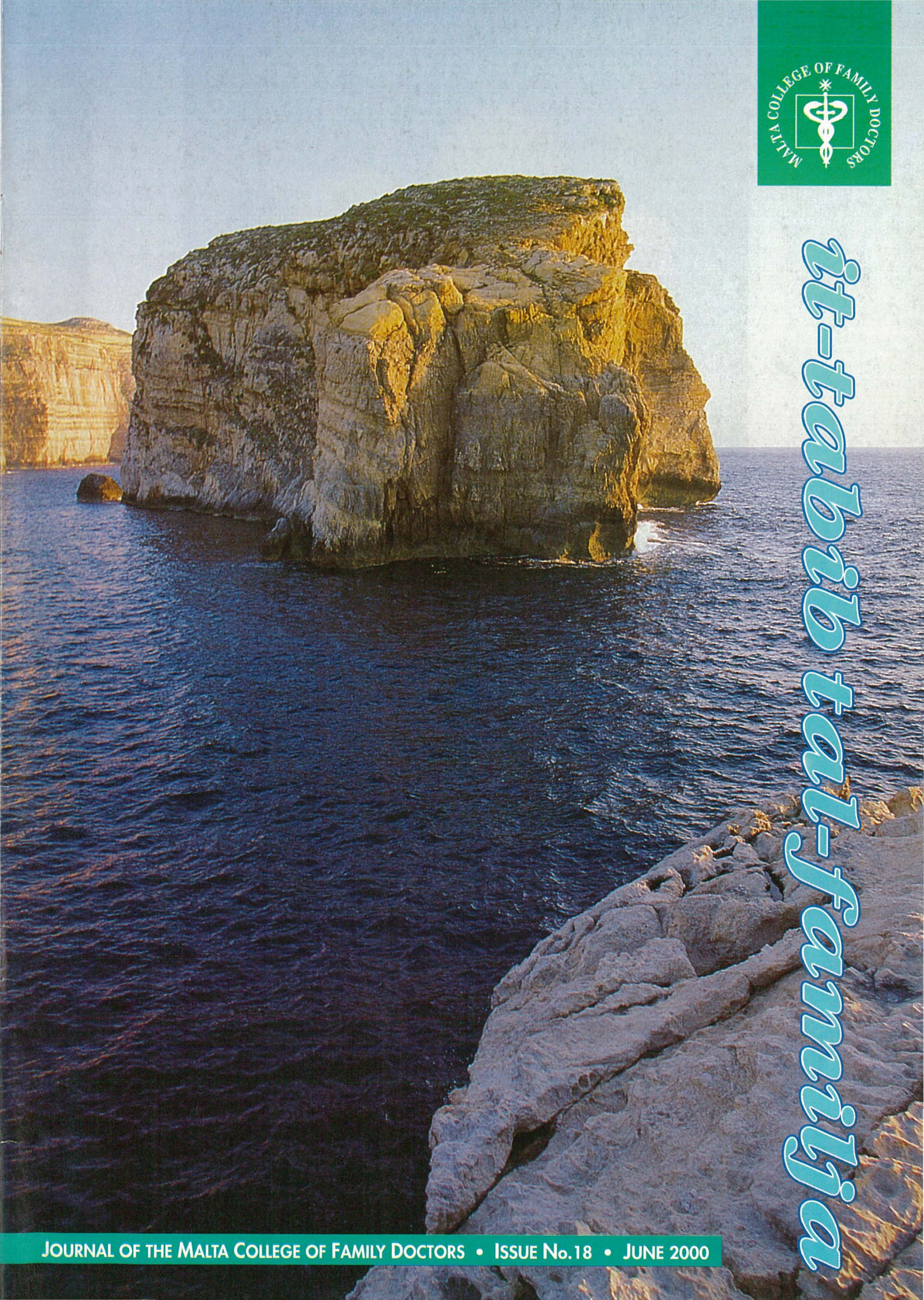

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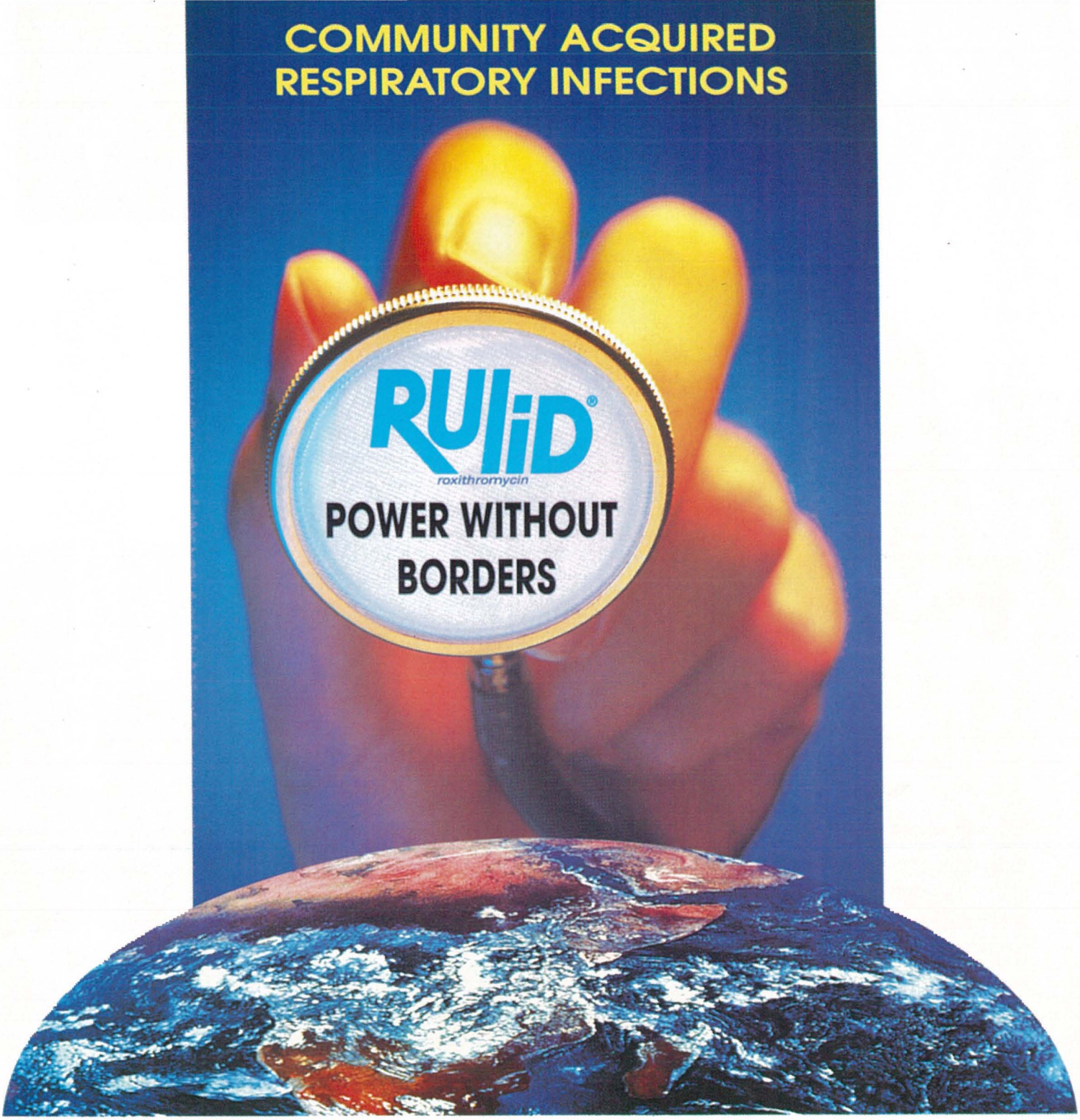

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Contents: INN: roxithromycin - Presentations : Oral route : Tablets : 50, 100, 150 mg. Properties : Semi-synthetic macrolide antibiotic. Indications : Infections caused by susceptible microorganisms (e.g. upper and lower respiratory tract infections, genital non gonoccocal infections, skin and soft tissue infections). Posology and method of administration : Adults : one 150 mg tablet twice daily. Renal impairment : Severe hepatic impairment : one 150 mg tablet daily. Elderly : It is not necessary to modify the dosage regimen. Children : The dosage regimen to be used is 5 to 8 mg/kg/day in two divided doses and treatment must not be prolonged beyond ten (10) days. Tablet forms must not be used in children below four (4) years of age . 12 to 23 kg : 50 mg twice daily 24 to 40 kg : 100 mg twice daily above 40 kg : 150 mg twice daily. Contra-indications : Hypersensitivity to macrolides. Concomitant therapy with vasoconstrictive ergotamine-type compounds. Adverse reactions. : Gastrointestinal : nausea, vomiting, abdominal pain, diarrhoea; in isolated cases, symptoms of pancreatitis. Hypersensitivity reactions, mainly mucocutaneous (rash, urticaria, angiooedema), exceptionally systemic (bronchospasm, anaphylaxis). Dizzy sensations. Liver function tests abnormalities : rarely cholestatic or acute hepatocellular liver injury. Disturbances of taste and/or smell. Possibility of fungal overgrowth. Special warnings and special precautions for use : in severe hepatic insufficiency, the dose should be reduced by half (1 tablet 150 mg daily). Pregnancy : roxithromycin crosses the placental barrier; the safety of the foetus has not been established. Lactation : roxithromycin is minimally excreted in human breast milk. Abnormalities of the growth plate have been observed in young animals at unbound plasma concentrations 30 to 60 times higher than those observed in clinical use. No abnormalities were observed at unbound plasma concentrations 10 to 15 times higher than those observed in clinical use. It is therefore recommended that the dose level of 5 to 8 mg/kg/day be adhered to for no longer than ten days (for paediatric forms of roxithromycin only). Drug interactions : There is no clinically significant interaction with carbamazepine, ranitidine, aluminium or magnesium hydroxide, oral contraceptives containing oestrogens and progestogens. In healthy volunteers, a slight increase has been detected in plasma concentrations of theophylline or ciclosporine A levels but this does not necessitate alteration of the usual dosage. An in-vitro study has shown that roxithromycin can displace protein-bound disopyramide ; such an affect in vivo may result in increased serum levels of free disopyramide. Like other macrolides, roxithromycin may increase the absorption of digoxin. The effects of midazolam may be enhanced and prolonged in patients treated with roxithromycin, as with other macrolides antibiotics. Certain macrolide antibiotics are capable of a pharmacokinetic interaction with terfenadine, leading to increased serum levels of terfenadine. This may result in severe ventricular arrhythmias. Caution should be exercised if roxithromycin is co-prescribed with terfenadine. List 1 : Full prescribing information available on request.

Hoechst Marion Roussel

Editorial

Dear Readers,

Welcome to the first issue of the New Millennium.

This issue is also special because the College has recently celebrated its tenth anniversary, and a short article about the proceedings is printed on the last page, along with the one properly focussed photograph of the event!

In this "forward-looking" issue, two articles deal with informatics applied to medicine in Malta. One looks at the past, while the other gives details of the local version of Transhis, which will allow Family Doctors to store electronic medical records with the electronic version of ICPC-2. Please read both, and if you are interested write to me and ask to participate in the project.

