

[www.mcfcd.org.mt](http://www.mcfcd.org.mt)



VOLUME 04 ISSUE 01  
MAY 2015

ISSN: 2304-8387

# JMCFD

JOURNAL OF THE MALTA COLLEGE OF FAMILY DOCTORS



## Paediatrics

# Medical Equipment



Automated External Defibrillator



Sleep Apnoea Solutions



Glucose meters



Blood pressure sets



Diagnostic sets



Littmann® Stethoscopes

Available from stock



# JMCFD

JOURNAL OF THE MALTA COLLEGE OF FAMILY DOCTORS

## Journal of the Malta College of Family Doctors

The mission of the Journal of the Malta College of Family Doctors (JMCFD) is to deliver accurate, relevant and inspiring research, continued medical education and debate in family medicine with the aim of encouraging improved patient care through academic development of the discipline. As the main official publication of the Malta College of Family Doctors, the JMCFD strives to achieve its role to disseminate information on the objectives and activities of the College.

Volume 4 • Issue 1 • May, 2015

Journal of the Malta College of Family Doctors  
127 The Professional Centre, Sliema Road, Għira GZR 1633 -  
Malta

Email: [mcfjournal@mcfcd.org.mt](mailto:mcfjournal@mcfcd.org.mt)  
[www.mcfcd.org.mt/jmcfcd](http://www.mcfcd.org.mt/jmcfcd)

Editor  
Prof. Pierre Mallia

Members  
Dr Mario R Sammut, Dr Anton Bugeja, Dr Lara Gerada

Copyright © Malta College of Family Doctors

All Rights Reserved. No part of this publication may be reproduced, stored in a retrieval system, or transmitted in any form or by other means, electronic, mechanical, photocopying, recording or otherwise without prior permission, in writing, of the JMCFD.

All Articles published in the JMCFD including editorials, represent the opinion of the authors and do not reflect the official policy of the Malta College of Family Doctors or the institution with which the authors are affiliated, unless this is clearly specified. The appearance of advertising in the Journal is not a guarantee or endorsement of the product or the claims for the product by the manufacturer.

Published by: Malta College of Family Doctors  
Design and Production: [www.outlook.coop](http://www.outlook.coop)



Paediatrics

**Subscriptions:** The Journal is distributed free of charge to family doctors of the Maltese Islands and is a not-for-profit publication. To order more copies write to: *Subscriptions, Journal of the Malta College of Family Doctors, 127 The Professional Centre, Sliema Road, Għira GZR 1633 - Malta*

## CONTENTS

Cross border movement of doctors <b>Prof. Pierre MALLIA</b>	04
Point-of-care genetic counselling <b>Prof. Pierre MALLIA</b>	06
A study of the management of head lice by paediatricians in Malta <b>Dr Marthese GALEA &amp; Dr Christopher SCIBERRAS</b>	13
Confidentiality and treatment of young adults. Proposals for amendments: the Gillick Proposition <b>Dr Ann Marie MANGION</b>	17
Minutes MCFD Annual General Meeting 2014	24
Proposals for Statute	26

Guidelines for authors: [mcfcd.org.mt/resources/documents?did=8](http://mcfcd.org.mt/resources/documents?did=8)

# Cross border movement of doctors

Prof. Pierre MALLIA

Recently there has been a problem in the area of accepting general practitioners from EU countries into the Specialist Register. This article is intended to clarify the issues at stake and therefore concerns only eligibility for the Malta Specialist Register in Family Medicine, and not the right to be granted a permit by the Medical Council to work locally. The two are different. The MCFD concerns itself with excellence in practice; this is a patient right. Excellence does not come from apprenticeship only but from a summative and work based assessment; assessment motivates learning. Hence why more than ten years ago the previous council sought to put Family Medicine on the Specialist Register. It was not merely for empty recognition, but for a merited recognition. Following the grandfather clause entry criteria became relevant.

One must distinguish clearly between the right of a doctor coming from an EU state to work in Malta once the doctor has completed the vocational training of the country of origin, and, the right to be listed on the Specialist Register which is something, at least for Family Medicine, which goes beyond mere licensing to practice. Being given the right by the Medical Council of Malta to work locally does not mean one has a right, as many are thinking, to be on the Specialist Register, even if one has completed specialist training in the respective country, for the simple reason that not in all EU states Family Doctors work towards a specialist level putting them on their specialist register. Therefore only by being seen as a specialist in your country can you be seen as a specialist in ours.

The EU directive on cross border movement provides for the free movement of workers from one EU state to another. This therefore includes doctors. A three year vocational training in a specialty gives one the right to be considered as having acquired enough experience to transfer between one EU state and another.

The problem rises because in Malta we have a dual system of private practices and health centres. The collective agreement between the Medical Association

of Malta and the Department of Health requires that any doctor working in a government health centre, be also a Specialist in Family Medicine. This is creating a problem for some doctors coming from countries whose Vocational Training does not lead to Family Doctors becoming specialists. The specialist register is a sign of further excellence in General Practice. Therefore whilst foreign doctors can and *are* coming to work in Malta, following the collective agreement between MAM and the Department of Health, they now insist on being put on the Specialist Register.

Many countries introduce legislation of their own and this is allowed by EU law.

These are some examples:

- (1) In the UK you must now do an exam which is valid for three years (even if you have been practicing in the UK and leave for three years; if you have not practiced at least once in the country (UK) within those three years you must repeat your exam).
- (2) In Italy there is no specialist register but you must have performed 3 years vocational training AND must speak the language (Italian).
- (3) In Malta we have to be on the Specialist Register which requires three years Vocational Training and passing the Summative Assessment and Work-Based Assessment (which the MCFD has set at the equivalent of MRCGP(INT)) - to work in the NHS (only). But technically, to *work* privately all an EU doctor needs is to pass their MD exam as locally you do not need to do VT to practice as a GP. We fought against this but unfortunately this is where we stand.

Therefore although doctors have a right to transfer, as with ALL other cross-border directives, that which applies to doctors going to the country has to be the same as the requirements for doctors working within that country.

The fact that other Specialties on our Specialist Register must accept specialists from other EU states even if they do not have a standard which reaches that of the

---

Royal Colleges, from where most local Specialists obtain their qualification, should not deter from understanding the basic difference to the Specialty of Family Medicine. This is so for the simple reason that in many EU states, Family Medicine is still not considered a Specialty. Therefore they *do* qualify as having had Vocational Training but not for a Specialist Register.

In the case of family practice, we are still in the unfortunate situation which defines working within the NHS means only (that is, it is interpreted only as) working with the government services. There had been issues raised that since the minister issues certificates allowing people to practice even working in private practice ought to mean you should be on the specialist register as private practice is part of the health system of the country and it alleviates a substantial burden off the state. Nevertheless this is not the case.

Therefore, *whilst the medical council may rightly issue a certificate to a doctor who has completed specialist training in another EU state to practice locally, this will only mean that they can do private practice.* It does not mean that they are entitled to be on the Specialist Register. This is fair, because it is the same for Maltese doctors who did not have opportunity to enter VT; even someone who has done VT but has not done the assessments will not be eligible for SAC.

For foreign doctors coming from EU states to work within the health care system, it is not a bending or misinterpretation of EU rules which ought to be practiced, but rather the collective agreement be amended to say that to work within our government NHS one needs only Vocational Training. The Specialist Register is a *bonus*. Of course if this amendment is not made then we may be *forced* to put them on the Specialist Register to which they are not entitled in order to satisfy a presumed EU principle of having a right to work within our NHS. It is presumed because we have not understood the principle behind having Family Practice defined as a specialty - and that not all GPs locally are put on the specialist register. What can be done, as is done in the UK, is to give them an exam equivalent to our summative assessment of Vocational Training.

In summary, had the government chose to employ even doctors who were not on the specialist register, but insisted only on 3 years VT, then they would be allowed to work at certain levels but not be put on the specialist register (and therefore cannot be considered specialist here). For primary care, government has bound itself that to work in health centers you need to be on the specialist register. This can always be modified without altering the principle. What the government has to respect at EU level is the eligibility for EU doctors who have done vocational training to be allowed to practice locally - perhaps even in the NHS because they have the VT from their country, but *not* to be put on the specialist register - as it is *not* simply VT which gives local doctors a right to be on this register but an additional summative assessment beyond mere apprenticeship and gives the equivalent of a higher level qualification (the MRCGP(INT)). That the Department of Health has bound itself for local doctors that they should be on the Specialist Register, means that unless foreign EU doctors have a specialist register in their own country then they cannot be put on ours.

As many countries, the Malta College of Family Doctors strives for excellence in General Practice and Family Medicine. This does not come merely by practicing as an apprentice for three years, as some EU states have. This is why we insisted on a framework. In the UK doctors must now pass the MRCGP, which has been recognized as the national qualification. *Doctors entering the UK from other EU states must do another entry exam.*

We have been faced with a silly case in which a foreign doctor working locally claimed to have obtained the Vocational Training certificate of his/her country as they seemed to have accredited the working time done in Malta. This is the situation which insults Family Medicine as a Specialty. We may as well do away with our system and once you have worked privately for three years go to this country and obtain their certification - what is fodder for the goose is fodder for the gander - they should not to be able to refuse.

I put it that this is not the intention and spirit of the EU directive for freedom of movement as it puts patients at risk.

# Point-of-care genetic counselling

## Should family physicians counsel patients on genetic testing and screening?

Prof. Pierre MALLIA

### ABSTRACT

Family medicine has come of age, with family doctors/general practitioners taking on greater roles and responsibilities and health care systems recognizing the important role of primary care. It is in this scenario that the question of pre- and post- testing counselling of genetic tests which are or would be offered directly to the general public through advertising and over-the-counter testing is being raised. This type of counselling would require enough personnel to deal with a large number of people; people who may not have genetic disorders in their families but who are curious about testing such as that for Breast Cancer (BRCA). It is argued that family doctors, albeit needing continuing professional development in this area, already have a solid foundation in genetics and are strategically placed in the community and numerous enough to impart such counselling. This would also liberate the responsibility from specialised geneticists who need to deal with families and individuals who have more serious genetic disorders to be managed.

**Key Words:** General practitioners, family doctors / physicians, strategically placed, community, genetic counselling, family medicine.

### INTRODUCTION

For more than a decade the debate on who should impart pre- and post- test counselling for genetic tests has been discussed. To many, it seems that family doctors (also known as family physicians or general practitioners) are the key to this solution as they are numerous enough, are strategically placed in the community, and easily available to the general public who may have questions regarding what they hear and see about such testing.

It is important in this regard to consider that specialized geneticists cannot be disturbed from the secondary care job they do and should not be dragged into a primary care scenario. They are usually clinic / hospital based and, although family oriented, are not

close to the same families in the midst of communities as family doctors are. Moreover, although updates and training in the type of counselling (as opposed to normal psychological counselling) is necessary, doctors have a clear understanding from the nature of their jobs of the underlying science of genetics. Their Colleges and Associations carry a responsibility to impart this continuing professional development for the good of society. It is argued as well that family medicine has 'come of age' and that it is no longer the Cinderella of medicine – family doctors are considered specialists and registered as such after having had formal training post-medical school.

### What is special about genetic tests – the real concerns

Genetic information has a tremendous potential to harm as well as to help and stands to affect a broad number of family members (McCanse, 2001). Even well-educated patients may be ill-prepared to understand or deal realistically with the results of genetic tests. The primary care culture is different from the genetics culture but primary care doctors are more community-oriented, asking what specific aspects of a genetic approach to this health problem (or potential problem) are likely to benefit this patient. Howard Brody warns family doctors about the perils of genetic testing for patients and the role the family physician must play (McCanse, 2001, p.1). The ability to genetically screen for diseases far outpaces the ability to treat conditions, such as breast cancer, Alzheimer's disease and prostate cancer. Nonetheless people often consider genetic tests as some sort of cure or prevention of the condition (Lapp, 2002).

Companies may use advertising to entice people into believing that they should have genetic tests carried out (Chandros Hull & Prasad, 2001). They sometimes advise potential patients that there is no need to consult the family doctor or anybody else as their own 'experts' will guide the patients into what tests they should carry out.

---

However genetic tests may not only affect individuals adversely, but also their family members. In this context it is fair for family physicians and their societies and colleges to be wary of the effect these tests can have over patients and their family members. Conversely family doctors, without the proper Continuing Medical Education (CME) imparted specifically to meet the needs of ongoing ethical dilemmas in genetic tests, may find themselves ordering such tests too liberally, once it is the patient who requests them, believing they are respecting the individual's autonomy. Family physicians have been 'urged to warn' patients of the potential pitfalls and dangers of using over-the-counter testing as prices start to fall. Whilst tests may sound enticing to patients, the impact they can have on their personal lives may not be divulged fairly and squarely by someone trying to market the test (Tanday, 2012).

