

Education  
in Family Medicine  
What has been achieved?

# Whatever the reason whatever the season



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## 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.

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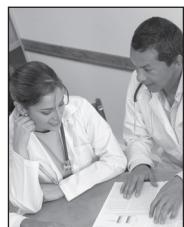
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# Education... historical landmarks

**Prof. Pierre MALLIA**

In this issue of JMCFD we have decided to implement some changes to the overall structure. This is the second issue of 2012 and three issues are planned for 2013. From now on we will have a main theme with contributors for each; these are then followed by the scientific contributions and a back-page column, called for that matter 'Back Pages', which discusses some relevant issue.

This issue of the journal focuses on Education in family medicine. It is indeed high time that the many activities going on in the field of education in this area is documented and discussed with our readers. Over the past several years the college has implemented Vocational Training, holding courses for Trainers in the process and, with the help of the Royal College of General Practitioners, building up a robust system of teaching and examining both at the end of the vocational training course and for a membership exam. Indeed this membership exam leads, a process which was not easy, to the International Membership of the Royal College, the MRCGP(INT). Then there are other developments – the inception by the MCFD of the Diploma in Family Practice, and the Masters in Family Medicine of the University of Malta. Before that we had the importation of diplomas and Masters degrees from abroad. Unfortunately for the latter we did not have response from our call on the college website. Hopefully in the future, those who organised these courses can give an update to members.

The decision to bring the MRCGP(INT) to Malta was taken by the Annual General Meeting (2005) with a unanimous vote in favour and *one* abstention from a considerable number of members present. This was a landmark decision. As President of the College at the time I felt that this could not be merely a council decision but we needed a binding vote for future councils to continue working as this required time. I had attended the meeting organised by the RCGP called *International Development Day*, at 15 Princes Gate, London. This meeting had been attended by my predecessor Dr. Denis Soler. However at that meeting I felt that this was too big an issue for a president to attend alone. In a private discussion with then International Secretary, Dr. John Howard, who kindly contributes to this issue, I frankly said that I wished to take the MRCGP(INT) seriously and wished

therefore for a delegation to come to London each year for this meeting should he offer to host us whilst I find sponsors for our flights. Happily a delegation continues to go to this year.

Alas the AGM voted not only for the MRCGP(INT) to be given to those who have completed their VT but to *all* college members and unfortunately this has got lost somewhere along the road with some expressing doubts whether this should be so. We forget that an AGM vote is binding and we have to respect it. Hopefully the next President will take this on board. I was accused at the time for wanting to bring about examinations and assessments. But in time people appreciated that the MRCGP(INT) was not to be handed away by merely attending CME and a buffet! This issue contains important contributions by the main RCGP protagonists – Dr. John Howard (International Secretary for RCGP), Dr. Adrian Freeman (Internal Development Advisor), who I am pleased to say we have also invited as guest lecturer in the Department of Family Medicine, and Dr. Jeremy Stupple (External Development Advisor).

Other contributions include those by Philip Sciortino, Mario Sammut & Gunther Abela, Dominic Agius, Renzo Degabriele, and myself, who all speak on some aspect of different developments in education which has pushed family practice to a post-graduate standard which we should all be proud of. As to MRCGP(INT) for 'grandfather clause' a system of merit has been set up for those who have contributed significantly; but, if one has a right to a personal opinion, this should be backed up by a membership by assessing performance over the years. There are family doctors out there who have contributed to the well-being of the population simply by providing good and robust family practice. I am mostly a teacher now; but I am aware of the old adage – *those who can, do; those who can't, teach*. Perhaps it is not true, but it is also a warning that experts are not necessarily teachers.

**Prof. Pierre MALLIA** MD MPhil MA(law) PhD MRCP FRCGP  
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# The Malta College of Family Doctors and the Royal College of General Practitioners

**Dr John V HOWARD**

Colleagues with longer memories than mine may go back further in the history of the wonderful collaborative relationship that we Family Doctors have enjoyed between our two countries and organisations.

When I was first appointed to the Royal College of General Practitioners (RCGP) International Committee over 20 years ago, I recall the reports of the visits by Dr Edwin Martin and the RCGP President, Dr Alistair Donald, to Malta. They informed us of the enthusiastic community of Family Doctors, some private and some working in the public sector, who wished to advance the development of family medicine in Malta and who had produced the charter for the Malta College of Family Doctors (MCFD). This process was led by Drs Denis Soler, Wilfred Galea and Ray Busuttil.

During a family holiday to Malta and Gozo some 17 years ago, I had the pleasure of meeting Denis, Wilfred and other members of the Malta College. Following a meal punctuated by a massive firework display, we agreed to collaborate on developing the first cohort of trainers of family medicine. Dr Philip Sciortino was appointed by the Malta College to attend the modules of the RCGP International Teachers Course, held in London. Subsequently Dr Marek Jezierski and I assisted Philip in delivering the first RCGP/ Malta College training the trainers course in Malta. Marek and Professor Rosslynne Freeman provided support for a further course, since when it has become self sufficient.

