or omission of an act, which falls below the established standard of care. By itself, such negligence may not be a cause for liability action, although it may still draw censure from disciplinary bodies such as that of the Malta Medical Council Once such negligence is causally proven to lead to any resultant harm of a patient, liability due to malpractice is said to exist.

The law here does not require the standard of an extraordinarily cautious obstetrician, nor of an extra-ordinarily gifted one but refers to one of ordinary capability and reasonable prudence. Thus, such negligence as discussed here would not be committed by a reasonably prudent obstetrician using reasonably prudent care in circumstances similar to the ones at hand

Failure to reach the established standard of care constitutes negligence. Breach of the standard of care leading to negligence which results in harm to the patient constitutes malpractice. A Court malpractice claim requires the patient to present evidence of the obstetrician's practice breaching the standard of care owed by the obstetrician to the patient with the result that this breach leads to the damage alleged by the patient. Such a claim requires the following elements:

I. The establishment of a duty of care by the obstetrician to the patient.

II. The establishment of the obstetrician's breach of the standard of care owed to the patient.

III. The causal link between the obstetrician's breach and the presenting damage.

IV. The quantification of the presenting damage.

Malpractice may involve the breach of the duty of care pertaining to:

I. Disclosure.

II. Diagnosis.

III. Treatment.

A case of malpractice may be subject to more than one claim in Court. Thus, a Court claim may cite deficient disclosure *and* negligent treatment in the form of negligent surgery.

(b) An action in a Civil Court is not prejudicial to disciplinary action by the Malta Medical Council and by any other bodies to which the obstetrician may appertain, e.g., the Malta College of Obstetricians and Gynaecologists. Moreover, the establishment of negligence in a Court of civil jurisdiction, where causation is not linked to the claimed damage, may still, if reported, be grounds for disciplinary action by the Malta Medical Council and other bodies.

Malpractice must be distinguished from maloccurrence which refers to an undesirable outcome not related to the quality of care provided. Such events may have even been

discussed pre-operatively and may be completely unpredictable, unavoidable and simply reflect the inherent uncertainty in medicine as in all other aspects of life.

(c) Establishing an obstetric Standard of Care in the Maltese Court

To guide obstetricians, legal practitioners, and assist the Court in its deliberations, in cases of alleged negligence involving claims of absent or defective disclosure, the Prudent Patient Principle holds, whereas in those cases concerning alleged negligence in diagnosis and treatment, the Bolam principle applies.

The Prudent Patient Principle sets the standard of practice of evaluation of matters related to disclosure and refers to the expectations of an ordinarily prudent pregnant patient who expects to be informed about all matters which may seriously affect her life and well-being as well as her child's life and well-being. These matters include all potential complications which, if they come to pass, irrespective of rarity of occurrence and despite procedures and interventions performed secundum artem, may result in detrimental changes affecting life, health, occupation and social inter-action of the patient and the life and health of her as yet unborn child.

The Bolam principle sets the standard of care for practice of evaluation of matters related to diagnosis and treatment. The principle states that

If the obstetrician's action, be it one of omission or commission, has reached the standard of a responsible body of obstetric opinion, he is not guilty of negligence, even if a body of opinion holds a contrary view.

However, this principle holds two caveats and is further qualified thus:

I. That the opinion of the responsible body makes logical sense according to the *established* principles of science, at the time. By logical sense, the law understands a wide meaning which when applied to scientific matters is based on the principles of evidence-based medicine.

II. That this opinion respects the other principles at law as stated here, such as the basic principles of patient autonomy.

(a) Official Guidelines

Official guidelines such as those issued by a recognised college of obstetricians and gynaecologists, may count as the standard of a responsible body of obstetric opinion. They are to be considered as one truth based on scientific evidence, but not necessarily exclusive of other views, which, shall be considered viable, if *scientifically backed.* Official guidelines are not the law, and hence their disregard is not unlawful and does not *per se* constitute negligence if the obstetrician has good basis for his action.

However, an obstetrician would do well to heed such guidelines, normally based on the latest scientific evidence, unless he has equally valid reasons not to. Such guidelines may constitute part of the evidence, on which is set the *standard of a responsible body of obstetric opinion,* as referred to in the Bolam Principle.

The Law reminds that the practice of obstetrics, like medicine and surgery in general, comprises both art and science. The practice of obstetrics may therefore, on occasion demand the obstetrician's discretion as to what is best for the patient. It therefore follows that there are occasions when an obstetrician may, for good reason, not follow official guidelines of clinical practice. This does not, in any way, diminish the general and normal importance of guidelines, which behoves all to follow, unless one has serious justification not to. One reminds here, that it is the Court's discretion and deliberation which effects the final judgement on what constitutes medical malpractice.

5.3.15 Article XV: Statute of limitations

The statute of limitations shall be set at three years for cases alleging damage resulting from obstetric intervention, with exceptions as judged at the Court's discretion. The statute of limitations for injuries to children only starts at the eighteenth birthday. In the case of brain damage such as cerebral palsy, the statute of limitations shall begin only when the victim has been medically acknowledged as regaining cognitive ability, with an upper limit of 20 years from the time of the alleged infliction of damage at birth. All and any statute of limitations may be waived at the Court's discretion.

5.3.16 Article XVI: The Court appointed obstetric expert

The obstetrician appointed by the Court to assist in cases pertaining to his specialty, is known as a Court appointed expert. An obstetrician appointed by a plaintiff or defendant to advise and guide him in Court proceedings is known as an ex parte obstetric witness. When an ex parte obstetric expert gives witness in Court, the

weighting of his evidence is equivalent to any other testimony. It has none of the weighting of the Court appointed expert. However, one reminds here, that the objective of the evidence given by any obstetrician, even an ex-parte one, is to assist the Court in uncovering the truth, irrespective of who finally pays the expert.

The law as expounded in the rest of Article XVI, applies to the Court appointed expert:

(a) Such an expert is to be ideally chosen from an official register in the form of an appendix to the annual register published by the Malta Medical Council. This register must be drawn up by the Malta College of Obstetricians and Gynaecologists and is to include those obstetricians who are both interested in acting as Court experts and who fulfil the following criteria:

i. Have his name on the Medical Register of the Malta Medical Council and the obstetric specialist register.

ii. Be of consultant status, whether active or retired.

iii. Be a certified specialist as required by law with at least twelve years post-certification experience.

iv. Be of good standing and have a clean police conduct.

v. Be free of any pending investigations, including criminal, civil or disciplinary proceedings such as by the Malta Medical Council.

The College shall forward this register to the Malta Medical Council which after its due scrutiny shall include the list, in combination with lists from other medical and surgical specialties as an appendix of the published annual register published by the same Council.

(b) The Court, at its discretion, in agreement with all parties involved, shall choose an obstetrician from the list published by the Malta Medical Council. The use of the register shall be at the discretion of the Court, which is encouraged to use such a register, unless a valid reason exists not to. Such a valid reason may for example involve required expertise in a branch of obstetrics best served by an obstetrician who although fulfilling all necessary criteria may have recently been registered by the Malta Medical Council and his name does not as yet appear on the list published by the said Council. The final decision will lie with the Court's discretion and the agreement of the parties involved.

(c) The expert obstetrician so chosen is to be officially notified by registered letter or by official hand delivery of his appointment. He must also be supplied with enough information to ensure that the subject matter lies full well within his competence. The identity of the plaintiff and defendant shall also be made clear. He must also be advised to read all available guidelines, which must be included in the letter of appointment to ensure his ability to their adherence. Based on this information, the obstetrician may accept the offer of the appointment:

I. If he considers the subject matter of the case falls within his knowledge and expertise.

II. If neither plaintiff nor defendant are first, second or third-degree blood relatives nor intimate friends. Acquaintances and work colleagues need not be considered in this category, unless so wished by the invited expert and approved by the Court.

III. If he signs and upholds the stipulated guidelines

(d) The guidelines to the Court appointed expert are the following:

The Court expert must:

I. Maintain a respectful and professional gravitas as reflected in behaviour and clothing.

II. Constantly remember that his sole duty is owed to the Court.

III. Possess the necessary knowledge and experience in the field of obstetrics pertaining to the case on which he will assist.

IV. Must comply with any rules, regulations and professional code of ethics which are available and as they be added or amended from time to time.

V. In his report he must express his opinions as based on the official current teachings and not on his preference or prejudice and shall desist from expressing opinions, outside his knowledge and outside official teaching on the subject.

VI. Be completely objective and impartial in his evaluation, conclusions and report.

VII. Realise that he is neither a mediator between the two parties nor does his role approximate that of the Court's prerogative and his duty must never infringe on the Court's own rights and duties.

VIII. Must direct and confine his opinion to the sole aspect of the case, relating to his knowledge and expertise, as directed by the Court.

IX. Shall indicate, without hesitation or procrastination, any aspects of the obstetric nature of the case which are outside his expertise as soon as this becomes known to him.

X. Shall consider and evaluate all facts made available to him. Aspects or evidence, which he knows should exist but are not available such as for example specific parts of the clinical information or the clinical notes, should be reported to the Court immediately.

XI. Shall refrain from divulging or discussing the case outside the Court, be it with plaintiff, defendant, their legal representations or any other third party.

XII. Shall not communicate or accept communication outside official Court sessions with either plaintiff or defendant or any of their representatives. Attempts at such communication or in any way to influence his report by any of the parties must be referred to the Court.

XIII. Shall update his knowledge concerning the case with the latest relevant scientific knowledge available at the time of the alleged negligence. If any publications or other literature have aided his decisions, he should cite and reference them. Such references must be from standard, evidence-based works in peer reviewed journals. With such evidence-based and updated knowledge of the alleged negligence, he must then formulate the requisite obstetric standard of care and establish whether there is clinical evidence of breach of the established standard of care, by omission or commission. He must also guide the Court as to whether such a breach bears a causal relationship to the plaintiff's presenting damage or complaints.

XIV. Must distinguish and clarify to the Court the distinction between medical malpractice and medical maloccurrence where this is relevant.

XV. Must explain to the Court that deviation from ordinary obstetric practice or even from College[506] guidelines do not necessarily constitute a breach of the standard of care nor must they *automatically* be assumed as such.

[506] In Malta, obstetricians tend to follow the clinical guidelines of the United Kingdom's Royal College of Obstetricians and Gynaecologists. However, over the last years the European College of Obstetricians and Gynaecologists has been attaining ever increasing importance.

XVI. Should indicate if his final opinion is provisional, qualified, requires further information or cannot be expressed with final determination.

XVII. Should inform the Court without delay of any change in his opinion and the reason for such a change.

XVIII. Should be aware that any failure to comply with the Civil Procedure Rules or specific Court orders which may draw the Court's sanction.

XIX. Should know that his report and evidence is not protected from civil action. On the other hand, any purposeful misdirection of the Court, may be open to criminal action.

XX. Shall abide with any Court orders or instructions or any Civil Procedure Rules if and when these are instituted and shall forward his report within a reasonable time, so as not to hold back unduly the Court's progress.

XXI. Shall be compensated along established tariffs once his report is completed and handed over to the Court.

(e) Potential or existent conflicts of interest be they financial, personal connections, obligations or of any other nature, must be disclosed as soon as they arise and as soon as the expert becomes aware of their existence. If known, at the beginning, they should be revealed in the latter of acceptance and then, it is the Court which decides if the matter constitutes a bar to the expert's involvement in the case.

(f) The expert must be ready to undertake any courses which the law of the time specifies as necessary to enable the expert both to appreciate and understand the legal ramifications of his position as well to enhance the delivery of his evidence in Court. Such courses may be short and limited or else they may be of a longer duration and lead to a certificate of qualification or even graduation which may or may not be required by any future law requiring the expert to be licensed as a proper obstetric (or other specialty) Court expert. Such courses would be organised by any authorised authority deemed suitable, such as a Maltese Institute of Medico-Legal Studies.

(g) In cases of a complex nature or requiring a specific clinical direction or ones where academic or clinical contention, the Court may ask for further expert direction. Examples may include electronic fetal monitoring or cerebral neuro-imaging interpretation say in a case of cerebral palsy. The following guidelines are meant to diminish such potential contention:

I. The expert must guide the Court as to the appropriate and just behaviour in cases where the alleged negligence involves, say, a potentially equivocal intra-partum cardio-tocograph. Where such interpretation is proving difficult or may be open to more than one interpretation, the expert may advise the Court that it may be prudent to ask for a second opinion of interpretation. Such a second opinion may be obtained from an obstetrician proposed by the Malta College of Obstetricians and Gynaecologists or from a second expert chosen from the Malta Medical Council's published list of obstetric Court experts.

II. In matters relating to brain damage, as in cerebral palsy, which is being alleged as the result of obstetric negligence in labour resulting in fetal oxygen deprivation in labour. In such a situation where a diagnosis of Hypoxic Ischaemic Encephalopathy must be established one reminds that this will entail Apgar scores, new-born fetal blood Ph and base deficit values, neuuro-imaging studies of the new-born within the first 48 hours of birth, and the establishment of the diagnosis of the *type* of cerebral palsy which *eventually* develops. It is up to the hospital and the OBGYN Department to ensure that the results of such investigations will be available for possible future legal use in cases where legal liability is likely to be sought.

The absence of the aforementioned criteria for establishing hypoxic ischaemic encephalopathy does not rule out the possibility of the existence of such encephalopathy. The existence of these criteria, if available and not consonant with the claimed hypoxic condition, shall be evaluated as evidence *against* the likelihood that such brain damage was the result of intra-partum hypoxia, be this caused by negligence or otherwise. In this case, evidence such as that from intra-partum fetal monitoring, especially if not accompanied by the results of intra-partum fetal blood sampling, carries limited value. This scenario brings forward the important conclusion that in cases of neonatal cerebral damage, it is the responsibility of the birthing unit to ensure that the required parameters be effected at birth or close to birth and be stored safely for any future evidence for a period of not less than 25 years from the day of birth.

Advice about such conditions may be altered or increased from time to time according to contemporary and established scientific knowledge.

5.4 A final reflection

The Maltese Islands have often excelled in academia including that related to all aspects of materia medica. The level of the practice of Maltese medicine has often superseded that provided by much larger nations and the level of contemporary obstetric care is clearly one par with that of its European peers. Having said that, no system anywhere in the world is perfect and devoid of human mistakes and mistakes in obstetrics come at a high premium, with the life and well-being of mother and an unborn child at stake. One important way of diminishing mistakes is to learn from those of others and this should apply to all levels of care of the unborn child which obviously embraces all aspects of obstetric care. This is where case law may further enrich the Lex Medica. Furthermore, when such mistakes lead to litigation, ideally such litigation should be solved out of Court and Alternative Dispute Resolution should be one of the crucial objectives of the Malta Institute of Medico-Legal Studies.

The current Maltese situation lacks both a serious reflection of the evaluation of local obstetric practice from the aspect of legal viability and its subsequent correction. This is a great loss of opportunity of both improvement of clinical practice as well as preparing for the inevitable future increase in obstetric litigation. The increase of undoubted future litigation should not be resolved by crisis management but by careful and long term planning as well as a total over-haul of the corresponding aspects of the current legal system.

This thesis proposes a substantial number of legal and medical amendments, all of which are considered indispensable but the first steps. If the medical proposals are taken up by the Maltese Obstetric Service the long-term benefits will be obvious, even if all change comes at some cost. On the legal front, establishing the Lex Medica will be a mammoth task but, in the opinion of this thesis, is an inevitable task. If ignored, future bitter experience may well force the legislator's hand. On the other hand, the creation of a Maltese Institute of Medico-Legal Studies in the near future would be a wise step and of great assistance to all, especially the legislator.

One genuinely hopes that the two volumes constituting this thesis will not simply gather dust on some shelf in the University of Malta but will serve as a springboard for genuine change. In the meantime, one may quietly dwell on the ancient Greek saying, "Acta non Verba".[507]

[507] "Actions, not words". Appropriated as motto by the US Merchant Marine Academy.

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Again, general aspects of the PhD research were the basis of the two chapters entitled *Legal and ethical issues in gynaecological practice* and *Legal issues in obstetric practice,* to be published in The EBCOG Postgraduate Textbook of Obstetrics and Gynaecology (2 Volumes) by Tahir Mahmood et al. (Cambridge University Press).

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APPENDIX 1

Attendance of the Mater Dei Hospital antenatal clinics for the years 2005-2012

2005

Nationality	No. Of Attendances	% of total attendances
Malta	9821	90.9
Albania	9	0.1
Argentina	2	0.0
Australia	8	0.1
Belarus	6	0.1
Belgium	2	0.0
Bosnia and Herzegovina	1	0.0
Bulgaria	23	0.2
Canada	1	0.0
China	17	0.2
Poland	3	0.0
Czech Republic	6	0.1
Ecuador	1	0.0
Egypt	2	0.0
Eritrea	45	0.4
Ethiopia	30	0.3

ex Yugoslavia	16	0.1
Georgia	3	0.0
Germany	6	0.1
Hungary	1	0.0
India	10	0.1
Iran, Islamic Republic of	1	0.0
Israel	1	0.0
Italy	5	0.0
Japan	10	0.1
Jordan	3	0.0
Korea, Democratic People's Republic of	1	0.0
Latvia	2	0.0
Lebanon	8	0.1
Libyan Arab Jamahiriya	9	0.1
Morocco	65	0.6
Nigeria	11	0.1
Philippines	12	0.1
Romania	3	0.0
Russian Federation	59	0.5
Saint Pierre and Miquelon	2	0.0
Slovakia	1	0.0
Somalia	9	0.1
Sweden	1	0.0

Syrian Arab Republic	16	0.1
Thailand	17	0.2
Togo	1	0.0
Tunisia	21	0.2
Ukraine	29	0.3
United Kingdom	91	0.8
Unknown	56	0.5
Uzbekistan	3	0.0
Not possible to link ID cards between registers	358	3.3
Grand Total	**10808**	**100.0**

2006

Nationality	No. Of Attendances	% of total attendances
Malta	9199	88.8
Albania	3	0.0
Algeria	1	0.0
Argentina	3	0.0
Armenia	2	0.0
Australia	2	0.0
Bulgaria	22	0.2
Cameroon	14	0.1
Canada	6	0.1
Chad	1	0.0
China	14	0.1
Congo	1	0.0
Croatia	6	0.1
Czech Republic	5	0.0
Denmark	10	0.1
Egypt	47	0.5
Eritrea	65	0.6
Ethiopia	31	0.3
ex Yugoslavia	31	0.3
Finland	4	0.0
France	2	0.0

Georgia	6	0.1
Germany	22	0.2
Greece	4	0.0
India	16	0.2
Iraq	6	0.1
Israel	2	0.0
Italy	9	0.1
Japan	7	0.1
Kazakhstan	1	0.0
Libyan Arab Jamahiriya	14	0.1
Macao	3	0.0
Malaysia	6	0.1
Moldova	10	0.1
Morocco	71	0.7
Netherlands	4	0.0
Nigeria	8	0.1
Philippines	24	0.2
Poland	1	0.0
Romania	14	0.1
Russian Federation	46	0.4
Serbia	10	0.1
Slovakia	1	0.0
Somalia	34	0.3
Sri Lanka	6	0.1