Whilst talking of looking forwards, and also of the new Millennium, one cannot fail to mention the 6th Mediterranean Medical Congress and the 2nd Mediterranean Summer School. I have the pleasure and honour of chairing the organising commitee of this prestigious event, which will deal with **"Challenges for the New Millennium"**. Participation by local doctors is encouraged, not least by the heavily discounted registration for local participants. Please see the advertisement in this issue, and the enclosed Congress brochure for more details.

Happy holidays, and see you at the Westin in September.

Jean Karl Soler

Cover photo: Fungus Rock - taken by J.K. Soler

Close to Dwejra point, in the Southwest of Gozo, one can admire the famous Fungus Rock, popularly known as "Il-Gebla tal-General" (The General's Rock). It is here that the famous "Fungus Gaulitanus" grew, a very rare plant which the Knights believed to possess strong healing powers. This rare and precious plant sometimes presented as a valuable gift to disyinguished noblemen - was, for centuries kept under constant guard and any actual, or potential, thief was instantly put to death. Due to the height of the Fungus Rock it was almost unreachable from the sea, therefore the Knights constructed a hoist resembling a funicular, on the watch tower. This tower known as "Qawra Tower" can still be seen.

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Viral Warts - Going, Going, Gone!

Lawrence Scerri
Consultant Dermatologist

INTRODUCTION

Cutaneous viral warts are caused by infection of the epidermis with human papilloma virus (HPV). It is also possible for viral warts to occur on mucosal surfaces namely genital, oral and laryngeal mucosa, but these will not be discussed in this article. The appearance of the lesions is influenced by the HPV type (strain), as well as by environmental and host factors. Viral warts are typically self-limiting in nature, however their resolution can be speeded up by active intervention.

EPIDEMIOLOGY & CLINICAL CHARACTERISTICS

Viral warts occur at any age but are somewhat more common in children and adolescents, the UK prevalence being in the region of 3.9 - 4.9% for this age group[1]. Although no accurate statistics are available, the prevalence for the Maltese Islands is not likely to be low when one considers that 30 - 40% of all new case referrals to the dermatology department concern 'warts'.

Warts are spread by direct or indirect contact. Impairment of the epithelial barrier function by trauma (such as abrasions and cuts), maceration or both, greatly predispose to inoculation of the virus. Plantar warts are commonly acquired from swimming pool or shower room floors. Nail biting and habitual thumb sucking facilitate spread of common warts across periungual skin. Shaving propagates spread of warts in the beard area. Occupational handlers of meat, fish and poultry have a high incidence of hand warts, better known as butcher's warts, due to cutaneous injury and prolonged contact with wet flesh and water.

Once warts develop, the body mounts a humoral immune response against the HPV, resulting in eventual clearance of lesions in immunocompetent individuals. According to various studies, spontaneous clearance of warts occurs in 23% at 2 months, 30% at 3 months, and 65 - 78% at 2 years[2,3]. Plantar and periungual warts tend to be the most persistent forms of warts, and likewise most recalcitrant to treatment. The different clinical forms of cutaneous warts are described in table 1.

Plantar warts must be distinguished from callosities which are ill-defined areas of waxy, yellowish thickening, that on paring reveal no black dots. Black dots, typically seen in viral warts, represent thrombosed dermal capillaries. Corns occur on pressure points and are usually smaller and painful with a central plug. Paring is therefore mandatory in order to clarify the diagnosis of plantar horny lesions, and it is ultimately the treatment of choice for callosities and corns.

TREATMENT

There is no single treatment that is 100% effective. It is a valid management option to leave warts untreated if this acceptable to the patient or the parents in case of children. However, plantar warts can be painful and hand warts sufficiently unsightly to affect school attendance or cause occupational difficulty. Destructive treatment may initially stimulates new neighbouring warts to develop (koebnerisation).

The **aims** of treatment are:

- To remove the wart with no recurrence
- Produce no scars
- Induce life-long immunity

Indications for treatment are:

- Pain (when acute, treat underlying secondary bacterial infection with oral antibiotic before embarking on destructive therapy)
- Interference with function
- Cosmetic embarrassment
- Risk of malignancy (in case of immunosuppressed patients and genital warts)

Keratolytic agents containing salicylic acid act by slowly destroying the virus-infected epidermis. The resulting mild irritation may stimulate an immune response. Salicylic acid alone has been shown to clear 67% hand warts and 84% plantar warts in 12 weeks[4]. Before daily application of wart paints, excess keratin should be pared away with a nail file or an emery board, preferably after bathing. Colloidon based products form an occlusive film that should be peeled off before re-application. Salicylic acid with podophyllin in ointment base is also available, and applied under occlusive adhesive plaster, this preparation is particularly useful for plantar warts. Alternate day application for up to 2 weeks at a time is recommended in view of the severe inflammatory reaction that this preparation tends to provoke. If indicated, further courses may be dispensed only after the inflammation has settled and the macerated necrotic tissue has been debrided. Keratolytic wart paints should never be prescribed for lesions on the face, neck, or flexures

in view of the severe irritation they produce in such areas.

Cryotherapy nowadays carried out with liquid nitrogen at -196°C, is believed to induce wart clearance by simple necrotic destruction of HPV-infected keratinocytes, or possibly by inducing local inflammation and consequent development of an effective cell-mediated immune response. Destruction of warts by freezing every 3 weeks can give clearance rates for hand warts of 69% in 12 weeks[4]. Two freeze thaw cycles per treatment session has been shown to improve clearance in plantar warts but not in hand warts[5]. Cryotherapy is a painful procedure and it is unlikely that a young child will co-operate even despite attempting to reduce discomfort by means of topical anaesthesia (with EMLA cream). Blisters resulting from cryotherapy normally resolve within 7 - 10 days. Although cryotherapy does not tend to scar, transient hypo- and hyperpigmentation can occur particularly in darker-skinned individuals.

Curettage and cautery is particularly useful for filiform warts. When applied to common or plantar warts, this surgical approach constitutes a rather messy and gruesome procedure, and invariably produces scarring. This procedure requires a local anaesthetic injection.

Tretinoin cream has been used successfully in the case of plane warts. Daily application however often produces skin irritation, which may necessitate a reduction in the frequency of application.

Topical sensitization with **Diphencyprone** has proved to be an effective treatment for recalcitrant warts, particularly plantar and periungual warts. The immune response it provokes produces life-long immunity to the HPV. The drawbacks are that some patients cannot be sensitized whilst others particularly those with an atopic predisposition get troublesome eczematous reactions[6].

Other **miscellaneous** less commonly utilized therapies that have been used for treating viral warts with varying success rates include intralesional bleomycin, intralesional and systemic interferon, high dose cimetidine (2400 g daily x 3 months), pulsed dye laser, and carbon dioxide laser destruction.

CONCLUSION

Patients should be informed that viral warts tend to resolve spontaneously. If treatment is indicated or desired, the value of simple properly administerd topical keratolytic therapy should never be underestimated. Patients not responding to an adequate course of topical keratolytic therapy (up to 3 months) may benefit from referral to a dermatologist for more aggressive destructive therapy or immunotherapy. A conservative approach is preferred in the case of young children.

Table 1

Clinical type	*Morphology and associated features*
Common warts	Firm, rough keratotic papules and nodules often demonstrating 'black dots'. Anywhere on the skin. May be single or grouped.
Plane warts *(Flat warts)*	2-4 mm in diameter, flesh coloured, slightly raised flat-topped, non scaly lesions. Most common on face and dorsum of hands.
Plantar warts *(Verrucas)*	May start as sago grain-like papules which develop a more typical keratotic surface with a collar of thickened keratin. Black dots usually present. Often develop on pressure points and may hence cause pain on weight-bearing.
Mosaic warts	Occur when palmar or plantar warts coalesce into large plaques. Often painless.
Filiform warts *(digitate warts)*	Consist of prominent finger-like projections with keratotic tips and black dots. Most common on face and neck, especially in males.
Myrmecia	Resemble deep clear vesicles. Found on palms and soles.

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Piloting GP Surveillance for Influenza-Like Illness, Malta 1999-2000 Season

Dennis Falzon, Chris Barbara, Mark Muscat & Jean Karl Soler

INTRODUCTION

Through a joint effort of a team of three private GPs, the Department of Public Health and the Department of Virology at SLH, an attempt was made to survey the influenza season in Malta through epidemiological and virological means. The main objectives of the endeavour were:

1. *Enhancing the process of influenza notification*
2. *Describing the epidemiology from private practitioners' perspectives*
3. *Obtaining virological evidence to support epidemiological findings*
4. *Piloting for the first time sentinel surveillance in general*

Methods

Two GPs based in the central and southern parts of Malta, and one in Gozo, were involved in notifying patients with influenza-like illness who fitted a particular case definition of fever with coryza over November 1999 through February 2000. Participant reporters were selected by convenience sampling: they were expected to complete a report form for each classifying patient seen, indicating name, sex, age, town of residence, symptomatology, date of onset, influenza vaccine status for the previous season and date of examination.

Blood serology was undertaken from amongst a sub sample of the reported cases to check specifically for IgA to influenzas A and B and respiratory syncytial virus[1]. IgM ELISA was used to differentiate 3 cases testing inconclusively and two others as an initial test.

Testing was not offered to:

- patients aged under 12 years
- members of the same household as someone already tested
- those having the influenza vaccine earlier on *in the same season*
- patients whose date of onset of first symptom had exceeded 2 weeks at the encounter

Results

Table 1 shows the distribution by age group and sex of the reported cases. The median age was 25 (range 2-77y). Patients originated from 12 villages in Malta and 9 in Gozo (Chart 1). Table 2 gives the dates of onset for the reported cases.

Age group (years)	F	M	Total
0 to 4	2	2	4
5 to 14	13	7	20
15 to 24	11	21	32
25 to 44	14	22	36
45 to 64	7	7	14
65 +	4	4	8
Total	51	63	114

Table 1. Distribution by age and sex.

The study failed to achieve completeness in reporting. One of the reporting GPs was suddenly inundated and stopped reporting from the start of 2000, while another failed to notify all cases.

Week of onset	Cases
45/1999	15
46/1999	13
47/1999	9
48/1999	2
49/1999	7
50/1999	3
51/1999	5
52/1999	9
01/2000	14
02/2000	24
03/2000	1
04/2000	7
05/2000	1
06/2000	0
07/2000	0
08/2000	4

Table 2. Week of onset for reported cases.

Table 3 summarises the list of symptoms reported by the cases apart from fever and coryza.

Symptom	Frequency
Headache	81.5%
Cough	76.3%
Sore throat	73.7%
Musculo skeletal pains	54.4%
Nausea	30.7%
Diarrhoea	13.2%
Vomiting	13.2%

Table 3. Frequency of symptoms for reported cases.

11.2% of cases reported having had the vaccine for influenza before the current season. Of the 39 tested (34% of cases), 18 were negative for all antibodies, 15 were positive for Influenza A alone and 2 for RSV. One sample was haemolysed and three others tested positive for Influenza A and B with IgM ELISA.

Univariate[2] and logistic regression analyses[3] failed to show significant associations between testing positive for Influenza A and age, sex, flu vaccination or the symptoms listed in Table 3.