During the Malta College Presidency of Professor Pierre Mallia, the Royal College was developing the academic framework to enable countries to develop their quality standards for family doctors, assessed by examination and accredited to the standard of the MRCGP[INT]. This new mechanism had been developed following a worldwide consultation, where there was an overwhelming request for the Royal College to support local colleagues to a standard that was of equivalent academic rigour of the MRCGP in the UK, but for the local context of family medicine. Pierre signed the first Memorandum of Understanding with Dr Roger Neighbour, the RCGP President, which

started the collaborative journey towards developing the Malta MRCGP[INT] examination. I think we were all hugely grateful and fortunate in the appointment by the Malta College of Drs Patricia de Gabriele, Doreen Cassar and Dominic Agius and by the Royal College of Dr Adrian Freeman, as the academic leads, as well as the tremendous academic and political support from others in the Malta College including the Curriculum Committee and Drs Mario Sammut and Gunther Abela who developed the 3 year Specialist Training Programme, which the Malta MRCGP[INT] provides the summative assessment.

We all appreciate that in a small country, where the Malta College is an example of an academic hothouse, different perspectives are passionately proposed and defended, so that the pathway to Malta MRCGP[INT] accreditation has not always run smoothly. At the Royal College, we are deeply impressed that the Malta College Councils and Presidents, through Drs Mario Grixti, Andrew Zammit and Jürgen Abela, as well as the vision and confidence that the Ministry of Health have placed in both our Colleges to be able to achieve the goal of accreditation and now re-accreditation of the exam.

The future for high quality primary care for the people of Malta will increasingly lie in the hands of the new generation family doctors, whom we at the Royal College are proud to call our International members. Malta and the MCFD are fortunate to lie geographically and culturally at a strategic point in the Mediterranean, from where in turn, they might provide academic support to other local colleagues who are attempting to develop their own models of family medicine for the benefit of their patients and peoples in difficult circumstances. The Royal College looks forward to be able to continue and increase its ongoing collaboration with the Malta College.

**Dr John V HOWARD FRCGP FRCP**  
Medical Director MRCGP[INT] Programme  
Chair, International Forum, Academy of Medical Royal Colleges.

# The MRCGP [INT] Qualification and Programme

**Dr Adrian FREEMAN**

The Malta College of Family Medicine examination is fully accredited for MRCGP [INT], but what is that?

The Royal College of General Practitioners (RCGP) recognises the need for examinations that reflect the highest standard of delivering primary care and Family Medicine. Many hospital specialists around the world such as surgeons and physicians will take British Royal College examinations. They are perceived as markers of quality and achievement. However the RCGP recognised many years ago that it was inappropriate for doctors outside the UK to take an examination of UK General Practice. Each country around the world has its own healthcare systems, its own epidemiology and disease profile and its own culture. These are all crucial aspects for primary care. The MRCGP exam was testing these aspects for UK practice. How useful was it for a doctor from outside the UK to learn these if they were never going to practice in the UK?

Nevertheless the RCGP acknowledged its responsibility to help enthusiastic General Practitioners worldwide and came up with a different solution. The college wanted to support the development of family medicine and to help to raise standards. It is a major component of the College's international strategy. We recognised that examinations and assessments are an integral part of any curriculum for postgraduate speciality training. However there are good examinations and some that are not so good. Medical education has developed a good evidence base on what is best practice for assessments.

The RCGP decided that if a country can demonstrate that their examinations are following good practice and are rigorous then they could be considered for accreditation for MRCGP [INT]. It is this accreditation process that forms the basis of the programme.

At first sight it might seem that there is more to a training programme and whole Family Medicine system than just the exams. That is quite true but it is the examinations that give the lens to the system that the RCGP can look through. For example, one of the cornerstones of assessment is to carefully blueprint the examinations to the curriculum of the programme. So

first of all there must be a curriculum and that must have an evidence base of what doctors who practice as family medicine specialists are expected to do. The curriculum must specify how a training programme will bring trainees to the expected level. So purely by specifying the need for and careful examination of an examination blueprint the RCGP can now confirm what Family Medicine does in that country and how doctors are trained. As the accreditation process goes on to consider the reliability and validity measures that are undertaken we begin to see the actual standard of family medicine. Looking at the selection/training of examiners and quality assurance processes for the examinations we begin to see the engagement of the community to the process and the political and economic support that is given to Family Medicine. Feedback systems to the trainees indicate how acceptable the examinations are and the newly qualified doctor's enthusiasms for their speciality. And so it goes on, it is that detailed review and fact finding about the examinations that allows the RCGP to be confident in its accreditation and happy for successful candidates to join the RCGP and use the post nominem title of MRCGP[INT].

The MRCGP[INT] programme began in 2001 and the first accredited site was Oman. There are now a further six accredited sites – Bahrain, Kuwait, Dubai, Egypt, a South East Asia group consisting of Bangladesh, India, Nepal, Pakistan and Sri Lanka and the first European site – Malta.

There are close to 1000 doctors who have attained MRCGP[INT] over the course of the programme and this year we appointed the first Fellows (FRCPG[INT]) from doctors who have held MRCGP[INT] in good standing for over five years and can demonstrate good CPD and other areas of good practice over that time.

As the sites mature they begin to work with each other. They share assessment material, provide external examiners for other sites and meet once a year at the educational International Development Days. Site members make presentations at these days and help to run workshops. Malta has also kindly hosted a delegation

from Kosovo to see how the exams are run on the island. Kosovo is at an earlier stage of development and Malta may be able to build stronger links to support them.

For Family Medicine and the qualified specialists we have seen significant benefits from the MRCGP[INT] programme. The successful candidates have entered seniority schemes on a par with consultant colleagues. They have been given much larger clinical and academic responsibility. The candidates have been real agents for change in their countries. There has been improved patient care, clinical research, development of Fellowship programmes, etc. Finally the Family Medicine training programmes have become much more popular with young

doctors with increased numbers on the programme.