Sudan	11	0.1
Sweden	7	0.1
Syrian Arab Republic	19	0.2
Thailand	8	0.1
Togo	5	0.0
Tunisia	5	0.0
Ukraine	16	0.2
United Kingdom	96	0.9
United States	1	0.0
Unknown	48	0.5
Not possible to link ID cards between registers	351	3.4
Grand Total	**10361**	**100.0**

2007

Nationality	No. Of Attendances	% of total attendances
Malta	9432	88.8
Albania	1	0.0
Australia	2	0.0
Azerbaijan	4	0.0
Bangladesh	1	0.0
Belarus	12	0.1
Bulgaria	23	0.2
Cameroon	1	0.0
Canada	15	0.1
China	49	0.5
Cyprus	3	0.0
Czech Republic	5	0.0
Egypt	13	0.1
Eritrea	59	0.6
Ethiopia	24	0.2
ex Yugoslavia	4	0.0
France	5	0.0
Georgia	18	0.2
Germany	12	0.1
India	2	0.0
Ireland	2	0.0

Israel	8	0.1
Italy	7	0.1
Japan	2	0.0
Jordan	6	0.1
Kazakhstan	1	0.0
Kyrgyzstan	1	0.0
Lebanon	10	0.1
Libyan Arab Jamahiriya	11	0.1
Lithuania	2	0.0
Macao	5	0.0
Malaysia	1	0.0
Mexico	2	0.0
Moldova	2	0.0
Morocco	36	0.3
Netherlands	8	0.1
Nigeria	16	0.2
Philippines	22	0.2
Poland	15	0.1
Romania	12	0.1
Russian Federation	54	0.5
Serbia	32	0.3
Sierra Leone	4	0.0
Slovakia	1	0.0
Somalia	37	0.3

Sudan	4	0.0
Suriname	12	0.1
Sweden	1	0.0
Syrian Arab Republic	4	0.0
Thailand	13	0.1
Tunisia	8	0.1
Turkey	3	0.0
Turkmenistan	4	0.0
Ukraine	20	0.2
United Kingdom	72	0.7
United States	1	0.0
Unknown	42	0.4
Not possible to link ID cards between registers	450	4.2
Grand Total	**10616**	**100.0**

2008

Nationality	No. Of Attendances	% of total attendances
Malta	12879	87.7
Albania	12	0.1
Algeria	7	0.0
Australia	1	0.0
Azerbaijan	9	0.1
Belarus	2	0.0
Belgium	1	0.0
Bosnia and Herzegovina	1	0.0
Bulgaria	41	0.3
Canada	15	0.1
China	22	0.1
Colombia	3	0.0
Costa Rica	1	0.0
Cuba	1	0.0
Czech Republic	9	0.1
Egypt	17	0.1
Eritrea	83	0.6
Estonia	1	0.0
Ethiopia	36	0.2
ex Yugoslavia	14	0.1
France	26	0.2

Georgia	1	0.0
Germany	22	0.1
Ghana	2	0.0
India	22	0.1
Iran, Islamic Republic of	3	0.0
Iraq	3	0.0
Israel	3	0.0
Italy	15	0.1
Japan	5	0.0
Korea, Democratic People's Republic of	2	0.0
Kyrgyzstan	5	0.0
Liberia	3	0.0
Libyan Arab Jamahiriya	21	0.1
Malaysia	3	0.0
Morocco	53	0.4
Netherlands	1	0.0
Nicaragua	5	0.0
Nigeria	39	0.3
Norway	1	0.0
Peru	20	0.1
Philippines	30	0.2
Poland	11	0.1
Romania	27	0.2

Russian Federation	105	0.7
Serbia	34	0.2
Sierra Leone	13	0.1
Slovakia	4	0.0
Somalia	83	0.6
South Africa	3	0.0
Spain	14	0.1
Sudan	24	0.2
Sweden	7	0.0
Syrian Arab Republic	20	0.1
Thailand	18	0.1
Tunisia	30	0.2
Turkey	36	0.2
Turkmenistan	6	0.0
Ukraine	26	0.2
United Kingdom	138	0.9
Unknown	42	0.3
Zimbabwe	4	0.0
Not possible to link ID cards between registers	602	4.1
Grand Total	**14687**	**100.0**

2009

Nationality	No. Of Attendances	% of total attendances
Malta	10654	85.2
Albania	2	0.0
Algeria	13	0.1
Australia	2	0.0
Belarus	6	0.0
Bosnia and Herzegovina	7	0.1
Brazil	13	0.1
Bulgaria	41	0.3
Canada	2	0.0
China	28	0.2
Congo	9	0.1
Costa Rica	10	0.1
Croatia	9	0.1
Czech Republic	3	0.0
Denmark	1	0.0
Dominican Republic	2	0.0
Egypt	19	0.2
Eritrea	77	0.6
Ethiopia	40	0.3
ex Yugoslavia	21	0.2
Finland	2	0.0
France	8	0.1

Georgia	2	0.0
Germany	18	0.1
Ghana	5	0.0
Greece	5	0.0
Hungary	6	0.0
India	15	0.1
Iraq	4	0.0
Italy	5	0.0
Japan	3	0.0
Latvia	3	0.0
Lebanon	6	0.0
Libyan Arab Jamahiriya	24	0.2
Lithuania	1	0.0
Malaysia	2	0.0
Moldova	4	0.0
Morocco	61	0.5
Netherlands	6	0.0
Nicaragua	1	0.0
Nigeria	46	0.4
Pakistan	2	0.0
Philippines	46	0.4
Poland	26	0.2
Romania	56	0.4
Russian Federation	89	0.7

Serbia	19	0.2
Sierra Leone	8	0.1
Slovakia	1	0.0
Slovenia	3	0.0
Somalia	158	1.3
Sri Lanka	2	0.0
Sweden	18	0.1
Syrian Arab Republic	19	0.2
Thailand	27	0.2
Tunisia	10	0.1
Turkey	13	0.1
Ukraine	23	0.2
United Kingdom	140	1.1
United States	2	0.0
Unknown	57	0.5
Not possible to link ID cards between registers	604	4.8
Grand Total	**12509**	**100.0**

2010

Nationality	No. Of Attendances	% of total attendances
Malta	11478	86.2
Albania	7	0.1
Argentina	3	0.0
Australia	4	0.0
Azerbaijan	6	0.0
Belarus	1	0.0
Belgium	4	0.0
Brazil	3	0.0
Bulgaria	14	0.1
Cameroon	6	0.0
Canada	17	0.1
China	17	0.1
Congo	5	0.0
Croatia	8	0.1
Czech Republic	1	0.0
Dominican Republic	3	0.0
Egypt	10	0.1
Eritrea	156	1.2
Ethiopia	25	0.2
ex Yugoslavia	5	0.0
France	19	0.1

Germany	14	0.1
Ghana	4	0.0
Hungary	10	0.1
India	15	0.1
Ireland	10	0.1
Israel	2	0.0
Italy	8	0.1
Japan	1	0.0
Kyrgyzstan	1	0.0
Latvia	2	0.0
Lebanon	1	0.0
Libyan Arab Jamahiriya	27	0.2
Lithuania	4	0.0
Morocco	26	0.2
Netherlands	1	0.0
Nigeria	50	0.4
Pakistan	11	0.1
Peru	1	0.0
Philippines	66	0.5
Poland	15	0.1
Portugal	1	0.0
Romania	24	0.2
Russian Federation	77	0.6
Serbia	32	0.2

Slovakia	10	0.1
Slovenia	3	0.0
Somalia	270	2.0
Spain	5	0.0
Sri Lanka	2	0.0
Sweden	5	0.0
Syrian Arab Republic	33	0.2
Tanzania, United Republic of	2	0.0
Thailand	8	0.1
Tunisia	24	0.2
Turkey	23	0.2
Ukraine	26	0.2
United Kingdom	184	1.4
United States	2	0.0
Unknown	23	0.2
Viet Nam	5	0.0
Not possible to link ID cards between registers	500	3.8
Grand Total	**13320**	**100.0**

2011

Nationality	No. Of Attendances	% of total attendances
Malta	13009	85.7
Algeria	10	0.1
Armenia	9	0.1
Australia	4	0.0
Azerbaijan	1	0.0
Bangladesh	2	0.0
Belarus	2	0.0
Belgium	4	0.0
Bosnia and Herzegovina	2	0.0
Brazil	10	0.1
Bulgaria	45	0.3
Canada	1	0.0
China	33	0.2
Croatia	10	0.1
Czech Republic	15	0.1
Denmark	2	0.0
Egypt	44	0.3
Eritrea	112	0.7
Estonia	1	0.0
Ethiopia	56	0.4
Finland	1	0.0

France	31	0.2
Germany	12	0.1
Ghana	11	0.1
Hungary	24	0.2
India	21	0.1
Iraq	14	0.1
Ireland	2	0.0
Israel	2	0.0
Italy	30	0.2
Jamaica	1	0.0
Japan	11	0.1
Korea, Republic of	1	0.0
Latvia	2	0.0
Liberia	1	0.0
Libyan Arab Jamahiriya	27	0.2
Lithuania	11	0.1
Macedonia, the former Yugoslav Republic of	9	0.1
Malaysia	4	0.0
Morocco	31	0.2
Netherlands	3	0.0
Nigeria	118	0.8
Norway	1	0.0
Pakistan	9	0.1

Peru	15	0.1
Philippines	38	0.3
Poland	51	0.3
Romania	20	0.1
Russian Federation	96	0.6
Serbia	48	0.3
Sierra Leone	3	0.0
Slovakia	3	0.0
Slovenia	2	0.0
Somalia	286	1.9
South Africa	1	0.0
Spain	16	0.1
Sudan	8	0.1
Suriname	5	0.0
Sweden	4	0.0
Syrian Arab Republic	21	0.1
Tanzania, United Republic of	4	0.0
Thailand	5	0.0
Tunisia	12	0.1
Turkey	21	0.1
Ukraine	41	0.3
United Kingdom	141	0.9
United States	1	0.0

Unknown	7	0.0
Not possible to link ID cards between registers	578	3.8
Grand Total	**15176**	**100.0**

2012

Nationality	No. Of Attendances	% of total attendances
Malta	10948	74.5
Australia	7	0.0
Austria	1	0.0
Belarus	3	0.0
Belgium	7	0.0
Bosnia and Herzegovina	5	0.0
Brazil	1	0.0
Bulgaria	53	0.4
Cameroon	6	0.0
Canada	1	0.0
China	25	0.2
Croatia	1	0.0
Cyprus	8	0.1
Czech Republic	23	0.2
Denmark	6	0.0
Egypt	20	0.1
Eritrea	60	0.4
Ethiopia	58	0.4
ex Yugoslavia	7	0.0
Finland	5	0.0
France	9	0.1

Georgia	3	0.0
Germany	40	0.3
Hungary	33	0.2
India	25	0.2
Iraq	13	0.1
Ireland	5	0.0
Italy	27	0.2
Jordan	3	0.0
Korea, Republic of	8	0.1
Kyrgyzstan	5	0.0
Latvia	17	0.1
Liberia	7	0.0
Libyan Arab Jamahiriya	31	0.2
Lithuania	6	0.0
Macedonia, the former Yugoslav Republic of	1	0.0
Malaysia	8	0.1
Moldova	8	0.1
Morocco	22	0.1
Netherlands	5	0.0
Nigeria	65	0.4
Pakistan	35	0.2
Peru	6	0.0
Philippines	47	0.3

Poland	16	0.1
Romania	39	0.3
Russian Federation	115	0.8
Serbia	66	0.4
Sierra Leone	2	0.0
Slovakia	4	0.0
Slovenia	3	0.0
Somalia	169	1.2
South Africa	1	0.0
Spain	16	0.1
Sudan	1	0.0
Sweden	14	0.1
Syrian Arab Republic	3	0.0
Thailand	3	0.0
Tunisia	19	0.1
Turkey	5	0.0
Ukraine	40	0.3
United Kingdom	199	1.4
United States	1	0.0
Unknown	9	0.1
Viet Nam	9	0.1
Zimbabwe	7	0.0
Not possible to link ID cards between registers	578	3.9

Grand Total	**14688**	**100.0**

Year	Maltese Nationals % of total attendance	Non-Maltese Residents and Foreign Non-Residents % of total attendance	Total visits
2005	90.9	9.1	10808
2006	88.8	11.2	10361
2007	88.8	11.2	10616
2008	87.7	12.3	14687
2009	85.2	14.8	12509
2010	86.2	13.8	13320
2011	85.7	14.3	15176
2012	74.5	25.5	14688

APPENDIX 2

INTRA-PARTUM ELECTRONIC FETAL MONITORING (EFM) – PANDORA'S BOX OR BITTERSWEET NECESSITY?

Contents

A2.1 Introduction

The appearance of electronic fetal monitoring (EFM), in the form of cardiotocography (CTG) in clinical obstetrics commenced a new chapter in the 1960's. Since then, in spite of offering a unique system of intra-partum fetal surveillance, CTG presented an aspect not dissimilar to the opening of Pandora's Box. One example of this was the unknowingly misdirecting role played by CTG monitoring in the medico-legal aspects of cerebral palsy commencing in America of the 1960's. Yet, in spite of this sad pregnant past as well as many eventually uncovered inherent scientific weaknesses, CTG remains the only routinely available method of fetal monitoring in labour.

CTG can be used to enable information about fetal wellbeing both antenatally as well as during labour. In the latter use, intra-partum CTG (I-P CTG) can be used intermittently or continuously. When it was clinically introduced in the 1960's, I-P CTG was greatly heralded as the great guardian of the fetus in labour from the evils of intra-partum hypoxia (IPH). Great things were expected from it including the diminishing in the incidence of cerebral palsy assumed in the 1960's as due in its preponderance to IPH. Sadly, the incidence of CP was not affected by the clinical use of I-P CTG.

A2.2 The need for I-P CTG

The need for monitoring of the fetal well-being in labour lies in the dual effect of uterine contractions. On one hand contractions are indispensable for cervical dilatation to proceed as well as to help in the descent, rotation and flexion of the fetal head. On the other hand, the same contractions temporarily impede the utero-placental blood flow, the diminution of the flow being inversely related to the increase in intra-uterine pressure. The greatest drop in fetal oxygen saturation is reached about 50 seconds after its completion and lasts approximately 30 seconds to recover.[508] With these parameters, a healthy uncompromised fetus can cope in normal labour, while a compromised one may develop evidence of fetal distress. Even a healthy baby who is subjected, say, to excessively forceful contractions or over-frequent contractions, may suffer from intra-partum hypoxia and also demonstrate signs of fetal distress.

The concept of fetal distress essentially appeared by the second half of the 19th century when the risk could be linked to a number of clinical signs,[509] although the actual term of fetal distress would not appear before the beginning of the twentieth century.[510] Today, the term implies a clinical situation resulting from fetal hypoxia as initially revealed by I-P CTG or auscultatory fetal heart rate abnormalities and confirmed by fetal blood biochemistry. Over the last decade, the ACOG has criticised (but

[508] East CE, Dunster KR, Colditz PB. Fetal oxygen saturation and uterine contractions during labor. Am J Perinatol. June 1998; 5(6):345-9.

[509] Such as FHR changes, diminished fetal movements and the passage of fetal faeces (menonium) per maternal vaginam.

[510] The term was used as such for the first time in 1908 by Hastings and Wench in Dublin.

subsequently revoked) the use of the terms 'fetal distress' and 'birth asphyxia.'[511] The latter is justifiably condemned being non-specific. Regarding the revoking of the term 'fetal distress' this thesis is not convinced of the ACOG Committe's view that it is imprecise and non-specific. Furthermore, The Royal College of Obstetricians and Gynaecologists (RCOG) has not accepted this impractical suggestion, as evidenced by the continuing normal use of the term. Medico-legally, the term has not been altered either in the USA or in the UK. This thesis retains the use of the term throughout.

As early as the second half of the 19th century,[512] even if still lacking its modern name, fetal distress was known to be associated with decelerations of the fetal heart rate during or outlasting the uterine contraction. The situation was considered ominous with progressive and persistent fetal bradycardia being noted as occasionally associated with impending fetal death. It was also noted that fetal bradycardia could be physiological and not of ominous significance.[513] In 1906 we have the first clarion call to EFM with the first fetal electrocardiographic recording by Cremer using string galvanometers. The mid-1950's saw improvements in measurement and amplification techniques. The modern fetal monitor was invented by Alan Bradfield, Orvan Hess and Edward Hon while Konrad Hammacher, working in conjunction with Hewlett Packard who

[511].Committee on Obstetric Practice. ACOG Committee Opinion. Number 326, December 2005 Inappropriate use of the terms fetal distress and birth asphyxia. Obstet Gynecol. Dec 2005;106(6):1469-70 (Withdrawn).

[512] Sureau C. Historical perspectives: forgotten past, unpredictable future. Baillieres Clinical Obstetrics and Gynaecology. 1996; 10(2):167-184.

[513] Van Geijn H, Copray F. Editors. A Critical Appraisal of Fetal Surveillance.Amsterdam: Elsevier; 1994.

produced a refined version. The first commercial CTG monitoring machine would be sold by 1968. A new era had dawned.[514]

The 1960's through to the 1980's witnessed further rapid scientific strides, but the misuse of results also became clear with CS rates exceeding 39%. In spite of the increasingly emerging inherent weaknesses of the method, no further refinement or improvement of CTG monitoring sensitivity appeared.[515]. The impressive medico-legal repercussions of the negative aspects of I-P CTG would decades later, especially regarding the abuse of CTG in strengthening the misconception of intra-partum hypoxia underlying most cases of cerebral palsy. However, the clock would never turn back for CTG had made itself an indispensable tool of safe modern labour. It became a dynamic, and visible manifestation of the progress of obstetric science.

Not all these losses [stillbirths] are preventable, but continuous surveillance of them is critical to identify trends and problem areas for developing services and provide better care. Furthermore, mortality is but the tip of an iceberg of morbidity.[516]

A2.3 Extensive and profound effects of I-P CTG

Close analysis of the multi-faceted effects resulting directly or indirectly from the clinical introduction of CTG in the care of the unborn will reveal most profound effects on obstetric jurisprudence and a substantial negative contribution to the epidemic of

[514] Schmidt JV, McCartney PR. History and development of fetal heart assessment: a composite. J Obstet Gynecol Neonatal Nurs. 2006 July 28; 2006; 29: 3:295-305.

[515] Steer PJ. Surveillance during labour. J Perinat Med. 2009; 37(5):451-456.

[516] Advances in Intra-Partum Fetal Monitoring, Obs Gynae & Midwifery News. 2007.

medical Court suing with its own evil effects such as the rapidly rising medical indemnity costs. Sartwelle et al. maintain that CTG monitoring contributed to the massive 10% increase of obstetric malpractice lawsuits noted between 1970 and 1985 [517]. There is clear evidence that the period 1982-1986 was showing evidence of extreme challenge resulting from massive increases in Court litigation, especially in the OBGYN specialty:

In response to proliferating malpractice claims, 49 out of the 50 states enacted tort reforms in the past decade to modify medical malpractice liability laws…….Despite these legislative reforms, the number of medical malpractice claims has continued to increase during this period. The number of claims filed against physicians nationwide rose at an average of 10 percent per year from 1982-1986 alone. Not only were there more claims, the severity of the claims – that is, the amounts paid out in both jury verdicts and settled claims – has risen considerably.