Main discussion points

- In conclusion, influenza A antibodies were elevated in over one third of the patients tested during this surveillance. No clinically useful associations were found between influenza A positivity and symptomatology, age or sex, largely because the small numbers surveyed precluded

significance testing.

- In the rest of Europe and in Tunisia, from October 1999 to end February 2000, 32 countries reported influenza to WHO. Almost all viral isolates have been Influenza A subtype H3N2, antigenically similar to the viruses that have predominated since the 1997-98 season, and well matched to A/Sydney/5/97 of the last vaccine. There were also a few other reports of influenza A (H1N1) and influenza B[4]. In a country-wide sentinel surveillance program linked to virological confirmatory testing in Italy, during the 1999-2000 season,[5] the Istituto Superiore di Sanita' also noted a steady rise in influenza activity over the weeks 51/99 to 02/00, with a gradual drop in incidence in the following 5 weeks. 99% of isolates successfully subtyped were Influenza A H3N2. A similar pattern of disease was observed in Denmark[6].
- Outbreaks of influenza-like illness (ILI) have been correlated with epidemics of meningococcal disease for up to 2 months during and after an epidemic[7]. Moreover, during the influenza season of 1989 in Britain, patients with meningococcal disease were nearly four times more likely to have had recent influenza A than controls[8]. Confirmation of such outbreaks may therefore have practical application in alerting the community physician to the increased likelihood of concurrent invasive N.meningitidis disease, more so that modern influenza treatments may offer protection from serious sequelae[9].
- The time trend is only crudely indicative of the epidemic coming to a peak in the first and second weeks of this year. It should only be used to indicate the profile of the cases studied rather than disease activity in the community. Similarly, Chart 1 maps the extent of the practices involved rather than the epidemic. There is ample evidence that the outbreak was countrywide[10]. As there was no attempt at reporting all cases fitting the definition over the period of surveillance, no extrapolation to the study population was possible.

Recommendations for future

Future attempts at a similar project would have to consider having in particular:

1. To adopt a more universally acknowledged (and internationally comparable) case definition such as the one applied by CDC for ILI[11], which is temperature $\geq 100^{\circ}F$ ($\geq 37.8^{\circ}C$) plus either cough or sore throat. The ILI definition used by the Italian group mentioned above was considered too restrictive for the local situation. Additionally, the monitoring index should be expressed as 'daily proportion consultations with ILI' – per 100 or 1000 - rather than absolute numbers without a denominator. This would avoid having to estimate the practice population and would be more accurate. Information about concurrent hospital activity such as proportional mortality from 'pneumonia and influenza', all cause mortality and hospital admissions for respiratory disorders have been usefully applied in the UK[12] and the US[12] to interpret better the influenza pattern in the community;
2. The paper reporting could be facilitated using spreadsheeted line-lists rather than individual forms;
3. Participant doctors should be better briefed and supported with feedback. Doctors who are willing to report electronically and regularly should be preferred. A motivation mechanism could entail accreditation points with the Malta College of Family Doctors, or involvement in official publication and presentation of findings in a subsequent conference;
4. Laboratory testing should primarily aim for virological isolation rather than indirect testing. In this instance, arrangements would need to be done with overseas centres that can do such testing as collaborative research or against payment. Only such analyses could give definitive characterisation of viruses for meaningful sero-epidemiological interpretation and comparison with regional researchers.

Acknowledgements

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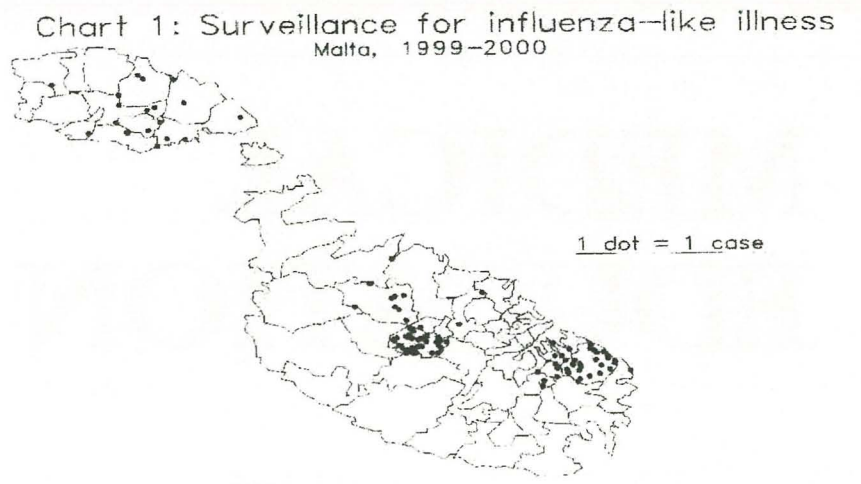

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GUIDELINES FOR THE MANAGEMENT OF GESTATIONAL DIABETES IN MALTA

CHARLES SAVONA - VENTURA
CONSULTANT OBSTETRICIAN I/C DIABETIC PREGNANCY JOINT CLINIC

1. INTRODUCTION

The Maltese population has repeatedly been shown to have an overall higher prevalence of DM/IGT, mainly of the Non-Insulin Dependent form. This higher prevalence is reflected in the pregnant population. Epidemiological studies have suggested that the prevalence of DM/IGT in the Maltese pregnant population approximates 6%, including a small proportion of pre-existing DM.

CLINICAL SEVERITY	% total pregnant pop.
Pre-existing DM	0.3%
Gestational DM	0.8%
Gestational IGT	4.7%

Table 1: Prevalence rates

2. SCREENING

Clinical screening alone using defined "historic" and clinical risk factors appears to enable the identification of about 40% of anticipated cases, particularly the severe forms of metabolic abnormalities. Minor forms of abnormalities can only be identified by performing routine 75 gm oral Glucose Tolerance Test screening in the whole pregnant population - the cost-effectiveness of which has still to be established.

- *Urine should be tested for glycosuria at every antenatal visit (preferably fasting urine specimen).*
- *Timed or random venous plasma glucose measurements should be made if fasting glycosuria is detected, or if historic and/or clinical risk factors are present before 28 weeks.*
- *75g oGTT should be carried out preferably after 28 weeks gestation if any of the following criteria are present:*
  **blood glucose >6.0 mmol/l 2hrs or more after food*
  **blood glucose >8.0 mmol/l <2hrs after food*
  **presence of "historic" or clinical risk factors*

A screening program for GDM/GIGT should identify those pregnant women with blood glucose levels that are associated with an adverse fetal outcome or increased risk of future diabetes in the mother. It is unlikely that the perfect screening program will be devised. This recommended program will need to be kept under review and may be revised as further evidence becomes available.

While "historic" risk factors can be identified during the booking visit, these patients should be booked for a 75 gram oGTT only after 26 weeks of pregnancy (unless strongly indicated). Earlier testing is often not conclusive, and may give a false sense of security since the metabolic state may deteriorate during the third trimester.

RISK FACTORS	**risk in Maltese population**
Historic	
Maternal Age >35yrs	x ~3.0-4.0 risk
P/H Abortions	x ~4.0 risk
P/H Perinatal loss	x ~2.0-3.0 risk
Multiparity 4+	x ~2.0-4.0 risk
P/H Macrosomia	x ~1.0-2.0 risk
F/H Diabetes	
Maternal	x ~2.5 risk
Paternal	x ~2.0 risk
Siblings	not assessed
Clinical	
Glucosuria x2+	x ~2.0 risk
Polyhydramnios	not assessed
Present macrosomia	x ~2.0 risk
Present malformation	x ~1.0-1.5 risk

3. DIAGNOSTIC CRITERIA

There is uncertainty and confusion around the subject of diagnosis of GDM/GIGT. The WHO criteria recommends using the same levels for pregnancy as the non-pregnant state. However, since carbohydrate metabolism alters during pregnancy, the EASD has recommended using the 95th centile of oGTT values as the cut-off point for diagnosis. The criteria for diagnosis are therefore recommended as:

Blood Glucose mmol/l	***NORMAL***	***G-IGT***	***GDM***
Fasting	<6.0	6.0-7.9	>=8.0
2 hour	<9.0	9.0-10.9	>=11.

4. ANTENATAL MANAGEMENT

The St. Vincent Declaration aim for pregnancy is: "To achieve pregnancy outcome in the diabetic woman that approximates that of the non-diabetic woman". This can be achieved by a multidisciplinary team, where a specialist team including a named physician(s) and a named obstetrician(s) should see all pregnant diabetic women in a combined

ANTENATAL SCREENING PROGRAM SUMMARY

1. *The presence of "Historic" or "Clinical" Risk Factors places patient as High Risk of developing gest. IGT/DM and needs to be investigated.*

2. *High Risk individuals identified prior to 28 weeks of pregnancy:*
   perform a blood glucose estimation:

   If elevated: refer patient for a 75g oGTT immediately

   If normal: refer patient for a 75g oGTT after 26 weeks

3. *All patients identified as High Risk [including those who have undergone an oGTT prior to 26 weeks and were found normal] should have a 75g oGTT performed after 26 weeks of pregnancy.*

clinic in a hospital with a neonatal intensive care unit. The Diabetic Pregnancy Joint Clinic was restructured in October 1998, after the criteria of referral and management were reviewed by the Department of Obstetrics & Gynaecology and the Diabetes Clinic. The Diabetic Pregnancy Joint Clinic is managed jointly by the Obstetric Department [Dr. C. Savona-Ventura - Dr. M. Chircop] and the Diabetes Clinic [Dr. J. Azzopardi - Dr. A. Ellul]. Consultations with the dietitian would be arranged after the first visit and subsequently if deemed necessary.

The scope of the Diabetic Pregnancy Joint Clinic is to ensure that all diabetic women have:

- Tight control of diabetes during pregnancy
- Education about treatment of hypoglycaemia and avoidance of ketoacidosis
- Access to a specialist team
- Quality ultrasound scanning to assess gestation and fetal growth
- Fetal monitoring, particularly if at very high risk
- Regular examination of fundi and assessment of renal function.

4.1 Criteria for Referral to Clinic

All patients who are diagnosed to suffer from any form of significant carbohydrate intolerance during their pregnancy should be referred to the Diabetic Pregnancy Joint Clinic. These patients include:

- Pre-existing Diabetes Mellitus or I.G.T. who have become pregnant;
- Gestational Diabetes Mellitus [oGTT 2-hr value >11.0 mmol/l];
- Gestational I.G.T. [oGTT 2-hr value 9.0-11.0 mmol/l].

4.2 Clinic Management policies

The precise roles of different members of the diabetes pregnancy care team cannot be clearly defined as all members of the team are involved, each adding their own contribution. It is planned that patients will be seen by the Diabetic Pregnancy Joint Clinic team at specific times during their pregnancy in line with the standard schedule given to antenatal patients and in harmony with the routine antenatal care being given to these patients either in the Hospital Antenatal Clinic or by their private specialists/doctors. Referral is direct by appointment with the Karin Grech Hospital Antenatal Clinic [tel. no. 2595-1381]. Visits are scheduled for:

12-14 weeks
20-22 weeks
28-30 weeks
34 weeks
36 weeks
38 weeks and
6 weeks postpartum.