Whilst the definition of genetic counselling continues to evolve, Ciarleglio et al. (2003) argue that the identification of susceptibility genes for common adult genetic diseases is moving the field of counselling into newer more challenging times. Genetic counsellors are also faced with having to translate more and more information which emerge from genetic tests into a way which can aid clients to make decisions, and which will reduce stress and anxiety, to enhance the ability to make life choices (Bennett et al. 2003). Weber and Corban (1996) note that although today geneticists perform most testing and counselling for genetic disorders, in the near future family physicians will increasingly become responsible for this role. Whilst the reasons for testing may be simple, they are likely to ignite fierce issues regarding cost, ethics, insurability, patient expectations and information which family members may wish not to know. How should family doctors consider the role in regard to genetic testing and counselling? In the light of this New Genetics, it may be envisaged that people will first inundate primary care physicians for answers to their questions. GPs accept they have an increasing role to play but may still show some lack of confidence in this area. Emery et al. (1999) say that the experience with counselling on cystic fibrosis in the UK is strong evidence to support the importance of providing genetic services in the primary care setting. Moreover the Association of American Family Physicians states in an editorial of its journal that several studies found that patients would prefer their family physician to facilitate an informed decision-making process on genetic testing and to counsel them about preventive measures. Although

family physicians may feel yet quite unprepared due to what the editors call the 'big bang' in the knowledge of genetics, they strongly believe in the 'larger role in genetic counselling' that family physicians should take (Martin & Wilikofsky, 2012)

### **What are the concerns of genetic tests?**

Why should genetic tests cause concern to family doctors more than any other form of test? The prime reason is indeed the novelty of these tests and the aura they are raising. Awareness campaigns sponsored by companies need to be considered for what they may actually be – an impetus for them to promote their product. While such a campaign need not to be bad in itself, if it is to be endorsed by the medical profession, the latter has the responsibility towards society not to be an accomplice in enticing patients to spend more than they should on such tests. Definitely not everyone needs do genetic tests and therefore fears must be quelled. Who is in a better position to quell such fears than family physicians who enjoy the trust of patients and their families? Some may argue that once these tests are available it is not the onus of any physician to try to convince someone not to do them. If one considers a commercially-available breast cancer (BRCA) test without any proper counselling however, there will be those who may not be aware of implications such tests carry to their employment, insurance and family when balanced against what management is available should they test positive - such as a radical mastectomy. This has enticed many states in the USA to have laws protecting against inappropriate access of such tests to the public. But in other countries such laws do not yet exist.

Studies on bilateral prophylactic oophorectomy vs. radical mastectomy (Kauff & et al, 2002; Rebbeck & et al., 2002) show that this is a highly evolving field in which it is wise to seek the advice of a doctor. Haber, analysing the relevance in the statics of such results, showed only that more studies are necessary. Thus by no means is there any certainty about outcomes of BRCA testing other than to recommend it to women past childbearing age and counselling them about an oophorectomy should they test positive (Haber, 2002). Again the operation does not exempt them completely from breast cancer. Notwithstanding the effectiveness of bilateral prophylactic radical mastectomy as has been demonstrated (Meijers et al., 2001), the controversy over such radical treatment remains.

---

## Point-of-care Genetic Counselling; the role of the Family Physician

Whereas it is undisputed that the General Practitioner is in an ideal position to counsel patients on genetic testing (BMA, 1998. p. 120) and to know where to refer patients for specialized counselling, Brody argues that a balance has to be struck between the physicians' hunches, the patient's wishes and the evidence of clinical trials (Lapp, 2002). As mentioned, one concern which is not being addressed adequately, for example, is the implications such tests pose for family members. A possible solution he proposes is that the family doctor is in a position to set up a 'family covenant' before an individual goes through with testing. Such a document would be negotiated among the family members with the help of the physician. Family members who 'opt in' for set conditions are privy to the knowledge that comes out (Lapp, 2002). Yet the concept of covenant is lagging behind advances in genetic testing and it is doubtful how much such a covenant is possible before family doctors establish themselves as the agents of basic counselling.

The British Medical Association (BMA) document argues that primary care physicians should be able to identify patients and families who would need further genetic counselling by specialists, arguing that the rapidity with which genetic technology is developing and the complexity of the decisions to be made in relation to genetic testing mean that specialized pre- and post-test genetic counselling are likely to be required (BMA, 1998. p121). This however only refers to identification of individuals and families who need specialist counselling. It is unlikely that genetic counsellors can reach the public as much as the family physicians because of their smaller numbers and their less easy accessibility for the more general genetic tests being advertised. Moreover the family doctor already knows much about the family and probably its requirements and would be able to identify who would benefit from genetic information. The family doctor is familiar with the background and family dynamics in a way that a specialized counsellor can never be: it is information obtained over time within the context of practicing family medicine. Indeed if it were possible for the counsellor to arrive to such knowledge, it could be argued that this would be a repetition and waste of time for health professionals and patients alike.

Boxes 1 and 2 (BMA, 1998. p. 123-124) show respectively the process of genetic counselling and the framework of exploring decisions laid down by both the BMA and the American Society for Human Genetics.

Nothing in this list is in fact beyond the capabilities of the average primary care physician. If people seek the advice of the family physician, it is appropriate that the latter should be able to handle most questions and counselling, leaving to the specialist those who have serious genetic inheritance problems. For those patients seeking to know more about cancer genes, paternity testing and even genetic screening of the unborn, the family physician is in an ideal and maybe better position to impart advice. Family physicians are moreover prescriptive by nature and thus tend to be more directive than the average non-directive genetic counsellor (Ibid. p122).

There are then additional reasons why general genetic counselling should be imparted by family doctors. The strategically placed primary point-of-care position of the family physician favours the role that genetic counselling should play in primary care physician. If people seek the advice of the family physician, it is appropriate that the latter should be able to handle most questions and counselling, leaving to the specialist those who have serious genetic inheritance problems. For those patients seeking to know more about cancer genes, paternity testing and even genetic screening of the unborn, the family physician is in an ideal and maybe better position to impart advice. Family physicians are moreover prescriptive by nature and thus tend to be more directive than the average non-directive genetic counsellor (BMA, 1998.p122).

Of course the family doctor can never replace the role of the specialized genetic counsellor just as he can never replace the specialized radiographer and cardiologist. But the energy of the specialist counsellor is better spent on the hard core cases like Huntington's and Tay Sachs, rather than where the industry is striking hard, namely the cancer genes and such tests as 'cardiovascular panels' and 'thrombosis panels' which are aimed to raise awareness of the public but which may also satisfy a profit motive trumping over a benevolent principle. Specialized counsellors can then continue doing what they have been doing up till now – provide specialised services.

Conversely, if one considers countries where newly-formed companies offer genetic testing to the public, where family physicians provide no such counselling, such fertile ground is the ideal incubator for releasing 'awareness information' onto the public catching doctors off guard. Before there is enough time to prepare for genetic counselling services, people will start believing that there is some inherent cure in carrying out such tests (Lapp, 2002). On the other hand, doctors unaware of



---

the implications of such tests will not counsel the public properly, as has been the subtle warning of the BMA. Specialized services, even if they do exist in theory in the main general hospitals, will not be enough to handle the everyday questions about genetic tests and definitely cannot direct patients into what tests are necessary. An appointment with the service may run into months just to handle the cases that truly need specialized counselling.

This highlights the importance of recognising that general practitioners are strategically placed to train themselves in imparting this counselling, which being a core medical subject is already in their realm. It is the responsibility of colleges, association and academics of family physicians to counsel members to learn more about genetic counselling. There will be no grass-root availability to answer questions about genetic tests of which one has heard about over the media.

### **The coming of age of Family Practice**

A second important reason is the coming of age of family practice. Whilst the history of medicine shows that the family doctor or community doctor was the traditional doctor (Porter, 1996) (p.118)), the last century saw a surge of specialists and sub-specialists. In Britain the Royal College of General Practitioners was founded after the war and incorporated within it almost all general practitioners. It became the strongest political body in Britain to bargain with government over the structure of the National Health Service (Porter, 1996). Conversely, in the United States, the American Academy of Family Physicians brought together Family Doctors raising the status of Family Medicine to that of a speciality. Similar roads were taken in other countries. Family Medicine is now recognised and listed as a Speciality in its own right in the European Union and other continents are adopting vocational training in the field.

Family doctors now provide more and more services which can be offered to people at more reasonable rates making it more acceptable to insurance companies. GPs have always traditionally carried out minor surgery such as removal of sebaceous cysts, cautery of warts and injection of internal haemorrhoids. Nowadays more and more GPs take on more engaging non-invasive surgery such as removal of lipomas, injection of varicose veins, circumcisions and even haemorrhoidectomies (Brown, 1992) Studies (Siepel et al., 2000) have shown that family doctors who attend a course in ultrasonography can perform ultrasounds as part of an annual physical examination, detecting pathology such as renal tumours,

aortic aneurysms and others, before any signs and symptoms are present. Family doctors in the United States train in sigmoidoscopy, gastroscopy, colposcopy and can even have a whole radiological set-up if economically viable. All of this is in the interest of quick diagnostics bypassing long referral lists and delays in a secondary care setting. The UK has been at the forefront experimenting with 'pathways' aimed at reducing costs and waiting times for the NHS and patients respectively, with the GP playing the key role in these reductions. In this setting it is reasonable to assume that family doctors with continued medical education (CME) are taking onto themselves more and more diagnostic techniques which not only increase the scope of general practice but which result in more benefit to patients. With proper CME a genetic counselling service to people and their families is clearly within the scope and definition of family practice.

What is needed with the impact of genetic technologies therefore is a primary care setting that can explain tests to all people, not only to those who have some genetic disorder in their lineage. Someone with a family history of colon cancer may inquire about the relevance and validity of genetic tests; it is reasonable to assume also that any woman may request information about whether she should have a BRCA test done. She may not know she needs counselling (in terms of implications for herself and her relatives and for insurance and employment interests). Therefore besides providing strategic community point-of-care contact, family physicians can bring a broader scope to genetic counselling. They are trained to think of issues such as getting patients to get their houses insured before getting tests done (Lavallee, 1999).

Consequently it is unreasonable to assume or request genetic counsellors to have to deal with this sort of mass population counselling. They would lose time which is valuable to what they are doing at present - counselling families, which may indeed be identified by family doctors, in need of further in-depth evaluation. Unless genetic counsellors increase in numbers and become almost as common as the family doctor they may not be able to handle the amount of information which necessarily would need to be imparted to keep up with the media and the rapidly expanding genetic industry. Starfield et al. (2002, p.51) argue that if genetic problems including initiating diagnosis and even management, should be considered, primary-care centred systems offer the greatest resource for improving health.

## Training – certification / re-validation and vocational training

Studies do show that one cannot take for granted that since someone is a doctor, no formal professional development in this regard is necessary. In the first instance the counselling to be imparted is not the type of counselling we usually associate with psychologists, or, for that matter the counselling GPs can usually give to patients with psychological or family problems (Patient UK, 2012). It is conversely an integral part of the genetic testing process to involve both pre-test and post-test counselling. Whilst a genetic test may be available, a family physician would typically ask why the patient is asking about such a test at that point in time; what does the patient seek and what do they intend to do with the results? Making an analysis of whether they are ready can guide family physicians in taking appropriate care about consequences at first-contact point-of-care.

Guidance will certainly include explaining the impact any result will have on relatives and the fact that laws may oblige one to disclose information to other family physicians who are responsible for their relatives (Fulda & Lykens, 2006) and any decisions and legislation taken in this regard at a national level. Where no such legislation and guidelines exist, family physicians can act as patient advocates cautioning against over-the-counter genetic testing, for example.

In a study in New Zealand, Morgan et al (2012) found that General Practitioners have an increasingly important role to play in genetics but that the best

way to implement future educational strategies need to be well considered. In their study, most GPs felt that they lacked experience and knowledge of genetic testing and had received very little formal training, even though they recognized the important role they have in this area. As highlighted earlier, Geller et al. (2012) confirmed that family physicians may be more directive in their counselling from conclusions of a study which included obstetricians, pediatricians, internists, family practitioners, and psychiatrists; this involved counselling patients on prenatal diagnosis and abortion. Certainly the change in attitude they advocate for primary care physicians would also have to include viewing genetic counselling from a much broader perspective than merely limiting it to reproductive issues.

The main areas of genetic clinical testing are antenatal screening and cancer genetics testing. More is promised in the future. However, the British Journal of General Practice has recently said that in providing genetic counselling, a family history may still be the most important tool so far, and that it is often neglected as part of a diagnosis (Walter & Emery, 2012). The editorial says that data from people who have taken over-the-counter genetic testing have not really had an impact on their change in life-styles. Perhaps this is a further argument why the pre- and post-genetic counselling should in fact be done by the family doctor, who stands in clinical equipoise (as opposed to someone trying to sell the test) with regard to the person considering the reason they want testing. Perhaps curiosity without a motivation to

### BOX 1 (BMA, 1998)

“The British Medical Association states that genetic counseling consists of a series of activities which make a coherent whole. For ease of analysis we separate them in the list given below. In reality, however they are not separate entities, but facets of one process. In general terms, genetic counseling includes:

- Taking a family history and establishing a diagnosis;
- Gaining an understanding of the social and cultural context within which a patient and his or her family live and the values they bring to the counseling process;
- Listening to the questions and anxieties of the patient;
- Providing information about the condition, its inheritance pattern, and its management and raising questions about the potential significance of sharing information with other family members;
- Giving information about reproductive options; and/or
- Giving information about predictive options (if applicable);
- Providing the opportunity to reflect upon the options (implications counseling);
- Providing emotional support; and
- Initiating sustained help, if necessary, to enable individuals to adjust to particular life circumstances (psycho-therapeutic counseling).”