Medical malpractice insurance premiums have reflected this upsurge in claims and payments…….

Medical malpractice insurances have reflected this upsurge in claims and payments….

These trends have been most pronounced in the practice of obstetrics.

[517] Sartwelle TP, Johnston JC. Cerebral Palsy Litigation: Change Course or Abandon Ship. Journal of Child Neurology. 2015; 30(7):828-841.

Claims against obstetrician-gynecologists are currently two to three times more numerous than the average for all other physicians and are comparable only with a handful of other high-risk surgical specialties. These trends in the practice of obstetrics. Claims against obstetrician-gynaecologists are currently two to three times more numerous than the average for all other physicians…[518]

The CTG's responsibility in all of this is debatable, but it is unlikely that this phenomenon could have resulted from one single factor. However, CTG monitoring did open up a vast and new strategy of attack by birth litigation lawyers. And this was instrumental for the emergence of the most expensive type of lawsuit in obstetrics–that related to cerebral palsy. For CTG monitoring, in contrast to auscultatory fetal assessment in labour, presented a complete *volte face* by producing a physical, permanent thermally burnt CTG strip. The lawyer now had solid artefactual "evidence" to dramatically strengthen his argument in Court.

A2.3.1 More than teething problems

Teething problems are universal in new systems and so it was with CTG. [519] Yet, what one might attribute to clinical teething problems were still around three decades after the introduction of CTG. The 4th Confidential Enquiry into Stillbirths and Deaths in Infancy (CESDI) in 1995 attributed nearly 50% of 800 intra-partum deaths to:

- a failure to recognise the CTG trace abnormalities;

[518] Bulger RJ, Rostow VP. Medical and Professional Liability and the Delivery of Obstetrical. Journal of Contemporary Health Law and Policy. 1990; 6:81-92.

[519] In the case of I-P CTG, these teething problems seems to have persisted to the current times.

- a delay in communication and timely action (regarding CTG abnormalities).

- a combination of these.

Other issues would surface. Thus, the 2013 Cochrane Report[520] states that:

Despite EFM s poor predictive value….CTG during labour is associated with a reduction in the incidence of neonatal seizures, has no obvious impact on cerebral palsy or perinatal mortality but is associated with an increase in the incidence of caesarean section and instrumental vaginal births.

Not only is this report worrying on its own, but it also implies another medico-legal issue, which by today's emphasis on patient autonomy is a major one. For the same report stresses that women should be informed about the above facts concerning the use of CTG. In other words, not only is disclosure important before the use of, say I-PCTG but here we have a *qualified* onus on some of the advantages and disadvantages associated with the monitoring. This holds special reference to the Maltese obstetric service where such monitoring is normally preceded by neither disclosure nor consent.

The original weaknesses, which may have been considered teething problems, are very much still alive and with us. Some of these detracting qualities were highlighted by the ACOG in 2005:

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[520] Alfirevic Z, Gyte GML, Cuthbert A, Devale D. Continuous cardiotocography (CTG) as a form of electronic fetal monitoring (EFM) for fetal assessment during labour (Review). Cochrane Library. Cochrane Database of Systematic Reviews. 2017.

In 2002, approximately 3.4 million fetuses (85% of approximately 4 million live births) in the United States were assessed with electronic fetal monitoring (EFM),making it the most common obstetric procedure. Despite its widespread use, there is controversy about the efficacy of EFM, interpretation of fetal heart rate (FHR) patterns, reproducibility of its interpretation, and management algorithms for abnormal or non-reassuring patterns. Moreover, there is evidence that the use of EFM increases the rate of caesarean and operative vaginal deliveries.[521]

Yet, one notes that in spite of all these drawbacks, the ACOG's document continues with:

The purpose of this document is to review nomenclature for FHR assessment, review the data on the efficacy of EFM, delineate the strengths and shortcomings of EFM, and describe the management of non-reassuring FHR patterns.[522]

Hence, the ACOG is justifiably re-affirming its trust in I-P CTG, albeit stating that many issues required resolving. This holds entirely today as it did in 2005. In spite of all problems, the ACOG concluded with the admonition that:

The labor of parturients with high-risk conditions should be monitored continuously.[523]

[521] ACOG Practice Bulletin. Number 62. 2005 May. Intrapartum Fetal Heart Rate Monitoring.

[522] See note 498.

[523] *Ibid.*

This thesis is convinced that the ACOG's expressed balanced view of the use of I-P CTG is fair and correct. Medico-legally, as will be evaluated, I-P CTG has an unfortunate track record and one cannot but feel a partial degree of sympathy at the broad and not wholly incorrect statement that:

medically and legally unsound, exposing obstetricians to liability instead of protecting them from liability, as most believe.[524]

However, this argument is faulty from conception for I-P CTG is not there to protect the obstetrician but help protect the fetus from the ravages of nature or even from human mismanagement. It is true that CTG can be as medically and legally abused as much as its opponents vociferously state. I-P CTG can be misinterpreted, abused and mis-sued and lead to maternal/fetal harm through unnecessary action. Yet its scope is good and although the challenge is not trivial it *can* serve its purpose

A2.4 Basic practicalities of CTG monitoring

In the antenatal period, no convincing evidence exists that antenatal CTG improves perinatal outcome.[525] Okusanyo also showed neither maternal nor fetal benefits with the use of *antenatal* CTG even in high-risk cases.[526] With regard to I-P CTG, the RCOG

[524] Lent M. The medical and legal risk of the electronic fetal monitor. Stan L Rev.1999 Apr; 51(4):807-837.

[525] Grivell RM, Alfirevic Z, Gyte GM, Devane D. Ante-natal cardiotocography for fetal assessment. Cochrane Database of Systematic Reviews, 2010 Jan; (1): CD007863.

[526] Okusanya BO. Ante-natal cardiotocography for fetal assessment: RHL commentary.The WHO Reproductive Health Library; Geneva: World Health Organization.2010 Jul 1.

recommends that this is limited to high risk situations. While intermittent auscultation should be the primary assessment method for low risk pregnant women in labour,[527] continuous I-P CTG should be reserved to medium and high-risk cases.[528]

There is little doubt that CTG has massively contributed to defensive medicine. It is a well-known phenomenon that malpractice exposure influences the use of CTG and that fear of malpractice influences the diagnosis of fetal distress both directly and through the use of CTG [529] However, one must keep in mind the fact that even as early as 1989, 70% of obstetricians reported that they had had at least one claim filed against them in their careers.[530] It is hardly surprising that CTG monitoring is among the first steps taken in defensive obstetrics. On the other hand, one should also bear in mind that failing to perform CTG monitoring where indicated, constitutes potential liability in the presence of an adverse clinical outcome. This was the case in *Tippett v. Guy's & St Thomas' Hospital NHS Foundation Trust*[531] where Court asked the crucial but rhetorical question: regarding *what (had) the 1105 to 1155 hours CTG trace showed?*

[527] Feinstein N, A Sprague, M Trepanier, Fetal Heart Rate Auscultation. 2nd edition. Washington. AWHONN; 2008.

[528] See note 333.

[529] Tussing AD, Wojtowycz MA. Malpractice, Defensive Medicine, and Obstetric Behavior. Med Care. 1997 Feb; 35(2):172-191.

[530] Institute of Medicine,'Medical professional liability and the delivery of obstetrical care', Vol. I. Washington, National Academy Press,1989.

[531] *Tippett v. Guy's & St Thomas' Hospital NHS Foundation Trust* [2014] EWHC 917 (QB), HQ11X04855.

Once a decision to monitor is taken, it is crucial that CTG documentation should be of adequate quality for proper visual interpretation.[532] Producing a non-decipherable tracing reveals a lack of interest in truly finding out the state of affairs of fetal well-being as occurred in *Popple v. Birmingham Women's NHS Foundation Trust*:

He went on to repeat the view of the claimant's experts in their supplementary joint memorandum that all the obstetric experts have emphasised extreme difficulty in reliably interpreting the CTG tracings due to poor quality and the obstetric experts in their meeting record that the CTG is uninterpretable from 14.21 onwards.[533]

It may sound pathetically patronising to add that once a decipherable CTG tracing is obtained, one must bother to evaluate and act accordingly. Yet in *A. B. Claimant (a child and protected party by X. Y. her mother and litigation friend) and C. D. NHS Trust Defendant,* [534] we find the strange case where in spite of the availability of a most worrying tracing from continuous CTG monitoring, the defendant showed total disregard by:

failing to make any or any proper interpretation or assessment of the CTG tracings which showed persistent tachycardia …

[532] Ayres-de-Campos D, Spong CY, Chandraharan E. FIGO consensus guidelines on intrapartum fetal monitoring Cardiotocography.International Journal of Gynaecology and Obstetrics. 2015 Oct; 131(1):13-24.

[533] *Popple v. Birmingham Women's NHS Foundation Trust* (2011) [2011] EWCA Civ 1650.

[534] *A. B. Claimant (a child and protected party by X. Y. her mother and litigation friend) and C. D. NHS Trust Defendant* ACF 32(2): 02/2013.

The defendant in this case was accused both of not referring to his seniors as well as not taking the initiative of performing any life-saving action, by:

failing to refer the Claimant's mother to the consultant obstetrician, alternatively senior registrar, at sufficient intervals…failing to perform an artificial rupture of the membranes by about … failing to perform fetal blood sampling by about … if it was not possible to obtain a fetal blood sample at that time, failing to proceed to a caesarean section immediately, alternatively, if it was possible to obtain a fetal blood sample, failing to proceed to a caesarean section once the pH reached … in any event failing to proceed to a caesarean section before…at the latest in the premises, displaying gross mismanagement of the Claimant's mother's labour in the manner set out above.

The end result of all this was a child suffering from asymmetrical quadriplegic cerebral palsy. On the other hand, admitting to inability to interpret an I-P CTG is acceptable as long as senior help is sought as we find in *Baynham v. Royal Wolverhampton Hospitals NHS Trust,*[535] where the Court ruled for the defendant:

In evidence, she explained that the CTG was extremely difficult to interpret. She called for medical assistance straight away…

In *Fabiyi v. Nursing and Midwifery Council,*[536] the opposite is revealed:

[535] *Baynham v. Royal Wolverhampton Hospitals NHS Trust*, [2014] EWHC 3780 (QB), HQ14X01568.
[536] *Fabiyi v. Nursing and Midwifery Council* [2012] All ER (D) 53 (Jul).

This second complaint was identified as having resulted from a practice deficiency in which EF had failed to notify a suspicious CTG to other more senior colleagues.

In *Reeve v. Heart of England NHS Trust*,[537] we see the Court turning its lens at the highest level of responsibility, namely the consultant, and questioning whether he should have actually left home (as it happens, in the early hours of the morning) and attend labour ward to analyse the CTG tracing himself:

Mr Maskrey formulates the central issues in this case as follows:

1. Was the CTG trace from 4.50 a.m. such that Mr Churchill should not have been informed that it was satisfactory but that it was suspicious?

If he should have been told that it was suspicious, would he or should he have attended the hospital after speaking to Dr Hady?

The case also illustrates the importance of the recording of all relevant times and details of consultations be they oral or via telephone conversations.

Although lack of correct response to an abnormal tracing is considered one relatively common form of human error,[538] it is still an action which recalls Lent's description of the CTG tracing as increasing *liability instead of protecting them from liability*.[539] There

[537] *Reeve v. Heart of England NHS Trust* [537][2011] EWHC 3901.
[538] Williams B, Arulkumaran S. Cardiotocography and the medicolegal issues. Best Practice & Research Clinical Obstetrics and Gynaecology.2004 June 18;18(3):457-466.

[539] See note 523.

may be various circumstances associated with this inaction, one of which may involve a doctor's sub-conscious obeisance to attending midwives especially if they are senior and the doctor is non-assertive and new or quite junior. In such circumstances one may end up with "*having (the) case managed by midwives*[540] which does not absolve the obstetrician of his own share of responsibility if things take wrong turn.

Correct CTG management implies that any action instituted as a response to any diagnosed CTG abnormality or query about normality must be acted upon correctly and in appropriate time. Most certainly, the plaintiff's complaint in *NM Pursuer and Reclaimer v. Lanarkshire Health Board Defenders and Respondents*[541] spanning a period of about eight hours of inaction in the face of an abnormal I-P CTG was a sincere *cri de coeur*.

In particular, it was submitted to the Lord Ordinary on behalf of the pursuer that at any of four points in the course of the labour on 1 October 1999, namely at 0810 hrs, 1230 hrs, 1345 hrs and 1600 hrs approximately, the CTG trace showed features which no competent obstetrician exercising reasonable care would have interpreted otherwise than as requiring the taking of a fetal blood sample, which failing, the carrying out of a caesarean section.

This is certainly a clearly justifiable complaint. The time interval between detection of CTG abnormalities and the obstetrician's response in management is often the subject

[540] *Parry v. North West Surrey Health Authority,* [1994] 5 Med LR 259.

[541] *NM Pursuer and Reclaimer v. Lanarkshire Health Board Defenders and Respondents* [2013] CSIH. 3.

of fierce attack and rebuttal in Court Thus in *Khalid v. Barnet & Chase Farm Hospital NHS Trust*, [542] the midwife, who in most cases is the first person who normally detects or fails to detect, CTG abnormalities, was condemned in Court for failing to report the problem in adequate time:

By 06:20, the CTG trace had revealed persistent tachycardia and variable decelerations of the fetal heart rate, but the midwife did not call the registrar until 07:15.

A breach of duty on the part of Midwife Han has been conceded on the basis that she should have called the doctor so that he would have arrived about an hour earlier than he did in fact.

There are occasions where the Court seems to be particularly harsh and stringent about time intervals, as in *L v. West Midlands Strategic Health Authority*:

In the claimant's clinical negligence action, the court determined that a reasonably competent obstetrician would have delivered the claimant at 21.49 and resuscitated him at 21.50, some six minutes sooner than was in fact the case.

However, six minutes may make the world of a difference between life and death and between a normal child and one in a future vegetative state.

A2.5 On writing notes, their safe storage and availability

[542] *Khalid v. Barnet & Chase Farm Hospital NHS Trust* - [2007] All ER (D) 479 (Mar).

It is a customary and acceptable habit to make notations on the I-P CTG strip such as 'Syntocinon started,' 'Syntocinon stopped' or 'patient turned onto side.' These notes and any others should be carefully entered and timed in the case file, which should also have recorded the time of commencement of the monitoring and any major changes of the I-P CTG tracing which need dealing with, even if this only involves active observation. Likewise, all times of informing senior personnel must be most carefully annotated as well as the times of response of people contacted, decisions taken when to perform FBS, actual time of performing and time of arrival of its result. Such information is extremely important and by its very presence speaks for efficiency and responsibility. This was the case in *Khairule v. North West Strategic Health Authority*[543] where the defendant was saved by the fact that excellent notes had been kept and were made available to the Court:

Given these clear descriptions within the contemporaneous case records, the loss of the CTG becomes significantly less important than if the records did not contain this degree of information.[544]

In all instances, the availability of the *original* CTG strip is of inestimable importance in Court. When the CTG strip goes missing and is not available in Court, this constitutes one form of what is known as spoliation of evidence. In such cases, the Court tends to

[543] *Khairule v. North West Strategic Health Authority,* [2008] All ER (D) 85 (Jul).

[544] Both CTG tracing and clinical notes should be available. The clinical notes may contain *subjective* opinions of the interpretation of the I-P CTG.

view the situation as inimical to the defendant. In *The Baglio v. St. John's Queens Hosp*[545] the Court stated that:

the fetal monitoring strips would give fairly conclusive evidence [546]*as to the presence or absence of fetal distress, and their loss deprives the plaintiff of the means of proving her medical malpractice claim against the Hospital.*

No Court is likely to take the situation lightly. Comments at Court such as *"the fetal heart tracing has been missing since delivery,"*[547] do *not* wash down well. In *Martelly v. New York City Health & Hosp. Corp*,[548] where the CTG tracing was missing, the Court gave the jury instruction to draw the strongest adverse inference against the defendant hospital which had a legal obligation both to safeguard the CTG strip as well as give a reasonable explanation for its disappearance. Again, in *London Strategic Health Authority v. Whiston*[549]:

The judge put in the scales the prejudice that the defendant would suffer by reason of the loss of the CTG

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[545] *The Baglio v. St. John's Queens Hosp*., 303 A.D.2d 341 (2d Dept. 2003), Appellate Court.

[546] Clinically, highly challengeable point.

[547] *Simms v. Birmingham Health Authority* 2000 All ER (D) 1978.

[548] *Martelly v. New York City Health & Hosp. Corp*., 276 A.D.2d 373, 373-74 (1st Dept. 2000).

[549] *London Strategic Health Authority v. Whiston* - [2010] 3 All ER 452.

Ennis et al. [550] reported that 19 CTG tracings were missing in an analysis of 64 case records of serious obstetric litigation held by the Medical Protection Society. Gaffney et al. [551] also found that there was an increased likelihood of a missing CTG trace in the first stage of labour in cases of neonatal death as well as an increased likelihood of a missing CTG trace for second stage. However, one should also consider the removal of such tracings due to teaching purposes, accidental losses as well as the fact of natural deterioration both of the tracing on the paper as well as of the paper itself.[552] Hence the importance of electronic storage or if not available, the scanning of the CTG in toto. Some overseas hospitals legally bind the relevant personnel to preserve such tracings as an intrinsic part of the medical record for a stipulated period of time. One such example comes from New York Hospital[553] where CTG strips must be safely preserved for whichever period is the longest, namely:

6 years from the date of patient discharge from hospital.

3 years after the child reached the age of maturity (18 years).

6 years after the child's death.

[550] M Ennis, Vincent CA. Obstetric accidents: a review of 64 cases. Brit Med J. 26 1990 May 26; 300(6736):1365 – 7.

[551] Gaffney G, Sellers S, Flavell V, Squier M, Johnson A. Case – control study of intra-partum care, cerebral palsy, and perinatal death. Brit Med J. 1994 March 19.308:743 – 50.

[552] Cynober E, Jeny R. The medico-legal value of monitoring of the fetal heart rate during labour. J Gynecol Obstet Biol Reprod (Paris). 1997; 26(6):561–6.

[553] New York Hospital Code §405.10(a) (4).

The Maltese Health system will eventually have to evaluate this point, either pro-actively or as a result of bitter experience. No health system can assume that all is well with a birth because no legal letter is received within weeks or months after the birth. Electronic storage is a must in this day and age although safe storage of the original is a continued must. not .Babies have a habit of growing up and having a mind of their own which may not at all tally with the pacifist attitude of the parents of the once little baby. *In Gossland v. East of England Strategic Health Authority,*[554] the *plaintiff was a seventeen-year-old, alleging that he had* sustained brain damage at or around the time of his birth as a result of medical negligence. Retrieval of a clinical file and hoping that the original CTG tracing is still in it is daunting task but one which the system must ensure.

The situation does not seem to be unique to Malta where any CTG tracings lie loose in the back folder of the patient's file. Although this was back in the UK of 1994, Kabukoba et al. [555] reported that in 72% cases there was no security for CTG tracings (in unsecured envelopes, pockets and bags) with 19% lying free in the notes. In 11%, tracings were incomplete. In 33%, tracings were not stored in the relevant case notes and in 14% where an important intra-partum event had taken place, the tracing was missing.