Of course the scheduled visits will depend on the stage of pregnancy that diagnosis is made and the severity of the condition. It is thus envisaged that patients with pre-existing disorders would attend all the scheduled visits, whereas patients diagnosed during the pregnancy would attend for visits scheduled during the last trimester. There is no need for routine admission in early or late pregnancy, other than when diabetic or obstetric complications of pregnancy are present. However admission may be necessary for those patients with gestational carbohydrate metabolism problems who find it difficult to self-assess their blood glucose levels. Referral to the Diabetic Pregnancy Joint Clinic will further ensure that these patients are reviewed in the postpartum period, and long-term metabolic advice given accordingly. It is to be emphasized that the overall responsibility for the patient care and management will remain that of the original attending Specialist Diabetologist and Specialist Obstetrician. The role of the Diabetic Pregnancy Joint Clinic is to facilitate and organize regular metabolic and obstetric assessments, including investigations to assess carbohydrate metabolism, renal function, and fetal growth and well-being. It must be emphasized that the visit regimen proposed above by the Diabetic Pregnancy Joint Clinic is not a comprehensive antenatal regimen since further interim visits to the attending Specialist Obstetrician and diabetologist should be scheduled. In addition, monitoring for fetal well-being in the last month of pregnancy may need to be done more frequently (even twice weekly) than the regimen proposed herein.

4.3 Targets in Antenatal Care

- Avoid destroying the normal experience of pregnancy through over zealous application of medical technology.

- The routine admission of patients in early or late pregnancy is not essential, especially when the patient is undertaking self-monitoring of blood glucose regularly and reliably.

- All pregnant diabetic women should be seen in a dedicated multidisciplinary combined clinic. The Specialist Team should include a named physician(s) and named obstetrician(s) with a special interest in diabetic pregnancy. These consultants should lead a team and liaison with the dietitian, the diabetes teaching nurse/midwife, and other specialists [neonatologist, ophthalmologist] as required. It is not acceptable for women to have to go to separate clinics on different days. Liaison with other consultants responsible for the care of the patient can be achieved by the use of a specific co-operation card.

- The precise role of the different members of the diabetes pregnancy care team cannot be clearly defined as all members of the team are involved, each adding their own contribution.

** Optimisation of diabetic control*

All women suffering from IDDM, NIDDM, or GDM should carry out regular blood glucose monitoring. The frequency can be individualized, but testing four times a day - before breakfast, before lunch, before evening meal and before late night snack - is recommended. Occasionally it may be desirable to suggest some post-prandial or night tests. Self-monitoring of blood glucose with a reliable system is the optimum, but this may not be suitable for those women diagnosed as diabetic for the first time late in pregnancy.

The target blood glucose should be as close to normal as possible, while avoiding hypoglycaemia. Each individual should therefore be encouraged to run their blood glucose levels at between 4 and 7 mmol/l [Fasting blood glucose 3.5-5.5 mmol/1 or 60-100 mg/dl; Post-prandial blood glucose 5.0-8.0 mmol/l or 90-145 mg/dl].

Long-term control can also be assessed regularly during pregnancy by measuring glycated haemoglobin or fructosamine, aiming to achieve levels within the normal non-diabetic range.

Insulin regimens should be individualized. It is usually preferable to use human insulin in the form of multiple injections of short acting insulin with long or intermediate acting insulin at night. Alternately, twice daily, short and intermediate acting insulin may be appropriate. In GDM, insulin should be introduced if the fasting or pre-meal blood glucose levels consistently exceed 6 mmol/l.

Estimation of insulin requirements can be gauged after metabolic daily blood glucose profiles have been obtained. The initial requirements can follow the administration of a short-acting insulin according to a sliding scale, the dose depending of the blood glucose level. The daily requirements can then be assessed and managed by the introduction of intermediate acting insulin.

Dietary advice is essential for optimal diabetic control during pregnancy. All women who have diabetes should have regular access to a dietitian. Dietary advice should be individualized on the basis of the woman's weight, home blood glucose monitoring, lifestyle and personal circumstances. Food intake should be adequate to maintain maternal and fetal nutrition. An energy prescription of 30-35 kcal/kg pre-pregnant ideal body weight is recommended, though this should be flexible to correct for any alteration in activity levels. Those women whose body weight exceeds 120% of their ideal body weight may require a lower energy intake per kg in order to limit their weight gain during pregnancy. Frequent small meals may facilitate improved blood glucose control. Complex carbohydrates should provide about 50% of the total calories. This should be distributed in the form of 10 gram exchanges as regular main meals and snacks throughout the day. Levels of dietary fibre of 30-50g per day should be advised. Foods rich in antioxidants - fresh fruits and vegetables - may have a role in reducing malformations. Sucrose and glucose ingestion in the form of sweets, cakes, soft drinks, etc should be completely avoided even in women with G-IGT or borderline cases [2hr post-oGTT glucose value of 8.0-9.0].

Folate supplements (4 mg/day) should be routinely prescribed in the first trimester to reduce the risk of neural tube defects.

** Screen for diabetic complications*

There should be a regular screening for ophthalmic and renal disorders each trimester of pregnancy with regular retinal examinations and measurement of renal function. The blood pressure should be assessed regularly throughout pregnancy in view of the increased risk of the development of pregnancy-induced hypertension in these patients.

** Antenatal Obstetric Surveillance*

There are no good data which demonstrate superiority of one type of surveillance program over another. There are wide variations between centers which share good and similar outcome results. Obstetric review in diabetics should be carried out every 2-4 weeks until 28 weeks, then every 2 weeks until 34-36 weeks and then weekly depending on the severity of the metabolic disorder. This can be done in conjunction with the regular attending obstetrician through the use of their joint Antenatal/Diabetic co-operation card.

Surveillance is dependant on regular clinical assessment, ultrasound scanning, and biophysical profile.

ANTENATAL MANAGEMENT SUMMARY

- *Dietary advice should encourage diets with high levels of complex carbohydrates and soluble fibre and reduced saturated fats. Folic acid supplements should be offered. Sucrose and glucose should be completely avoided.*
- *All women should undertake frequent home blood glucose monitoring, and blood glucose levels should be maintained as near normal as possible.*
- *Metabolic control should be assessed by measurement of glycated Haemoglobin; and ketonuria should be searched for if blood glucose is high or in the presence of intercurrent illness.*
- *Fundi, blood pressure and renal function should be assessed.*
- *Ultrasound scanning must be made available for assessing gestational age, examining for congenital anomalies and for assessing fetal growth.*
- *Maternal monitoring of fetal movement should be encouraged. Fetal monitoring with cardiotocography and biophysical profiles is controversial, but it should definitely be used for high risk pregnancies.*

5. Post-Puerperal Management

The long-term follow-up of patients with IDDM or NIDDM requires a regular reassessment of their carbohydrate metabolism status to ensure optimum control. Patients identified during pregnancy to suffer from GDM or G-IGT should be referred to the Diabetic Pregnancy Joint Clinic in the post-puerperal period in order that their carbohydrate metabolic status is re-assessed. These women have a ~60% risk of eventually developing diabetes mellitus within the next 20 years, particularly in the presence of obesity. Obese women should be encouraged to lose weight even if their glucose tolerance returns to normal in the postpartum. An annual check of fasting or postprandial blood glucose allows for the early identification of asymptomatic diabetes. All women with a history of gestational IGT/DM should be screened for GDM during any subsequent pregnancy. Those mothers whose impairment of glucose tolerance persists in the postpartum period should be advised about the importance of optimum control prior to embarking on another pregnancy. Contraception should be discussed as early as possible. Contraceptive advice for IDDM need not differ from that given to non-diabetic women. The contraceptive pill does marginally impair carbohydrate tolerance, though it does not generally increase insulin requirements in IDDM patients. The pill may not be suitable for women with a genuine latent gestational diabetes. There may be an increased risk of infections with the use of the IUCD in overt diabetics.

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References:

1. Perry CM & Brogden RN. Drugs 1996; 52(1): 125-158.
2. ZINNAT Approved Product Information.

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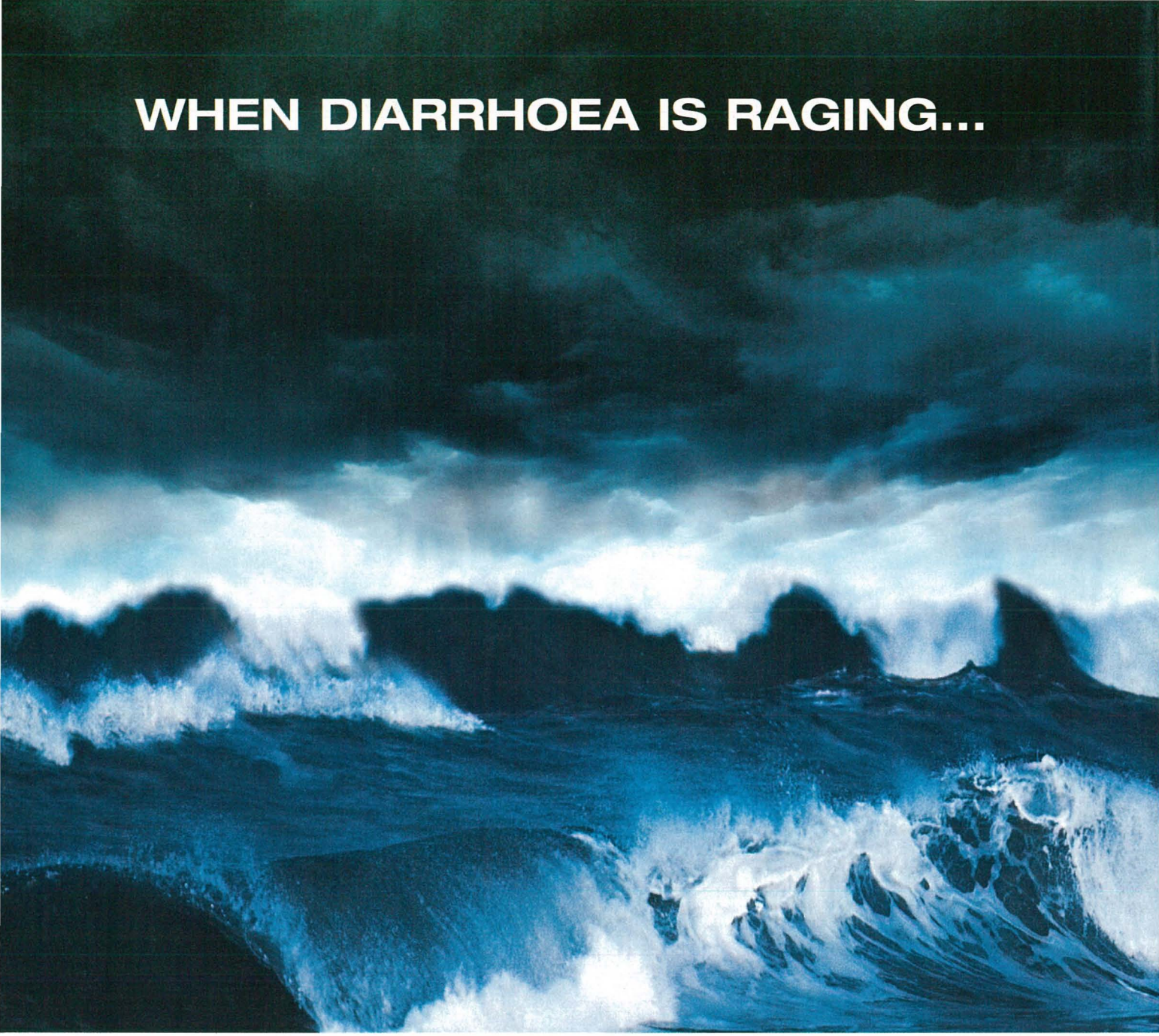