Malta can be very proud of its College of Family Medicine and of its excellent training programme and examinations. It can also be proud of being a part of a much larger group around the world that shares common values and standards in Family Medicine within the MRCGP[INT] programme.

**Dr Adrian FREEMAN FRCGP**  
International Development Adviser for Malta  
Deputy Chair of MRCGP[INT] Board

## ANNOUNCEMENT

# The Adult Down Syndrome Clinic

The Adult Down Syndrome Clinic was set up following the signing of an agreement in 2012 between the Department of Health and the Down Syndrome Association. The main scope of this clinic is to offer an annual general medical check-up to all Down syndrome persons residing in Malta and Gozo who are aged 16 years or older. Additionally, the clinic promotes healthy lifestyles and nutritional advice to individuals with Down syndrome, as well as support to their carers.

The physical examination and the blood tests that are carried out at the clinic are targeted to diagnose early signs and symptoms of health problems known to occur more commonly in adult Down Syndrome individuals. Where indicated, the client is then referred to a specialist. The clinic strives to make use of the resources available in primary healthcare.

The clinic is based at the B'Kara Health Centre and is held by a dedicated doctor and nurse every Saturday morning. All data collected on each individual client is stored in an electronic system; a hard copy is given to the carers at every visit. Likewise the family doctor would also be kept informed and updated on clinical findings. Family Doctors are able to refer their clients directly, by calling the clinic on 21494960 or by email on [dsc.mhec@gov.mt](mailto:dsc.mhec@gov.mt).

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# Malta from the view of an External Development Advisor

**Dr Jeremy STUPPLE**

In July 2010 two External Development Advisors (EDAs) visited Malta and recommended to the UK Royal College of General Practitioners (INT) Council that the Membership examination for the Malta College of Family Doctors was to be accredited for MRCGP(INT).

## WHAT IS AN EDA?

Many family doctors in Malta are very familiar with the role of EDAs, particularly those who are officers of the Malta College of Family Doctors (MCFD) or involved in the training and assessment of young family doctors in Malta.

For those who are less familiar with this role, the EDAs are appointed by the UK Royal College of General Practitioners (RCGP) to:

- Assess all aspects of the Membership of the Malta College of Family Doctors assessment process, taking into account the Academic Framework and Quality Assurance standards required for MRCGP(INT) accreditation.
- To advise on the current examination's suitability for MRCGP(INT) accreditation.

EDAs are experienced Examiners for the UK Royal College assessments and familiar with the principles and methodologies detailed in the MRCGP(INT) Workbook. The workbook is used as a template. An EDA visit usually lasts around 6 days and requires a great deal of commitment and effort from all who are involved.

Important principles are that the assessment should be: Fair, Relevant, Test widely, Quality Assured and provide feedback.

## BACKGROUND:

Maltese Family Doctors have changed their approach to practice enormously in the past 7 years. They have been recognized as Specialists in Family Medicine, developed an outstanding 3 year Specialist Training Programme and delivered a membership examination (MMCFD) which

has been scrutinized at international level and accredited for MRCGP(INT). This is an achievement to be proud of and a credit to the work, skill and commitment of those involved in its delivery. Most importantly, there is a renewed interest in standard setting, professional development and professional reputation amongst all Family Doctors in Malta, not just those involved in training and assessment.

This comes at a time of increasing requirement for health care to be delivered in primary care and is supported by the Maltese Government.

## WHAT IS THE PURPOSE OF THE MMCFD?

The Membership examination for the Malta College of Family Doctors (MMCFD) is an end point exam at the completion of Specialist Training in Family Medicine and entitles successful candidates to registration as a Specialist in Family Medicine.

The exam has a responsibility to ensure that accredited doctors have a depth of skill, knowledge and performance worthy of patient confidence in Malta.

Achieving this requires that suitable doctors are selected for training in a broad range of specialties and supervised by doctors with additional skills in teaching and assessment.

The assessment must sample widely across areas of family medicine that are of importance in Malta either by virtue of their prevalence or seriousness. Performance must be set at a suitable standard and measured by appropriate methods (i.e. must have appropriate content and construct validity and good triangulation).

The Specialist Training Programme in Family Medicine (STPFM) also has a responsibility of fairness towards those young doctors undertaking Specialist Training. In order to achieve this, trainees need to be confident that:

- They will be selected on suitable, transparent criteria such as past experience, previous

- performance, interpersonal skills etc
- They will benefit from exposure to a broad range of training based on a published curriculum
- The quality of teaching will be to a uniformly high standard both in quality and quantity
- Assessment standards are evenly applied and that as far as possible there is concordance between assessors.
- That there is feedback and a support mechanism in place for those having difficulty.

## HOW IS THIS DELIVERED IN MALTA?

The 3-year STPFM was established in 2007 and this has been extremely successful. It provides 18 months of training in hospital medicine and 18 months in Family Medicine. Exposure to a wide range of smaller specialties such as ENT, Palliative care and Dermatology is particularly impressive and this is reflected in the increasing number of applicants to the scheme.

Teaching is based around an extremely comprehensive curriculum and Workplace Based Assessments (WBA) are rigorously monitored. They include use of videos, case based discussions, clinical supervisor reports, learning logs, tutorial notes, satisfaction questionnaires etc and mirror those used in the UK. There is a specific appeals procedure in place for those who are having difficulty but individual feedback from trainees is that the training scheme is highly regarded.

Final assessment is by a 200 question Applied Knowledge Test (AKT) and a 13 station Clinical Skills Assessment (CSA).