In the Maltese scenario, the storage situation needs rectifying including electronic storage and failing that the official scanning of the tracing in clinically worrying cases

[554] *Gossland v. East of England Strategic Health Authority* [2008] EWHC 2175.

[555] Kabukoba JJ, Gale J, Penna L, Chamberlain GVP. Cardiotocograms: Their storage, identification and retrieval. J Obstet Gynaecol, 2 July 2009 Jul 2;14(6):388–91.

because the thermo-sensitive CTG paper may show signs of deterioration at times, even within 3–4 years. Such scanning must be done in toto and not in separate strips. However, the original tracing must always be safely stored away. The MOS should also consider full computerized clinical information systems (CIS) for CTG tracings. All storage in whatever form must respect the Data Protection Act and be guided both by relevant College advice as well as any National guidelines on storage of medical information which is operative at the time.[556]

Although the format and storage of CTG tracings is complicated by issues of security, retrieval, space and preservation, one must remember that these tracings are highly important medical and legal documents. The UK NHS Health Service [557] identifies a minimum retention period of 25 years for all obstetric and midwifery records including CTG tracings. The legal statute in such cases dates from the time the person becomes aware that they have suffered harm, with a time limit for minors often being extended to the age of majority if permanently disabled and at times even beyond that. This naturally has a direct bearing on the period of storage of CTG tracings. A minimum period of twenty-five years is a fair period to stipulate such storage.

A2.6 Confirming hypoxia in an abnormal I-P CTG Tracing

The time-honoured method of confirming the presence of intra-partum hypoxia is to obtain a drop of fetal scalp blood and absorb it in a capillary tube for analysis of the

[556] American Health Information Management Association (AHIMA) Code of Ethics, Principles and Guidelines. 2017.

[557] NHS Executive. For The Record: Managing Records in NHS Trusts and Health Authorities. London; 1999. Health Service Circular HSC 1999/053. Appendix B.

fetal pH and lactate levels[558] by performing a fetal blood sampling (FBS). Confirming a dropping pH and an elevated lactate demonstrates the presence of true hypoxia. Up until this is carried out, I-P CTG monitoring is no more than a screening test, although most, justifiably, do not accept FBS as some ideal test of IPH. [559,560] However, the fact is that the use of FBS is still advised by most official guidelines, including the RCOG as well as the NICE guidelines and its value in Court remains officially unchallenged. FBS is still positively considered by the UK Courts. In the 2013 UK Court case *Chappell v. Newcastle upon Tyne Hospitals NHS Foundation Trust*,[561] the performance of FBS firmly favours the defendant when the child was born with extensive brain damage:

On the other hand, there was positive evidence of the absence of hypoxia as 01.55 when the FBS was taken and at birth with the cord blood samples and, on the basis of Mr Tuffnell's interpretation of the CTG, no evidence of hypoxia in the intervening period.

The obstetrician was acquitted.

In Malta, FBShas not been adopted in clinical practice and disturbed I-P CTG tracings are often taken at face value proceeding to CS on their evidence. The toll on the national health budget must be inestimable and will benefit both from the introduction of CTG

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[559] Mahendru AA, Lees CC.Is intra-partum fetal blood sampling a gold standard diagnostic tool for fetal distress? European Journal of Obstetrics & Gynaecology and Reproductive Biology, 2011; 56:137–139.

[560] Incidentally the same authors further discount scalp lactate while suggesting that pulse oximetry, fetal ECG waveform analysis, and central haemodynamics in labouring rhesus monkeys provide more accurate parameters.

[561] *Chappell v. Newcastle upon Tyne Hospitals NHS Foundation Trust* [2013] EWHC 4023 (QB), 8NE90052.

training programmes/seminars and assessments as well as the introduction of FBS. In all truth, FBS has been shown to have a *poor* positive predictive value for intra-partum hypoxia[562] and recent systematic reviews have reported no evidence of benefit in reducing the operative interventions.[563] However, this hardly justifies relying on CTG alone as the final arbiter of fetal distress as a practical alternative

Medico-legally the performance of FBS is still equated with an obstetrician being a "competent", as seen from the 2013 US Court case *NM Pursuer and Reclaimer against Lanarkshire Health Board Defenders and Respondents*[564]:

…….the CTG trace showed features which no competent obstetrician exercising reasonable care would have interpreted otherwise than as requiring the taking of a fetal blood sample, which failing, the carrying out of a caesarean section.

In the 2012 UK case Ludwig *(by her mother & litigation friend Della Louise Ludwig) v. Oxford Radcliffe Hospitals NHS Trust and another*[565] we find direct reference to the NICE guidelines advising the use of FBS:

[562] Clark SL, Hankins GD. Temporal and demographic trends in cerebral palsy — fact and fiction. Am J Obstet Gynecol. 2003 Mar;188(3):628 – 633.

[563]Alfirevic Z, Devane D, Gyte GML,C. Continuous cardiotocography (CTG) as a form of electronic fetal monitoring (EFM) for fetal assessment during labour (Review). Cochrane Library. Cochrane Database of Systematic Reviews. 2017.

[564] NM *Pursuer and Reclaimer against Lanarkshire Health Board Defenders and Respondents* [2013] CSIH 3.

[565] *Ludwig (by her mother & litigation friend Della Louise Ludwig) v. Oxford Radcliffe Hospitals NHS Trust and another* [2012] EWHC 96 (QB).

In cases where the CTG falls into the suspicious category, conservative measures should be used. In cases where the CTG falls into the pathological category, conservative measures should be used and fetal blood sampling be undertaken where appropriate/feasible. In situations where fetal blood sampling is not possible or appropriate then delivery should be expedited.

Since officially FBS still holds its place, a conscientious and updated obstetrician will encounter an enigma. Even if as far back as 2008, Wiberg-Itzel et al[566] found no significant differences in rate of acidaemia at birth after the use of lactate analysis or pH analysis of fetal scalp blood samples.[567] Hence, one must decide whether to respect and act on evidence-based facts or kowtow to the official guidelines such as those recommended by NICE [568] which still advise FBS[569] in the presence of a pathological FHR trace, unless there is clear evidence of fetal compromise[570] when a caesarean section should be resorted to immediately. This is one situation, where disobeying official guidelines may be justified *but* in a UK Court, such reasoning may encounter little sympathy in Court for although guidelines are not legally binding, they carry an understandable de facto advantage in Court reasoning. As matters stand, the equivocity of the situation calls for an ideal combination of a modern method like T waveform analysis of fetal electrocardiogram for intrapartum surveillance (STAN) with CTG *and* FBS, unless one has the full support of the unit where one works, in which case,

[566] See note 264.

[567] Interpreting the pH results on any previous measurement, ≥ 7.25 being considered normal, 7.21–7.24 as borderline and ≤ 7.20 as abnormal.

[568] Intra-partum care: Care of healthy women and their babies during childbirth, National Institute for Health Care and Excellence. Published Sep 2000.

[569] Evidence level 1b.

[570] Such as a prolonged deceleration exceeding three minutes.

departmental guidelines should be followed and may be quoted as such in Court. In fact, while the present situation holds, such official departmental backing may be the only legally safe compromise and therefore departmental guidelines should be clearly defined. .

However, one fact is certain, the evidence casting aspersions on the validity of FBS can never ever justify acting solely on an abnormal I-P CTG tracing, as is the situation in Malta, unless say, marked persistent bradycardia supervenes. There *is* no logic in the present situation and, medico-legally, one has absolutely no support whatsoever if a Court challenge arises as to the indication of a caesarean section done on such basis. Presumably if such a challenge were to arise, one might consider the claim of customary practice. However, in *Toth v. Community Hospital,*[571] the Court ruled that physicians may be liable for failure to apply "best judgment" where they have particular knowledge of the risks associated with a *customary* practice but nonetheless still employ the practice. And in *Incollingo v. Ewing*,[572] admittedly a case not related to any CTG aspect, the Pennsylvanian High Court ruled that the defendant physicians could not rely solely on conformity with custom to establish due care. In 1982, in *Burton v. Brooklyn Doctors Hospital*[573], the Court once again upheld liability against defendant and the Hospital for ordering the customary administration of oxygen in increasing dosage to a premature baby (with resultant death) despite his knowledge of the danger of increased oxygen and of the child's satisfactory progress on the existing lower dose of oxygen.

[571] *Toth v. Community Hospital*, 239 N.E.2d 368, 373 (N.Y. 1968).

[572] *Incollingo v. Ewing* 444 Pa. 263 (1971).

[573] *Burton v. Brooklyn Doctors Hospital* 88 A.D.2d 217 N.Y. 1982.

With special reference to the Maltese situation, some thought should be given to the U.K. from 2000, *Simms v. Birmingham Health Authority,*[574] where the hospital had no facilities for FBS to be done. The Court found the defendant obstetrician guilty of negligence. In the Maltese scenario, the official labour ward protocol, copied from overseas without consideration of local needs, does recommend FBS where indicated, and this raises the liability of the individual obstetrician. The MOS should decide whether to install the necessary simple facilities for carrying out an FBS or whether to install a newer method such as STAN. At this stage this thesis proposes both the local introduction of FBS as well as a newer more evidence-based test such as STAN. This will lay the ground for the newer tests of the future while satisfying the advice of systems still advocating FBS. The introduction of STAN along with FBS is justified along advice which advises the use of FBS:

Ideally all maternity units where CTG is employed should have ready access, 24 hours a day to an accurate blood gas analyser." [575]

And also, advice which warns about the *negative* potential medico-legal risks of FBS:

[574] *Simms v. Birmingham Health Authority*,Queen's Bench Division **[**2000] All ER (D) 1978.

[575] Talaulikar VS, Lowe V, Arulkumaran S. Intra-partum fetal surveillance. Obstetrics, Gynaecology & Reproductive Medicine 2014 Feb;24(2) 2:45–55.

Continuing to perform FSBS without scientific evidence may result in risks associated with the procedure without any potential benefit, which may lead to adverse clinical and medico-legal consequences. [576]

STAN is based on the fact that hypoxia affecting the unborn child through its effect on the muscle (myocardium) of the heart itself causes alterations of the ST segment of the fetal ECG which is recorded continuously from an electrode attached per maternal vaginam to the fetal scalp. Computer analysis of the fetal ECG is continuous but one drawback is that the technology relies considerably on human interpretation of the CTG to indicate the appropriate action when ST segment changes occur.[577] Most serious researchers are giving STAN the green light[578] but the medico-legal implications are anybody's guess. To this author's knowledge up till the time of writing no case law exists involving STAN.

However, doing away with FBS may not be as easy as one supposes. Thus the ACOG-AAP criteria for establishing HIE have as one of their *core* criteria the confirmation of the presence of fetal metabolic acidosis, confirmed by the presence of a pH < 7 and a base deficit of ≥ 12 mmol/L, as discussed in section 4.14 and illustrated in Table 3. Again, such values are an integral part of cerebral palsy litigation:

[576] See note 265.

[577] Sacco A, Muglu J, Navaratnarajah R, Hogg M. ST Analysis for intra-partum fetal monitoring. The Obstetrician & Gynaecologist. 2015 Jan 23; 17(1):5.

[578] Neilson JP. Fetal electrocardiogram(ECG) for fetal monitoring during labour', Cochrane Database Syst Rev, 3 (2013); 5:CD00016.

"During litigation procedures, it is necessary to have access to a readable CTG, a well-documented partogram, a complete analysis of umbilical cord gases, a placental pathology and an extensive clinical work-up of the new-born infant including cerebral MRI., use of adjuncts such as fetal blood sampling for pH or lactates."[579]

One must tread lightly where FBS is concerned and certainly not many are rushing to discard it irrespective of all de jure argumentation against it.

A2.7 The disadvantages of CTG

Unfortunately, the disadvantages of CTG are substantial and range extensively from inherent scientific weaknesses to serious misinterpretation reflecting human error, including cognitive impairment of CTG abnormal pattern recognition. An oft forgotten added disadvantage is the distraction of the obstetrician from his patient, who may be subsequently hardly glanced at while full attention is riveted on a dubious I-P CTG tracing. This disadvantage must be given increasing weight in a medical world ever considering the patient's autonomy and perceptions. The phenomenon may in itself lead to a breakdown of a relationship during labour. Cultivating such a relationship can, not infrequently, mitigate or even dispel future litigation in the presence of an adverse clinical outcome. Medico-legally one can never over emphasise the importance of the continued awareness of a labouring patient of all that is happening to her. In such a physically trying time as labour is, the patient is often scared, worried and hyper-sensitive to the least look of her attendants. Ignoring a patient to look at an I-P CTG

[579] Boog G. Cerebral palsy and perinatal asphyxia (II--Medicolegal implications and prevention, Gynecol Obstet Fertil. 2011 Mar; 39(3): 146-73.

tracing and dashing out without a word to the mother induces both worry and a sense of alienation which engenders a feeling of being just a patient in a numbered bed.

A2.7.1 Changing nomenclatures and classifications and their clinical and medico-legal implications

As early as 1967, Caldeyro-Barcia[580] modified the original CTG nomenclature which he had designed and which he later found inappropriate.[581] Yet, reference to the pre-1967 classification still occasionally surfaces both in clinical use and even more worryingly in Court transcripts. This, in spite of the fact that the pre-1967 terms as such 'dips' and type I and type II decelerations of the FHR (now replaced by early, late and variable decelerations) do not even make sense in the light of modern feto-maternal physiology. An example of such long outdated terminology comes from *Bruce v Kaye*, surprisingly a 2004 case, where we find:

He arrived at 11.35pm Inter-alia, he found Ms Chevelle six centimetres dilated and read the trace as type 2 decelerations with variable dips.

Here we find reference to 'type 2 decelerations,[582] which simply do not exist now or even pre-1967 when type 2 dips where in use. In any case the 'Type 2' terminology had

[580] Roberto Caldeyro-Barcia (26.9.1921 -2.11.1996), an Uruguayan pioneer of maternal-fetal medicine who in 1958, along with others, researched the effect of uterine contractions on fetal heart rate – the basis of fetal monitoring.

[581] Day E, Maddern L, Wood C..Auscultation of Fetal Heart Rate: An Assessment of its Error and Significance. Brit Med J. 1968 Nov 16; 4(5628):422–424.

[582] Caldeyro- Barcia's never used the term Type 2 Deceleration but Type 2 Dips.

become extinct a good thirty-seven years previous to the Court case. Again, in the 2009 case *Whiston v. London Strategic Health Authority*,[583] we find:

It is said that if the CTG had still been available the court would be able to tell when it was discontinued and whether there were Type II dips and, if so, for how long (i.e. whether they were continuous).

Other terms such as 'beat to beat' variation rather than 'variability' reflect CTG interpretation pertaining to the older CTG machines. The latest terminology accepted by NICE[584] is limited to the following terms: Normal Baseline fetal heart rate, bradycardia (moderate or abnormal), tachycardia (moderate or abnormal), baseline variability (normal, non- reassuring or abnormal), accelerations and decelerations (early, late, variable, atypical variable and prolonged) and sinusoidal pattern.[585]

Both modern obstetric practice as well as contemporary obstetric jurisprudence should exclude any but the most recent, standardized, quantitative nomenclature to interpret I-P CTG if justice is to be fairly meted out. Lack of rigorous attention to such factors render a difficult subject unnecessarily more difficult and contentious. Using wrong nomenclatures is akin to using an outdated language but, with the added implication, for those who detect such lack of serious detail that if the language was wrong, what technical conclusions could be drawn that were correct? For, unless the tenets of science

[583] *Whiston v. London Strategic Health Authority* [2009] EWHC 956 (QB), HQ06X03108.

[584] NICE guideline CG190. Intrerpretation of cardiotocograph traces. February 2017.

[585] The sinusoidal pattern is rare but often indicates that the fetus is in immediate serious jeopardy.

are respected meticulously what remains is not science but, to use Daubert terminology, *junk science*.

It is not only the use of wrong and outdated terminology and nomenclature that rings alarm bells when jurisprudence turns its focus on I-P CTG. Even more worrying are pointers at the fact that the real significance of CTG is not appreciated within its narrow remit and limitations as stipulated by science. Thus, in the 2003 case *The Baglio v. St. John's Queens Hosp*[586] we read:

the fetal monitoring strips would give fairly conclusive evidence [587]*as to the presence or absence of fetal distress, and their loss deprives the plaintiff of the means of proving her medical malpractice claim against the Hospital.*

The first part of the this statement shows a disconcerting lack of true appreciation of the real significance of I-P CTG monitoring and here we seem to be backtracking to the 1960's for we are being informed that an abnormal I-P CTG is "fairly conclusive of fetal distress". Yet, it would be wrong to generalise and state that there is no Court commitment to mainstream science, preventing inconsistent verdicts in mass tort litigation".[588] In *Smith v. West Yorkshire Health Authority (t/a Leeds Health Authority*,[589] it is reassuring to hear Silber J deliberate on the CTG with some detail:

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[586] See note 544.

[587] Clinically, highly challengeable point.

[588] Green MD. Bendectin and birth defects: The challenges of mass toxic substances litigation Philadelphia University Press; 1996.

[589] In *Smith v. West Yorkshire Health Authority (t/a Leeds Health Authority. Queen's bench Division.* [2004] Lexis Citation 1053.

Baseline variability describes the changes in the baseline of the FHR. Such changes occur slowly unless there is an acute accident. Accelerations are the increases in the FHR, and they are a positive and reassuring sign if they occur as a response to uterine contractions or movements in which case they are seen occasionally. They may not occur regularly, but they should be seen occasionally. Decelerations are reductions in the FHR of more than 15 beats per minute from the baseline rate, while accelerations are increases in the FHR of more than 15 beats per minute.

Again, in *Brodie McCoy v. East Midlands Strategic Health Authority*,[590] defence was versed enough to attack FIGO and its frequently changing classification:

…reference was made to the 1987 FIGO Guidelines for interpreting CTG tracings. Mr Porter pointed out that there was an apparent internal inconsistency in the FIGO classification of decelerations in antepartum CTGs…

The timely amendment of changes of classifications of any discipline are normally indicative of healthy evolution in the light of progressing science. However, in the case of CTG, repeated and non-universal acceptance of different classifications over the last five decades is evidence of much confusion and such a situation has many negative repercussions both clinically and inevitably medico-legally.

[590] *Brodie McCoy v. East Midlands Strategic Health Authority*. 118 BMLR 107,[2011] Med LR 103,[2011] EWHC 38 (QB).

Partly quoting Macones et al.,[591] Ayres-de-Campos et al.[592] make a justifiable plea when as late as 2008 he stated:

Making guidelines simpler and more objective may be an important step to guarantee a wide application and assimilation of the recommendations, as well as an enhanced reproducibility and increased memory retention.

This has by no means been a lonely voice calling in the wilderness of clinical CTG use. In 2004 The Joint Commission Sentinel Event Alert, Preventing Infant Death and Injury During Delivery[593] stressed the:

…urgent need to develop clear guidelines for fetal monitoring of potential high-risk patients including protocols for the interpretation of fetal heart rate tracings and to educate nurses, resident physicians, nurse midwives and attending physicians to use standard terminology to communicate abnormal fetal heart rate tracings.