## BOX 2 (BMA, 1998)

The description of genetic counseling set out by the American Society of Human Genetics is as follows:

Genetic counseling is a communication process which deals with the human problems associated with the occurrence or risk of occurrence, of a genetic disorder in a family. This process involves an attempt by one or more appropriately trained persons to help the individual or family:

- (1) comprehend the medical facts, including the diagnosis, the probable course of the disorder and the available management;
- (2) appreciate the way heredity contributes to the disorder, and the risk of recurrence in specified relatives;
- (3) understand the options for dealing with the risk of recurrence;
- (4) choose the course of action which seems appropriate to them in view of their risk and their family goals and act in accordance with the decision;
- (5) make the best possible adjustment to the disorder in an affected member and/or to the risk of recurrence of that disorder.

change life style may make the patient reconsider testing unless there are more important reasons to do so, such as new forms of treatment. O'Brian says that there is no evidence that information obtained from genetic tests 'will be as valuable as the marketing suggests' (O'Brian, 2012). Moreover, family physician Nancy Stevens stresses the importance of injecting the family practice perspective into genetic medicine (McCanse, 2001). As this perspective is still underrepresented in conversations of genetic medicine, it means that patients of family practitioners are underrepresented. For example, she points out that only someone from high-risk families tends to benefit from BRCA testing.

### The role and responsibility of associations and colleges

Certainly the responsibility taken on by family physicians is greater and respective colleges and associations may need to undertake the training of their members both in what we mean by counselling; what counselling should be done by family physicians, and of course when they should refer. Once it is accepted that the family doctor has this role to play in imparting knowledge and genetic counselling to patients, associations and colleges have an obligatory role to see that its members get the CME required in genetic counselling. Family doctors, by their very nature, are already in a position to give evidence-based information, genetics being one speciality they have always had in their curriculum. It would be unreasonable not to accept their role in providing such evidence-based counselling.

Associations and colleges of family doctors, which strive to guarantee excellence of their members to the public, have a special role to play here. But primary-care centred systems may pose a risk of underdetection and undermanagement of genetic problems if information

and other educational networks do not actively support practitioners (Starfield et al. 2002, p. 51). Whereas it may be obvious that a family doctor intending to carry out diagnostic ultrasonography would require training, it may not be that obvious that to do genetic counselling one also needs training, because genetics has always formed part of the medical undergraduate curriculum. The focus of counselling is not on Mendelian inheritance explained in layman terms, but is a matter of explaining the social, legal and ethical implications of these tests and also of having a clear understanding of why they are so different than merely having a blood count done. Doctors need to understand and explain that genetic tests are largely non-therapeutic and predictive. The patient therefore needs to be empowered with information by someone who realizes the full potential of these tests and how industry may exploit fear of disease without concern for other family members and implications on employment and insurability.

Associations must guarantee that their members will explain the harm/benefit of genetic testing and screening. They must also guarantee that they will continue to seek the interests of the family and not only of individual people seeking testing. In other words, family doctors need to maintain the trust of the public, that financial gain is not the main motive of the counselling as may be the case for the company providing that test.

### CONCLUSION

Whilst more recently a qualitative study published in the British Journal of General Practice has raised concerns about British GPs welcoming an enhanced role in clinical genetics and that the effectiveness on education policy aimed solely on knowledge is questionable (Mathers et al., 2010), it should be acknowledged that generally patients will go to their family doctors for enquiry because

they are strategically placed and available. In any case, in many instances they would need a referral by their doctor for genetic services. The family doctor will already have considerable 'genetic' knowledge through the patient's family history (Mathers et al., 2010) and should be in a position not only to act as gatekeeper, given that genetic counsellors are limited, but to recognize his/her role in prevention and intervention – to avoid direct-to-consumer advertisement and over-the-counter analysis, and to counsel patients through the information they would need to know both before and after a test and indeed empower patients to make an informed choice.

**Prof. Pierre MALLIA**

MD MPhil MA(law) PhD MRCP FRCGP

*Dept. of Family Medicine, University of Malta  
Coordinator, Bioethics Research Programme*

Email: pierre.mallia@um.edu.mt

**Reference**

- BMA. (1998). In British Medical Association (Ed.), *Human genetics; choice and responsibility*. London: Oxford University Press.
- Bennett, R.L., Hampel, H.L., Mandell, J.B., Marks, J.H. (2003). Genetic counselors: translating genomic science into clinical practice. *Journal of Clinical Investigation*, 112, 1274-1279.
- Brown, J. S. (1992). *Minor surgery: A text and atlas*. London, New York, Tokyo.: Chapman & Hall Medical.
- Chandros Hull, S., & Prasad, K. (2001). Reading between the lines: Direct-to-consumer advertising of genetic testing. *Hasting Center Report*, 31(3), 33-35.
- Ciarleglio, L.J., Bennett, R.L., Williamson, J., Mandell, J.B., Marks, J.H. (2003). Genetic counselling throughout the life cycle. *Journal of Clinical Investigation*, 112, 1280 - 1286.
- Emery, J., Watson, E., Rose, P., & Andermann, A. (1999). A systematic review of the literature exploring the role of primary care in genetic services *Family Practice*, 16(4), 426 <last\_page> 445. doi:10.1093/fampra/16.4.426
- Fulda, K. G., & Lykens, K. (2006). Ethical issues in predictive genetic testing: A public health perspective *Journal of Medical Ethics*, 32(3), 143-147. doi:10.1136/jme.2004.010272
- Geller, G., Tambor, E. S., Chase, G. A., Hofman, K. J., Faden, R. & Holtzman, N. (2012). *Arch Fam Med – abstract: Incorporation of genetics in primary care practice: Will physicians do the counseling and will they be directive?, November 1993, Geller et al. 2 (11): 1119* Retrieved 1/11/2012, from <http://archfami.ama-assn.org/cgi/content/abstract/2/11/1119>
- Haber, D. (2002). Prophylactic oophorectomy to reduce the risk of ovarian and breast cancer in carriers of BRCA mutations. *New England Journal of Medicine*, 346(21), 1660-1661.
- Kauff, N., & et al. (2002). Risk-reducing alpingo-oophorectomy in women with BRCA1 or BRCA2 mutation. *New England Journal of Medicine*, 346(21), 1609-1615.
- Lapp, T. (2002). Rise to challenges posed by genetic screening. *Family Practice Report*, 8(1), 5.
- Lavallee, M. (1999). Who better than their family physician to hold their hand and walk them down that scary road? *Family Physician Report, Special Section*, , 1-2.
- Mathers, J., Greenfield, S., Metcalfe, A., Cole, T., Fanagan, S., Wilson, S. (2010). Family history in primary care: understanding GPs' resistance to clinical genetics - qualitative study, *British Journal of General Practice*, 60(574). 358-364.
- Martin, J. R., & Wilikofsky, A. S. (2012). *Editorials: Integrating genetic counseling into family medicine - December 15, 2005 - American Family Physician* Retrieved 1/11/2012, from <http://www.aafp.org/afp/2005/1215/p2444.html>
- McCanse, C. (2001). First do no harm...genetic counselling. *Family Physician Report*, 7(9), 1-2.
- Meijers, H., & et al. (2001). Breat cancer after prophylactic bilateral mastectomy in women with BRCA1 or BRCA2 mutation. *New England Journal of Medicine*, 345, 159-164.
- Morgan, S., McLeod, D., Kidd, A. & Langford, B.(2012) *Genetic testing in New Zealand: The role of the general practitioner* Retrieved 1/11/2012, from <http://journal.nzma.org.nz/journal/117-1206/1178/>
- O'Brian, M. (2012) *Genetic testing a useful tool for future GPs - medical observer* Retrieved 1/11/2012, from <http://www.medicalobserver.com.au/news/genetic-testing-a-useful-tool-for-future-gps>
- Patient UK. (2012). *Genetic counselling for GPs | doctor | patient UK* Retrieved from <http://www.patient.co.uk/doctor/Genetic-Counselling-for-GPs.htm>
- Porter, R. (1996). *The Cambridge history of medicine*. Cambridge, London: Cambridge University Press.
- Rebbeck, R., & et al. (2002). Prophylactic oophorectomy in carriers of BRCA1 or BRCA2 mutations. *New England Journal of Medicine*, 346(21), 1616-1622.
- Siepel, T., et al. (2000). The ultrasound assisted physical examination in the periodic health evaluation of the elderly. *The Journal of Family Practice*, 49(7), 614-621.
- Starfield, B., Holtzman, N.A., Roland M.O., Sibbald, B., Harris, R., Harris, H. (2002). Primary care and genetic services. Health care in evolution. *European Journal of Public Health*, 12(1): 51-56.
- Tanday, S. (2012) *GPs warned over genetic testing kits | GPonline.com* Retrieved 1/11/2012, from <http://www.gponline.com/News/article/935251/GPs-warned-genetic-testing-kits/>
- Walter, F. M., & Emery, J. D. (2012). Genetic advances in medicine: Has the promise been fulfilled in general practice? (editorial). *British Journal of General Practice*, 62(596), 120-121.
- Weber, R., & Corban, G. (1996). Genetic testing: Are family physicians ready? *Family Physician Report*, 53(6), 1-3.

# A study of the management of head lice by paediatricians in Malta

Dr Marthese GALEA, Dr Christopher SCIBERRAS

## ABSTRACT

Head lice infestation is a condition found in every country in the world about which it is important to have proper education and awareness. This study aimed to examine the treatment of head lice and the education given to the patient and their parents from the paediatrician's point of view.

A questionnaire consisting of multiple choice questions and a covering letter was sent by post to all the paediatricians that were registered in Malta's specialist register as of May 2014. Guidelines from the UK and America were used to draw up this questionnaire.

According to 80% of the paediatricians who replied, the majority of the patients seek help from the pharmacist or the family doctor. Just over 50% prescribe permethrin; however, under the age of 2 years, a non-neurotoxic agent (dimethicone) is what 37% of paediatricians prefer to prescribe followed by permethrin (28%). Shampoo is the form of application that Maltese paediatricians prefer to use.

Fifty-five per cent of those that replied to the questionnaire think that there is no product suitable for the prevention of head lice. Forty-three per cent think that re-infestation occurs in over 30% of patients. If re-infestation occurs, half would prescribe the same treatment as before while the other half would prescribe a different class. Only 5% ever prescribed oral treatment.

Less than 1 out of 10 patients present with head lice to paediatricians and the majority are over 4 years of age. Forty-seven per cent advise that the child should keep on going to school.

It was concluded that the absolute majority of paediatricians are well informed about the treatment and the advice that needs to be given. The authors recommend that a patient awareness campaign is to educate the parents and make them aware of head lice. A survey among pharmacists and family doctors could also be carried out.

## INTRODUCTION

As described by Maunder (1983) head lice do not fly and spend their life cycle on one host. Maunder (1983) describes head lice as having short legs explaining why they cannot jump or walk properly on flat surfaces. Maunder (1983) also confirmed that head lice are more a cosmetic problem and are not considered by many as a medical threat. Secondary infections are rare and they only result from scratching. Although the condition is not a serious medical threat, it still has a significant impact on the life of the child and their parents.

The incidence of head lice varies from country to country. According to Frankowski & Bocchini (2002) in America there are around 9 million patients a year, while in Europe according to Durand et al. (2007), Volcsik et al. (1990) and Ciftci et al. (2006) the incidence varies from 0.8% and 9.9%. The authors know of no study in Malta that can shed light on the incidence of head lice in our population.

Many treatments are available to eradicate the head lice; unfortunately these treatments do not act on the eggs. Wet combing can be used for the eggs, but perseverance is needed as this needs to be done over a number of days. Broad et al. (2012) explains that using a hair dryer is as effective as wet combing of the eggs; however it will have limited effect on the hatched lice.

Lack of proper diagnosis, incorrect treatment, dose and duration can all lead to treatment failure and resistance as has been mentioned in recent years by Tebruegge et al. (2011).

The authors hypothesised that education for the patients and continuous updates to the healthcare providers might ensure proper diagnosis and treatment. The aim of this study is to obtain the paediatrician's perspective of the ideal treatment for head lice and to assess the knowledge that paediatricians in Malta have on the condition.

---

## METHOD

Following extensive literature review of guidelines from the UK and America, a questionnaire was set up consisting of 14 multiple-choice questions. A pilot study was done to assess its validity. From the pilot study it was concluded that 3 questions were not too clear and therefore had to be rephrased. The questionnaire was designed to take not more than 15 minutes to fill.

Once the questionnaire was ready it was submitted in May 2014 to the Chairman of the Department of Child and Adolescent Health at Mater Dei Hospital, Malta who gave his go ahead for the questionnaire to be sent to all the paediatricians on the specialist register in Malta. As this study did not involve research on human subjects, there was no need for approval to be obtained from a research ethics committee. The questionnaire was sent by post with an attached letter explaining the reason for the questionnaire and a self-addressed envelope to make it easier for the responder to send back the filled questionnaire and also to ensure anonymity. Four weeks was the deadline that was set for the questionnaire to be returned back to the authors. The questionnaire was written in English since all the paediatricians in Malta are literate in this language, and therefore there was no need to translate it into the Maltese language.

The software programme Microsoft Excel was used to collect and analyse the data collected.

## RESULTS

Fifty per cent of the paediatricians filled and returned the questionnaire. According to 80% of paediatricians the majority of the patients seek help from the pharmacist or the family doctor for the management of head lice. Just over 50% of the paediatricians prescribe permethrin while one paediatrician suggested the use of malathion in alcohol which is unavailable in Malta. However, for patients under the age of 2 years, a non-neurotoxic agent (dimethicone) is what 37% of paediatricians prefer to use, while 28% of respondents still prefer permethrin.

Shampoo is the form of application that the Maltese paediatricians prefer to use, followed by creams, gels and foams. The paediatricians that filled the questionnaire stated that if the right product is used there is no need to repeat the treatment. Fifty-five per cent of those that replied to the questionnaire think that there is no product that is effective for the prevention of head lice. Forty-three per cent think that re-infestation occurs in over 30% of the patients and 60% of the paediatricians think that this is caused by re-infestation in the community not due to resistance or due to inadequate treatment.