Newly accredited graduates of the STPFM are justifiably proud of their specialist status and worthy of public confidence.

## WHAT ARE THE OPPORTUNITIES AND CHALLENGES THAT LIE AHEAD?

As in many countries, the role of family doctors is expanding to meet the ever-increasing health needs of the population.

There is a wave of enthusiasm for professional development amongst family doctors and an opportunity to embrace these challenges and raise the profile of family doctors in Malta.

The AKT and CSA examinations have been delivered to a high standard due the extraordinary efforts of a small number of people. Going forward, however, there is a need to share some of this workload and to continue to develop and disseminate this expertise.

Experience from the MRCGP(UK) shows that assessment drives standards and it is probable that the current STPFM and its associated assessment will deliver increasingly able young Specialists in Family Medicine.

This provides 3 challenges:

- To ensure that the quality of teaching develops at a comparable rate and is delivered to a uniform standard.
- To continue to refine the methods used for assessment and the skills and concordance of assessors.
- To nurture these young specialists who will become the future trainers and assessors in Family Medicine.

Given the current enthusiasm for professional development amongst all family doctors in Malta, there is little doubt that these challenges will be met.

I congratulate those of you who have recently accepted positions on the Council of the Malta College of Family Doctors with responsibility for delivering these challenges. I look forward to seeing you again soon and wish you all the best for the future.

**Dr Jeremy STUPPLE**

External Development Advisor for Malta,  
Royal College of General Practitioners

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# The Specialist Training Programme in Family Medicine - Malta

**Dr Mario R SAMMUT, Dr Gunther ABELA**

## INTRODUCTION

Following the approval by Malta's Specialist Accreditation Committee in 2006 of the Specialist Training Programme in Family Medicine (STPFM) prepared by the Malta College of Family Doctors, the programme was launched on the 9<sup>th</sup> July 2007 when the first intake of GP Trainees commenced their training. Dr Mario R Sammut had been appointed as National Coordinator of the programme in 2005, and in 2008 Dr Sammut and Dr Gunther Abela were appointed as Postgraduate Training Coordinators in Family Medicine. The numbers of GP trainees who have so far completed successfully the STPFM are eleven in 2010, ten in 2011 and, following a limited intake in 2009, five in 2012.

## TRAINING

Each GP Trainee undergoes training by working under the supervision of a GP Trainer in primary health care, and under the supervision of a specialist in other specialties (Medicine, Paediatrics, Obstetrics & Gynaecology, Accident & Emergency, Dermatology, Ear Nose and Throat, Geriatrics, Palliative Care, Ophthalmology and Psychiatry). Such training is evaluated by the programme coordinators together with the heads of the departments concerned on the basis of feedback provided from the trainees, trainers and other-specialty supervisors, with changes being made in the provision of training. During October-June, the trainees participate in a Half-Day Release Course (HDRC) consisting of a weekly 4-hour (1-5pm) teaching session.

## FORMATIVE ASSESSMENT, ANNUAL APPRAISAL AND SUMMATIVE ASSESSMENT

The GP Trainees undergo continuous Formative Assessment throughout their training programme and this is recorded in an Education Portfolio. An Annual Appraisal is performed at the end of each academic year. At the end of the 3-year programme, a Summative Assessment is held consisting of a Work-Based Assessment, an Applied Knowledge Test and a Clinical Skills Assessment. In collaboration with the Malta College of Family Doctors, a pilot summative assessment was held in February 2010 and followed by the first-ever summative assessment in June-July 2010. The latter exam subsequently was awarded accreditation for the MRCGP (INT) by the Royal College of General Practitioners (RCGP)

of the UK. An ePortfolio for the STPFM is presently being developed to replace the present paper-based version.

## SPECIALIST TRAINING COMMITTEE IN FAMILY MEDICINE

The Specialist Training Committee in Family Medicine oversees the STPFM. On the 14<sup>th</sup> February 2008, the first meeting of the Specialist Training Committee was held, chaired by the coordinator/s with representatives of the Primary Health Care Department, the Malta College of Family Doctors, the GP Trainers and the GP Trainees. Two or more such meetings are held every year according to the need.

## QUALITY ASSURANCE

As already mentioned, the training programme is monitored systematically through the regular feedback received from the trainees and trainers/supervisors after each placement, with any action deemed necessary being taken. This feedback system is applicable also to the Half Day Release Course. Attendance and punctuality to the various activities which form part of the programme is also closely monitored. Recommendations regarding the STPFM that were made by the RCGP External Development Advisors in their visit in July 2010 were closely reviewed and implemented, with a Quality Assurance Report of Annual Appraisals being prepared by the coordinators on a yearly basis.

## PROMOTING THE SPECIALIST TRAINING PROGRAMME IN FAMILY MEDICINE

A number of initiatives were taken to promote the STPFM after the limited intake of GP Trainees in 2009. These included an interview with the STPFM Coordinators regarding the training programme published in The Times (1<sup>st</sup> August 2009), the establishment of a website for the Specialist Training Programme ([www.stpfm.ehealth.gov.mt](http://www.stpfm.ehealth.gov.mt)) in 2010, and the organisation from 2010 of introductory seminars for Foundation Programme Trainees on a yearly basis.

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# Psychometrics – MCFD/MRCGP[INT] summative examination

**Dr Dominic AGIUS**

## PSYCHOMETRICS – PROPOSALS AND THE WAY FORWARD

Summative assessments represent a high stakes activity for trainees and examiners. For trainees, such assessments may determine their professional pathways, while for examiners they may represent important benchmarking tools.