In 2008, the ACOG reflected its worries and suggested re-classifying CTG abnormalities:

In the United States, there was growing concern that the existing two-tiered system for classification of fetal heart rate patterns (reassuring and non-reassuring) was

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[591] See note 498.

[592] Ayres-de-Campos D, Bernardes J. Twenty-five years after the FIGO guidelines for the use of fetal monitoring: Time for a simplified approach? International Journal of Gynaecology and Obstetrics 2010 Jul; 110(1):1–6.

[593] Sentinel Event Alert, Issue #30, Preventing Infant Death and Injury During Delivery, 2004 July 21.

inadequate and did not accurately reflect the physiologic implications of various fetal heart rate patterns obtained via electronic fetal monitoring. As did RCOG in 2001 and SOGC in 2007, members of the 2008 NICHD workshop on EFM recommended the adoption of a three-tiered classification system for interpretation of fetal heart rate patterns.[594]

One must bear in mind that these upheavals without a clear final outlook were occurring forty years after universal CTG use in clinical practice as well as in Court cases. It is hardly surprising that such confusion is reflected in Court argumentation as we find in the 2014 case *Tippett v. Guy's & St Thomas' Hospital NHS Foundation Trust*[595]*:*

Those guidelines were for intra-partum (in labour) fetal surveillance, but it was common ground that they were the best available guidelines for antenatal monitoring. The guidelines (at tables 3 and 4 on p 5) categorised tracings as being "normal", "suspicious" or "pathological". *The distinction between the categories depended on whether the four features were* "reassuring", "non-reassuring*" or* "abnormal*". If all four features were reassuring, the trace would be "*normal*". If one feature was non-reassuring, but the other three were reassuring, the trace would be "*suspicious*". If two or more features were non-reassuring or there was one or more abnormal category the trace would be "pathological"…..*

[594] See note 498.

[595] *Tippett v. Guy's & St Thomas' Hospital NHS Foundation Trust* [2014] EWHC 917 (QB), HQ11X04855.

That such argumentation may be the stuff on which hangs the plaintiff's or the defendant's destiny is worrying indeed. There is an absolute urgency to heed the advice that:

the adoption of a standardized nomenclature for EFM is recommended.[596,597,598]

In 2014, the Royal College of Physicians of Ireland (and its Institute of Obstetricians and Gynaecologists) also expressed its concern about terminology – with point 4 of its Key Recommendations stating:

Communication between staff should convey the clinical context and use consistent terminology to describe the features of the CTG, the level of concern and the urgency of the situation. CTG s can be classified as normal, suspicious or pathological.[599]

However, all fingers seem to point to the sad likelihood that

[596] Simpson KR, Knox GE. Common areas of litigation related to care during labour and birth: recommendations to promote patient safety and decrease risk exposure. J Perinat Neonat Nurs. 2003 Jun; 17(2): 110-127.

[597] Miller LA. Safety promotion and error reduction in perinatal care: Lessons from industry, J Perinat Neonat Nur. 2003 Jun; (17)2:128-138.

[598] Simpson KR, Knox GE. Risk management and electronic fetal monitoring: Decreasing risk of adverse outcomes and liability exposure. J Perinat Neonat Nurs, 2000 Dec; 14(3): 40 -52.

[599] Clinical Practice Guideline No.6 (revision date: April 2014), Intra-partum Fetal heart Rate Monitoring, Institute of Obstetricians and Gynaecologists, Royal College of Physicians of Ireland and Directorate of Strategy and Clinical Programmes, Health Service Executive, Published 2012 (Revision date: April 2014).

… intra-partum EFM can be expected to remain contentious for some time to come…. ’’[600]

A2.7.2 Operative birth increase.

The increase in the rate of intervention at birth through the use of I-P CTG is by now an unchallenged fact, as attested to by myriad publications. For example, in 1995 Vintzelos et al[601] showed that through the labelling of “fetal distress”, CTG monitoring had increased the (general) caesarean section rate by 53% and the Caesarean-section rate specifically for fetal distress by 155%. He also showed an increase in both vacuum extraction as well as forceps deliveries. Another such study, by Sweha et al. four years later, [602] showed that 38 extra Caesarean deliveries and 30 extra forceps operations are performed per 1,000 births with continuous EFM versus intermittent auscultation. By 1997, the obstetric colleges were calling for selective use of CTG in labour.[603]

The great increase in Caesarean Sections has exploded national financial burdens and added substantially to related complications and subsequent litigation. The explosion of caesarean sections has naturally led to the ever-increasing problem of pregnancies in a scarred uterus and the concept of VBAC with its special clinics and management

[600] Sholapurkar Sl. NICE’s draft guideline on intra-partum care. Editorial. Brit Med J.2014; 348 g 4279.

[601] Vintzileos AM, Nochimson DJ, Guzman ER, Knuppel RA, Lake M, Schifrin BS. Intra-partum electronic fetal heart rate monitoring versus intermittent auscultation: A meta-analysis. Obstet Gynecol, 1995;85(1):149-155.

[602] [602] Sweha A,Hacker TW, Nuovo J. Interpretation of the Electronic Fetal Heart Rate During Labour., American Family Physician. 1999 May 1; 59(9):2487-2500.

[603] See note 528.

including medico-legal issues of disclosure. Meta-analysis of all published randomized trials has shown that EFM is associated with increased rates of surgical intervention[604] resulting in increased costs.[605] Some arguments on the matter produce rather negative views as that by that by Cesarelli et al[606]:

Numerous randomized trials have agreed that continuous EFM in labor increases the operative delivery rate, without clear benefit to the baby.[607]

Others, such as Albers, aim at locating the reasons with some suggested light at the end of the tunnel:

CTG usefulness is undoubted; nevertheless, there is, still nowadays, substantial intra- and inter-observer variation in the assessment of FHR patterns, due mainly to the visual inspection of CTG, which can lead to intervention when it is not required or lack of intervention when it is. Hence, several analysis methodologies (in time domain, in frequency domain, with semi-automatic software which compute specific time-domain parameters, etc.) were proposed in recent years to improve reliability and objectivity of CTG signals interpretation.[608]

[604]ACOG Practice Bulletin Clinical Management. Guidelines for Obstetrician-Gynecologists, Number 106, 2009 July. Intrapartum fetal heart rate monitoring, Interpretation, and General Management Principles.

[605] See note 600.

[606] Cesarelli M, RomanoM, Ruffo M, Bifulco P, Pasquariello G..Fetal heart rate variability frequency characteristics with respect to uterine contractions', J. Biomedical Science and Engineering; October 2010; 3(10): 1013-1020.

[607] Albers L.Monitoring the fetus in labour: evidence to support the methods', J Midwifery Women's Health. 2001 Nov-Dec; 46(6):336 -373.

In spite of serious repercussions on national health budgets, morbidity and mortality statistics, etc., this negative aspect of CTG monitoring also has a direct impact on litigation. Ideally this situation would lead to the use of master classes, electronic education tools and assessments to achieve one language for all. For one worrying element of the situation where a babel of languages is spoken is an increase of defensive medicine in the presence of uncertain interpretation of a worrying I-P CTG. One can hardly be surprised that the use of I-P CTG is likely to lead to an increase in unnecessary intervention, when as Kraus [609] states:

Despite EFM s poor predictive value, plaintiff's attorneys can almost always find an expert who will retrospectively identify an abnormality in EFM tracings that "should" have led to a Caesarean delivery.

It is extremely difficult to cure this aspect of defensive medicine in an increasingly legalised obstetric world. Confidence in effecting or omitting operative interference in both first and second stages of labour can only be born out of confidence in interpretation. Such confidence is obviously often lacking as witnessed by the repeated evidence of common and widespread inability to interpret CTG adequately.

[609] Kraus F. Perinatal Pathology, the Placenta, and Litigation. Human Pathology. 2003; 34(6):517 – 521.

A2.7.3 Low sensitivity and high specificity

It is rather worrying that an investigation performed on at least 300,000 women annually in the UK alone[610] has high specificity (86%) and a low sensitivity (15.38%) with a resultant positive predictive value of only 11.76% but a negative predictive value of 89%. [611] This means that a normal CTG tracing in labour can be taken as truly reflecting a healthy unborn child, but an abnormal tracing does not necessarily equate with fetal hypoxia. In a bad CTG case scenario, exhibiting a fetal baseline tachycardia, with reduced variability and no accelerations and late decelerations, the incidence of fetal hypoxaemia and acidosis can be confirmed in only 40–60% of cases.[612] One must also remember that regarding the detection and prevention of cerebral palsy, Nelson et al[613] showed that CTG tracings may have such low sensitivity that its false positive rate may be as high as 99.8%. In their own series, *only 0.19% of their abnormal CTG tracings were associated with moderate or severe cerebral palsy*. These, by now well-established facts, need to be driven home again and again in the MDH labour ward where pathological CTG tracings bypass confirmation of evidence of fetal hypoxia and lead directly to expedited delivery.

[610] Weston N. Electronic Fetal Monitoring project launched to improve birth outcomes and reduce medical litigation. Royal College of Obstetricians and Gynaecologists, 2011 May 18.

[611] Parveen S. Umbilical cord arterial blood base excess as gold standard for fetal well- being screening test validity at term delivery. J. Pak Med Assoc. 2010 May; 60(5):347-50.

[612] See note 333.

[613] See note 497.

A2.7.4 High intra- and inter-observer errors

Among the most worrying weaknesses of CTG monitoring is its high observer error of interpretation. This applies to both intra-observer as well as inter-observer errors. The former applies to errors incurred by the same observer on reviewing the same CTG tracing on separate occasions while the latter refers to the different opinions expressed by two observers or more when viewing the same tracing. It is both clinically worrying and potentially medico-legally catastrophic to read that:

Observers agreed poorly with each other and fair to good with themselves on CTG classification and clinical management. They achieved the highest agreement on abnormal CTG patterns and on the clinical management option 'continue monitoring.[614]

These errors repeatedly confirmed since the 1990's, apply both to clinicians' agreement as based on quantitative measures as well as to the resultant data-driven analysis of the clinical evaluation. Whatever parameters are analysed and however large the number of clinicians involved, there is a constantly high inherent inter- and intra-observer variability of CTG evaluation.[615] Back in 1985, the ACOG looked at the CTG interpretation and the subsequent response in labour by four obstetricians examining 50

[614] Grant JM. The fetal heart rate trace is normal, isn't it? Observer agreement of categorical assessments. Lancet. 1991 Jan 26; 337(8735):215-218.
[615] Spilka J, Chudáček V, Janků P, Hruban L, Burša M, Huptych M, Zach L, Lhotská L. Analysis of obstetricians' decision making on CTG recordings, Journal of Biomedical Informatics. 2014 Oct; 51:72–79.

CTG tracings. They agreed in only 22% of the cases.[616] Two months later, during a second review the clinicians interpreted 21% of the tracings differently than they did during the first evaluation.[617] In another study with five obstetricians interpreting 150 CTG tracings, [618] agreement was obtained only in 29% of the cases. Ayres-de-Campos et al[619] and several other researchers have not only confirmed this difference of informed opinion on the same observed artefact but furthermore differentiated which aspects were likely to be subjected to such inter-observer error.

The unfortunate but inevitable conclusion is that:

"The subjectivity of CTG interpretation and inconsistencies in interpretation should also be considered in intra-partum management, clinical audit and in medico-legal settings."[620]

A2.7.5 Of human error

It is a sad and surprising fact that there *are* a substantial number of obstetricians, in training or otherwise, who cannot interpret a CTG tracing correctly. A ghastly

[616] Helfand M, Marton K, Ueland K. Factors involved in the interpretation of fetal monitor tracings. Am J Obstet Gynecol. 1985 March 15; 151(6):737–44.

[617] Nielsen PV, Stigsby B, Nickelsen C, Nim J.Intra- and inter-observer variability in the assessment of intra-partum cardiotocograms, Acta Obstet Gynecol Scand. 1987 Jan; ;66(5):421–4.

[618] Beaulieu MD, Fabia J, Leduc B, Brisson J, Bastide A, Blouin D, Gauthier R, Lalonde A. The reproducibility of intra-partum cardiotocogram assessments. Can Med Assoc J. 1982; 127(1): 214–6.

[619] See note 591.

[620] Devane D, Lalor J. Midwives' visual interpretation of intra-partum cardiotocographs: intra- and inter-observer agreement. J Adv Nurs, 2005 Oct; 52(2):133-41.

indictment of one such obstetrician can be found in *Azzam v. General Medical Council,*[621] where the on-call obstetrician's lack of knowledge led to the loss of a baby:

The expert evidence, which was accepted by the appellant, was that if he had not made an error in the assessment of a cardiograph (CTG) reading, it was likely that the child would have been delivered successfully. In October 2007, a Fitness to Practise Panel (the panel) of the respondent General Medical Council (GMC) found that the appellant had not interpreted or recognised signs of fetal distress as shown by the CTG trace…. The panel's conclusion was that the appellant's assessment of the CTG scan had been inappropriate, inadequate and irresponsible, not in the best interests of the mother and below the standards which could reasonably have been expected of a competent obstetrician.

In *Simms v. Birmingham Health Authority,*[622] the obstetrician admitted his mistake of interpretation through lack of knowledge in Court:

With hindsight I consider it showed some reduced variability and was thus abnormal. This reduced variability warrants continued observation, but it does not warrant Caesarean section, unless other significant abnormalities develop.

[621] *Azzam v. General Medical Council* - [2008] All ER (D) 149 (Dec).

[622] *Simms v. Birmingham Health Authority* 2000 All ER (D) 1978.

In *A. B Claimant (a child and protected party by X. Y. her mother and litigation friend) and C. D. v. NHS Trust, Defendant,*[623] another even more flagrant case of CTG ignorance is uncovered. Here, the defendant failed to interpret correctly and act on a CTG tracing showing persistent tachycardia. This is surprising for surely in the twenty-first century there should hardly be any query that all working in a delivery unit need to be well versed in basics of CTG interpretation. Again, in *Fabiyi v. Nursing and Midwifery Council,* Court made yet another condemnation along similar line:

"...on 26 April 2008, EF showed lack of skill in reviewing a suspicious CTG in a timely manner as part of her co-ordinator duties at UCLH."[624]

As is apparent form these cases, the serious problem of inability to interpret the CTG tracing correctly is not a negligible one. The need for the ability to interpret CTG correctly by all labour ward staff goes without question. In a series of 3600 deliveries at the Middlesex Northwick Park Hospital (UK) between 1996 and 2000, 22% of the management care problems were directly attributed to CTG misinterpretation.[625] More than 1 in 5 of serious mismanagements resulting from CTG misinterpretation in this series were preventable. This preventability is stressed by Hove et al.[626] who showed that all hypoxic brain injuries are potentially avoidable using established obstetric

[623] A. *B. Claimant (a child and protected party by X. Y. her mother and litigation friend) and C. D. NHS Trust, Defendant,* [ACF 32(2): 02/2013].

[624] See note 535.

[625] Lorin L, Spencer JAD. Care management problems on the labour ward: 5 years' experience of clinical risk management', Journal of Obstetrics & Gynaecology. 2001 Sep; 22(5):470-476.

[626] Hove L D, Bock J, Christoffersen JK, Hedegaard M. Analysis of 127 peripartum hypoxic brain injuries from closed claims registered by the Danish Patient Insurance Association', Acta Obstet et Gynecol. 2008 Jan; 87:72-75.

practice to avoid CTG misinterpretation, which in turn demands adequate CTG education and training. However, those possibly unmeasurable elements underlying CTG misinterpretation and pertaining to cognitive aspects of psychology must also be borne in mind and further explored. One cannot simplify the situation by ensuring that CTG interpretation is enforced or else, for although this aspect of the situation needs taking care of, the problem is deeper than that and further light neds to be thrown on the aspect of cognitive psychology involved.

Such CTG misinterpretation with resultant fetal hypoxia comes at a massive cost. In 2011, intra-partum hypoxia comprised 50% of the UKNHS litigation costs,[627] and in the 2000-2010 decade, the same UK NHS forked out £3.1 billion for maternity medico-legal claims[628] mostly involving cerebral palsy and CTG misinterpretation. The need for improvement in general CTG education and its support by experienced doctors is a frequent occurrence:

The interpretation of a baby's heart rate tracings requires special knowledge and experience. Quite often subtle changes in the CTG as early warning signs of asphyxia can only be interpreted by experienced doctors and junior doctors need to be supported and educated to acquire this skill. It is therefore crucial to have experienced obstetricians (consultants) working in labour ward during the out-of-hours period.[629]

[627] NHS Resolution. Factsheet 3: Information on claims. 2017-18. London.

[628] The highest of any speciality.

[629] Spencer C, Murphy D, Bewley S..Caesarean delivery in the second stage of labour. Editorial. Brit Med J. 2006 Sep 21; 333 (7569):613-614.

It is striking that this rampant degree of interpretative problems still pervades a discipline which has been clinically established since the 1960's. All sources stress that:

Malpractice litigation in obstetric care can be reduced by permanent CTG education and respecting national CTG guidelines.[630]

Many and persistent have been the calls for improving the situation, some stressing particular aspects over others. In evaluating Daubert guidelines, Christenson et al. [631] stress that in CTG interpretation one must evaluate error in its various forms, while Murphy et al. stress that improving the quality of interpretation significantly improves the benefits of EFM.[632] The indispensability of training has long been recognised by all leading Colleges including the RCOG and the Royal College of Midwives. Thus, the Clinical Negligence Scheme for Trusts of the UK now insists that all maternity units in England verify that their clinical staff receive training in the management of high-risk labours and CTG interpretation every 12 months.[633] This ignorance of what is a basic requirement in obstetric management must be counterpoised against the increasing scrutiny leading to merciless medio-legal response. There is no doubt that :

Due to the rising costs of litigations related to birth asphyxia and increasing complexity of obstetric patient populations, it has become absolutely mandatory that all health

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[630] See note 578.

[631] Steer PJ. Has electronic fetal heart rate monitoring made a difference? ' Seminars in Fetal and Neonatal Medicine. 2008 Feb. 13(1): 2–7.

[632] Murphy KW, Johnson P, Moorcraft J,,Pattinson R, Russell V, Turnbull A. Birth asphyxia and the intra-partum cardiotocograph. Br J Obstet Gynaecol, 1990 Jun; 97(6):470–479.

[633] The Clinical Negligence Scheme for Trusts (CNST) of the UK, Fetal Monitoring Training System.

professionals responsible for the care of women in labour are trained adequately in interpretation and documentation of CTG tracings, as well as the guidelines for actions based on the assessment of the trace and overall clinical situation."[634]

And yet, year after year and generation after generation of obstetricians somehow seem incapable of overcoming this problem, such that as late as 2014, a good fifty years plus into the use of CTG, the same exhortations are still being repeated:

"It is important that each individual obstetrician or midwife makes an effort to learn how to interpret CTG findings correctly and maintains these skills through continued medical education from time to time."[635]

While this thesis feels all constructive comments are of some degree of value, the final responsibility must lie both with the individual obstetrician as well as the unit employing him. Regular in-house certified training and assessment must lead to the right official response at the end of a stipulated period. Failure to achieve the required level of knowledge must lead to suspension of labour ward duties. Furthermore, it may be a useful suggestion for the RCOG to consider a compulsory section purely concerned with clinical CTG interpretation and its medico-legal consequences in the membership examination.