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effect on gastrointestinal motility. It reduces intestinal hypersecretion of water and electrolytes caused by cholera toxin or inflammation without affecting basal secretion. There is therefore no effect in the normal intestine. When given orally, enkephalinase inhibition is purely peripheral. Hidrasec does not affect central nervous system enkephalinase activity, and has not been shown to produce habituation or central nervous stimulant or sedative effects. *Pharmacokinetic properties* Racecadotril is rapidly absorbed by the oral route. It is rapidly hydrolysed to (RS)-N-(1-oxo-2-(mercaptomethyl)-3-phenylpropyl) glycine, its active metabolite, which is in turn converted into inactive metabolites which are eliminated through the kidneys, faeces and lungs. The extent and duration of action of racecadotril depends on the dose administered. Activity against plasma enkephalinase starts within 30 minutes, with peak activity corresponding to 75% inhibition for a dose of 100mg, occurring one to three hours after administration. The biological half-life of racecadotril is three hours. For a dose of 100mg the duration of activity against plasma enkephalinase is about eight hours. (RS)-N-(1-oxo-2-(mercapto-methyl)-3-phenylpropyl) glycine, the active metabolite of racecadotril, is 90% bound to plasma proteins, mainly albumin. Tissue distribution only affects about 1% of the administered dose. The pharmacokinetic properties of racecadotril are not changed by repeated administration or in elderly subjects. The bioavailability of racecadotril is not affected by food but the peak activity is delayed by one and a half hours. *Preclinical safety data* No further information of relevance. **Pharmaceutical particulars** *List of excipients* Lactose, maize starch, magnesium stearate, colloidal anhydrous silica. Capsule contains gelatin, titanium dioxide (E171), yellow iron oxide (E172). *Incompatibilities* None known. *Shelf-life* The expiry date is indicated on the packaging. *Special precautions for storage* Store below 30°C. *Nature and contents of container* Hidrasec 100mg capsules: blister packs of nine capsules in a carton. *Instructions for use/handling* No further information of relevance. Racecadotril will be available under the trade mark Hidrasec* but in some countries will be known as Tiorfan*. Tiorfan* and Hidrasec* are marketed under licence from Bioprojet (France). *Trade mark

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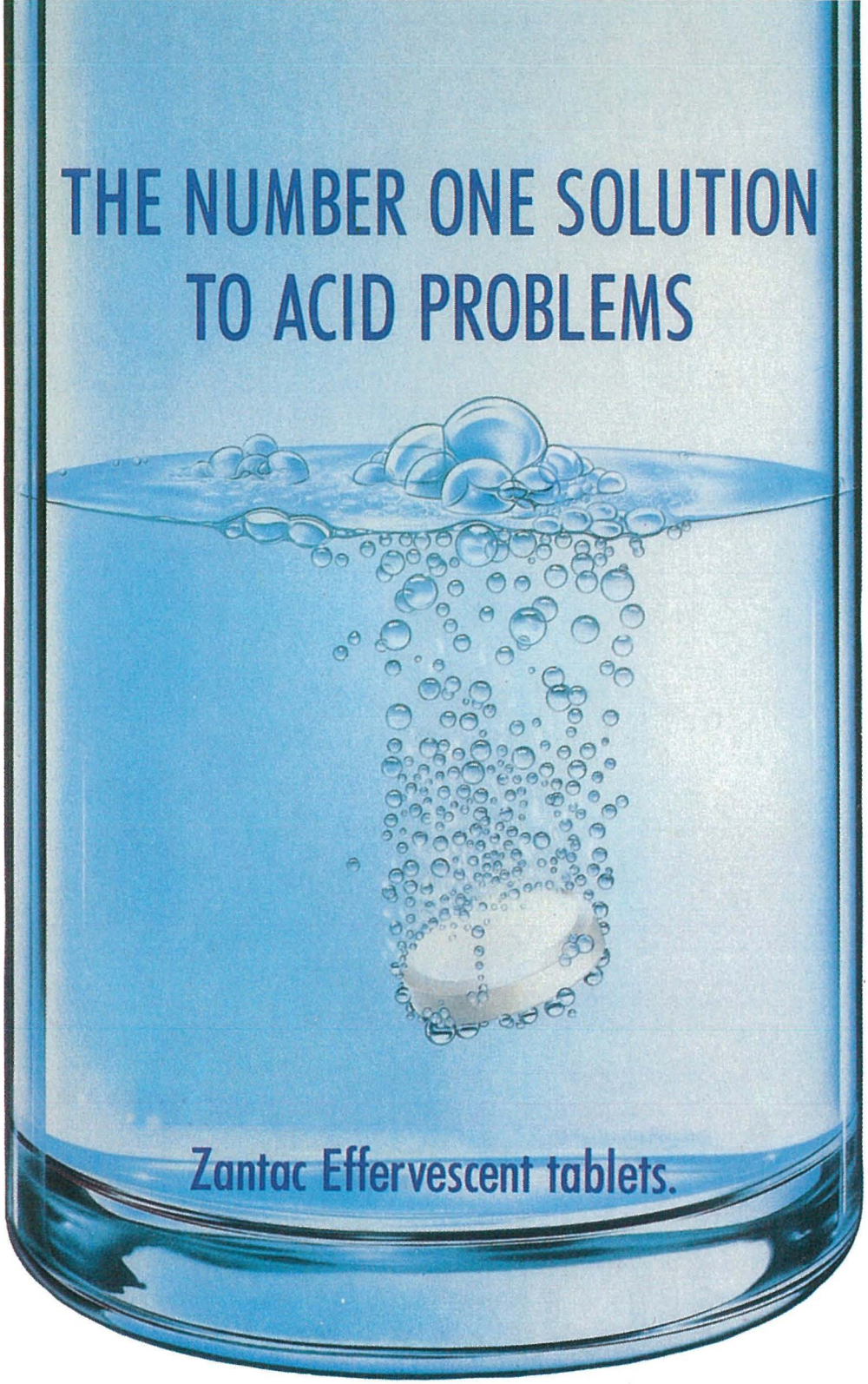

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History of Medical Data Collection in the Maltese Islands

Charles Savona-Ventura
Medical Historian

The collection of medical information is today an essential administrative tool, allowing the state, department or the individual practitioner to audit the prevalent practice and to assess the level of health care, identify problems and focus on priorities for improvements. These objectives can be reached by the collection of event-oriented databases that can have several levels, each with its utility status. These levels may include (1) demographic data and vital event registration, and (2) clinical event-oriented data. The move towards the collection of person-oriented medical data ensures that the collected database can be extended to better serve the medical needs of the individual patient.

Demographic and Vital-event Data

The concept of assessing population size and growth of a community has a long history with known population counts being recorded in Babylon, China and Egypt between 2800 and 2200 BC. These counts were aimed at assessing the strength and wealth of the country. It has been recorded that the first count of population in Malta was carried out by the Emir Yusuf-al-Futah in the year 991 for the purpose of securing certain privileges for the inhabitants, while subsequent medieval counts were made by the Bishop of Strasbourg in 1175 and Abbot Gilibertus in 1241. These latter counts were concerned with taxation. Population counts made during the period of the Knights of St. John were conducted in connection with the importation of grain from Sicily free of export duties[1].

The ecclesiastical authorities were also required to conduct population counts in order to known how many souls were under the Bishop's care, and the 'status animarum' contains information about population size. The Synod of Augsburg held in 1548 prescribes four books to be kept by the parish priest "Primum in quo baptizatorum; secundum confitentium et communicantium; tertium, in quo eorum, qui matrimonium in facie ecclesiae contraxerunt; et quartum in quo mortuorum...nomina et cognomina....descibantur." The formal universal prescription was extended to five parochial registers in 1614 by Paul V in the Rituale Romanun. The five registers included (1) Liber Baptizatorum, (2) Liber Confirmatorum, (3) Liber Matrimoniorum, (4) Liber Defunctorum, and (5) Liber de Statu Animarum. The same norm has remained unchanged, though in the 1983 revision of the Codex Juris Canonici, the Liber de Statu Animarum no longer features among the Libri Paroeciales. In Malta, long before the official declarations, parish priests had been keeping their own records. In fact, the Mdina Baptismal registers start from 1539, while the missing first 38 folios suggest that the original records started in 1528. The preserved records from Naxxar date to 1546, those of Birgu from 1552 and of Birmiftuh from 1556[2].

Civil registration of births was introduced in Malta by Napoleon Bonaparte by decree of 24 August 1798 which made it obligatory for the doctor or midwife assisting at a birth to present certificates of the birth within 24 hours to the municipality under penalty of suspension from practice and infliction of a fine and imprisonment[3]. Subsequent regular civil registration of vital event data in Malta can be traced to 1863[4]. Ordinance II of 1870 required that prior to burial in cemeteries, a certificate showing the cause of death was required[5]. Mortality statistics by cause of death started to be published regularly by the Chief Police Physician in May 1872. These fortnightly reports gave the number of deaths by cause, sex and district. The causes of death were classified into: Zygomatic, Constitutional, Local, Developmental, and Violent Death[6]. After April 1873, further information pertaining to age at death was also included. The first annual report on a regular basis was published in 1896[7] and continued throughout the twentieth century. The first regular census in a series of decennial censuses was carried out on 21 March 1842[8]. Demographic data remains the responsibility of the Central Office of Statistics.

Clinical Event-oriented Data

The concept of collecting medical statistics was introduced by John Graunt of London in 1662 with his work "National and political observations upon the bills of mortality", wherein he showed among other things that the maternal mortality was one in two hundred and that one-third of infants perished before the age of three years. It was only in the nineteenth century that regular statistics were collected with the scope of identifying medical and social problems to enable measures to be taken to control population health. In the United Kingdom, the Registrar General's Office in 1837 started to keep accurate records of all births, stillbirth and maternal deaths. In that same year, the

Presidents of the Royal Colleges of Physicians and Surgeons asked the medical profession to submit certificates of deaths stating if possible the cause. These regulations were also taken up by the British Naval authorities, who in 1825 required the Naval Surgeon to submit regular nosological tables. One British Naval surgeon who worked in Malta in the early decades of the nineteenth century published detailed clinical reports of the cases treated at Bighi Naval Hospital in Malta during 1842-1844[9].

The Civil authorities in Malta started requesting the certification of disease and cause of deaths in 1870-1871. The first Ordinance published in 1870 was that respecting cemeteries, whereby a death certificate became a requirement for burial - this to have the date of death, the name, surname and profession of the deceased, and the cause of death[5]. A subsequent Government Notice issued in 1871 required all physicians and surgeons to submit information to the Superintendent of Police of any communicable disease. The list of reportable infectious disease was revised in 1899[10,11]. Fortnightly publication of the collected data was initiated in May 1872, while annual reports were initially published in 1896 [6,7].