Validity and reliability are terms used in relation to assessment quality. Psychometric principles and statistical analyses utilize probability theories in the form of Item Response Theory, Classical Test Theory and Generalisability (G) Theory.

These theoretical constructs are used to assess the standard of Face validity, Content validity and Construct validity of the individual items and the tests as a whole.

## TOOLS THAT ARE USED TO ANALYSE RESPONSE AND RESULTS OF ASSESSMENTS

Reliability of Applied Knowledge Test (AKT) response and results are analysed using mainly Cronbach alpha. This is the accepted norm used throughout the major educational institutions world-wide. However, some studies have thrown new light on the possibility of using a combination of tools to achieve more valid and reliable outcomes (Burton, 2004).

Other statistics that have been suggested, that complement Cronbach alpha include:

- Facility index
- Discrimination Index
- Distractor effectiveness Index
- Rasch Analysis and
- Item-person map analysis.

These tools greatly facilitate the interpretation of item and test responses (Baker, 2001) and thus increase the reliability and validity of assessments. The use of G-Theory as an overarching means of overcoming the distinction between validity and reliability is explored and implemented.

## STANDARD SETTING

At present, standard setting is within the domain of experienced General Practitioners, who are trained teachers and assessors. In the future, I envisage that standard

setting for both AKT and Clinical Skills Assessment (CSA) exams will also involve 'ordinary' practitioners and possibly patients – the issue of security will definitely have to be considered when extending such a delicate task to a larger assessing group. A core group of examiners with the necessary skills and expertise is already in place.

## SETTING STANDARDS FOR CLINICAL EXAMINATIONS

A modified Angoff's method has, up to now been used to 'capture judgements at the level of the CSA station' (Norcini, 2003) ie. Clear Pass, Pass, Fail and Clear Fail. This has made standard setting for CSAs manageable and feasible.

The use of Hofstee's Method – with standard setting following the number of cases needed to pass – strengthens the process.

The Contrasting Group Method is too time consuming and would require a relatively large sample size to ensure a reliable result.

## WEIGHTING OF CASE EXPOSURE

The setting of Family Medicine in Malta presents particular issues that need to be researched and addressed. The effects of specific epidemiological and cultural factors will need to be considered when selecting cases for CSAs. Focus Groups, Nominal Group technique and/or Delphi method (involving patients, practitioners and public health experts), will need to be used to generate the necessary data for analysis and then weighting of case exposure in the local scenario.

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# Continued professional development

**Dr Philip SCIORTINO**

## **Continued professional development - changes to meet the challenges of the times**

One of the major statutory obligations of the Malta College of Family Doctors (MCFD) is the provision of a program of Continued Professional Development (CPD). This lifelong learning or maintenance education, together with the entry examinations for new specialists in Family Medicine, constitute the prime focus of the academic output of our College.

The College is now consistently fulfilling these two major obligations. This CPD is being organised by a team of dedicated Family Doctors who are doing the research, development, organisation and promotion to develop an educational package. This has to be relevant, interesting and innovative for our two major customer groups: the Family Doctor community and the sponsors.

The team consists of Dr Philip Sciortino who is the overall team leader and responsible for conceptual and structural development of the academic aspect of the CPD activities; Dr Tania van Avendonk who does a lot of organisational work with the venue, the sponsors, the CPD team and the MCFD council; Dr Dorothy Zammit who takes care of the market research and publishing; Dr Adrian Micallef, the College registrar, who is in charge of verifying and recording the Continued Professional Development Accreditation System (CPDAS) and finally a very significant contribution from Dr Kenneth Vassallo who is taking care of Information Technology especially the MCFD website CPD section and the site apparatus. This team has been able to work seamlessly for the benefit of the whole community. The frequency of the meetings and the number of participants has increased reaching best ever levels. This was satisfying to the team doing this voluntary work. Interest from sponsors has also improved to the extent that it is not always possible to satisfy requests for participation. The package was designed in view of a business model to achieve a balance that allows for financial sustainability of the whole CPD

system permitting future investment in IT, interactivity and low volume, high intensity educational activities. The focus is on accessible quality education rather than entertainment.

The CPD team has also modified the CPDAS (MCFD Continuing Professional Development Committee, undated) by increasing the range of active learning options available to the members of the MCFD through encouraging the self-directed and self-learning component of the CPD portfolio. Online learning is being included and three very good sites have been accredited. The CPD academic year starts with the calendar year and a whole CPD cycle consists of three academic years, after which a portfolio of CPD activities has to be submitted to the College Registrar for verification, quality control and possible feedback. It has also increased the flexibility of the accreditation system allowing for compensation across the years within a single CPD cycle. This will help Family Doctors who for some reason cannot achieve all the yearly CPDAS targets because of illness, pregnancy, travel and other personal issues. Events not organised by the MCFD are still being accredited; however their accreditation would have to be issued on a case by case basis strictly on educational merit only. Accreditation of CPD events is being increasingly regulated in both the USA and Europe with many large pharmaceutical companies integrating the regulations into their standard operating procedures (Accreditation Council for Continuing Medical Education, undated). The system is giving greater emphasis on teaching, research and community development or practice development. This will prepare individual practitioners to achieve the most enduring and rewarding kind of learning, that is reflecting and recording learning achieved from the actual practice of teaching, patient consulting and developing such activities. On another level the College is paving the way for Family Doctors to an accreditation system that sooner or later may be requested from the EU or other regulating bodies.