Finally, a word of warning in assuming that all interpretative errors can be avoided by the teaching and assessment of CTG abnormality patterns. This is over-simplification

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[634] See note 574.

[635] *Ibid.*

of the problem at its best for there are elements of misinterpretation which fall under cognitive psychology rather the discipline of the class. This aspect of the situation requires exploring and may yield surprising future results. For example, a serious review of the state of mental alertness/exhaustion when I-P CTG mismanagement declares itself may shed light on working conditions and working hours in individual units.

A2.7.6 IP CTG and cerebral palsy.

A meta-analysis study shows that although EFM reduced the risk of neonatal seizures, there is still an unrealistic expectation that a non-reassuring FHR can predict the risk of a baby being born with cerebral palsy. The false-positive rate of EFM for predicting cerebral palsy is greater than 99%. This means that out of 1,000 fetuses with non-reassuring readings, only one or two will actually develop cerebral palsy"[636]

This 2009 statement by the ACOG, besides giving a useful bird's eye view of the true relationship between CTG and cerebral palsy, is most worrying in that it states that *there is still an unrealistic expectation that*…medico-legally, false expectations between CTG and cerebral palsy exist, and these have done past enough damage at Court level. The statement makes it clear – once again – that CTG is not useful in reducing the incidence of cerebral palsy.[637] However, let us forget the fact that I-P CTG *does* have a preventive role to offer in the 14.5% of cases of cerebral palsy resulting

[636] ACOG Practice Bulletin. Number 106, July 2009.Intrapartum Fetal Heart Rate Monitoring: Nomenclature, Interpretation and General Management Principles.
[637] See note 498.

from intra-partum hypoxia.[638] Such a resulting cerebral palsy would be a spastic quadriplegia especially if accompanied by dyskinesia,[639, 640] although the latter may not set in before 3-4 years.[641] Cerebral palsy truly caused by IPH is also preceded by a neonatal encephalopathy (HIE) and seizures.[642] causally. However abnormal an I-P CTG is, when associated with a cerebral palsy *not* showing these features, cannot be not causally linked to the cerebral palsy. Hence even if negligence can be demonstrated in the management of such an abnormal I-PCTG, such negligence cannot be causally linked to the cerebral palsy, i.e. it is negligence which does not amount to malpractice. One may also consider looking at the *composite* outcome of intra-partum hypoxia in the form of still-births, early neonatal deaths and cerebral palsy when due to intra-partum hypoxia.

A2.8 CONSENT

In Malta, no consent is asked for specifically before CTG monitoring is commenced. This is hardly surprising as even in the USA:

..... most women in our country do not give informed consent for electronic fetal monitoring. The vast majority of women in the U.S. have no idea about the benefits and

[638] See note 344.

[639] Blumenthal I. Cerebral palsy – Medicolegal Aspects. J R Soc Med.2001; 94(12):624 – 627.

[640] This term means difficulty or abnormality in performing voluntary muscular movements.

[641] Hence full clinical diagnosis is not possible immediately at birth. Also mild to moderate CP may improve in the first few years.

[642] Evans K, Rigby AS, Hamilton P, Titchiner N, Hall DMB. The relationships between neonatal encephalopathy and cerebral palsy: a cohort study. J Obstet Gynaecol. 2001; 21(2): 114-20.

risks of the most common obstetric procedure used in labor and delivery– electronic fetal monitoring.[643]

Even in situations where CTG is consented for, one often senses a wavering uncertainty instead of a firm decision based on the conviction that such consent is a wise requirement which must be complied with. Thus, if one looks at the Procedure Overview for patients attending the University of Rochester Medical Centre concerning CTG monitoring, one reads:

You may be asked to sign a consent form that gives your permission to do the procedure. Read the form carefully and ask questions if something is not clear. The consent form for fetal heart rate monitoring may be included as part of the general consent for your labor and birth.[644]

This sentence from a Procedure Overview manual contains the word 'may' twice. One is no wiser after reading this hospital guideline as to whether consent will be asked for and if so in what form. Knowing full well the frequency of CTG medico-legal litigation, there could hardly be one single argument against the existence of a formal consent for CTG monitoring. Furthermore, one cannot truly accept the performance of CTG monitoring, particularly I-P CTG monitoring without full disclosure and obtaining a signed consent, when medical autonomy has reached its present state of influence both clinically and legally. Despite the widespread lack of the considered need of such disclosure and consenting for CTG monitoring, this thesis strongly recommends such

[643] Decker R. Evidence Based Birth. 2012 July 17.

[644] External and Internal Heart Rate Monitoring of the Fetus. Procedure Overview for External and Internal Heart Rate Monitoring of the Fetus. University of Rochester Medical Center.2019.

disclosure and *written* consent and that the consent be accompanied by a printed information sheet which should include the facts that:

"…… women should be informed that continuous CTG during labour is associated with a reduction in the incidence of neonatal seizures, has no obvious impact on cerebral palsy or perinatal mortality but is associated with an increase in the incidence of caesarean section and instrumental vaginal births. Women also need to be informed of the loss of mobility associated with the use of continuous CTG in labour."[645]

A2.9 THE LOCAL SCENE

However undesired, medico-legal challenge is, it does have the advantage that the system must rapidly find out the status quo legal vulnerability of a topic, in this case the CTG and take steps to amend the situation. Such honing of CTG management, including regular assessment of pattern recognition, patho-physiology, interpretative skills and clinical management is completely lacking in Malta. Regular training along these lines as well as assessment and reviews based on the 'burnt finger phenomenon' must become *de rigeur*.

The MOS must review its situation with regard to the crucial subject of CTG monitoring, however legally unchallenged it remains so far. Particular emphasis must be laid on many points, including the facts that:

[645] See note 519.

- CTG offers *screening* for intra-partum hypoxia (IPH). An abnormal I-P CTG cannot be assumed as evidence of such hypoxia,[646] but needs confirming by FBS and/or one of the newer methods such as STAN.

- Cerebral Palsy is only due to IPH in 14.5%[647] of cases, and therefore this represents those cases where IP CTG *may* be of value preventive value clinically. However, one reminds that CTG cannot predict cerebral palsy.

- Much debate still bedevils the subject regarding nomenclature and classification. It is important to be updated and familiar with the latest official views. It must be made amply clear that this periodic re-shuffling does not alter the basic facts pertaining to CTG interpretation and may not be used as an excuse for ignorance of interpretation and management.

- Partly due to the present intrinsic drawbacks of the subject, e.g., its low sensitivity leading to false high positive results, and partly due to defensive obstetrics, CTG monitoring is associated with a rate of unnecessary intervention which should be guarded against.

- The subject lends itself to a high misuse in defensive obstetrics. One way of diminishing this is through engendering confidence of interpretation. Another

[646] See note 333.

[647] See note 344.

is to *insist* on confirmation (and its evidence) of fetal hypoxia prior to any expediting of delivery in labour.

- There still seems to be worrying confusion *in overseas Court* regarding basic principles including but not limited even to the persistent use of outdated terms terminology. The situation must be pre-emptied in Malta where CTG Court challenge is not yet known. This may involve collaboration between the Ministry of Justice, the MOS and the MCOG. Although the Maltese Courts have had no exposure to CTG litigation, this state of affairs cannot be realistically expected to maintain the status quo.

- Updated courses and assessments of the subject need to be organised after the status quo of knowledge is determined. Such courses should ideally lead to certification and be renewed every year or two. Repeated failing of such courses or inability to reach the requisite standard should result in suspension from labour ward duties until the situation is rectified.

- The MOS must review the present practice of storage of CTG tracings and organise modern electronic storage and access. All recorded information must be maintained for a minimum of twenty-five years from birth in view of the frequent late presentation of claims in cases of brain damage alleging birth negligence.

- In many of the medico-legal initiatives, the MOS may be advised and helped by the Institute of Medico-Legal Studies. Furthermore, the MIMLS may take the

initiative of gathering the relevant statistics, organising courses of training, as well liaising between the MOS, the MCOG and the Ministry of Justice. Also, within its remit would be the setting up of a formal standing working group on CTG evaluation, which besides maintaining the local obstetric world au courant of all new developments may also provide assistance where issues of interpretation reach an impasse at Court over specialised CTG issues.

APPENDIX 3

CEREBRAL PALSY: ROOTING FOR THE TRUTH

Contents

A3.1 Why single out cerebral palsy?

It was felt that a thesis about the legal liability of caring for the unborn in the Maltese Islands ought to be concerned with *general* review of new-born pathology and not the discussion of a specific condition. On the other hand, cerebral palsy brings out so many crucial points of clinical, medico-legal, jurisprudential and historical value, that its evaluation apart from the main text was felt incumbent. Such text also serves as a point of reference, when relevant, within the main body of discussion.

The specific choice of cerebral palsy out of the many birth injuries, for which medical liability has been sought in Court, is based on many aspects which are the core essence of this chapter. Firstly, this heart-breaking condition is about the worst which can assail the new-born and his family, apart from the terrible finality of stillbirth. The tragic birth of a child with cerebral palsy is not simply a heart-rending life sentence, but an unforeseen disaster which cruelly replaces the family's expectant anticipation of perfect life with a metaphorical earthquake. The family's life changes from day to night. Apart from the parental heartbreak, as the child grows such families need to undergo overnight and often nightmarish re-adjustments demanding living and housing changes, regular or daily transport to hospital for multi-discipline medical, surgical, paediatric and physiotherapy sessions and later on special educational arrangements. Major adjustments in the medical, social and educational sector need much long-term planning. Life becomes one big paradigm shift which necessitates a brave response to a situation which was unplanned for and which substituted the dream of a healthy chid by a nightmare scenario. It is small wonder that, at times, the stress shatters family bonds from sheer exertive pressure. In other cases, it serves to unite and strengthen.

As the sad reality of the truth unfurls with time, progress from anger, resentment, and anguish may settle into seeking legal redress. The length of this process may vary from months to decades. In countries with published relevant medico-legal statistics, it is clear that cerebral palsy is the cause of the largest liability pay-outs of all obstetric claims for negligence, and in some countries account for all individual *medical* claims. Furthermore, extremely painful medico-legal and jurisprudential lessons stand to be learnt from the unique happenings in the evolution of the theories of cerebral palsy causation which contributed to the 'great cerebral palsy myth'. The last five decades have witnessed a unique review of the scientific principles involving the causality and other aspects of cerebral palsy, with a rather uncommonly seen reversal of opinion. However, the resultant effects on medico-legal and jurisprudential considerations have certainly involved a long lag period of self- correction with the result that some of the negative fall-out effects persist to this day. These aspects are of great relevance to one of the scopes of this thesis, which is the raising of the local profile of Legal Medicine and the dissemination of its modern principles.

A3.2 What is Cerebral Palsy?

While this condition was first described by Hippocrates[648] in the 5th century BC, "modern" medical science turned its extensive attention to it in the 19th century through the work of William John Little.[649] The term Cerebral Palsy was coined by William

[648] Hippocrates of Kos (c. 460 – c. 370 BC), universally considered the 'Father' of Western Medicine.

[649] In fact, the form of cerebral palsy known as spastic diplegia was also known as Little's Disease.

Osler,[650] from the German expression 'cerebral child-paralysis' (zerebrale Kinderlähmung), and was described as a permanent condition appearing in early childhood with the signs and symptoms becoming more obvious over the first few years of life.

The condition as a rule is a very serious one ravaging not only the suffering individual but also wreaking havoc on the socio-economic balance of the whole family with a serious resonant effect on society at large. Some of the symptoms often appear soon after birth but the whole picture, which may include learning difficulties, may take a few years to appear in its full form. De novo symptoms may appear but the underlying pathology, fixed ab initio, does not change or deteriorate even if the signs and symptoms appear to worsen with the child's growth. Every case varies depending on a number of factors such as the gestation period of any *in utero* damage, if hypoxia (oxygen deprivation) is involved, the extent and duration of such hypoxia, and the brain areas affected.

The external and physical symptomatology may include muscle tremors, jerky involuntary movements say of face or limbs, blindness, deafness, inability to swallow or speak and paralysis of various muscle groups and limbs. Various neurological and psychological defects affecting learning, behaviour and other psychological aspects may be present and may become more apparent with growth. The individual may end up suffering from a wide spectrum of problems, ranging from minimally disturbing damage to complete immobility and inability to swallow normally. Since the term

[650] Sir William Osler, a Canadian physician often described as the "Father of Modern Medicine" and one of the four founding professors of Johns Hopkins Hospital.

Cerebral Palsy is really an umbrella term comprising a groupage of conditions and symptomatology, individual multi-disciplined assessment is indispensable both for therapeutic planning as well as for claims of malpractice liability.

A3.3 Incidence and Prevalence of Cerebral Palsy

The prevalence[651] of cerebral palsy generally is not increasing, or if so only minimally. A slight rise in prevalence was noted between the 1970's to the 1990's,[652] in Europe and elsewhere such as USA, China and Australia.[653] However, if the prevalence is not rising significantly, neither is it decreasing. Thus, if we look at spastic cerebral palsy in Atlanta, Georgia, USA between the years 1985 – 2002, the prevalence of congenital spastic cerebral palsy did not decrease at all.[654] The condition, which is the commonest childhood motor disability, has an over-all prevalence of about 3 to 4 per 1000 children in the United States.[655] The term 'over-all' is of significance as further analysis may be looked at in a heterogeneous metropolitan country like the USA. Such sub-divisions include birth weight, gestational age and ethnicity. These sub-divisions may show

[651] Prevalence refers to the actual number of sufferers alive during a period of time (period prevalence) or at a particular date in time (point prevalence). Period prevalence is more significant in that it includes all new cases and all deaths between two specific dates, while point prevalence only counts those alive on a particular date. Incidence, on the other hand, refers to the rate of newly diagnosed conditions.

[652] Colver AF, Gibson M, Hey EN, Jarvis SN, Mackie PC, Richmond S. Increasing rates of cerebral palsy across the severity spectrum in north-east England 1964–1993. The North of England Collaborative Cerebral Palsy Survey. Arch Dis Child. Fetal and Neonatal Ed. 2000; 83: F7–12.

[653] Odding E, Roebroeck, Stam H J. The epidemiology of cerebral palsy: Incidence, impairments and risk factors. Disability and Rehabilitation. 2006; 28(4):183–191.

[654] Braun KVN, Doernberg N, Schieve L, Christensen D, Goodman A, Allsopp MY. Birth Prevalence of Cerebral Palsy: A Population-Based Study. Pediatrics. 2016 Jan ; 137(1).

[655] Boyle CA, Boulet S, Schieve LA, Cohen R, Blumberg S, Yeargin-Allsopp M, Visser S, Kogan M.. Trends in the prevalence of developmental disabilities in US children, 1997-2008. Pediatrics. 2011 June; 127(6):1034–1042.

different prevalence rates. For example, cerebral palsy prevalence decline has been noted in infants with very low birth weight (<1500g),[656] very preterm infants (< 32 weeks)[657] and moderately pre-term (32 – 36 weeks) infants[658] while, on the other hand, prevalence has been stable among children with moderately low birthweight (1500 – 2499g)[659] or normal birth weight (from 500g up).[660] The small sub-group frequencies have been insufficient to alter the overall rate of Cerebral Palsy.[661]

Similar findings in relation to the reduced prevalence of moderate-to-severe cerebral palsy sub-groups have also been reported in the Netherlands and in Victoria, Australia over similar time periods.[662] This might be ground for very cautious optimism although, in the most recent data from Western Sweden for the period 2003 to 2006, a rise was noted within the same parametric cohort. Hence, *cautious* optimism is the key word. One *may* speak of improvements in neonatal survival, and an improvement in the

[656] Platt MJ, Cans C, Johnson A, Surman G, Topp M, Torrioli MG, Platt Krageloh-Mann I. Trends in cerebral palsy among infants of very low birthweight (<1500 g) or born prematurely (<32 weeks) in 16 European centres: a database study. Lancet. 2007 Jan 6; 369(9555):43–50.

[657] See note 655.

[658] Andersen GL, Romundstad P, De La Cruz J,Himmelmann K, Sellier E,Cans C,Kurinczuk JJ, Vik T. Cerebral palsy among children born moderately preterm or at moderately low birthweight between 1980 and 1998: a European register- based study. Dev Med Child Neurol. 2011 Oct; 53(10):913–919.

[659] See note 657.

[660] Sellier E, Surman G, Himmelmann K, Andersen G, Colver, Krägeloh-Mann I, De-la-Cruz J, Cans C. Trends in prevalence of cerebral palsy in children born with a birthweight of 2,500 g or over in Europe from 1980 to 1998. Eur J Epidemiol. 2010 Sep;25(9):635–642.

[661]. Smithers -Sheedy H. Declining prevalence of cerebral palsy in Europe: good news? Developmental Medicine & Child Neurology. 2016 Jan; 58(1): 5–15.

[662]. Van Haastert IC, Groenendaal F, Uiterwaal CSPM, Termote JUM, Heidi-Jalving MV, Eijsermans MJC,Willem-Gorter J, Helders PJM, Jongmans MJ, De Vries LS. Decreasing incidence and severity of cerebral palsy in prematurely born children. J Pediatr 2011 Jul; 159(1): 86–91.

quality of life of the survivors. One may also speak of a stability in the prevalence of the condition, but not of convincing diminution in the over-all prevalence.[663] It is a sad fact that the 1987 conclusion reached by Stanley[664] still holds over-all: *There is little evidence of any recent decline in the incidence of either cerebral palsy or mental retardation despite improved obstetric standards*. Colver et al.[665] have stated the same truth as recently as 2014: the overall prevalence of cerebral palsy has remained stable in the past 40 years at about 2–3·5 cases per 1000 live births

With regard to the Maltese scene, it is surprising that for a critically important subject, which has attracted vast studies and scrutiny elsewhere for the last odd 60 years, an official register of cerebral palsy new cases was only started in 2016.[666] There does exist one published study[667] covering the period 1981 – 1990, which stated the local prevalence as 2.4 per 1000, which was comparable to that in Sweden (2.2. per 1000),[668] England (1.9 per 1000),[669] Finland (2.5 per 1000)[670] and Norway (2.5 per 1000).[671]

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[663]. Van Naarden Braun K, Doernberg N, Schieve L, Christensen D, Goodman A, Yeargin-Allsopp, M. Birth Prevalence of Cerebral Palsy: A Population-Based Study. Pediatrics. 2016 Jan; 137(1): 1–9.

[664] Stanley FJ. The changing face of cerebral palsy. Dev Med Child Neurol. 1987;29: 263-5.

[665] Colver A, Fairhurst C, Pharoah PO. Cerebral palsy. Lancet. 2014 April 11; 383(9924): 1240- 1249.

[666] Information given by the Malta Health Department, 16 August 2016.

[667] Sciberras C, Spencer N, Cerebral palsy in Malta, Developmental Medicine & Child Neurology 1999; 41: 508–511.

[668] Hagberg B, Hagberg G, Olow I, von Wendt L. The changing panorama of cerebral palsy in Sweden. V: The birth period 1979–82. Acta Paediatrica Scandinavica. 1989; 78: 283–90.