Previous to these ordinances, the Civil Hospitals had maintained an admissions register that included an admission diagnosis. The earliest register viewed by the author pertains to the Hospital of St. John the Baptist at Rabat, Gozo and covers the period 31st December 1841 to 31st August 1851. Maternity data is included in this register. In later decades maternity data was amplified by the introduction of a Lying-in register. The second volume of Registers of Lying-in Women for the Gozo civil hospital covers the period 29th March 1876 to 11th April 1884. Presumably the first volume approximately covered the previous decade[12,13]. The maintenance of admission registers of the various Government Charitable Institutions was formalised by the 1851 regulations[14].

While the national data was collected by the Public Health Department and could be utilised for public health measures, the hospital clinical data was managed and collected by the Commissioner for Charitable Institutions whose concern towards data collection was purely administrative and budgetary. The situation changed after 1937 when the Public Health Department and the Charitable Institutions Department were amalgamated in the Medical and Health Department. This allowed the medical administrators to audit clinical data and assess medical management in the various hospital clinical departments. The annual reports after 1937 contain appendices detailing audits of clinical departments, besides reports from various support services[15].

In the second part of the twentieth century, the advances in medical sciences and public expectations, and new trends in administration placed increasing pressure for more and for better medical information. In Malta, the Department of Obstetrics and Gynaecology has been in the forefront of this development, and its history can serve as a model for that of other departments. The first annual clinical report for the obstetric department in the main State Hospital was published in 1937[16]. There has been since a regular series of annual reports issued from the department, reports that unfortunately have not always been published formally. The annual clinical reports were laboriously assembled by hand from the Labour Ward Birth Registers (in use since the mid-19th century) and the case records of patients with a bad obstetric outcome. While these reports are interesting to the clinicians and the hospital administrators, they are of limited utility epidemiologically since they gave information only about abnormalities and did not provide national standards for comparison. It was realised that the volume of data that requires to be processed on an annual basis can only be suitably managed by the use of computers.

Data collection using computer services was initiated in conjunction with the International Fertility Research Programme (USA) in 1981. The purpose of this programme was to collect, analyse and report data relating to obstetric delivery in a standard manner for all contributors to the programme. For the Department, the experiment served as a feasibility study of data collection of circa 5000 maternities. The data was transcribed onto standard data sheets by a trainee obstetrician and the data sheets forwarded to the IFRP where the data was handled electronically[17].

During 1982, arrangements were made through the Department of Health with the Government Computer Centre (Malta) for the initiation of local electronic handling of clinical data of all obstetric deliveries occurring in the main State Hospital. The program, based on the experiences with the IFRP system, was finally initiated in January 1983. This event-based data collection continued until the end of 1986 (Table 1). The data was transcribed from the patients' files onto a series of three obstetric-related Data Forms [Obstetric Coding Sheet; Multiple Birth Record; and Neonatal Coding Sheet] by a midwife under the overall supervision of an obstetric registrar responsible for the Department's audit program. An Instruction Manual defining specific problems was prepared. The collected information facilitated the preparation of a series of detailed annual clinical re-

ports, the evolution of a number of epidemiological studies which helped to identify particular obstetric risk groups in the Maltese situation, and served as a basis of clinical practice audit in the Department [17,18].

Similar progress in clinical event-oriented data collection was made in Cancer Registration. Following the Cancer Notification Act of 1957, registration of cancer cases was initiated by the oncological department at St. Luke's Hospital. This was taken up in a computerized form by the Department of Health Information in 1984 and is still maintained today.

Year	State Hospital (Malta) No. of maternities	Computer recorded maternities	%	System in use
1981	5212	4619	89.01	FRP (USA)
1983	5286	5286	100	Comp.Centre (Malta)
1984	5083	5031	99.0	
1985	5014	4968	99.1	
1986	4789	4787	99.9	

Table 1: Data Collection Efficiency

Person-Oriented Database

An event-oriented database is only of general value assisting health planning and hospital resource management. It gives no direct benefits to the individual patient. During 1986, the Department of Health in conjunction with the World Health Organization introduced a computer-based INDIVIDUAL HEALTH PROFILE aimed as a person-based record for all patients who encountered government medical services with the aim of providing readily available clinical information to medical practitioners on the patients they were treating, of scheduling appointments and follow-up procedures, of managing immunization and other preventive programs, and of conducting surveys and research. The INDIVIDUAL HEALTH PROFILE included socio-medical information about each patient and the medical diagnosis at each encounter[19,20]. This profile was eventually termed the Patient Master Index. This has now evolved in the Patient Administration System [PAS] still in use today.

The system used initially was the CMG-COSTAR [Computer Stored Ambulatory Record] as modified by the Central Medical Group of Imperial Chemical Industries. The system was basically a highly structured medical case record designed for use as an extension of the traditionally manually operated medical records. CMG-COSTAR was written in the MUMPS language, which was specifically developed for medical purposes by the Massachusetts General hospital of Boston. MUMPS was a high-level interpretative data management system particularly suited to interactive systems where rapid and efficient management of textual data was required. MUMPS was used in many applications outside the medical field including financial and administrative purposes in industry.

The Department of Obstetrics and Gynaecology was offered these new facilities for introducing a computer-based Medical Record for its obstetric patients. This involved the modification of the previous statistical event-oriented program in use during 1983-96 to a patient-oriented one, thus necessitating a number of encounter forms [Initial Encounter Form; Antenatal Examination Form; Intrapartum Data Form; Infant Characteristics Form; Postpartum Care Form] to be devised for data collection[21].

It was initially planned that the relevant encounter forms will be completed by the attending physician who was also responsible for the manual Medical Record. However, after a feasibility study, this was found to be impractical in view of the large numbers of patients attending the antenatal clinics at Karin Grech Hospital and the reluctance of the physicians[18]. A system was thus organized whereby data transfer from the manual medical record onto the encounter forms was done by a team of two part-time midwives and a health assistant clerk. The completed forms are then sent to the Health Services Information Unit where the data is transferred to the computer by trained personnel. The system of using a team of data collectors was found to be more reliable and efficient than when data was collected by medical personnel. The team became very used to the notes and could find their way through these quickly. They were made to feel a part of the medical team and had free access to the doctors for any queries. The data capture rate of the system during 1987 approximated 91% (Table 2).

The transfer of information from the manual medical record to the data collection forms and eventually onto computer al-

DATA FORMS	Computer Data	Hospital Records	%
Initial Encounter Forms	4474	4834	92.6
Antenatal Examination Forms			
a] Hospital Follow-ups		15217	
b] Health Center Follow-ups		5047	
c] Ward Admissions		2378	
Intrapartum Data Form	4470	4899	91.2
Infant Characteristics Form	4451	4952	89.9
PostPartum Care Form		340	

Table 2: Data Capture - 1987

lowed for the possibility of transcription errors, especially where text was involved. The case record data sheets were structured with this possibility in mind and information items were clearly defined whenever possible. Another problem associated with the system was breakdown of confidentiality. Security and confidentiality of patient information were inherently ensured by the CMG-COSTAR System if a dedicated computer was used. The only possible breakdown in confidentiality that could occur was during the period between data collection and its processing onto computer. However by encouraging the use of the national Identity Card Number, the risk was considered to be not greater than access to the Manual Record. The scope of this person-oriented program, besides facilitating statistical analysis, was to make easily available the individual patient records to the practitioner. The data could be arranged by the computer in flow-chart format mimicking the manual medical data record with which the practitioner was familiar. Four obstetric flow charts were designed. The first chart identified obstetrical important socio-biological characteristics, the past medical history and the general examination of the patient. The second chart outlined the antenatal obstetric observations in chronological order, while the final chart tabulated in chronological order the antenatal investigations.

The hardware used for the system consisted of two Burroughs mainframes which held the Master Index and the record files. A Wang 380 personal computer was linked via dedicated telephone lines to the peripheral centres in the Hospital and the Primary Health Care Centres. The system was accumulative, and within a few years the Master Index and record files became indunated with information and unwieldy to use effectively as medical case records or for statistical evaluation.

The Department of Obstetrics & Gynaecology in liaison with the Department of Health Information in 1991 returned to an event-oriented system entitled Maternity Information System. Data collection for the MIS commenced once the mother delivers her child. Information regarding the course and outcome of pregnancy is recorded onto a standard maternity information sheet, comprised of four sections [MATER - maternal identification; BOOKDEL - antenatal booking data; DELNEW - delivery data; and INFANT1 - infant data]. The main objective of the system is to provide information to clinicians and management personnel on obstetric care and outcomes in the hospital. The data collection is performed by two nurses stationed in the Post-Natal Ward with data being gathered from the Patients' Maternity Co-operation Card, Nursery Infant Notes, and the Labour Ward Registers. The completed data sheets are eventually passed on to the data entry operators at the DHI who validates the maternal identification information with the Patient Master Index. The latter is part of a comprehensive Healthcare Information System that holds demographic details on all residents on the Islands. The medical data in the sheets are then coded according to the International Classification of Disease (ICD-9), and once coded are entered into a dBase IV program. Data capture has reached 100% efficiency for the main State Hospital, accounting for over 80% of maternities occurring in the Islands. The data has been validated since 1993, initially whenever obstetric information was requested, but after 1995 more regularly with an annual report being issued by the DHI (Table 3)[22].

In 1998 after exposure to the WHO-Euro OBSQID project, the data sheets were reviewed in the light of the OBSQID-BIS. The presently used data sheets were found to lack information about a few specified data items. The MIS database was thus adapted to conform with the requirements of the OBSQID project and the new database – the National Obstetric Information System – initiated in 1999. In addition, the maternity information was extended to all the other state and private run maternity hospitals which increased their role in the maternity services of the Islands, their contribution rising from about 3% of the total deliveries on the Islands in 1995 to 18% in 1997.