The paediatricians are split in half when it comes to the treatment of the patients when re-infestation occurs. Half would prescribe the same treatment as before while the other half would prescribe a different class. Only 5% ever prescribed oral treatment for head lice.

Head lice is not a common condition that the paediatrician in Malta treats. Less than 1 out of 10 patients present with head lice to the paediatrician. The majority (53%) of responders stated that the majority of patients that present with head lice are over 4 years of age and the remaining 43% of the paediatricians stated that those that they normally treat are between 2-4 years of age.

All the paediatricians (100%) offer advice to the parents of the child such as to pull back the hair and keep it healthy and well-conditioned or cut the hair very short. Another piece of advice given was to keep an eye open for head lice, so to be able to detect the problem as early as possible and avoid close head contact. Nearly half (47%) of the paediatricians give advice that the child should keep on going to school while 28% disagree.

## DISCUSSION

### Help and advice

Forty-two per cent of the paediatricians that replied to the survey stated that the majority of the patients will seek help from their pharmacists. However 38% of them also mentioned the family doctor as the health care provider that the parents also seek help from. This is higher than other countries as described by Doulgeraki (2011), Counahan et al. (2007) and Silva & de Aguiar (2008), the reason perhaps being that the family doctor in Malta might be easier to access than other countries.

Giving the right advice to the parents is a top priority when it comes to the treatment and prevention of head lice. This is mentioned in the majority of the literature reviewed and by the responders of this questionnaire.

### Treatment with insecticides

According to the American Academy of Paediatrics' guidelines (Page, 2014), 1% permethrin should be used as first line, while other guidelines such as the Scottish guidelines (Scottish Executive Health Department, 2003) just recommend insecticide lotions with no reference to any particular ingredient. From the questionnaire it results that the paediatricians in Malta follow the American guidelines when it comes to prescribing a treatment for children over the age of 2. Dimethicone is perceived by the paediatricians in Malta as safer

than permethrin which is the reason given why under the age of 2 the majority of the paediatricians in Malta prescribe dimethicone. For children under 2 years of age dimethicone could be a good alternative, because it has no odour, it is not toxic and well tolerated by patients aged 6 months and older as concluded by Pickering et al. (2009) and Broad et al. (2012). Dimethicone works by covering the head lice to cause suffocation therefore it is not pediculocidal nor ovocidal. However permethrin is still widely used by the responders in patients under the age of 2.

UK guidelines as described by Broad et al. (2012) recommend malathion as the treatment of choice for head lice; however this treatment as pointed out by one of the respondents is not available in Malta. Between 2011 and 2012 the U.S. Food and Drug Administration approved 2 new topical treatments for head lice: spinosad (Natroba) topical suspension 0.9% and topical ivermectin lotion (Sklice) (Skerrett, 2012), which no paediatrician mentioned in the questionnaire and both of which to date are not available on the Maltese Islands.

### **Other treatment forms**

Only 24% of the paediatricians that took part in the questionnaire highlighted wet combing as their first preference for the removal of head lice under the age of 2 years. It is important that if paediatricians advise the use of wet combing, the paediatrician needs to show the parents how it is done as clearly stated by Hill et al. (2005).

Regarding other treatment options, no paediatrician that took part in the survey suggested the use of drugstore products such as coconut extract, essential oils or tea tree oil. This might be because there are not enough studies to show their efficacy and safety as concluded by Frankowski & Bocchini (2010). According to the results from the questionnaire, oral treatment is rarely prescribed which correlates well with the literature reviewed.

### **Re-treatment and treatment failure**

Another result arising from the questionnaire was that 50% of the paediatricians advise re-treatment for all topical medications, ideally on day 7–9, as many experts such as Frankowski & Bocchini (2010) suggest. Improper timing of the second application of pediculicides should be considered an important cause of treatment failure.

Resistance to the standard treatment of head lice is increasing as stated by Pariser et al. (2012). However, as perceived by the paediatricians interviewed, there does not seem to be a great concern clinically as 43% of

those interviewed stated that re infestation rarely occurs while 38% stated that re-infestation occurs in 10% or less. During the literature review, the authors could not find any figure to define the percentage of re-infestation in children.

The absolute majority of the paediatricians surveyed believe that re-infestation is due to a re-infestation in the childhood community. It is important to note that to have re-infestation, head lice have to be detected approximately 48 hours after stopping the treatment. It is also important to take into consideration what Broad et al. (2012) have stated, that for the treatment to be considered as failed, two applications 7 days apart need to have already been applied.

The reason for resistance can be due to a number of reasons, such as lack of compliance, under dosing or inappropriate duration of treatment. A number of different treatment approaches are being suggested to try and avoid treatment failure. A strategy that has been suggested by Pickering et al. (2009) and Broad et al. (2012) is the use of one particular product for a full-course and, if the treatment fails, this is followed by a second complete cycle of treatment of a different class from that used previously. Only 31% of paediatricians interviewed used this approach. The majority (60%) will prescribe the same treatment.

### **Limitations of study**

One limitation that the authors encountered is their lack of awareness of any another study carried out about the knowledge, advice and the treatments that paediatricians give to patients suffering from head lice in Malta. Also no data was found on the incidence of head lice in Malta. Therefore the information gathered was entirely from international studies.

Another limitation of the study was that, since the majority of patients with head lice prefer to seek advice from the pharmacist or family doctor, these should have been included in the study.

Fifty per cent of the paediatricians filled and sent back the questionnaire. Although 50% is a very good response rate, it may be said that the other 50% who did not respond could have done so because they are less updated on the management of head lice compared to those who took part in the questionnaire.

### **CONCLUSIONS**

Head lice infestation is a condition that is normally not seen by a paediatrician in a hospital or government health centre setting where paediatric services are given

free of charge. This could be the reason why the majority visits the family doctor or pharmacist as the latter are more readily available and the consultation is free from a pharmacist or if the family doctor works in a government health centre.

From the survey it was concluded that the absolute majority of paediatricians are well informed about the treatments and the advice that need to be given. Since paediatricians seem to be well informed one can educate more the parents, teachers and school nurses on head lice so as to facilitate an improvement in management in the community setting. Moreover a patient awareness campaign is recommended to educate the parents and make them aware of head lice. A survey among pharmacists and family doctors could also be performed since, according to this study, more patients seek help for head lice from them rather than from paediatricians.

#### Dr Marthese GALEA

MD, MRCPCH

Resident Specialist, Paediatric Department, Mater Dei Hospital, Msida, Malta

Email: [akgalea@maltanet.net](mailto:akgalea@maltanet.net)

#### Dr Christopher SCIBERRAS

MD, MRCPCH, MRCP(UK), MSc. Comm.Paed. (Warwick),

DCH (Dublin), Cert. Dev. Paeds.(London)

Consultant Paediatrician, Community Paediatrics and Disability Services, Department of Paediatrics, Mater Dei Hospital, Msida, Malta

Email: [kris.sciberras@gmail.com](mailto:kris.sciberras@gmail.com)

#### Reference

- Broad, P., Carney, J. & Gee, S. (2012) Health Protection Agency North West: *The prevention, identification and management of head lice infection in the community*. <http://www.hpa.org.uk>. [1<sup>st</sup> November 2014].
- Ciftci, I.H., Karaca, S. & Dogruo O. (2006) Prevalence of pediculosis and scabies in preschool nursery children of Afyon, Turkey. *Korean J Parasitol* 44:95-98.
- Counahan, M.L., Andrews, R.M. & Weld, H. (2007) What parents in Australia know and do about head lice. *Rural Remote Health* 7:687.
- Doulgeraki, A. (2011) Parental attitudes towards head lice infestations in Greece. *Int J Dermatol* 50:689-692.
- Durand, R., Millard, B. & Bouges-Michel, C. (2007) Detection of pyrethroid resistance gene in schoolchildren from Bobigny, France. *J Med Entomol* 44:796-798.
- Frankowski, B.L. & Bocchini, J.A. Jr (2002) Council on School Health and Committee on Infectious Diseases: Head lice. *Pediatrics* 110:643-683.
- Frankowski, B.L. & Bocchini, J.A. Jr. (2010) Council on School Health and Committee on Infectious Diseases: Head lice. *Pediatrics* 126:392.
- Hill, N., Moor, G., Cameron, M.M. & Butlin, A. (2005) Single blind, randomised, comparative study of the Bug Buster kit and over the counter pediculicide treatments against head lice in the United Kingdom. *BMJ* 13;331(7513):384-7.
- Maunder, J.W. (1983) The Appreciation of Lice. *Proceedings of the Royal Institution of Great Britain (London: Royal Institution of Great Britain)* 55: 1-31.
- Page, R. (2014) *The American Academy of Pediatrics Guidelines for Management of Head Lice: An In-Depth Guide*. Published Online: Thursday, August 21, 2014 <http://www.pharmacytimes.com/news/The-American-Academy-of-Pediatrics-Guidelines-for-Management-of-Head-Lice-An-In-Depth-Guide#sthash.hdSDHMkD.dpuf>
- Pariser, D.M., Meinking, T.L., Bell, M. & Ryan, W.G. (2012) Topical 0.5% Ivermectin Lotion for Treatment of Head Lice. *N Engl J Med* 367:1687-1693.
- Pickering, L.K., Baker, C.J. & Kimberlin, D.W. (2009) American Academy of Paediatrics (AAP): Pediculosis Capitis. In *Red Book: Report of The Committee of Infectious Diseases*. 28th edition. Edited by Pickering L.K. Elk Grove Village: 495-497.
- Scottish Executive Health Department (2003) *National Guidance on Managing Head Lice Infection in Children*. <http://www.scotland.gov.uk/Publications/2003/03/16774/20133>. [5<sup>th</sup> July 2014].
- Silva, L. & de Aguiar, A.R. (2008) Survey assessment of parental perceptions regarding head lice. *Int J Dermatol* 47:249-255.
- Skerrett, P.J. (2012) New anti-lice lotion is good news for nitpickers. Harvard Health <http://www.health.harvard.edu/blog/new-anti-lice-lotion-is-good-news-for-nitpickers-201202104248>. [20<sup>th</sup> July 2014].
- Tebruegge, M., Pantazidou, A. & Curtis, N. (2011) What's bugging you? An update on the treatment of head lice infestation. *Arch Dis Child Educ Pract*. 96:2-8.
- Volcsik, R., Preuss, P & Knaus, B. (1990) Head lice infestation in the Cottbus district. *Z Gesamte Hyg*, 36:614-615.



# Confidentiality and treatment of young adults

## Proposals for amendments: the *Gillick* Proposition

Dr Ann Marie MANGION

### ABSTRACT

The law does not determine between legal competency and actual competency of minors in medical issues. The objective of this paper is to put forward proposals to amend the legislation to redefine legal competency on the base that understanding should have more bearing than age.

The English landmark case of *Gillick* is used to analyse the Maltese situation. The Maltese legislation was examined and it resulted that there is no legal definition of what competency is. Various legislations use different ages to define competency. The Genito-Urinary (GU) Clinic was even given permission to assess a minor's competency itself and if it is determined by the medical professional that the minor is competent then such minor will be treated without the need for parental consent.

To substantiate the claim, in 2009 the researcher carried out empirical research using both qualitative and quantitative methods. Questionnaires were given to children aged between 6 and 18. Structured and semi-structured interviews were used to interview legal and medical professionals involved in the field.

By triangulating the results the conclusion reached is that minors do seek treatment without parental consent and that there are medical professionals who already treat minors without parental consent. There is the need for legal reforms to substantiate the reality of actual competency of minors.

**Key words:** competency; parental consent; *Gillick*; best interests; minors

### INTRODUCTION

The main aim of this research was to determine whether age is more important than understanding when it comes to a minor's competency to consent to medical treatment. The law on competency is age-based. Therefore, the research question is whether understanding and maturity should form the basis of

determining a minor's competency to consent.

One can start off the discussion by defining what the legal definition of 'childhood' is. A quick look at the various Maltese legislative documents conclude that there is no such definition. The only terms used in the Maltese Civil Code to refer to the various stages of childhood are 'minors' and 'children'. Article 157 of the Civil Code (Chapter 16 of the Laws of Malta) defines a minor as 'a person of either sex who has not yet attained the age of eighteen years'. This reflects the United Nations Convention on the Rights of the Child (UNCRC), wherein a child is defined as 'every human being below the age of eighteen years unless under the law applicable to the child, majority is attained earlier' (Part 1, Article 1). 'Juvenile' is used for children who have been caught up with the criminal justice system.

Minority and childhood has been artificially construed by society to give definition to such concepts as the age of majority. The age of majority has changed over time. In the past the age of majority was twenty-one which was then lowered to eighteen. Thus competency was attained at eighteen instead of at twenty-one. According to the UNCRC, the right of participation belongs to all children, and due weight to their opinion is given according to their age and maturity. Therefore, a new notion, has been introduced, that of maturity, in other words, understanding.

The Ministry of Health in New Zealand (Ministry of Health, 1998, p. 43) put forward two approaches to determine competency:

(1) The 'status' rule:

Children from eighteen years upwards can consent to treatment.

(2) The maturity approach:

A child's competence, even if he is under eighteen years of age, is determined as to whether he has sufficient knowledge or understanding of the consequences.

Justice Thorpe in *Re C (Adult: Refusal of Medical Treatment)* defined the legal test for competence as being 'first comprehending and retaining information, secondly, believing it and thirdly, weighing it in the balance to arrive at a choice'. In other words this is the basis of an informed consent be it for a child or an adult.