[669] Pharoah POD, Cook T, Rosenbloom I, Cooke RWI. Trends in birth prevalence of cerebral palsy. Archives of Disease in Childhood. 1987; 62: 379–84.

[670]Riikonen R, Raumavirte S, Sinivuori E, Seppala T. Changing patterns of cerebral palsy in the south-west region of Finland. Acta Paediatrica Scandinavica. 1989 July; 78(4): 581–7.

[671] Meberg A. Declining incidence of low birth weight – impact on perinatal mortality and incidence of cerebral palsy. Journal of Perinatal Medicine. 1990; 18:195–200.

A3.4 A catastrophic misunderstanding.

Cerebral palsy, as an example of birth injury, provides a unique facet for evaluation, namely its modern mistaken causality theories of the 1960's and their unfortunate massive impact in misleading subsequent Court evaluation of such facts. In spite of the obstetric world realising and correcting these facts, a similar legal rectification has shown to be slow on the uptake and one cannot truly say that the effect of the original junk science[672] has been completely and universally eradicated.[673] It is in reference to the ensuing outcome to this underlying scientific and medico-legal confusion that Beller's [674] statement refers to the *''the cerebral palsy story... a catastrophic misunderstanding*". It is crucial to underlie that the knowledge about cerebral palsy is still very much in evolution regarding all its aspects ranging from is aetiology to its management, in spite of the modest progress achieved particularly with regard to knowledge of aetiology.

One aspect of the medico-legal damage resulting from the 'catastrophic misunderstanding' is that some form or other of the former junk science theories still motivate a number of unjustified Court claims. These often lead to much waste of time and money and raise pityingly false hopes in vulnerable patients and their families who have already been dealt hard blows by fate. More often than not, an ill-advised case is

[672] In a Daubert Court, CTG could have easily been labelled as such.

[673]As evidenced by comments such as *"the fetal monitoring strips would give fairly conclusive evidence as to the presence or absence of fetal distress, and their loss deprives the plaintiff of the means of proving her medical malpractice claim against the Hospital." The Baglio v. St. John's Queens Hosp*., 303 A.D.2d 341 (2d Dept. 2003), Appellate Court.

[674]Beller FK. The cerebral palsy story: a catastrophic misunderstanding in obstetrics. Obstet Gynecol Surv. 1995 Feb; 50(2):83.

opened under the uncharitable auspices of one of the less respectable of birth litigation lawyers. Such cases, clearly destined to fail either in proving negligence or at the stage of linking by causality any proven negligence to the Court presenting cerebral palsy, especially the more clearly baseless cases, may be weeded out at a pre-trial hearing with obvious saving of the time, money and plaintiff distress involved in a long trial.

A3.5 The myth and the science

At this point, it would be opportune to analyse from its very roots the 'great myth,' originating in the 1960's in the USA. This myth was based on two pillars, one of which related to the wrong assumption that most cerebral palsy cases result from intra-partum hypoxia, and the other misconstrued aspects of CTG monitoring in labour.

A3.5.1 "Birth hypoxia" is the culprit!

Commencing in the 1950's and wrongly extrapolated from well-conducted research by Apgar and James,[675] this myth mushroomed out into the medical and legal worlds of the USA becoming firmly entrenched by 1961.[676] The myth held that intra-partum hypoxia (IPH) was the prime cause of cerebral palsy. The assumptions of the theory were spin-offs of serious research conducted by well-intentioned scopes in improving the condition of neonates. In 1953, anaesthetist Virginia Apgar[677] justifiably proposed

[675] Obladen, M. Lame From Birth: Early Concepts of Cerebral Palsy. Journal of Child Neurology. 2011; 26(2): 248-256.

[676] Courville CB. Paranatal anoxia and its residual encephalic lesions. Can Anaesth Soc J. 1961 Jan; 8(1):3-13.

[677] Apgar V. A proposal for a new method of evaluation of the newborn infant. Curr Res Anesth Analg. 1953 Jul-Aug; 32: 260-267.

a birth score to assess the survival chances of new-borns, as well as guide their resuscitation, which was then anything but commendable. Had another aspect of Apgar's work been given sufficient attention, it is just possible that matters might have evolved differently, for in her 1955 publication of the follow up study of 215 asphyxiated infants, the same author found:

..no significant correlation between I.Q. [at 4 years] and oxygen content or saturation at any time during the first 3 hours of life.'[678]

Later, with James and others, she described acidosis in birth asphyxia and concluded that:

The severe degrees of metabolic and respiratory acidosis seen in depressed infants stress the need for active ventilation and re-oxygenation of these infants immediately after birth.''[679]

The results, laudably enough, led to the administration of oxygen in delivery rooms, but unfortunately also fostered the wide-held belief that oxygen deprivation led to brain damage. The last statement *is* correct if the hypoxia is severe enough and prolonged enough, but its converse is not - brain damage is not (in its preponderance) the result of oxygen starvation. This is as illogical as saying that a dog is an animal, hence an animal

[678] Apgar V, Girdany BR, McIntosh R, Taylor HC. Neonatal Anoxia. 1955 June; 15 (6): 8-12.
[679] James LS, Weisbrot IM, Prince CE, Holaday DA, Apgar V. The acid-base status of human infants in relation to birth asphyxia and the onset of respiration. The Journal of Pediatrics. J Pediatr. 1958 April; 52(4): 379-394.

is a dog. However, the myth was born and traces of it still worryingly appear from time to time in various quarters.

As one would expect, the spreading fallacy was of tremendous interest to lawyers since now the causation of CP in the form of IPH was a new element of serious obstetric malpractice to pursue. At the same time, scientists were beginning to review the assumption of IPH as the major cause of CP and challenge it. In 1981, Nelson and Ellenberg[680] following up 49,000 children at age 7 years found a remarkably weak association between IPH (then called birth asphyxia) and neurological sequelae. In 1991 Nelson and Leviton[681] pointed out the weak association between neonatal neuronal lesions and obstetric complications, fetal distress, and biochemical markers of perinatal asphyxia. Furthermore, they also stated in the same publication that most infants survive severe birth asphyxia without neurological sequelae. However, by then, the myth had gained ever increasing popularity fanned by increasingly lucrative litigation. The hypoxia-brain damage theory had proved to be a goldmine. From 1985, obstetric litigation in the USA mostly involving neurological sequelae jumped from quasi negligible to 10% and Sartwelle et al.[682] contribute this to the 'Cerebral Palsy Myth'. No one could blame the legal establishment for the concept was blindly accepted by the majority of medical men. Not only so, but the medical world would yet give lawyers the greatest tool for their CP Court work. For commencing in the 1960's, a method which detected intra-partum hypoxia had become clinically available. The

[680] Nelson KB, Ellenberg JH. Apgar scores as predictors of chronic neurologic disability. Pediatrics. 1981 July; 68(1):36-44.

[681] Nelson KB, Leviton A. How much of neonatal encephalopathy is due to birth asphyxia? Am J Dis Child. 1991; 145:1325-1331.

[682] See note 516.

second pillar supporting the myth had been born in the form of electronic fetal monitoring with the name of cardio-tocography or CTG.

CTG consisted of an external fetal heart pick-up and the recording of its rate and its response to various stimuli including hypoxia by the electronic burning of a thermal paper producing a hard strip tracing easily reproducible anywhere including Court. In fact, obstetrics was also surmising that intra-partum CTG (I-PCTG) would be able to *predict* during labour those cases where cerebral palsy would be developing and thus help prevent it by timely delivery involving a caesarean section. The legal world was, as expected, overjoyed. The medical world was in for a big and sad disappointment.

Although the CTG owed its origin to numerous inputs, it is Alan Bradfield, Orvan Hess and Edward Hon who stand out with the clinically usable CTG monitor being attributed to Konrad Hammacher working in association with the firm Hewlett-Packard. By the late 1960's and certainly in the 1970's, CTG monitoring in labour was in use in most major obstetric units not only in the USA, but also in the UK and most major developed countries. Considered as science's final solution to detecting intra-partum hypoxia, obstetrics was yet to discover its many detracting factors, although to date, no alternative exists or is even foreseen in the close future. Although its role as a *screening test* in detecting intra-uterine hypoxia has with many limitations withstood the test of time, its uselessness in cerebral palsy was unwilfully misrepresented for a long time.

Unfortunately for humanity, CTG monitoring did not and does not predict CP.[683] Confirmed by a multitude of controlled studies, WHO does not even recommend continuous CTG monitoring in under-resourced settings.[684] Yet its use rose from 45% of all labours in 1980 to 85% in 2014 with CTG based litigation rising at a frightening rate.[685] In the aftermath of its negative role in CP jurisprudence, Sartwelle et al[686] go to the extreme of recommending that CTG monitors are thrown out of the labour ward. This is one heavily jaundiced view for I-P CTG still has much to offer in high risk labour. Furthermore, Sartwelle et al. are here confusing the medico-legal abuse with the original clinical indication of CTG, which was designed neither to defend nor crucify obstetricians in Court but to monitor the fetus in labour. Having said this, one must also admit that the science of CTG has been so travestied, misused, abused and at times prostituted in Court that such outright condemnation is understandable. And probably the greatest disservice to humanity by CTG has been perpetrated in Court and in cerebral palsy litigation.

A3.5.2 CTG monitoring: The second pillar of the Cerebral Palsy Myth.

The pernicious medico-legal misuse of CTG monitoring in addition to its intrinsic flaws as well as medical mismanagement has been evaluated in appendix two. All these

[683] Ellenberg JH, Nelson KB. The association of cerebral palsy with birth asphyxia: a definitional quagmire. *Dev Med Child Neurol.* 2013;55:210-216.

[684] WHO recommendation on routine antenatal cardiotocography. 08 March 2018.

[685] See note 516.

[686] *Ibid.*

factors may be considered as contributory to serious medico-legal repercussions.[687] In the emerging years in the 1960's where CTG was almost immediately corralled into cerebral palsy these intrinsic flaws had not even become known. A Court tolerance of even basic un-updated nomenclature use in Court evaluation[688] is evidence of the frequent slipshod way by which grave evidence emanating from a crucial investigation is dealt with where major decisions need to be taken. However, probably the chief culprit was the presumption of fetal hypoxia based on the presence of a pathological CTG. The situation must have been more alarming in the early decades of CP jurisprudence, a time where a label of pathological CTG tracing was based on criteria which have been since changed countless times.

The 1960's are repeatedly mentioned and this may lead to a misconception The 'cerebral palsy myth' as such is considered a phenomenon arising from that period and generally extinguished. Well, the CTG contribution to the myth unfortunately shows its living presence even in the twenty-first century in some aspect or other. This refers particularly to the incorrect and widespread attitude equating the presence or absence of CTG monitoring disturbances as synonymous with intra-partum hypoxia even in the absence of FBS confirmation. This unscientific attitude becomes alarmingly more serious when used in CP litigation. One example comes from *Smithers v. Taunton and Somerset NHS Trust*[689], where one reads

[687] Buttigieg GG. The shifting sands of medico-legal intra-partum Ctg (I-P Ctg) monitoring. Med Leg J. 2016 Mar; 84(1):42-5.

[688] See note 686.

[689] *Smithers v. Taunton and Somerset NHS Trust* [2004] EWHC 1179 (QB).

The paediatric and neuroradiological experts instructed by both sides in this dispute are all agreed that Lewis's cerebral palsy and consequent disabilities were caused by a period of near total profound asphyxia (the severe interruption in the delivery of oxygenated blood to the brain) shortly before his delivery at 01.46 on 29 March (see the joint note at trial bundle 4, tab 5, page 209, (4-5-209)). They further agree (a) from their reading of the cardiotocograph….

A word search of the Court transcript of this UK Court case reveals the word CTG to have been used 24 times but no reference at all exists to FBS, fetal blood sampling, pH or acid base deficit. And this was 2004 and not the 1960's or 1970's. Furthermore, not only is hypoxia being diagnosed from an I-P CTG tracing in this case, but we are also told that *the paediatric and neuro-radiological experts….further agree (a)from their reading of the cardiotocograph….* In a twenty-first century medical world, abounding with specialists, sub-specialists and super sub-specialists, why should the UK Court accept I-P CTG interpretation from paediatric and neuro-radiological experts with all due deference to expertise in *their* fields. Although gross acute profound hypoxia with prolonged bradycardia with prolonged bradycardia can proceed CTG disturbances which are obvious to one and all and no time could be wasted in performing an FBS, surely a fetal cord sample could have been secured for pH and base excess and furthermore the Court could have been informed of the circumstances.

A3.5.2.1 Further reflections

It is unwise to condemn authors like Thomas P Sartwelle, JC Johnston and Margaret Lent for their persistent vitriolic attacks on I-P CTG. While, not supporting their

aggressive stance in that CTG should be discarded, the misuse and outright abuse of I-P CTG with CP topping the list of the abused subjects has justifiably earned a well-deserved title for notoriety.

Numerous Court cases exist and indeed some have been quoted already where CP jurisprudence involved CTG misuse. In this regard one note that this thesis does not in any way suggest that the outcome of these cases was unjust. The scope of this thesis in discussing such cases is purely to demonstrate the vulnerability of CTG of being used incorrectly or without due consideration of its weaknesses. Furthermore, one is wrong if one assumes that the Court is not capable of rising to the challenge of dealing with CTG matters or indeed any other scientific investigation. In *Pauline McKenzie Pursuer vs Fife Acute Hospitals NHS Trust Defenders*,[690] the Court as personified by Lord Hodge made subtle reference to the relationship of CTG to cerebral palsy when he stated that CTG

is able to pick up events which have the potential to cause brain damage although it is not specific as to the nature of those incidents.

In other words, there *is* a place for CTG monitoring argumentation (backed by confirmation of hypoxia/acidosis) within the limits of the science and when applied to Cerebral Palsy litigation. Anything more is tantamount to a serious miscarriage of justice. The question is: *when* will Court, extensively and uniformly, attain the modern

[690] *Pauline McKenzie Pursuer vs Fife Acute Hospitals NHS Trust Defenders* [2006] CSOH 63.

scientific facts, with the same alacrity it showed in the 1960's, when science was, unconsciously working on mistaken facts?

There is a further misuse of CTG related neither to its scientific weaknesses nor to its interpretation but involving the use of CTG as a misdirecting factor. An example would be the 2008 case *Gossland v. East of England Strategic Health Authority*[691] which involved a 17-year-old boy suffering from symmetrical quadriplegic cerebral palsy alleged malpractice leading to CP caused by a traumatic Kiellands' forceps delivery complicated by shoulder dystocia and IPH. The new-born weighed 5.22kg and the story suggested a clear case of macrosomia, missed both antenatally and intra-partum, unwarranted force in effecting Kiellands delivery ending up in shoulder dystocia followed by shoulder dystocia, fractured clavicle and severe resultant traumatic brain injury compounded by hypoxia. Fascinatingly, the plaintiff's defence managed to get embroiled in I-P CTG evaluation and the lack of performance of FBS when the one and only elephant in the room was macrosomia. Driving oneself in a cul-de-sac with equivocal CTG oriented arguments was grossly illogical when the case essentially concerned a persistent misdiagnosis of gross macrosomia with subsequent equally gross labour mismanagement, including a traumatic forceps delivery. One of the Court experts maintained *that there was clear evidence of obstruction, the mother was a grand multipara and therefore ran a risk of rupturing her uterus and yet the obstetricians chose to use oxytocin.* And yet, among the Court's final conclusions we find not an evaluation of a baby which could hardly have suffered more, but a reply to the defendant's lawyer CTG argumentation

[691] See note 553.

The cardiotocograph trace was not such as to lead an obstetrician of ordinary competence to take the view that Omar had a 'complicated tachycardia' such as to make it imprudent to administer oxytocin or to make it mandatory to take a blood sample from Omar's scalp. The cardiotocograph trace showed a tachycardia aptly described by Mr MacKenzie as a 'moderate' one which could not properly be characterized as a complicated tachycardia. In Dr Emmerson's words it was 'somewhat abnormal' but nevertheless 'a common occurrence'.

In dismissing the claim, the Court made direct reference to Bolam:

It was settled law that the standard of care demanded of medical practitioners was the standard of the ordinary skilled man exercising and professing to have that special skill. A man needed not to profess the highest skill; it was well established that it was sufficient if he exercised the ordinary skill of a competent man exercising that particular art. In the instant case, on the evidence, whilst another competent obstetrician might have acted differently to the doctor, neither he nor any other member of the staff of the defendant had acted inconsistently with the standard of care demanded.

A sad but typical example of how I-P CTG may completely misdirect from the significance of truly pertinent issues. One also notes that if Bolam were correctly used in this case, the level of obstetrics in the area was worrying indeed.

A3.6 The underlying brain damage in cerebral palsy

A consideration of the underlying brain pathology in CP is of crucial importance in linking it with a specific alleged cause reflecting alleged negligence. This should be the first step in evaluating possible liability from negligence in such cases. For allegations of obstetric negligence in causing a cerebral palsy, trauma aside, will revolve around proving that such negligence led to IPH and when, IPH is severe enough to lead to CP, aparticular pathology assails it. We refer here to CP alleged to have resulted from fetal oxygen deprivation in labour.

The underlying original insult in CP is that of an encephalopathy which is a non-specific umbrella term referring to brain dysfunction resulting from multiple causes. Such causes may be many and varied, including trauma, oxygen deprivation, genetic causes, metabolic disorders, chemical exposure, etc. Reversibility is exceptional unless the damage has resulted from specific toxins and nutritional deficiencies. Encephalopathies may also rarely be fatal as when due to spongiform and transmissible agents such as prions,[692] best known as the agents causing Creutzfeldt–Jakob disease, its new variant Creutzfeldt–Jakob disease, Gerstmann–Sträussler–Scheinker syndrome, fatal familial insomnia, kuru, and variably protease-sensitive prionopathy.

Of specific interest to the present discussion, is the *new-born* or *neonatal* encephalopathy defined by Nelson and Leviton,[693] as

[692] Aetiology may be genetic, sporadic, or infectious via ingestion of infected foodstuffs such as animal (or human) brains or through infected blood transfusions.

[693]See note 680.

a clinically defined syndrome of disturbed neurological function in the earliest days of life in the term[694] *infant, manifested by difficulty with initiating and maintaining respiration, depression of tone and reflexes, subnormal level of consciousness, and often by seizures.*

Nelson and Leviton's definition of neonatal encephalopathy, however, does not reflect aetiology which is crucial in any discussion of liability of care of the unborn. The fact that CP is due to such neonatal encephalopathy as the underlying pathology brings us no closer to establishing the actual causation as being due to oxygen deficiency or not.

At this point it is relevant to recall that the nervous system commences soon after conception with a specific small number of cells multiplying into billions of cells and forming the neural tube, one end of which will develop into the brain while the other into the spinal cord. Cells with different inherent qualities, once they have formed, group themselves together and migrate to form specific brain areas each with specific roles. The nerve cell extensions or fibres also develop a sheath (insulation, as in any electric wire known as a myelin sheath), and the cells communicate with each other at important junctions known as synapses. Within a period varying from two to five years, the brain is fully developed.