MATERNITY INFORMATION SYSTEM	1995	1996	1997
TOTAL BIRTHS Karin Grech Hospital	4482	4212	3977
TOTAL REGISTERED BIRTHS Maltese Islands	4613	4944	4835
% DATA CAPTURE	97.2	85.2	82.3

Table 3: Data Capture

Another unit which availed itself of the person-oriented COSTAR system in 1986 was the Diabetes Clinic of the Department of Medicine where data was inputted directly on terminals placed at the clinic[20]. This was after 1989 replaced by the DiabCare computer program launched by the St. Vincent's Declaration. This later program enables health care personnel to record and analyse data from a large number of patients and to compare results with those of other centres. By 1999, a total of 14300 diabetic patients were registered in the Clinic's computerised management system [23]. The DiabCare project has

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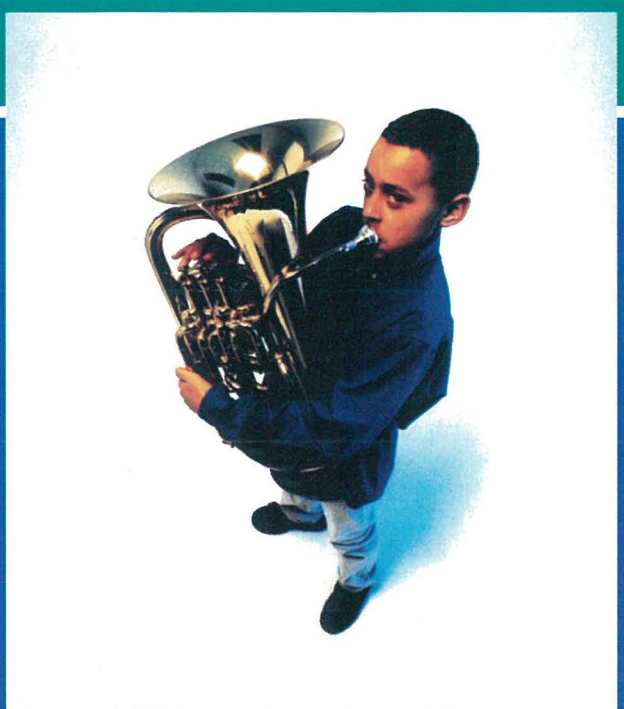

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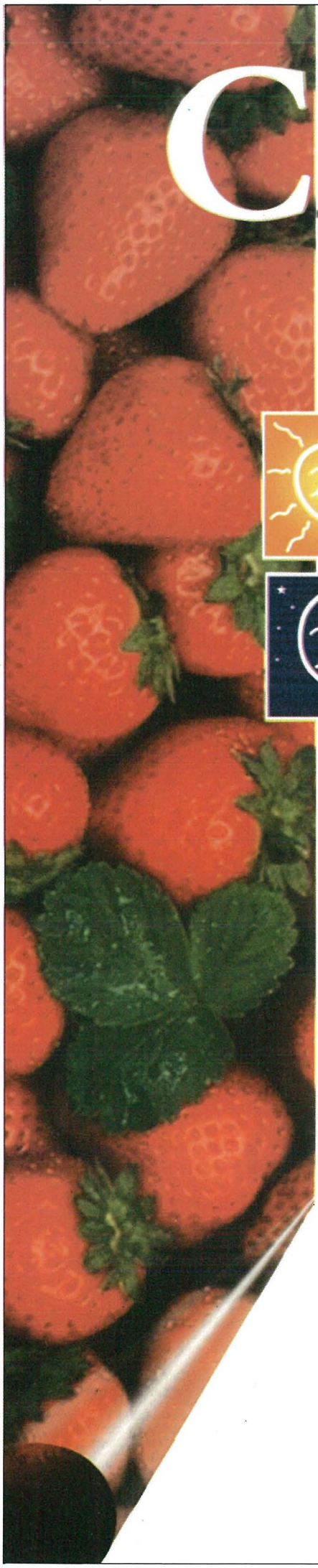

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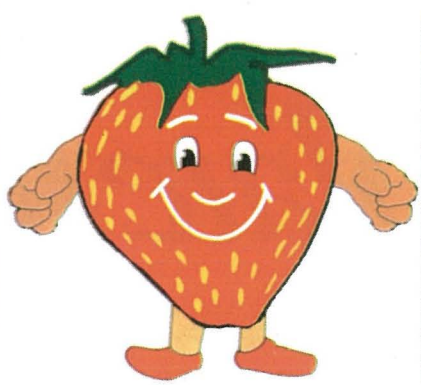

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Lilly

been extended to diabetes during pregnancy – DiabPregCare – which has been adopted by the Diabetic Pregnancy Joint Clinic at St. Luke's Hospital.

The COSTAR system was also piloted for the management of clinical data collection from the Floriana Health Centre, with plans to extend these to all the health centres by 1990. This system however became defunct with the abandonment of the COSTAR System in the early 1990s[20]. Several data programs have been proposed locally for general practice, and the number of general practitioners who utilise information technology systems to maintain their practice is steadily increasing. IT systems in health care are the way forward, not only for better management of hospitals and general practice but also for better individual patient care. Attempts should be made to link the hospital clinical data, such as major diagnosis and treatment prescribed, with primary health care. This can be facilitated though the introduction of smart cards containing important clinical data about the individual. These cards, issued and updated by the hospital, are then given to the individual to be presented to medical practitioners whenever necessary.

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TRANSHIS - THE MALTESE EXPERIENCE WITH ICPC-2

JEAN KARL SOLER
FAMILY PHYSICIAN

INTRODUCTION

Since its formation in 1990, the Malta College of Family Doctors has strived to promote and improve the standard of Family Medicine practised in Malta. The concept of keeping good quality medical records is central to achieving this goal. Audit, essential for quality assurance, is almost impossible without medical records, and similarly research is also difficult without data from records to provide information about the population under study. It is not surprising then, that record-keeping was always considered important to allow development of Family Medicine as a discipline.

Unfortunately, only a few doctors outside hospital regularly keep medical records. In the Government Health Centres, record keeping is very rudimentary, and has improved very little over the years. A minority of self-employed family doctors keep medical records, but most of those that do use a manual system of sorts, such as a card-file system. Such systems make data retrieval for analysis laborious, and also prone to errors.

Recently, the availability of database development software has allowed solo practitioners to develop customised electronic medical record solutions. Furthermore, a handful of professional medical software packages have become available on the local market during the last few years. However, there is no standard for data storage and retrieval, and most of these programs are incompatible. In addition, there was no consensus about a classification system to use and most solutions do not incorporate an international classification to allow data to be summarised and analysed.

The College's initiative

Late in 1997, the author brought up the subject of computerised medical records during a College Council meeting. Little had been done till then to promote medical record-keeping in a pro-active way. The introduction of a standardised program allowing coding with an international classification such as ICD-9 or ICD-10 was believed to be a good way to do this. Various Council members had been toying with the idea of developing a system either alone or in small groups, and it was decided to join forces and work together.

In September 1997, the sub-committee to develop computerised medical records was formed. Members included the author, Dr. Anthony Mifsud, Dr. Philip Sciortino, and Dr. Wilfred Galea. A call for applications was made to invite software companies to participate in the project to develop an EMR (electronic medical record) in partnership with the College.

After much effort, nearly a dozen companies applied, with the sub-committee outlining proposals and requirements for such a package during a meeting at St. Philip's Hospital. The Minimum Dataset developed by Hugo Agius Muscat, Anthony Azzopardi and Wilfred Galea was also presented as a guide to developers. A detailed proposal was requested as a basis for future discussions, and one company produced a detailed brief that met all reasonable expectations. The proposed project would allow for the development of a cheap, powerful application to be used by GPs. A drug prescribing system had already been developed, and could be included. However, unfortunately, the amount of financial support required to sustain the project in the long term was so large as to require substantial sponsorship on an on-going basis. The project seemed unsustainable and was shelved.

So, in April 1998 the sub-committee had not yet defined a viable solution.

The International Classification of Primary Care (ICPC)

Later on that year, the author was invited to act as Maltese representative on the WONCA (World Organisation of Family Doctors) International Classification Committee. Through his activities on this committee, the author became familiar with the ICPC in its second version, published that year by Oxford University Press[1].

The International Classification of Primary Care is a classification designed for Primary Care, as its name suggests. It has been in development since 1975, with the birth of the International Classification of Health Problems in Primary Care (ICHPPC) by WONCA and the American Hospital Association. In 1979 WONCA and WHO published ICHPPC-2, which was published with inclusion criteria for the rubrics as ICHPPC-2 Defined in 1983. ICPC was first published by WONCA in 1987[2], and the second edition was published in 1998[1].

A – general	R – Respiratory
B – Blood, immune system	S – Skin
D – Digestive	T – meTabolic, endocrine
F – Eye (oFthalmic)	U – Urological
H – Ear (Hearing)	W – Women's health, pregnancy, family planning
K – Circulatory (Kardiovascular)	X – female genital
L – musculoskeletaL	Y – male genital
N - Neurological	Z – social problems
P - Psychological	

Table 1: ICPC-2 chapters[1]

Component 1 – Complaints and symptoms
Component 2 – Diagnostic, screening and preventive
Component 3 – Medication, treatment and procedures
Component 4 – Test results
Component 5 – Administrative
Component 6 – Referrals and other reasons for encounter
Component 7 – Diagnostic and disease component (infectious, neoplastic, injuries, congenital anomalies, other)

Table 2: ICPC-2 components[1]

ICPC is a classification for primary care. It has a bi-axial structure, with seventeen letters referring to body systems or areas of health care (Table 1), and two-digit numbers in seven components (Table 2) defining the actual code or rubric.

Rubrics in components 2 to 6 are common to all chapters (e.g. –50 refers to medication, treatment or prescription in any chapter), while rubrics in components 1 and 7 are unique to each chapter (e.g. R71 refers to whooping cough, U71 refers to cystitis, D71 is mumps).

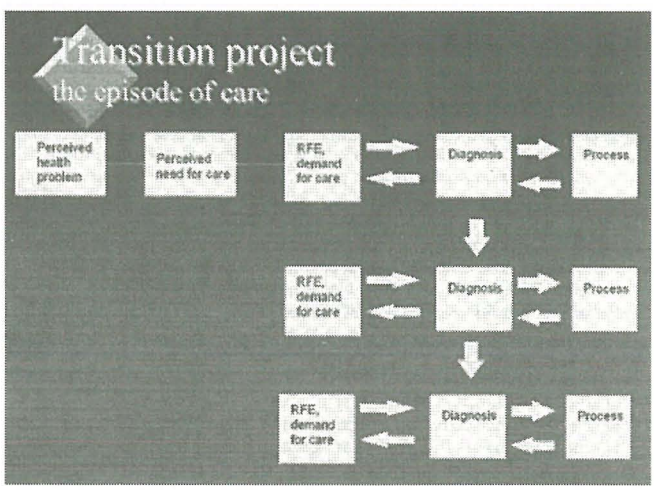

Figure 1 – an episode of care, comprising three encounters with the care provider.

The episode starts with the first reason for encounter (RFE) presented to the care provider at the first encounter. Each of the three encounters comprises a reason for encounter by the patient, a diagnosis made by the provider and which gives the title to the episode, and process of care (diagnostic and therapeutic interventions).

Episode-oriented epidemiology

The episode of care is defined as a health problem from its first encounter with a health care provider through to the completion of the last encounter. An episode of care is distinct from an episode of illness and from an episode of disease[3].

The concept of an episode of care is central to the use of ICPC. The unit of an episode of care is a useful validated measure of comprehensiveness and longitudinality of primary care. A diagrammatic representation of an episode is illustrated in figure 1, where one episode of care made up of three encounters is illustrated.

The College's choice of Transhis and ICPC-2

Thus, ICPC is an international classification of primary care, which can be used to code for reasons for encounter by the patient, process of care, diagnostic titles of the episode by the doctor, and various investigations, therapeutic interventions and referrals. The concept of an episode of care can be used to measure activity in primary care and the relationships, which will change over time, between the various entities mentioned above.

Moreover, ICPC is easily introduced into an electronic medical record system as the core for coding all elements of the consultation. This obviates the need for repetitive text entry, and allows for storing information in a way that is easily retrieved for analysis. The classification is international, and data can be compared with that from studies done abroad.

During the WICC meeting in Dublin in June 1998, the author met Professor Henk Lamberts and

Dr Inge Okkes from the University of Amsterdam. In fact, they demonstrated just such a computer record system, which they were prepared to allow Maltese GPs to use for the purpose of data collection for comparative studies. They were immediately interested to collaborate with the College to collect this data and jointly publish it as part of international collaborative studies.