Children are differentiated according to their understanding. Sixteen is an age of great significance in the Maltese legal system because at sixteen one can get married, one can work, one can be emancipated and carry out commercial acts of trade and yet one cannot seek medical treatment by himself except at the Genito-Urinary (GU) Clinic. Moreover, through research which will be shown further on it transpires that at that age young adults are already seeking out treatment by themselves and sometimes with their parents' blessing!

It is suggested by the British Medical Association (Shaw, 2001, 151) that a child's competence should include:

- (1) The ability to understand that there is a choice and that the choices have certain consequences;
- (2) The willingness and ability to make a choice even if that choice entails that someone else makes a choice for you;
- (3) The understanding of the nature and purpose of the procedure;
- (4) The understanding of the risks and side-effects of the procedure;
- (5) The understanding of the alternative treatments available and of their risk and the understanding of choosing not having any kind of treatment;
- (6) There is freedom from any kind of pressure.

Shaw (2001, p. 152) states that children who have a healthy and supportive relationship and who are allowed to participate in the decision-making process are more likely to be competent. It is also imperative that the child has a trustworthy relationship with the doctor, and the child must be given adequate information about the procedure in an appropriate way fit for his age. For the child to be competent, such child must be free from pressure, panic, pain and any other temporary debilitating factors such as fear (Shaw, 2001, p. 152).

Understanding should include the comprehension of the nature of the illness; the nature of the recommended intervention and of any alternative treatment available; the risks or benefits and the long-term consequences of having such intervention or not; that a decision must be made and that a decision has consequences (Shaw, 2001, p. 152).

## GILLICK TEST

In *Gillick v. West Norfolk and Wisbech Area Health Authority*, the age versus understanding debate was clearly tested, wherein the House of Lords recommended that the arbitrary chronological age should be replaced by a test of maturity. Likewise this has been adopted in other countries such as New Zealand and Australia. This test places an additional burden on the clinician in order to secure that the child is indeed competent, but such a test is essential to safeguard the rights of the child (UNESCO, 2007). Before providing medical treatment, the practitioner must determine whether the child below sixteen years of age has the understanding and maturity to form a balanced judgement about the proposed treatment (Ministry of Health, 1998, p. 13).

If so, the child can be treated without obtaining parental consent and, if not, parental consent must be obtained before treatment is administered (Ministry of Health, 1998, p. 13).

The Court in *Gillick* said that the practitioner should encourage the child to involve the parents but if the former does not want to, then the practitioner has to respect the child's wishes and proceed with the treatment if it is in the child's best interests and if the practitioner is satisfied that the child has the sufficient maturity and understanding to take such a decision. The latter is deduced not from a fixed chronological age but on a case by case basis. Lord Scarman adds that '...Parental right yields to the child's right to make his own decisions when he reaches a sufficient understanding and intelligence to be capable of making up his own mind on the matter requiring decision.' Ekeelaar (1986) observed that his quotation was interpreted quite literally to mean that the attainment of competence by the child would terminate parental responsibility over the matter in question and would give the child an exclusive right to decide.

The 'Gillick Test' was held as consisting of three steps:

- (1) If a doctor is of the view that the procedure can be said to be in a child's best interests, and
- (2) If that doctor cannot persuade the child to tell his/her parents, and
- (3) Provided that the child is able to understand the nature and consequences of the medical procedure.

After the three steps have been taken, then the child is competent to consent without the knowledge or consent of his/her parents.

However Carabott (2008) stated that 'the child's best interests' should be rephrased into 'the patient's

---

best interest'. We must stop looking at the child as a child but we should look at the child as a patient when he seeks medical advice.

Article 9(i) of Malta's Commissioner for Children Act states that children should be given the 'highest standards of health'. However if a competent minor is deterred from seeking medical help because he/she does not want parental involvement, then such minor is not being given the highest standards of health. By imposing parental consent for treatment or therapy one is breaching Article 24 of the UNCRC which states that no child should be 'deprived of his or her right of access to such health care services'.

Sub-article 10(d) of the same Act states that children should be allowed to participate in the decision-making process. This sub-article is very pro-*Gillick*.

The Public Health Act (Chapter 465 of the Laws of Malta) considers health issues which are of public concern. The requirement of consent is removed and it is the Superintendent of Public Health who decides and takes decisions affecting public health. Nevertheless, consent in this Act is defined as 'approval given by an individual without any force, fraud or threat' (Article 2). It is interesting to note that this definition is not constrained to adults only but it is open to any individual who feels free to give consent without any duress of any kind.

Article 3(2) of the Mental Health Act is very interesting as it sets an age lower than the traditional age of competency. It states that if a minor is aged sixteen years and upwards and is capable to form his own opinions (usually formed if the child has sufficient understanding and intelligence – that is *Gillick* competent) such minor can be informally admitted to the mental hospital without the need of any parental consent. By setting the age limit at sixteen, this article shows that the traditional concept that competency is reached on the 18<sup>th</sup> birthday is outdated.

Consent is a form of contract undertaken by the person giving the consent in return for health treatment (Cauchi et, 2006, p. 26). Article 960 of the Civil Code defines a contract as 'an agreement or an accord between two or more persons by which an obligation is created'.

For a contract to be valid, one of the requisites is the appropriate capacity of the parties and Article 188(1) of the Civil Code states that minors who have not yet reached the age of eighteen are incapable to contract. However as per Article 969(2) such rule is diminished to the extent that a contract entered into by a child between the ages of nine and fourteen is valid in so far as it in

his favour. However, as per Article 970, for those who entered into a contract at fourteen years of age, such contract will be legally valid.

This clearly shows that in the eyes of the law minors from the age of fourteen years upwards have the faculty to contract if such contract is deemed to be valid, and for children from the age of nine upwards the law felt that they also have the faculty to contract but since they are still young it feels the added need to protect them by upholding the agreement if it is in the child's favour.

Perhaps the most important document which strengthens the argument in favour of adopting *Gillick* competency in Malta is a letter by the Medical Council to the Doctor-in-Chief at the GU Clinic. The Medical Council quoted Article 7(1)(a) (repealed by Act XII of 2003) of the Medical and Kindred Professions Ordinance which states that medical practitioners are bound to practise their profession without any delay and to prescribe the appropriate remedies.

The Medical Council rightly interpreted this provision as stating that the parental consent of the minor is 'subordinate' to the innate medical profession to help out and to prescribe remedies. Thus a medical professional need not obtain parental approval before treating the minor.

This interpretation adds strength to the argument in favour of *Gillick* competence since medical help should not be held back from minors because of lack of parental consent. This principle should also be applied where a competent minor seeks medical help on his own initiative.

In the Regulations no distinction is made between minors and adults since only the term patient is used. This can be taken to mean that in medical eyes no distinction should be made between a minor or an adult since both are patients.

Consent under the Clinical Trials Regulations is defined as informed written consent by 'any person capable of giving consent' (Article 3 of SL 458.43). Article 5(a) of the Regulations states that although parental consent is required, such consent must 'represent the minor's presumed will' and if not, it can be 'revoked at any time'. Article 5(b) and (c) are very pro-*Gillick* competency as well – a clear indication that Europe is moving towards adopting competency according to maturity and intelligence instead of the traditional age determined competency. They state that the minor should be given sufficient information according to his intelligence and if the minor 'is capable of forming an opinion and assessing this information' such opinion

will be given 'due consideration'. Therefore the criteria of competency in this sub-article are two: the ability to form an opinion and the ability to assess such information. This is similar to *Gillick* competency's sufficient understanding and intelligence because the child must have enough understanding and intelligence to be able to assess the information and form an opinion.

## METHOD

As part of my research on the subject matter, in 2009 I conducted quantitative and qualitative research.

Quantitative research involved school children from Grade 2 to 6<sup>th</sup> Form. The students selected were from church schools so that the study covers as wide a spectrum of students as possible since these students come from all over Malta. The study consisted of a questionnaire with carefully selected questions and the purpose was to find out what minors think about competency and how they look at taking medical decisions for themselves. Questions were given out to each student in each classroom and were filled out without any parental assistance. The questions were a mix of 'yes' or 'no' answers and open ended questions. Parental consent was obtained for each minor involved in the study. The study was anonymised.

Qualitative research involved structured and semi-structured one-to-one interviews with legal and medical professionals. The interviews were not recorded. The transcript was sent out to the interviewees for approval. The study was not anonymised.

Research ethics clearance was obtained from the University of Malta Research Ethics Committee.

## RESULTS

Despite their young age, the results for males aged 6-13 years show that male minors want to be active decision-makers in their own health. Fifty-seven per cent of 237 male students in this category believe that they should be the ones taking the decisions as shown in Q.19. However, as they know that they are young, they feel that their parents should be present when the doctor is explaining the illness and the available treatment. This is shown by 66% answering 'No' to Q.18 being 'Do you prefer that the doctor tells you and not your parents what you are suffering from?' Answers to Q.14 show that 19% wanted to go to the doctor and their parents still didn't take them – this is quite alarming.

If *Gillick* were to be implemented, these minors would be able to go to the doctor on their own. In fact a 12 year old wrote that he had gone to the doctor on his own

because of an earache. This shows that minors do care for their health and some are mature enough to actually go to the doctor even though their parents disagree. A poignant remark was made by a 10 year old who wrote 'I would like that the law would leave us and make a decision by our own'.

Sixty per cent of 112 male minors interviewed between 13 and 16 years prefer that the doctor speaks to them and not their parents about what they are suffering from, leaving them at liberty to tell their parents themselves as shown in Q.20. Thus minors in this age group value the issue of confidentiality. A 15 year old boy wrote 'If there is a sex-transmitted disease, I wouldn't want my parents to know.' This can be contrasted with the fact that 89% stated that presently the doctor addresses their parents rather than them about their health as shown in Q.23.

In Q.19, 96% would like the doctor to tell them exactly what they are suffering from. Two 15 year olds wrote that as teenagers they should be informed about their health and be allowed to take decisions. A 14 year old wrote 'Children have the right to know when it comes to their health on their own demand'. Another 14 year old wrote '*Iddiskuti mal-ġenituri imma id-deċiżjoni finali int teħodha*'. ('Discuss with parents but you must make the final decision.') Although parental involvement is welcomed, minors in this category want to be the ultimate decision-makers.

Even though presently they are legally incompetent, 19% of the minors have already gone on their own to seek medical advice without parental consent as shown in Q.13, and when asked why in Q.14, the answers varied from mere sickness, influenza and pain to fracture, sports related injury, to how their body works, while some opted to just write confidential.

As they grow older minors become less dependent and parental responsibility fades into parental guidance. In fact in Q.21, 84% of 218 males who filled out the questionnaire aged 16-18 years believe that they have the right to decide themselves for their own health. The majority remarked that maturity is the key to decision-making and not age. Twenty-five per cent of respondents aged 16-18 actually made health visits without their parents' knowledge. This is an increase of 6% on minors aged 13-16 (19%). The independent visits included a number of reasons such as mere medical advice, cough and influenza, chest pain, stomach problems, asthma, fungi in feet, severe neck pain, knee injury and muscular pains, respiratory problems, insomnia, infections, ear blockage, nutrition advice and sexual advice.

An 18 year old wrote that 'When people are over 16 they should have an option to keep their health issues private. Otherwise psychologically they will not be so ready to visit the doctor, subconsciously knowing that their information will not remain confidential'.

Almost half of the 205 female minors aged 6-13 years prefer to be able to decide by themselves in Q.19. In Q.18 70% said that they prefer if the doctor talks to them and their parents simultaneously. A 13 year old girl wrote 'Health is important for our life. It's important that our parents know what I have'. Another wrote 'I would let my parents to come with me to the doctor if needed'. In Q.17 91% prefer if the doctor tells them what they are suffering from. A 13 year old girl wrote 'Health is very important. I like that doctors tell me the truth even if it is a bad thing'. The Chairman of Paediatrics, Prof. Simon Attard Montalto during the interview said that the majority of minors know what is in their best interests and this is shown in Q.14 where 17% wanted to go to the doctor and their parents did not take them. A 12 year old wrote 'Sadly a lot of parents don't let their children know what they are suffering from and sometimes the parents don't take action, after their children say they are sick'. If *Gillick* competency were to be applied minors could go to see the doctor by themselves.

All 98 (100%) female minors aged 13-16 years who filled out the questionnaire prefer that the doctor tells them exactly what they are suffering from and 69% believe they have a right to decide by themselves as shown in Q.21. A 15 year old wrote '...sometimes because we're young certain parents do not take notice of their children and ignore what young pupils have to say'. However 64% prefer parental participation as shown in Q.20. A 14 year old wrote 'I think I'm mature to take decisions but it's always right to ask for parent's opinion'. Six per cent visited the doctor on their own because of a cold, a dental appointment, prescription for eye infection, pain in the stomach and one girl went to the doctor because of a sore throat with her parents' permission to go on her own. Therefore these parents already consider their minor daughter competent enough to go to the doctor on her own.

A majority of 80% of 181 females aged 16-18 years (Q.21) believe that they should have the right to decide on health issues with 55% (Q.20) preferring that the doctor tells them and not their parents about their health and 96% (Q.19) preferring that the doctor tells them exactly what they are suffering from. A 16 year old wrote 'One should go in to see the doctor on their own'. Another 16 year old wrote '...if a person, even if

under age, has an illness like cancer, she should be told as it is her life'. Another 16 year old wrote 'Information about general health should be more available to people my age'. Sixteen per cent stated that there were times when they wanted to go to the doctor and their parents didn't take them as indicated in Q.16, while 13% actually visited the doctor on their own as shown in Q.13, for various reasons amongst which general sickness, check-up, influenza, throat, advice and consultation, ear infection, strong headaches, stomach pain, stress migraines and physiotherapy. One of them was refused medical assistance because she was underage.