The various currently known causes of encephalopathy may inflict damage in various ways, at various times and at various points of the developing brain which keeps developing in the first years of life. For example, the stage of cell migration may be

[694] 'Term infant', is stressed in this definition, as it excludes pre-term infants who, commonly, exhibit feeding difficulties and abnormalities of tone and reflexes.

disrupted by genetic or environmental factors. The same or other factors may impede proper myelination or sheathing of the developing nerve cell fibres. Blood vessels may rupture or oxygen may be interrupted to the developing nervous system leading to perinatal brain cell death during birth as a result of oxygen deprivation, trauma or a combination of both. After birth, the developing brain may still be assailed by hypoxia, trauma, chemicals or infections. Specific damage may inflict specific clinical problems. Thus, any damage to brain cell connections will result in loss of cell functionality or inappropriate functionality in the conduction of electrical nerve impulses as is their normal function. Damage may be also be inflicted at various stages of development of the child's brain in utero and up to the first few years of life. Such damage may be inflicted by metabolic[695] disorders such as mitochondrial encephalopathy[696] or glycine encephalopathy [697] and similarly rare conditions. The case *Gard and others v. United Kingdom*[698] concerned the management (non-obstetric) of Charlie Gard suffering from the extremely rare inherited mitochondrial disease called infantile onset encephalomyopathic mitochondrial DNA depletion syndrome which comprises cerebral palsy, severe convulsions and inability to breathe spontaneously. Rare fetal conditions such as Gard's are hardly likely to be appear in Court masquerading as resulting from obstetric negligence, but they have been used as a legal ruse to muddy the waters, as for example in *Dunne (an infant) (suing by his mother and next friend*

[695] An inherited single anomaly most likely of autosomal recessive nature where the body's normal metabolic processes are altered through abnormal chemical reactions within the body.

[696] A condition where mitochondrial DNA dysfunction effects many of the body's systems including the brain and the nervous system.

[697] A condition involving excess production of glycine.

[698] *Gard and others v. United Kingdom.* (App no 39793/17. European Court of Human Rights (First section).

Fiona Murphy) v. Coombe Women and another [699] where the defendant's legal team, searching wildly for some cause, stated that the child in question could have been :

…born with an underlying mitochondrial disease, muscular or neuromuscular disorder, or some other type of complex genetic defect…

It is pointless to the present discussion to mention all possible causes of encephalopathy such as that resulting from renal and liver failure or even poisoning such as from lead.

However, infective encephalopathy may be a different story, for this is attaining increasing attention in the causation of CP. The source of such an infection may be an ascending infection after breach of the amniotic membranes or via a blood-borne route. Diseases such as syphilis, toxoplasmosis, rubella, cytomegalus and zika viruses all may reach the fetus via a blood borne route. The increasing recognition of infective encephalopathy may open new fields of prevention and treatment as well as new avenues of looking for obstetric liability, and this implies a mentality shift in antenatal care[700] along the lines discussed in section 3.3.2.1.6.1.2. Antenatal infective encephalopathy from an ascending infection was one of the unsuccessful claims alleging negligence in a 2010 case of CP in *Ingram (a protected party by his mother and litigation friend Anita Jones) v. Williams*, [701]

[699] *Dunne (an infant) (suing by his mother and next friend Fiona Murphy) v. Coombe Women and another* - [2013] IEHC 58.
[700] Buttigieg GG Obstetric/Paediatric Interaction in Brain Damage Litigation: Learning from the Courts. J Pediatr Neurol Med. 2016; 1:115.

[701] *Ingram (a protected party by his mother and litigation friend Anita Jones) v. Williams* [2010] EWHC 758 (QB).

Other causes of encephalopathy worth including here include hypothyroid encephalopathy. Evidence has accumulated to suggest that thyroid hormone deficiency might be one cause of cerebral palsy[702]. Antenatal scrutiny of maternal thyroid dysfunction is expected in all patients. Traumatic encephalopathy may play an important role in the causation of new-born CP often resulting from mismanaged assisted delivery, e.g., instrumental, or breech delivery. One example comes from *Fotedar v. St George's Healthcare NHS Trust*[703] where the obstetrician was found guilty of negligence in the performance of a ventouse extraction in the absence of full cervical dilatation and in the presence of cephalo-pelvic disproportion, with resultant traumatic brain haemorrhage and severe brain damage. In *Whitehouse v. Jordan and another*[704] where a ruling upholding breach of the standard of obstetric care was delivered, the force used in the delivery was such that the mother herself was *"was pulled to the bottom of the delivery bed".* At times, an admixture of elements are present as causative factors in encephalopathy. In *Parry v. North West Surrey Health Authority,* [705] we find a traumatic forceps delivery associated with both trauma and hypoxia.

A discussion of CP must evaluate encephalopathies of congenital origin. This implies an intrinsic anomaly within the brain itself, e.g., resulting from an MECP2 gene[706]

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[702] Hong T, Paneth N. Maternal and infant thyroid disorders and cerebral palsy. Semin Perinatol. Dec 2008; 32(6):438-445.

[703] *Fotedar v. St George's Healthcare NHS Trust [*2005] EWHC 1327 (QB), [2005] All ER (D) 28 (Jul).

[704] *Whitehouse v. Jordan and another*[704] [1980] 1 All ER 650.

[705] *Parry v. North West Surrey Health Authority [1994] 5 Med LR 259.*

[706] The gene that encodes the MECP2 protein and which s responsible for normal nerve cell function.

mutation (Rett syndrome[707]) or by any factor intrinsic to the body and with a secondary effect on the brain, e.g., a metabolic encephalopathy may in fact be classified under congenital encephalopathy. The emerging importance of congenital anomaly as a cause of CP in terms of frequency has had resounding implications in medico-legal litigation. Even though by no means fully explored as yet especially with regard to full mechanisms of causation, this cause seems to be *much* commoner than previously considered. At present, the preponderance of causation of CP by congenital causes have displaced the position of honour once held erroneously by intra-partum hypoxia. And this popularity, renders it liable to be thrown in as a spoke in the wheel of allocating liability at Court. For example in *Smith v. Sheridan*, [708] a patient who as a new-born suffered intracranial subdural bleeds allegedly from a negligent forceps delivery and subsequently suffered from quadriplegia, with mixed dyskinetic and hypotonic features, axial hypotonia, a convergent squint, cerebellar ataxia and developmental delay. The defendant sought to explain this away through a congenital bleeding diathesis[709] of the child, but the Court upheld liability ruling that the bleeding *was* indeed the cause of the brain damage, but the primary cause of bleeding was trauma from the negligent forceps delivery.

The tremendously important encephalopathy which goes by the specific name of Hypoxic Ischaemic Encephalopathy (HIE) is important enough to be discussed on its own in the following section.

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[707] A dominant, x-linked condition, with a prevalence of 1 per 10,000 and almost always affecting females, who within 6 – 18 months of birth mainly found in girls develop speech and motor function problems. Later, other signs develop including seizures, growth delay, cognitive and further motor impairment.

[708] *Smith v. Sheridan* [2005] EWHC 614 (QB).

[709] Abnormal blood clotting disorder.

A3.6.1 Enter hypoxic ischaemic encephalopathy.

Hypoxic ischaemic encephalopathy (HIE) *is* now the stablished and indisputable precursor of CP and is the direct result of oxygen deprivation. This is so concretely established that if HIE is not present, then hypoxic induced cerebral palsy is not possible to have followed. This implies that no obstetric liability with regard to obstetric mismanagement leading to oxygen deprivation in labour can be entertained. This refers purely to obstetric mismanagement leading to fetal oxygen deprivation in labour and to no other mismanagement which may still be present. Thus, for example, the obstetrician could have mismanaged a maternal thyroid condition or an ascending chorio-amnionitis during antenatal care or performed an improper forceps delivery in labour with resultant trauma.

HIE is associated with a number of specific clinical features such as spastic paralysis of all four limbs, known as spastic quadriplegia and tardive dyskinesia characterised by repetitive, involuntary movements, like grimacing, lip smacking, lip puckering/ pursing and eye blinking. Since HIE results from severe hypoxia, other hypoxic induced damage may affect other locations besides the fetal brain such organs like the kidneys with resultant evidence of renal malfunction. A third group of signs may be demonstrated by neuro-imaging such as MRI scanning and/or specialised ultra-sonography of the fetal brain that will show evidence of acute non focal cerebral abnormalities. Such abnormalities as oedema will be evanescent after the first forty-eight hours of birth.

The establishment of the sequence of development of CP passing through the obligatory stage of HIE was and is an obvious tremendously important factor both in planning early and effective management as well as in its medico-legal implications. Although, the medico-legal story of CP still has much ground to cover, it is probably correct to state that the relevance of establishing the importance, aetiology and chronology of HIE to CP pathogenesis is on par in importance with the elimination of the 'great cerebral palsy myth'. However, the importance of HIE remained subject to the ability of establishing the diagnosis of HIE, a subject of controversy and some confusion until the ACOG stepped in.

In 2003, the American College of Obstetricians and Gynaecologists (ACOG) in conjunction with the American Academy of Pediatrics (AAP) took the initiative of setting up a Task Force to start the ball rolling in issuing scientifically established facts and criteria of diagnosis of HIE. The result was the 2003 publication of *Encephalopathy and Cerebral palsy: Defining the Pathogenesis.*[710] The ACOG-AAP report established clearly that an intrapartum hypoxic-ischemic insult causes a moderate to severe neonatal encephalopathy that subsequently results in cerebral palsy. The criteria for defining HIE were established on four major criteria, namely:

I. Evidence of metabolic acidosis in fetal umbilical cord arterial blood obtained at delivery (pH less than 7 and base deficit of 12 mmol/L or more)

[710] Hankins GD, Speer M. Defining the pathogenesis and pathophysiology of neonatal encephalopathy and cerebral palsy. Obstet Gynecol. 2003 Sep; 102(3):628-636.

II. Early onset of severe or moderate neonatal encephalopathy in infants born at 34 or more weeks' gestation

III. Cerebral palsy of the spastic quadriplegic and dyskinetic type

IV. Exclusion of other identifiable aetiologies, such as trauma, coagulation disorders, infectious conditions, or genetic disorders. This is important if a *hypoxic* origin is to be established.

It is essential to note that the criteria speak of a gestation of 34 weeks or more since neurological behaviour in the premature child prior to 34 weeks is extremely challenging to assess. Also, the specifying of the type of cerebral palsy as quadriplegia and tardive dyskinesia is most important, as all other types are specifically excluded. Thus, hemiplegia, spastic diplegia, ataxia, intellectual disability, autism, and learning disorder in a child without spasticity have not been associated with acute intrapartum hypoxia.[711] None even fit even basic criteria of the CP type resulting from IPH. The establishment of these four criteria provide a solid bases for evaluation of a case alleging obstetric birth mismanagement liability to be subjected to a pre-trial hearing as discussed in section 4.14.

It should also be noted that Court cases opened within a few months of birth cannot present to the Court a correct final picture of the damage presented as such damage is still evolving. Not only is it *not* possible to make a full assessment of the new-born

[711] It is important, in this context, to exclude Rett and Angelman syndromes.

suffering from CP, but a four or five year interval is necessary to allow full symptomatology to establish itself.[712] With time, symptoms may appear when none where present before, others worsen or become more florid, and uncommonly, some might even improve. It is then that the condition may be reliably sub-classified, e.g., spastic CP (stiff musculature), ataxic CP (poor co-ordination), athetoid CP (writhing movements). CP associated with severe mental retardation demands a definite peri-partum cause to be considered.[713] Clinical presentation may at times lead to difficulty or confusion. Thus, in *Fallon (a child by her mother and litigation friend) v. Wilson*,[714] where malpractice liability was upheld, the plaintiff suffered from mental retardation, epilepsy and behavioural problems in addition to quadriplegic cerebral palsy. On the other hand, severe mental retardation *unaccompanied* by the clinical features of CP, is considered to be unrelated to perinatal hypoxia. An example is found *Ian O'Mahony (an infant suing by his mother and next friend Ann O'Mahony), Plaintiff*[715] *v. Timothy Tyndale and David Corr, Defendants* [716] where no obstetric liability was found.

The 2003 ACOG-AAP report also established a number of secondary non-specific criteria, not sufficiently specific to diagnose HIE but still important in aiding to determine the *timing* of a specific insult or sentinel event in labour. These are shown in in Table 3 in section 4.14. and among them we find CTG. This contrasts sharply with

[712] National Institute of Neurological Disorders and Stroke. Cerebral Palsy Information Page. 2019.

[713] Perlman JM. Intrapartum hypoxic-ischemic cerebral injury and subsequent cerebral palsy: medicolegal issues. Pediatrics, 1997 Jun; 99(6):851 – 859.

[714] *Fallon (a child by her mother and litigation friend) v. Wilson* - [2010] All ER (D) 205 (Nov).

[715] The plaintiff also suffered from hemiplegia – not considered typical of cerebral palsy where the typical physical paralysis is spastic quadriplegia.

[716] *Ian O'Mahony (an infant suing by his mother and next friend Ann O'Mahony), Plaintiff, v. Timothy Tyndale and David Corr, +Defendants*[2002] 4 IR 101.

the 1960's USA placing of I-P CTG, not as among the first rank assessing parameters, but as *the only* clinical parameter gauging related response and subsequently the only clinical factor guiding related jurisprudence. At this point, one can appreciate much more clearly the extent of scientific misdirection in CP jurisprudence commencing in the 1960's and not completely eradicated in this present century.

Also noteworthy is the fact that Apgar scoring, placed in the secondary criteria, may be influenced by an element of subjectivity and this may have to be evaluated if the scoring is inconsistent with the other secondary criteria. Regarding neuro-imaging, one should remember that features resulting from the sentinel event, such as oedema, may appear within 6-12 hours and completely disappear within maximally within 4 days. Hence these investigations should ideally be performed within 24 – 48 hours of birth.

In 2014, another and updated ACOG-AAP report, entitled *Neonatal Encephalopathy and Neurologic Outcome,*.[717] drew attention to a broader view of preventive CP care by highlighting the antenatal care. Special attention was drawn to role of antenatal causation or contributory causation (along the 'two-hit theory' – see section 3.3.2.1.6.1) of CP, including care of diagnosis and management of maternal thyroid dysfunction, coagulopathies, inflammations and infections which though theoretically known as causes of CP. These were far from being accorded their clinical worth. This is of great relevance as a 'wake-up call'. Neither has the concept been missed by birth litigation

[717] Neonatal Encephalopathy and Cerebral Palsy. Neonatal encephalopathy and cerebral palsy: defining the pathogenesis and pathophysiology.: Executive Summary. ACOG-AAP Task Force Report. Obstet Gynecol. 2004 April; 2004 April; 103(4):780-781.

lawyers who have put forward a number[718] of Court cases claiming in toto or in part obstetric antenatal breach of the standard of care.

A3.7 Returning to sensible basics.

At this stage, it would be dangerous to allow the pendulum to swing too far unilaterally. The relevant points have been made concerning the unjustness of the 1960's USA originating concepts of presumption of birth asphyxia as a major cause of CP with its implied inference of the effects of obstetric malpractice in the causality of IPH. At this stage it is prudent to re-iterate that breach of the obstetric standard of care of labour remains a possible cause of CP, and furthermore that this element is more often than not preventable. It is important not to fall in the trap of playing the other extreme and downplaying the estimated 14.5%[719] of causation of CP from intra-partum hypoxia. It is most disturbing that such gross negligence as abject disregard of basic obstetric practice through injudicious use of Syntocinon is still a cruel cause of such heart-rending suffering as is present in CP, as discussed in section 3.3.2.1.3. *Evans v. Birmingham and the Black Country Strategic Health Authority*[720] was one such CP case where part of the claim related was based on the fact that:

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[718] Examples include *Ingram (a protected party by his mother and litigation friend Anita Jones) v. Williams*. [2010] EWHC 758 (QB), 6CH90047; *Cowley v. Cheshire and Merseyside Strategic Health Authority* [2007] EWHC 48 (QB); *AW v. Greater Glasgow Health Board* [2015] CSOH 99; *Webster Applicant and Burton Hospital NHS Foundation Trust Respondent.* CA Civil Division, Neutral Citation Number: [2016] EWCA Civ 388; No: B3/2015/0327.In none of these cases was breach of standard of care confirmed.

[719] See note 344.

[720] *Evans v. Birmingham and the Black Country Strategic Health Authority* [2007] EWCA Civ 1300.

…. when Syntocinon was administered, it was administered at too high a dose. The result was that the uterus was over simulated, causing excessive contractions. …..For significant periods the records show that the Appellant's mother was experiencing contractions at five to six or six per ten minute period.

That such damaging ignorance does exist in an individual and is allowed to occur by any obstetric unit is truly disconcerting. With such happenings, maybe one should not be too surprised at the preponderance of CTG misinterpretation. Equally worrying are cases, examples of which have been given here were simple basic rules of safe instrumental delivery are ignored with the involvement of brute force, absence of full cervical dilatation and misdiagnosis or flagrant ignoring of obvious signs of cephalon-pelvic disproportion. These cases which do surface are probably the tip of the iceberg and should reflect the guilt of the unit and the system which allows them to happen.

On the other hand, one commiserates with the prudent obstetrician who may find himself unfairly accused and embroiled in the psychological hell of an unjustified Court trial, even if the case is eventually thrown out. That 'eventually' may well comprise a period in one's life during which practice, personal and family life may be drastically changed and even destroyed by the resultant stress. On a similar footing, there are occasions where one remains somewhat puzzled by the resultant severity of a Court ruling such as that in *DS (by mother and litigation friend FS) v. Northern Lincolnshire and Goole NHS Foundation Trust*, [721] where obstetric negligence was confirmed as being liable for the resulting CP in an eleven-year-old boy where at birth the mother

[721] *DS (by mother and litigation friend FS) v. Northern Lincolnshire and Goole NHS Foundation Trust* [2016] EWHC 1246 (QB).

suffered a severe abruptio placentae [722] and a *three-minute* delay was claimed as responsible for the resulting brain damage.

A3.8 Divining the Future

In following the logic of the above arguments, one cannot but feel a sense that the medico-legal aspects of CP are very much at some giant cross-roads. The massive evolution occurring in the scientific evolution regarding the aetiology and the resulting effect on the jurisprudence of liability are indeed striking and a rich lesson in prudence and discretion of accepting new science. Much is also changing in the shifting of the focus of attention from labour to the whole of antenatal care.

There is no doubt that the natural and gradual filtration of CP Court cases will witness the classical plea of obstetric labour mismanagement eventually more or less reflect the limited and true incidence of existence of the phenomenon. Yet, the vacuum is likely to be filled by alleged breaches of standard of care based on challenged antenatal mismanagement involving both diagnosis and treatment of conditions which so far had not provided main issues at Court. Conditions such as intra-uterine growth restriction, prematurity, multiple pregnancy, artificially assisted pregnancies, antenatal infections, antenatal jaundice thrombophilic disorders, auto-immune thrombocytopenia, factor V Leiden and polycythaemia are still to rear their head in significant proportions in the future.

[722] Placental separation from the uterine wall, in whole or in part, while the child is still in utero. If major, it is associated with a high degree of stillbirth rate. In severe cases, even the mother's life may be at risk.

The cerebral palsy story is far from concluded in the annals of mankind, both at clinical and human level as well as in its medico-legal aftermath. These are whole new chapters which are yet to be written. And following closely behind all new clinical scientific facts and resultant applied medical practice, no doubt, will come closely at the heels, the dogs of war and litigation.