The organised CPD events have included Family Doctors, multidisciplinary team professionals and non-clinical contributors (such as a clinical ethicist) which reflect the wider issues that we, as Family Doctors, have to include in our clinical practice. The accessibility of the event location and event timing are important issues which we hope to keep in our sights. The main criterion for the selection of the topics is the relevance to the discipline and the actual educational need for a review of that particular area. Women's Health, the care of the elderly and the use of laboratory tests in General Practice are three areas that are not system based and are undergoing major changes. These areas are emerging challenges that would require greater capacity from the Family Doctor because of demographic changes and increasing access to novel technology (tests and pharmacological agents).

During the CPD events the CPD team has evaluated the program by means of a quantitative and qualitative feedback from the participants. Less than one third of participants were female; however the female participation rate has improved on the following CPDs. On the other hand, 65% of the participants reported that they work in the private sector. When specific questions about agreeableness of the event were asked, the scores were very high. However it is evident that the change in practice is more difficult to achieve. This is consistent with the literature in medical education showing actual change in behaviour or medical practice is hard to achieve

unless the education is emerging from real practice (Davis, Thomson, Oxman and Haynes, 1995).

This latter argument is the major challenge facing CPD organisers – that of helping Family Practitioners change their practice for the benefit of their patients and their practice. The medical literature is rife with evidence of what works and what does not help in this respect. The change in culture required after years of disempowering medical education will take time and considerable leadership in medical education. The support from you is very encouraging in this respect.

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# The Diploma in Family Practice in retrospect

**Prof. Pierre MALLIA**

During my term as President of the Malta College of Family Doctors (MCFD), several Council members including myself conceived the idea of giving our College the prestige of having its own postgraduate diploma. In retrospect one realises that historically this was the first local postgraduate course for Maltese family doctors. The University Master's degree in Family Medicine was still to start and other diplomas and courses had been imported by the MCFD from abroad. Having said that, without the experience and impetus obtained through these 'imported' certificates, the College would not have had the experience and perhaps the motivation to do so.

The College, through past efforts of members of the Council, had offered several diplomas/certificates which the Irish College of General Practitioners offer as distance learning. The first was a Diploma in Therapeutics. This was followed by a Diploma in Preventive Medicine and one in Women's Health, and also a certificate in Diabetes. It was high time that the MCFD should offer its members a Diploma in Family Practice (DFP). Certainly foreign diplomas cost more, and the College had a lot to offer.

Initially there had been some debate on whether to call it a Diploma in Family Health or in Family Medicine (with 'health' being a broader and more philosophical term than 'medicine'), but eventually it was decided to adopt the name 'Diploma in Family Practice'. The DFP consisted of eighteen modules, one module per month and therefore spread over 2005-7. The modules ranged from pure clinical ones, such as cardiovascular and genitourinary medicine, to more 'bread-and-butter' subjects such as office practice, substance abuse, vaccination, ethics, etc. It also looked to the future with some modules such as genetic counselling in primary care. Dr Frank Portelli had kindly offered the conference room with refreshments at St Philip's Hospital as the venue for each module every last weekend of the month.

No less than 45 family doctors applied for the diploma, 27 of whom graduated on the 10th May 2008. One cannot say that there were no problems, this being the College's first such initiative. However the MCFD did its utmost to overcome such problems in order to provide a diploma in local general practice for family doctors who were practicing locally. Its popularity was also

shown through requests for participation from General Practitioners who worked abroad. Unfortunately, not only did the College never offer it by distance learning, but subsequent Councils did not offer the diploma again. This may have been due to the MCFD's need to focus its efforts on the Specialist Training Programme in Family Medicine, the Membership examination (MMCFD) and the International Membership of the RCGP – MRCGP[INT].

The high standard achieved by the MCFD Diploma in Family Practice was eventually awarded the recognition it deserved by the Medical Council of Malta. Moreover, the DFP also obtained support from the RCGP International Development Advisor, Dr Adrian Freeman, who had stated that with a more rigorous assessment process (beyond a reflective diary and an assignment), the diploma could have served as the sole requirement for practicing family doctors to be awarded the MRCGP[INT]. It is a pity that at present only those who undergo the formal specialist training programme can obtain the MRCGP[INT]. Perhaps some kind of assessment by performance can be developed for established family doctors to enable them to acquire the RCGP's International Membership.

The question now is whether the DFP should be offered again. It certainly increases prestige and knowledge, and experience has shown that local family doctors are interested. But there are challenges in implementation: if the College decides to invest in providing it, an organiser needs to be appointed to run it in a professional manner. This could be done by an individual against remuneration, or in collaboration with another educational body with whom costs and profits could be shared. However, the MCFD would do well to take such initiative itself and forestall the possibility of this being taken by another institution.

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# Report on MCFD Assessment Course

**Dr Renzo DE GABRIELE**

The Malta College of Family Doctors has always sought to provide educational courses for its members in order to develop their educational expertise. It has also strived to continually develop the Specialist Training Programme in Family Medicine (STPFM) by investing in training for its members so that there is the necessary expertise in order to enhance the programme. With these two aims in mind, the College decided to organize an Assessment Course for Trainers in Family Medicine.

## **BACKGROUND TO TRAINING SCENARIO IN MALTA**

The STPFM is a three-year programme based in family practice and taught by GP (general practitioner) trainers, while supplemented by attachments with appropriate hospital specialties. At the end of the three year programme, a summative assessment takes place. This is made up of three components - the Applied Knowledge Test, the Clinical Skills Assessment and the Work Based Assessment. An educational portfolio is used to assess the Work Based Assessment.