## DISCUSSION

The conditions of confidentiality are twofold: firstly the practitioner must agree not to disclose the patient's secrets and secondly the patient must disclose information which he deems secret.

Jackson (2006, p. 33) observed that in England competence doesn't determine confidentiality as the latter is extended to minors independently of whether they are competent or not and disclosure to parents is carried out only if the practitioner feels it is in the child's medical interests.

In Malta the confidentiality of a minor whether he is competent or not should be respected. This conclusion has been extracted from regulation 12(a) of Schedule A and regulation 5 of Schedule B of SL 94.15 (Ethics of the Medical Profession Regulations) where it states that medical practitioners and dental practitioners shall not breach patient confidentiality without the patient's consent preferably in writing. No mention is made to the age or competency of the patient or not thus following in the vein of England's British Medical Association (BMA).

Age is an artificial method to assess competency. Competency is gained through maturity and maturity is gained gradually and not everyone attains maturity at the same time. This is why *Gillick* competency is the best method to ensure that minors are not discriminated against by denying them the right to decide because they are not yet legally competent, when in fact on the basis of their maturity they are competent.

However, although age should not be the factor to assess competency, a cut off age delineating when parental responsibility ends and minors become fully competent in the eyes of the law, should be retained, and 16 seems to be the best safe age for the following reasons:

- (1) At 16 minors are legally entitled to work; can terminate education; carry out acts of trade and even get married;

- (2) Care Orders are issued till 16, the Child Development Assessment Unit (CDAU) and the Child Guidance Unit (CGU) cater for minors till 14 and 16 respectively;
- (3) The study conducted among school children revealed very clearly that the majority of minors deem themselves to be mature enough to be able to take decisions regarding surgery, vaccinations and blood tests at age 16;
- (4) The opinions drawn up by the various medical and legal professionals.

As evidenced by the past, the age of competency is not a sacrosanct age but one which needs to be adapted to the different ages.

In the not so distant past the age of competency was 21, and then it was lowered to 18. More and easier access to education and information resulting in higher levels of knowledge calls for a decrease in the age of competence. Sixteen is the perfect age for health competency since it coincides with various other forms of competency such as work and marriage.

Maturity is the real test of competency and anyone below 16 should have the right to be able to decide regarding his health if he is deemed mature enough. The right to access to health should not be denied to a minor simply because he does not have the appropriate parental consent. If the minor is mature and seeks help regarding his health, such minor should be deemed competent and given the required medical assistance. Sufficient understanding and intelligence can be assessed by the minor's understanding of the nature of the illness, the risks and benefits of the treatment or of no-treatment, any alternative treatment, and the ability to arrive to a reasoned decision.

A committee should be set up within the Medical Council to serve as guidance to all medical practitioners when it comes to assessing competence. The committee should be formed by legal professionals and health professionals ranging from paediatricians, child psychologists, child psychiatrists and other professionals whom the Medical Council deems fit to appoint.

Parental participation differs from parental consent in that the former refers to mere moral support and/or guidance of the parents whereas parental consent is the legal requirement that parents should give on behalf of their child.

Parental participation should always be encouraged as parents can contribute to the minor's health by giving advice and moral support.

However parental participation can never be imposed. Therefore if the minor wishes not to have parental involvement, such choice should be respected.

A new legislation is being proposed to contribute to the requirement that competent minors should be allowed to be able to decide for themselves. The proposed legislation is to be modelled on English legislation namely S.8 of the FLRA 1969, and the Children (Scotland) Act 1995 and New Zealand's Guardianship Act 1968 as general guidance.

## CONCLUSION

The following Legislation on Consent is proposed:

### **Article 1: Consent by persons over 16 to any health treatment:**

The consent of a minor who has attained the age of sixteen years to any health treatment be it surgical, medical, dental, psychological or psychiatric and any ancillary treatment, which, in the absence of consent, would constitute a trespass to his person, shall be as effective as it would be if he were of full age; and where a minor has by virtue of this article given an effective consent to any treatment it shall not be necessary to obtain any consent for it from his parent or guardian.

### **Article 2: Consent by persons under 16 to any health treatment:**

The consent of a minor who has not attained the age of sixteen years to any health treatment be it surgical, medical, dental, psychological or psychiatric and any ancillary treatment, will be valid only if such minor has sufficient understanding and intelligence, and such consent shall be as effective as it would be if he were of full age. A minor who has by virtue of this article given an effective consent to any treatment it shall not be necessary to obtain any consent for it from his parent or guardian.

Sufficient understanding and intelligence means to be able to analyze the risks, benefits and consequences of the proposed treatment and of any available alternative treatment and to be able to arrive to a reasoned decision.

The following Legislation on Confidentiality is proposed:

### **Article 3: Confidentiality of Minors:**

- (1) The confidentiality of any minor, competent or otherwise to any health treatment be it surgical, medical, dental, psychological or psychiatric and any ancillary treatment, shall be upheld as it would be if he were of full age.

(2) An exception to the abovementioned sub-article will be allowed where the minor is at risk of harming himself/herself or others be it through his direct or indirect actions.

The benefits of the proposed legislation is the general move towards accepting the competency of minors who are mature enough to be able to decide for themselves, increased access to healthcare to minors who without such legislation would not have sought such healthcare, and alleviating the Court from having to give medical authorisation where parents withhold their consent.

### ACKNOWLEDGEMENTS

I would like to thank Prof. Pierre Mallia for giving me the opportunity to present my research at the seminar organised by The Bioethics Research Programme of the Faculty of Medicine and Surgery in collaboration with the Medicine and Law Programme of the Faculty of Laws, University of Malta & Office of the Commissioner for Children, entitled, 'Confidentiality and Treatment of Young Adults: Proposals for Amendments' (17 October 2012, Medical School Auditorium, Mater Dei Hospital, Malta).

### Source

This paper is a summary of my Doctor of Laws thesis entitled, *Competency and Best Interests of the Child relating to Health Issues – A Maltese and International Legal Perspective* which was also published as a monograph by VDM Verlag in 2010.

### Reference

- British Medical Association and the Law Society, 1995. *Assessment of Mental Capacity, Guidance for Doctors and Lawyers*. BMA, London
- Cauchi, MN, Aquilina, K, and Ellul, B, 2006. *Health, Bioethics and the Law*. MUP Malta.
- Ekeleaar, J, 1986. *The Eclipse of Parental Rights* 102 LQR 4.
- Gillick v West Norfolk Wisbech Area Health Authority*, [1986] 1 AC 112, [1985] 3 All ER 402, [1985] 3 WLR 830, [1986] 1 FLR 224, [1986] Crim LR 113, 2 BMLR 11
- Interview with Dr. Philip Carabot, Doctor-in-Chief, GU Clinic (Floriana 11<sup>th</sup> December 2008)
- Jackson, E, 2006. *Medical Law: Texts, Cases, and Materials*. OUP, Oxford.
- Ministry of Health, 1998. *Consent in Child and Youth Health: Information for Practitioners*, Ministry of Health, Wellington
- Re C (Adult: Refusal of Treatment)* [1994] 1 FLR 31, 37
- Shaw, M., 2001. *Competence and Consent to Treatment in Children and Adolescents* 7 APT 150
- The United Nations Convention on the Rights of the Child
- UNESCO, 13 April 2007. *The Working Group of IBC on Consent, 'International Bioethics Committee'* (Draft Report) (Paris) SHS/EST/CIB-13/O6/CONF.505/2 Rev.1, 12.

### Dr Ann Marie MANGION

LL.B., LL.D., LL.M (Family Law) (Lond.), M.A. Mat. Can. Law (Melit.)  
*Family Law and Medical Law*  
Email: [annmarie@mangionlegal.com](mailto:annmarie@mangionlegal.com)

# Minutes MCFD Annual General Meeting

held on Thursday 8th May 2014 at the Professional Centre, Sliema Road, Gzira at 8:00pm.

**Present:** Abela Gunther; Abela Jurgen; Borg Francis; Calleja Frank; Camilleri Mark; Caruana Marika; Casha Frank; Cassar Doreen; Cauchi Jean Pierre; Farrugia Myriam; Fenech Frank; Gauci Ian; Gauci John Peter; Grech Marlon; Mallia Pierre; Micallef Adrian; Moran Vincent; Muscat Christopher; Pace Rita Odette; Padovani Jaqueline; Portelli Demajo Joseph; Saliba Joseph; Sammit David; Sciortino Philip; Sciortino Marthese; Van Avendonk Tanya; Xuereb Daryl; Zammit Edward

**Members present:** 28

**Quorum:** reached

## 1. Reading of minutes of previous AGM

Minutes of last AGM were read by Dr. Jean Pierre Cauchi

## 2. Amendments and approval of minutes

A vote for the approval of the AGM 2013 minutes was taken as follows:

**In favour:** 28

The minutes were thus approved.

## 3. Secretary's Report

Dr. Jean Pierre Cauchi read the Secretary's report.

### Comments:

Profs. Pierre Mallia thanked Dr. Jason Bonnici for his valuable work during the year. Dr. Doreen Cassar said that there needs to be an amendment in the CSA reports. Dr. Van Avendonk pointed out that Dr. Jason Bonnici is going to attend the next WONCA meeting which is going to be held next July in Lisbon and that they found sponsorships for travel and accommodation expenses. She also explained that the council has submitted an application for EU funds in the ERASMUS Plus Programme for a Project for VLE. This was done with the support of the consultants Camilleri & Camilleri.

Dr. Philip Sciortino said that applying for funds involves a lot of work and it is a long process. The aim was to improve connections for those who attend CPD

and for foreign strategic partners to participate together with a British quality assurance expert.

A reply for this application was expected on the 23<sup>rd</sup> May.

*A vote for the approval of the Secretary's report was taken as follows:*

*In favour:* 28

As such the Secretary's report was approved.

## 4. Treasurer's Report

Dr. T. Van Avendonk read the Treasurer's report.

### Comments:

Profs. Pierre Mallia thanked Dr. Van Avendonk for all her work. Auditor said that this year's report was clean.

*A vote for the approval of the Treasurer's report was taken as follows:*

*In favour:* 28

As such the Treasurer's report was approved.

## 5. President's Report

Professor Mallia read the President's report.

### Comments

Dr. Moran queried whether there are any other contacts with other Colleges apart from Royal College. Profs. Pierre Mallia said that through WONCA the College meets with other Organisations but it is still not the same as the relationship with the Royal College. He also said that through European projects they collaborate with other universities.

Dr. Doreen Cassar pointed out that the universities they contacted were very happy to collaborate with MCFD for the next three years.

Profs Pierre Mallia said that the MCFD has to have a vision for the future and that it has to become a hub for medical education in Family Medicine in the



---

Mediterranean. Next year the college will be celebrating its 25<sup>th</sup> year and this implies that MCFD has long standing years of experience.

*A vote for the approval of the President's report was taken as follows:*

*In favour: 28*

As such the President's report was approved.

### **7. Approval of accounts**

*A vote for the approval of the accounts was taken as follows:*

*In favour: 28*

As such the 2013 accounts were approved.

### **8. Appointment of Accountant / Auditor.**

*A vote for the appointment of Mr. Rolan Micallef was taken as follows:*

*In favour: 28*

As such the appointment of Mr. Micallef as the auditor was approved.

### **9. Approval of Statute**

Section 1: Vote: 28 in favour

Section 5: Vote 28 in favour

Dr. Gunther Abela queried about the involvement of GP Trainees in Committees and Subcommittees relating to the Assessment of Vocational Trainees.

Dr. Portelli Demajo said that in the Statute there is written that to vote a member has to be paid up.

Dr. Moran queried about the Legal power of the College.

Profs Pierre Mallia said that the College has applied to be registered as a Voluntary Organisation.

Dr. Portelli Demajo queried about the specialist Registry and how and why it was created. Dr. Sciortino explained the matter further and Profs. Mallia continued explaining the SAC process.

Dr. Gunther Abela mentioned the need for other Associate members besides trainee GPs. Dr. Doreen Cassar mentioned that according to Medical Council law any medical practitioner can only practice if they are licensed and registered on a specialist register.

Profs Pierre Mallia proposed that associate membership status should be studied further and other changes proposed so a committee will be formed.

Section 7: Vote - 27 in favour

1 abstention

Section 8: Vote – 28 in favour

Dr. Philip Sciortino proposed to change word of mandate to term.

Section 12: Vote – 27 against

1 abstention

Section 16: Vote – 28 in favour

All other changes were voted in favour.

### **10. Appointment of Electoral Commission.**

*A vote for the appointment of the same Electoral commission was taken as follows:*

*In favour: 28*

As such the Electoral Commission was approved.

### **11. Appointment of Subcommittee on Revision of Statutes.**

*A vote for the appointment of the same subcommittee, with the addition of the MCFD Secretary, was taken as follows:*

*In favour: 28*

As such the subcommittee was approved.

### **12. Appointment of Subcommittee for 25<sup>th</sup> Celebration**

Call for application for subcommittee with Dr. Tania Van Avendonk as co-ordinator.

Proposal is for the subcommittee to discuss with other medical bodies.

The AGM was concluded at 23.45 hours.