The College Council immediately saw this as an opportunity to solve the impasse we had reached in developing our own EMR. This was a much better system which could be modified with less financial resources than those necessary to develop and support a new system. The College invited Prof. Lamberts and Dr. Okkes to Malta to talk to Maltese GPs at a one-day workshop at the Forum Hotel in November 1998. The program was well received, and the College decided to co-operate with the "Transition project" in December 1998.

In March 1999, at the 4th Maltese Medical School Conference, the College was invited to host the first Family Practice session at the Conference. Prof. Lamberts was invited to open the session, and he presented a talk about "General Practice – the key to health care in a new era". This was followed by a presentation by the author and Dr. D. Soler discussing "Presentation of an analysis of 539 consecutive consultations, coded with ICPC, in a Family Doctor's Practice. Do they reflect the core of General Practice?"

The focus was very much on ICPC and episode-oriented epidemiology, and soon after the College was officially recommending the use of ICPC for coding contacts in Primary Care in Malta, and specifically via the use of Transhis[4,5] software. Even in the first call for applications for part-time lecturers in family medicine, candidates were expected to use "... electronic patient records coded with ICPC[6]".

Transhis

To facilitate the use of ICPC-2, the Maltese Family Doctor has the opportunity to use "Transhis", electronic medical record software designed by the University of Amsterdam Transition Project[4,5]. The Maltese version is one of the first international versions to use the electronic version of ICPC second edition, E-ICPC-2[7], and is also modified to better suit Maltese Family Medicine. The program is written in DOS Clipper, and will run on low-end machines based on Intel 386 microprocessors, but also on high-end Pentium machines running Windows 95 and 98.

The program is in English, and the forms have been adapted to local characteristics, as can be seen from the screenshots illustrated (Figures 2, and 3)

Data stored for each encounter includes the date, the doctor ID (in group practices), the type of encounter, reason/s for encounter and request/s for intervention by the patient, history of the presenting complaints, interventions, episode title (diagnosis), whether the episode is old or new, diagnostic certainty, and resulting interventions (therapeutic, referrals, investigations, etc.). All coding is taken care of by the program, and terms are entered in free text. The option to also code diagnoses with ICD-10, to add clinical specificity, is also incorporated. The user is allowed to store free text at every stage of the consultation, and separate modules allow for storage of investigation results, parameters (blood pressure, weight, peak flow rate, etc.), and treatment prescribed.

The author has organised a series of small-group meetings to train doctors to use ICPC, and Transhis. Twenty users have been recruited, and the programme allows for many more users to join.

Support for users is presently web based, with a dedicated e-mail listserver servicing the user group. Regularly, updates of the program are received from Holland, and distributed to users. The data collected by users is also forwarded to the University of Amsterdam in anonymised format, with all patient particulars being stripped out of the database. This allows for detailed analysis of the data by our distinguished colleagues abroad.

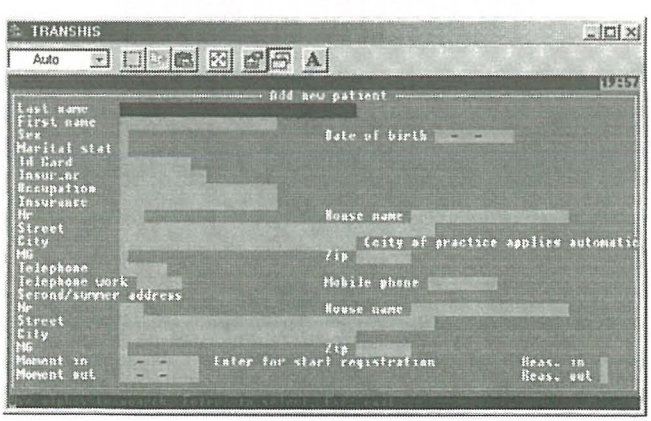

Figure 2 - the patient input screen modified for Maltese users

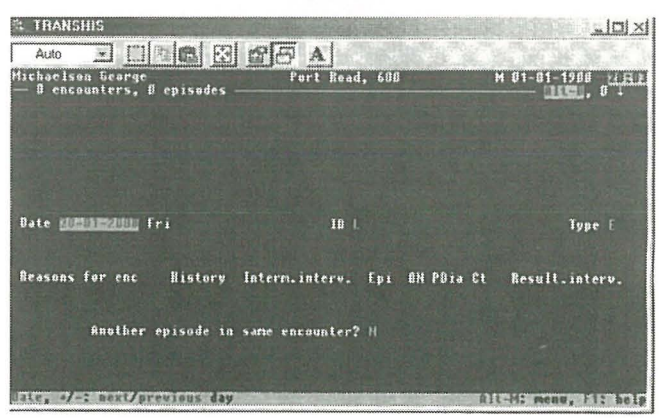

Figure 3 – the patient screen, ready to accept data input

To follow this up, a series of workshops, small-group sessions and practice visits were held in Malta at the end of May and beginning of June in collaboration with Prof. Lamberts and Dr. Okkes. The feedback received was that the data collected was indeed of high quality.

Opportunities for research

The data collected by users allows ongoing research in the field of Family Medicine to be conducted in Malta for the first time. Doctors using the program in their day-to-day practice have access to an excellent medical record that assists them to practice good medicine. Patients are impressed by the doctor's access to up-to-date information about their past history, with problem lists and medication lists available at the touch of a button. A decision support system is included, with data from more than 118,000 encounters in Dutch General Practice[7].

The data collected is available to primary care researchers, to allow them to collect data and provide evidence to policy-makers that what is being done is valid and cost-effective. This research will allow us to justify more resources being made available to primary care.

Interested parties are invited to write to the author to participate in this important project.

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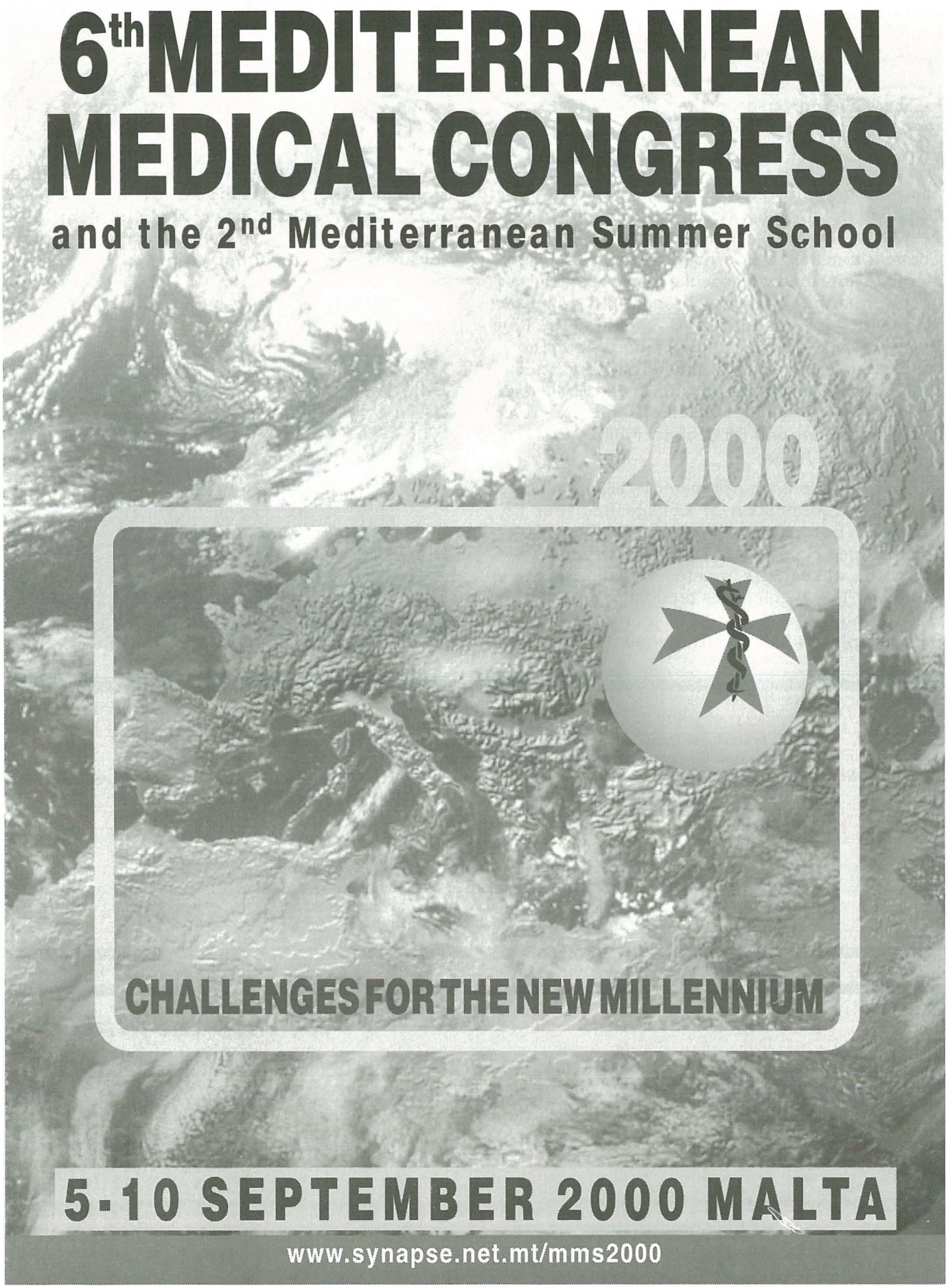
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Tenth Anniversary of the Malta College of Family Doctors

Gala Dinner, Coastline Hotel, Salina,
9th December 1999

The 10th Anniversary of the Collage's foundation (one evening during November 1989 in the kitchen of the home of Dr. Denis Soler with Dr. Ray Busuttil and Dr. Wilfred Galea) was commemorated appropriately enough by a Galea Dinner held at the Coastline Hotel, Salina on the 9th December 1999. Besides all the present members of the College Council, together with a good number of College members, the following special guests were invited to celebrate the occasion. These were the Minister of Health the Hons Dr. Louis Deguara, Dr. Ray Busuttil (the College's first Honorary Secretary), the Dean of the Medical School Prof. Mark Brincat (instrumental in the setting up of the University Department of Family Medicine), and Dr. Frank Portelli, Director and CEO of St. Philip's Hospital (the College's hosts).

After a delicious meal prepared by Island Caterers under the coordination of College Registrar Dr. Michael A. Borg, College President Dr. Denis Soler and the special guests all said a few words for the occasion, which were greeted with appreciative applause. The evening was brought to an end with the taking of a number of commemorative photographs, which (through no fault of the volunteer photographers but most certainly due to the playing-up of the camera provided by Honorary Secretary Dr. Mario R. Sammut) nearly all turned out blurred - with one fortunate exception. This is reproduced here and immortalises for posterity the Malta College of Family Doctors Council for 1999-2002 (form left to right): Mario R. Sammut, Anthony Mifsud, Michael A. Borg, Jean Karl Soler, Denis Soler, Wilfred Galea, John P. Gauci, Joseph G. Pace, Philip Sciortino, Frank P. Calleja and Anthony P. Azzopardi.

Correspondence and contributions to this journal are to be sent to:
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