It is, therefore, very important to provide training to GP trainers in the field of assessment so that they would be able to refine their skills when assessing their trainees. This will also lead to continuous improvement in the level of the training programme in general. For the College, it is also important to provide this training so as to amplify the pool of assessors for the summative assessment.

## **THE PREPARATIONS FOR THE ASSESSMENT COURSE**

It was decided that the format of this Assessment Course would follow that of Assessment Courses that are currently being organized by EURACT (European Academy of Teachers in General Practice and Family Medicine). It was thought that it would be of benefit to follow this format since some local trainers have already been exposed to such a course format. The expertise of EURACT was also desirable in order to have an expert input to this Assessment Course. However, the principle of EURACT courses is also to cascade such courses to different countries and allow different countries to modify course content according to the local scenario and local

needs. Therefore, it was planned that the Assessment Course to be held for our local trainers would be modified in order to better suit our local scenario and cater for our trainer needs. It was also decided to contact Prof. Justin Allen from EURACT to ask him to participate as a foreign faculty member on the proposed Assessment Course in order to provide his expert input to the course. Prof Allen is, in fact, one of the authors of the EURACT Assessment Course and, amongst other things, he is a past president of EURACT and Honorary Professor of Family Medicine at De Montfort University, Leicester, UK. Prof Allen very generously and willingly accepted to come over to Malta in September when the Assessment course would be held to be part of the faculty.

At the beginning of June 2012, the College issued a call for applications for participants to attend this course. A call was also issued for those who were interested to form part of the faculty that would help in the organisation and delivery of the course. As expressed in the call itself, this course was intended for those wishing to improve their knowledge, skills and competence in the field of assessment. The objectives of the course would be:

- To understand the different purposes of assessment
- To understand the theoretical frameworks for assessment, and the terminology used
- To understand the assessment methodology most suited to family medicine
- To develop skills in using the appropriate assessment tools
- To practice their skills in assessment and feedback in a secure learning environment
- To understand the impact of assessment on teaching and learning
- To be able to apply their knowledge and skills in their own context as teachers

There was a very good response to this call for applications. In fact, there were twelve applications and eventually eleven actually underwent the course. All the faculty applicants were chosen and the course faculty that delivered the course was composed of Professor Justin Allen, Dr. Patricia De Gabriele, Dr. Renzo De Gabriele and

Dr. Philip Sciortino. Dr Tania van Avendonk took care of the logistical preparations for delivery of this course. The venue was chosen from a number of suitable venues.

## THE MODULES FOR THE ASSESSMENT COURSE

The faculty then started to work on the modules in order to prepare a course that besides addressing the general principles of assessment, as has been outlined before in the course objectives, would also address the local scenario and our local needs.

EURACT material was shared and then each faculty member took care to prepare the respective modules. The modules that constituted this course were the following:

- Module 1 - Introduction and overview of methods
- Module 2 - Theoretical background of assessment
- Module 3 - Applied Knowledge Test
- Module 4 - Workplace Based Assessment
- Module 5 – The Consultation Observation Tool
- Module 6 - Clinical Skills Assessment

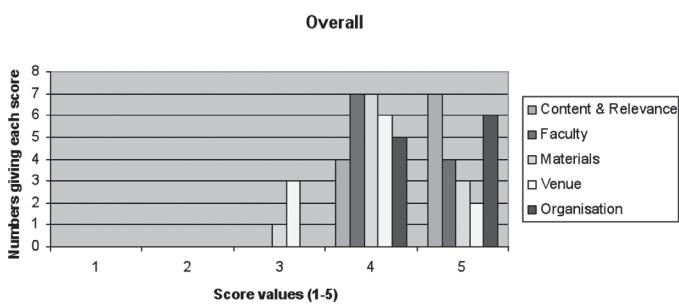
Module 1 and 2 were originally three modules (in the original EURACT Assessment Course) but work was done by Prof Allen on these three modules in order to produce two modules to have a shorter introduction which made the modules more concise and focused. The Workplace Based Assessment module was also modified from the original EURACT module to focus as well on our local workplace based assessment. The Applied Knowledge Test module, the Consultation Observation Tool module, and the Clinical Skills Assessment module were written *de novo* for this course by the local faculty.

The Assessment Course was delivered between the 21<sup>st</sup> and 23<sup>rd</sup> September 2012. In total, this course provided 18 hours of actual study work that involved plenary presentations, small group work and discussion, plenary discussions and feedback. All the participants contributed through their discussion and feedback to a positive learning experience. Many interesting learning points were brought up and, as was demonstrated by the feedback given, the discussions helped the participants in learning more about assessment. Some concrete proposals for improving our Specialist Training Programme were also put forward.

## END OF COURSE EVALUATION

This positive experience, in fact, reflected itself in the feedback that was given by the participants. The participants were asked to rate the whole course in 5 areas. Each area had to be given a score, with 1 being a

Table 1: Participants' feedback on course



low score and 5 being the highest possible score for that area. The results were collated and reported by Prof. Allen (see Table 1).

As regards content and relevance of the course, the mean score was 4.64; Faculty quality, the mean score was 4.36; pre-course material quality, the mean score was 4.18; venue standards, the mean score was 3.91; Course organisation, the mean score was 4.55.

Participants particularly highlighted the benefit of group work, interaction, and group presentations. They also found that analysis of the different assessment tools was particularly helpful. The course content and presentations provided a comprehensive cover of assessment methods. A large percentage of the participants, in fact, expressed their desire to have more time for discussions and suggested that such educational activities are done again in the future.