# Proposals for Statute

AGM 5th May, 2015

## Fellowship of the Malta College of Family Doctor

- 1.1. The Malta College of Family Doctors will be offering an Honorary Fellowship, which is the highest award of the College and which can be given to non-members and lay people who have contributed to Family Medicine.
- 1.2. The Malta College of Family Doctors will be offering a Fellowship to College Members which is to be awarded on grounds of merit listed in 1.3 below
- 1.3. The award of Fellowship shall be offered, upon application, to those members who satisfy the following criteria:
  - a. Have been registered on the Specialist Register for a period of at least ten years.
  - b. Have contributed to the work of the Malta College of Family Doctors for a minimum period of five years by being a member of council, or, being a member of a subcommittee listed among those acceptable for Fellowship (appendix), or, having served regularly in a capacity, such as examiners, etc., which capacity must also be on the approved list.
  - c. Show an interest in Family Medicine beyond their immediate work and practice.
  - d. Are in good standing with the MCFD, including being fully paid up members.
  - e. Have an acceptable record of CME attendance.
- 1.4. There shall be a board set up for a period of three years and which shall be approved at an AGM.
- 1.5. The College shall award not more than ten Fellowships per year, unless there are special circumstances decided upon by council.
- 1.6. Those who obtain fellowship shall have the designated letters FMCFD after their names and shall drop the letter MMCFD.

## Obligations of contractual agreements in case of a care-taker council

In order to ensure the smooth running of contractual obligations, in case, for any reason, council resigns, there shall be a care taker council. This shall be chaired by the President, Vice-president, Hon. Secretary, Hon. Registrar, Hon. Treasurer, in that order depending on who has remained on council.

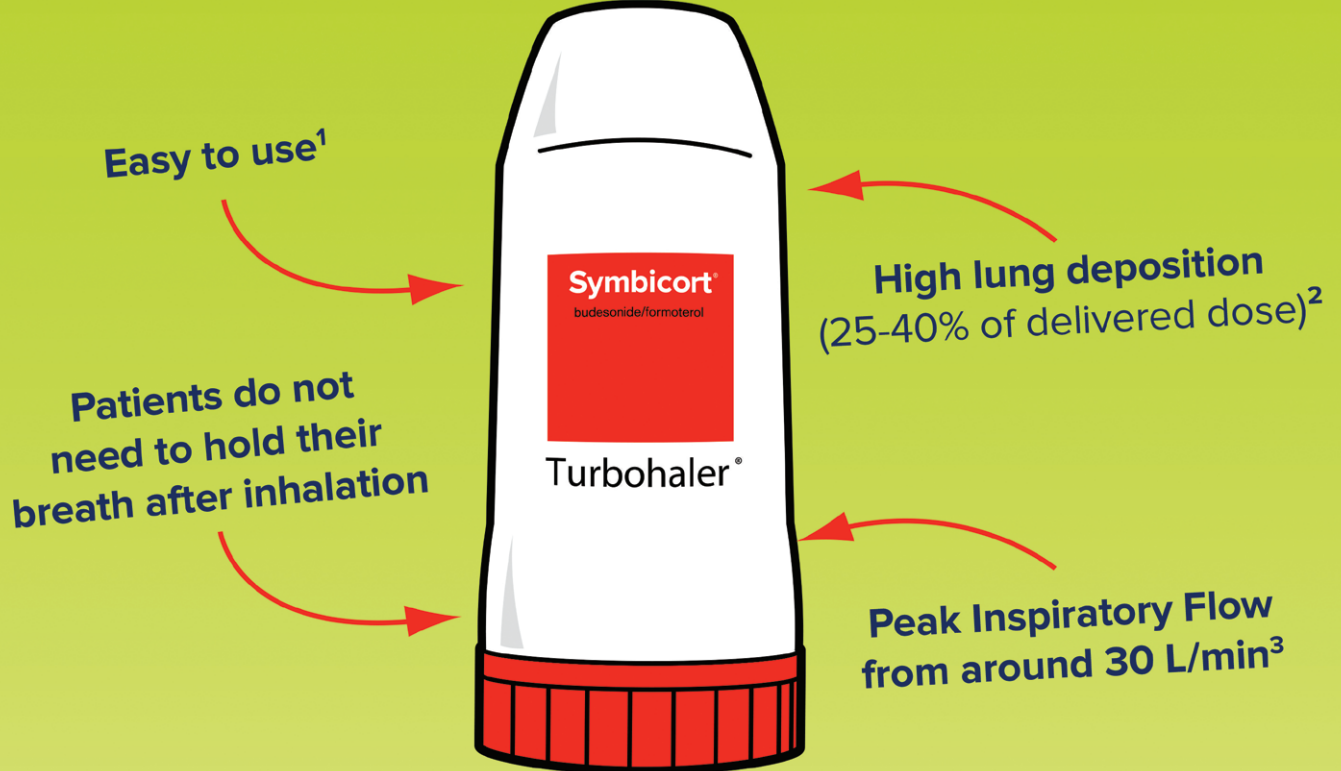
In case of the whole of council resigning or forced to resign en-bloc by an AGM, a care taker council shall be elected by the same AGM. Should the AGM fail in this duty, then the existing council has the right to occupy the care-taker role.

The care-taker council must see to all contractual obligations, which include:

- 2.1 Preparation of a new election
- 2.2 Oversee other contractual obligations and ensure the smooth running of duties such as the summative assessment exam of Vocational Trainees, courses to which participants have paid, CME for which sponsorship has already been committed, the publication of the Journal of the MCFD (JMCFD) when there are commitments to advertisers.
- 2.3 The implementation of 2.2 shall take place by the persons who already occupy the positions at the time, unless they resign or are forced to resign.
- 2.4 Preparation of payments will continue to be effected by those who are signatories with the bank until they are duly and formally replaced according to rules of statute.
- 2.5 Oversee ant obligations of care-taker councils which are obligatory under the law and under the regulations of Voluntary Organizations.
- 2.6 Those who resign or are forced to resign must assume professional responsibility and give a proper hand over, failing which the new council may take the necessary disciplinary action allowed by law.

# Symbicort® Turbohaler®

(budesonide/formoterol)



## Symbicort® Turbohaler® – For Asthma and severe COPD

Consult SmPC for full information

Symbicort®  
Turbohaler

### ABBREVED PRESCRIBING INFORMATION

Refer to Summary of Product Characteristics (SmPC) before prescribing

**Symbicort® Turbohaler® 100 micrograms/6 micrograms/inhalation, Inhalation powder**  
**Symbicort® Turbohaler® 200 micrograms/6 micrograms/inhalation, Inhalation powder**  
**(budesonide/formoterol fumarate dihydrate)**

**Indication:** Asthma: Treatment of asthma where the use of a combination (inhaled corticosteroid and long acting  $\beta_2$  adrenoceptor agonist) is appropriate. Symbicort Turbohaler 100/6 is not appropriate for patients with severe asthma. COPD (**Symbicort 200/6 only**): Symptomatic treatment of patients (with severe COPD (FEV1 <50% predicted normal) and a history of repeated exacerbations, who have significant symptoms despite regular therapy with long-acting bronchodilators.

**Presentation:** Inhalation powder: **Symbicort Turbohaler 100/6:** Each metered dose contains 100 mcg budesonide/inhalation and 6 mcg formoterol fumarate dihydrate/inhalation. **Symbicort Turbohaler 200/6:** Each metered dose contains 200 mcg budesonide/inhalation and 6 mcg formoterol fumarate dihydrate/inhalation. Refer to the SmPC for information on the method of administration.

**Dosage and Administration:** Asthma: Not intended for the initial management of asthma. Dose should be individualised. If a patient requires dosages outside recommended regimen, appropriate doses using individual inhalers should be prescribed. When long-term symptoms are controlled, titrate to the lowest effective dose, which could include a once daily dosage. **Symbicort maintenance therapy – regular maintenance treatment with a separate rescue medication:** **Adults (≥18 years, including elderly):** 1-2 inhalations twice daily (maximum 4 inhalations twice daily). **Adolescents (12-17 years):** 1-2 inhalations twice daily. **Children 6-11 years (Symbicort 100/6 only):** 2 inhalations twice daily. **Children under 6 years:** Not recommended.

**Symbicort maintenance and reliever therapy – regular maintenance treatment and as needed in response to symptoms:** consider for patients with (I) inadequate asthma control and in frequent need of reliever medication (II) previous asthma exacerbations requiring medical intervention. **Adults (including elderly):** 1 inhalation twice daily or 2 inhalations once daily. A total daily dose of more than 8 inhalations is not normally needed; however, up to 12 inhalations a day could be used for a limited period. Patients using more than 8 inhalations daily should be strongly recommended to seek medical advice and should be reassessed; their maintenance therapy should be reconsidered. Patients should be advised to always have Symbicort for reliever use. **Children and adolescents under 18 years of age:** not recommended. COPD (**Symbicort 200/6 only**): **Adults (≥18 years):** 2 inhalations twice daily.

**Contraindications:** Hypersensitivity to active substances or excipient.

**Warnings and Precautions:** If treatment is ineffective, or exceeds the highest recommended dose therapy should be reassessed. Sudden and progressive deterioration in control requires urgent medical assessment. Treatment should not be stopped abruptly. Patients should have their appropriate rescue medication available at all times i.e. either Symbicort or a separate reliever. If needed before exercise a separate reliever should be used. Therapy should not be initiated during an exacerbation. Serious asthma-related adverse events and exacerbations may occur. If asthma symptoms remain uncontrolled or worsen patients should continue treatment but seek medical advice. If paradoxical bronchospasm occurs Symbicort should be discontinued. It responds to a rapid-acting inhaled bronchodilator and should be treated straightaway. Systemic effects may occur, particularly at high doses prescribed for long periods e.g. Cushing's syndrome, Cushingoid features, adrenal suppression, growth retardation in children and adolescents, cataract, glaucoma and more rarely a range of psychological or behavioural effects including psychomotor hyperactivity, sleep disorders, anxiety, depression or aggression (particularly in children). Height of children should be monitored. Potential effects on bone should be considered especially in patients on high doses for prolonged periods that have co-existing risk factors for osteoporosis. Prolonged treatment with high doses of inhaled corticosteroids, particularly higher than recommended doses, may also result in clinically significant adrenal suppression. Additional systemic corticosteroid cover should be considered during periods of stress e.g. severe infections or elective surgery. Transfer from oral steroid therapy to Symbicort may result in the appearance of allergic or arthritic symptoms which will need treatment. In rare cases, tiredness, headache, nausea and vomiting can occur due to insufficient glucocorticosteroid effect and temporary increase in the dose of oral glucocorticosteroids may be necessary. To minimise risk of oropharyngeal candida infection patients should rinse mouth with water. Observe caution in patients with thyrotoxicosis, phaeochromocytoma, diabetes mellitus, untreated hypokalaemia, or severe cardiovascular disorders. Re-evaluate need for Symbicort in patients with active or quiescent pulmonary tuberculosis, fungal and viral infections in the airways. Hypokalaemia may occur at high doses. Particular caution recommended in unstable or acute severe asthma. Monitor serum potassium levels. In diabetic patients consider additional blood glucose monitoring. The small amounts of milk proteins present may cause allergic reactions.

**Drug Interactions:** Concomitant treatment with potent CYP3A4 inhibitors should be avoided. If this is not possible the time interval between administration should be as long as possible. Symbicort maintenance and reliever therapy is not recommended in these patients. Not recommended with beta adrenergic blockers (including eye drops) unless compelling reasons. Concomitant administration with quinidine, disopyramide, procainamide, phenothiazines, antihistamines (terfenadine) and TCAs can prolong the QTc-interval and increase the risk of ventricular arrhythmias. L-Dopa, L-tyrosine, oxytocin and alcohol can impair cardiac tolerance. Concomitant administration with WACIs, including agents with similar properties such as furazolidone and procarbazine, may precipitate hypertension. Elevated risk of arrhythmias in patients receiving anaesthesia with halogenated hydrocarbons. Hypokalaemia may increase the disposition towards arrhythmias in patients taking digitalis glycosides.

**Fertility, Pregnancy and Lactation:** No data available on the potential effect on fertility. During pregnancy, use only when the benefits outweigh the potential risks. Budesonide is excreted in breast milk, however at therapeutic doses no effects on the child are anticipated.

**Undesirable effects:** Common: headache, palpitations, tremor; Candida infections in the oropharynx, coughing, mild irritation in the throat, hoarseness. Uncommon: tachycardia, muscle cramps, nausea, dizziness, bruises, aggression, psychomotor hyperactivity, anxiety, sleep disorders. Rare: hypokalaemia, cardiac arrhythmias including atrial fibrillation, supraventricular tachycardia and extrasystoles, bronchospasm and immediate and delayed hypersensitivity reactions including anaphylaxis, urticaria, pruritus, dermatitis, angioedema and anaphylactic reaction. Very Rare: depression, behavioural changes (predominantly in children), angina pectoris, prolongation of QTc-interval, hyperglycaemia, taste disturbance, Cushing's syndrome, adrenal suppression, growth retardation, decrease in bone mineral density, cataract, glaucoma and variations in blood pressure. As with other inhalation therapy, paradoxical bronchospasm may occur in very rare cases.

**Package Quantities:** Each Symbicort Turbohaler contains 120 inhalations. **Legal Status:** POM. **Marketing Authorisation Numbers:** MA 046/00901-2. **Marketing Authorisation Holder (MAH):** AstraZeneca AB, Gårtnavägen, S-151 85 Soerteråle, Sweden. **Further product information available on request** from AstraZeneca Drug Company Limited, Triq l-Esparturi, Miehlel, Birkirkara BKR 3000, Malta. Tel: (+356) 2277 8115.

**Abbreviated Prescribing Information prepared:** 12/14. Symbicort and Turbohaler are trademarks of the AstraZeneca group of companies.

URN No: 13/0125  
Date of preparation: April 2015

Reference: 1. Adelpchi Respiratory Disease Specific Programme 2009. 2. Olof Selroos et al. *Treat Respir Med* 2006; 5 (5): 305-315. 3. Engel et al. *Br J Clin Pharmacol* 1992; 33(4): 439-44.

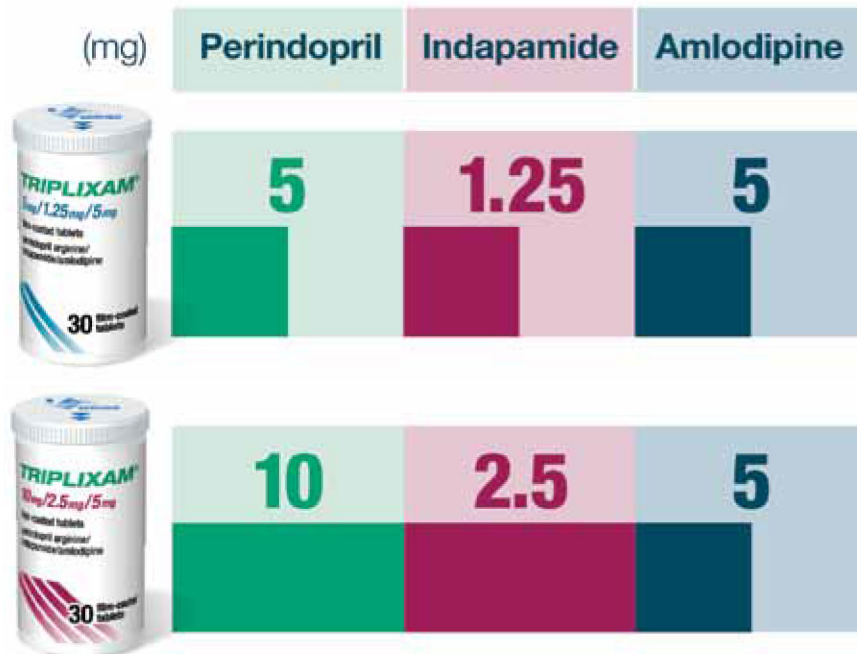
AstraZeneca  
Respiratory

New

# TRIPLIXAM®

perindopril / indapamide / amlodipine

## Triple-drug combination in hypertension



▼ The power to reduce and control blood pressure<sup>1</sup>

▼ The power of an excellent compliance<sup>1</sup>

▼ The power to reduce mortality<sup>2</sup>

**1 TABLET DAILY**

**COMPOSITION:** Triplixam 5mg/1.25mg/5mg film-coated tablets 5 mg perindopril arginine (per)/1.25 mg indapamide (ind)/5 mg of amlodipine (amlo); Triplixam 10mg/2.5mg/5mg film-coated tablets: 10 mg per/2.5 mg ind/5mg amlo; **INDICATIONS:** Substitution therapy for treatment of essential hypertension, in patients already controlled with perindopril/indapamide fixed dose combination and amlodipine, taken at the same dose level. **DOSAGE AND ADMINISTRATION:** One tablet per day, preferably in the morning and before a meal. The fixed dose combination is not suitable for initial therapy. If a change of the posology is required, titration should be done with the individual components. Paediatric population: should not be used. **CONTRAINDICATIONS:** Dialysis patients. Patients with untreated decompensated heart failure. Severe renal impairment (Clcr < 30 mL/min). Moderate renal impairment (Clcr 30-60 mL/min) for Triplixam 10mg/2.5mg/5mg and 10mg/2.5mg/10mg. Hypersensitivity to the active substances, to other sulphonamides, to dihydropyridine derivatives, any other ACE-inhibitor or to any of the excipients. History of angioedema (Quincke's oedema) associated with previous ACE inhibitor therapy. Hereditary/idiopathic angioedema. Second and third trimesters of pregnancy (see Warnings and Pregnancy and lactation sections). Lactation (see Pregnancy and lactation section). Hepatic encephalopathy. Severe hepatic impairment. Hypokalaemia. Severe hypotension. Shock, including cardiogenic shock. Obstruction of the outflow-tract of the left ventricle (e.g. high grade aortic stenosis). Haemodynamically unstable heart failure after acute myocardial infarction. Concomitant use with aliskiren in patients with diabetes mellitus or renal impairment (GFR < 60mL/min/1.73m<sup>2</sup>) (see Warnings and Interaction(s) sections). **WARNINGS:** Special warnings: Neutropenia/agranulocytosis/thrombocytopenia/anaemia: caution if collagen vascular disease, immunosuppressant therapy, treatment with allopurinol or procainamide, or combination of these complicating factors, especially if pre-existing impaired renal function. Monitoring of white blood cell counts. Hypersensitivity/angioedema, intestinal angioedema: stop treatment and monitor until complete resolution of symptoms. Anaphylactoid reactions during desensitization: Caution in allergic patients treated with desensitization and avoid if venom immunotherapy. Temporally withdrawal of ACE-inhibitor at least 24 hours before desensitization. Anaphylactoid reactions during LDL apheresis: Temporally withholding ACEinhibitor prior to each apheresis. Haemodialysis patients: consideration to use a different type of dialysis membrane or class of antihypertensive agent. Pregnancy: no initiation during pregnancy, stop treatment and start alternative therapy if appropriate. Hepatic encephalopathy: stop treatment. Photosensitivity: stop treatment. **Precautions for use:** Renal function: In certain hypertensive patients without pre-existing apparent renal lesions and for whom renal blood tests show renal insufficiency, stop treatment and restart at a low dose or with one constituent only. Monitoring of potassium and creatinine, after two weeks of treatment and then every two months during therapeutic stability period. If bilateral renal artery stenosis or single functioning kidney: not recommended. Risk of arterial hypotension and/or renal insufficiency (in cases of cardiac insufficiency, water and electrolyte depletion, in patients with low blood pressure, renal artery stenosis, congestive heart failure or cirrhosis with oedema and ascites): start treatment at low doses and increase progressively. Hypotension and water and sodium depletion: Risk of sudden hypotension in presence of pre-existing sodium depletion (in particular if renal artery stenosis): Monitoring of plasma electrolytes, re-establish blood volume and pressure, restart treatment at a reduced dose or with only one of the constituents. Sodium levels: More frequent monitoring in elderly and cirrhotic patients. Potassium levels: Hypokalaemia: Monitoring of serum potassium if renal insufficiency, worsening of renal function, age (> 70 years), diabetes mellitus, intercurrent events, in particular dehydration, acute cardiac decompensation, metabolic acidosis and concomitant use of potassium-sparing diuretics, potassium supplements or potassium salts, or other drugs associated with increases in serum potassium. Hypokalaemia: risk for elderly and/or malnourished subjects, cirrhotic patients with oedema and ascites, coronary patients, patients with renal failure or heart failure, long QT interval: monitoring of serum potassium. Calcium levels: hypercalcaemia: stop treatment before investigating the parathyroid function. Renovascular hypertension: if renal artery stenosis: start treatment at hospital at low dose; monitor renal function and potassium. Dry cough. Atherosclerosis: start treatment at low dose in patients with ischaemic heart disease or cerebral circulatory insufficiency. Hypertensive crisis. Cardiac failure/severe cardiac insufficiency: Caution if heart failure. Severe cardiac insufficiency (grade IV): start treatment under medical supervision with reduced initial dose. Aortic or mitral valve stenosis / hypertrophic cardiomyopathy: Caution if obstruction in the outflow tract of the left ventricle. Diabetic patients: If insulin dependent diabetes mellitus, start treatment under medical supervision with reduced initial dose; monitor blood glucose during the first month and/or in the case of hypokalaemia. Black people: higher incidence of angioedema and apparently less effective in lowering blood pressure than in non-blacks. Surgery / anaesthesia: stop treatment one day before surgery. Hepatic impairment: Mild to moderate: caution. Stop treatment if jaundice or marked elevations of hepatic enzymes. Uric acid: hyperuricemia: Increased tendency to gout attacks. Older people: testing of renal function and potassium levels before treatment start. Dose: increase with care. **INTERACTION(S):** Contraindicated: Aliskiren in diabetic or impaired renal patients. Not recommended: Lithium, Aliskiren in patients other than diabetic or impaired renal patients. Concomitant therapy with ACE inhibitor and angiotensin-receptor blocker, Estramustine, Potassium-sparing drugs (e.g. triamterene, amiloride, ...), Potassium salts, Dantrolene (infusion), Grapefruit or grapefruit juice. Special care: Baclofen, Non-steroidal anti-inflammatory medicinal products (included acetylsalicylic acid at high doses), Antidiabetic agents (insulin, hypoglycaemic agents), Non-potassium-sparing diuretics and Potassium-sparing diuretics (epplerone, spironolactone), Torsades de pointes inducing drugs, Amphotericin B (IV route), glucocorticoids and mineralocorticoids (systemic route), tetracosactide, stimulant laxatives, Cardiac glycosides, CYP3A4 inducers, CYP3A4 inhibitors. To be taken into consideration: Imipramine-like antidepressants (tricyclics), neuroleptics, other antihypertensive agents and vasodilators, tetracosactide, Allopurinol, cytostatic or immunosuppressive agents, systemic corticosteroids or procainamide, Anaesthetic drugs, Diuretics (thiazide or loop diuretics), Glitines (linagliptine, saxagliptine, sitagliptine, vildagliptine), Sympathomimetics, Gold, Metformin, Iodinated contrast media, Calcium (salts), Ciclosporin, Atorvastatin, digoxin, warfarin or ciclosporin, Simvastatin. **PREGNANCY AND BREASTFEEDING:** Not recommended during the first trimester of pregnancy. Contraindicated during the second and third trimesters of pregnancy and lactation. **FERTILITY:** Reversible biochemical changes of spermatozoa in some patients treated by calcium channel blockers. **DRIVE & USE MACHINES:** May be impaired due to low blood pressure that may occur in some patients, especially at the start of treatment. **UNDESIRABLE EFFECTS:** Common: dizziness, headache, paresthesia, vertigo, somnolence, dysgeusia, visual disturbances, tinnitus, palpitations, flushing, hypotension (and effects related to hypotension), cough, dyspnoea, abdominal pain, constipation, diarrhoea, dyspepsia, nausea, vomiting, pruritus, rash, maculopapular rashes, muscle cramps, ankle swelling, asthenia, fatigue, oedema. Uncommon: eosinophilia, hypoglycaemia, hyperkalaemia reversible on discontinuation, hyponatraemia, insomnia, mood changes (including anxiety), mood disturbances, depression, sleep disorder, hyposhaesthesia, tremor, syncope, diplopia, tachycardia, vasculitis, bronchospasm, rhinitis, dry mouth, altered bowel habits, urticaria, angioedema, hypersensitivity reactions, mainly dermatological, in subjects with a predisposition to allergic and asthmatic reactions, alopecia, purpura, skin discoloration, hyperhidrosis, exanthema, photosensitivity reactions, pemphigoid, arthralgia, myalgia, back pain, micturition disorder, nocturia, increased urinary frequency, renal failure, erectile dysfunction, gynaecomastia, pain, chest pain, malaise, oedema peripheral, pyrexia, weight increase, weight decrease, blood urea increased, blood creatinine increased, fall. Rare: confusion, blood bilirubin increased, hepatic enzyme increased. Very rare: agranulocytosis, aplastic anaemia, pancytopenia, haemoglobin decreased and haematocrit decreased, leucopenia, neutropenia, haemolytic anaemia, thrombocytopenia, allergic reactions, hyperglycaemia, hypercalcaemia, hypertonia, peripheral neuropathy, angina pectoris, arrhythmia (including bradycardia, ventricular tachycardia and atrial fibrillation), myocardial infarction, possibly secondary to excessive hypotension in high risk patients, stroke possibly secondary to excessive hypotension in high-risk patients, eosinophilic pneumonia, gingival hyperplasia, pancreatitis, gastritis, hepatitis, jaundice, abnormal hepatic function, erythema multiform, Stevens-Johnson Syndrome, exfoliative dermatitis, toxic epidermic necrolysis, Quincke's oedema, acute renal failure. Not known: Potassium depletion with hypokalaemia, particularly serious in certain high risk populations, torsades de pointes (potentially fatal), possibility of onset of hepatic encephalopathy in case of hepatic insufficiency, possible worsening of pre-existing acute disseminated lupus erythematosus, electrocardiogram QT prolonged, blood glucose increased, blood uric acid increased. **OVERDOSE. PROPERTIES:** Perindopril is an inhibitor of the angiotensin converting enzyme (ACE inhibitor) which converts angiotensin I to angiotensin II. Indapamide is a sulphonamide derivative with an indole ring, pharmacologically related to the thiazide group of diuretics. Amlodipine is a calcium ion influx inhibitor of the dihydropyridine group (slow channel blocker or calcium ion antagonist) and inhibits the transmembrane influx of calcium ions into cardiac and vascular smooth muscle. **PRESENTATION:** Box of 30 tablets of Triplixam 5mg/1.25mg/5mg, and 10mg/2.5mg/5mg. LES LABORATOIRES SERVIER, 50 rue Carnot, 92284 Suresnes cedex France. www.servier.com For complete information, please refer to the Summary of Product Characteristics.