## CONCLUSION

This Assessment Course was definitely a success and managed to reach the targets that it had set out to reach. This will provide impetus to continue this path of trainer training that will enhance the already high standard of our Specialist Training Programme in Family Medicine.

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# Complementary and alternative medicine: Facts and figures - Part 2

**Dr Odette PACE**

## ABSTRACT

**Background:** The popularity of complementary and alternative medicine (CAM) is evident in both developed and less developed societies. It is perceived as being more natural and having fewer side effects than conventional medicine. Claims for efficacy are often unsubstantiated.

**Objectives:** In this second article, other forms of CAM will be described including herbalism, chiropractic, osteopathy, reflexology and iridology. Proposed mechanisms of action and evidence-based research about their efficacy will be presented, while issues related to safety and regulation will be discussed.

**Method:** Evidence for or against the efficacy of these forms of complementary and alternative medicine was obtained from studies, reviews and meta-analyses researched from various online publications.

**Results:** There is evidence for efficacy of osteopathy and chiropractic in low back pain, but little evidence for efficacy of herbal medicine. No evidence was demonstrated in iridology and reflexology.

**Conclusion:** CAM practices should be researched for efficacy and safety applying the same standards used in conventional medicine.

**Keywords:** Complementary and alternative medicine, herbal medicine, chiropractic, osteopathy, reflexology, iridology, research, safety.

## INTRODUCTION

Complementary and alternative medicine (CAM) is “a group of diverse medical and healthcare systems, practices and products that are not currently part of conventional medicine” (National Center for Complementary and Alternative Medicine, 2011a). Ancient traditional practices like acupuncture share this definition with newly conceived ones, like iridology. Common to most systems is a lack of scientific evidence for efficacy (Kopelman, 2004). As these practices become more widespread, conventional medical practitioners should update their knowledge about different types of

CAM and become aware of potential benefits or adverse effects associated with them. This knowledge will help them educate patients and guide them to make informed choices.

CAM practices can be classified as genuine, experimental or questionable (London, 2001). Genuine alternatives are supported by scientific evidence and exhibit a favourable risk-benefit ratio. Experimental practices are as yet unproven, but are being studied rigorously. Questionable alternative practices have no sound scientific basis and no evidence for efficacy.

Reasons why patients seek out alternative care include: recommendations by “word of mouth” (32%), fear of side effects associated with conventional therapies (21%), chronic medical problems (19%), dissatisfaction with conventional medicine (14%), and desire for more personalized attention (9%) (Eisenberg et al., 1993). CAM is commonly described as being holistic, caring for the patient in all his/her aspects; this more compassionate approach increases its attraction. Being holistic is not the sole provenance of CAM; conventional medicine is striving to become more holistic, especially in the field of family practice (Winnick, 2006).

An article on complementary medicine which has concentrated on acupuncture and homeopathy has already been published (Pace, 2012). This second article will deal with herbalism, chiropractic, osteopathy, reflexology and iridology. The vastness of the subject precludes discussion of all existing CAM practices.

## HERBAL MEDICINE

This is defined as traditional medicinal practice based on the use of plants and plant extracts, also known as phytotherapy (ScienceDaily, 2011). The different chemical compounds that have been produced by plants during the course of evolution e.g. antioxidants, have often been found to have beneficial effects in humans. Like conventional medicines, plant compounds bind to receptor molecules with the same potential for effectiveness and harmful side effects (Tapsell et al., 2006).

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1. Data on file. Alcon Laboratories, Inc. 2. Ketelson HA, Davis J, Meadows DL. Characterization of a novel polymeric artificial tear delivery system. *Invest Ophthalmol Vis Sci*; 2008; 49: E-Abstract 112. (US based study).

It is estimated that 25% of modern pharmaceuticals are derived from plants. Some well-known examples include aspirin, digitalis and quinine. Eighty per cent of the 120 active compounds or phytochemicals widely used in modern medicine show a positive correlation between their current therapeutic use and the way in which they were used traditionally (Fabricant and Farnsworth, 2001).

### **Prevalence of Use**

A 2002 survey carried out on adults in the United States showed that herbal medicine was the most popular CAM therapy (18.9%) excluding prayer (Barnes et al., 2004). Herbal remedies are widely used in Europe, especially in Germany and France (De Smet, 2005).

### **Evidence for Efficacy**

The National Centre for Complementary and Alternative Medicine (NCCAM) in the United States has funded various trials on the efficacy of particular plants but the results have not been very promising (National Centre for Complementary and Alternative Medicine, 2011b). A study carried out to determine the effect of saw palmetto on benign prostatic hypertrophy, found its effect to be comparable to placebo (Barry et al., 2011). Similarly, other studies funded by NCCAM found that ginkgo biloba did not decrease the incidence of dementia or improve memory (DeKosky et al., 2008), and echinacea had no effect in preventing or treating viral colds (O’Neil et al., 2008). Garlic was found to have a modest effect on hypertension but negligible effect on cholesterol levels (Gardner et al., 2007). An independent review of food supplements glucosamine and chondroitin by the Agency for Healthcare Research and Quality was unsuccessful in proving efficacy in osteoarthritis of the knee (Agency for Healthcare Research and Quality, 2007) although trials funded by manufacturers obtained more positive results (Vlad et al., 2007).

In other NCCAM trials, St John’s Wort demonstrated an effect comparable to placebo on mild depression (Rapaport et al., 2011) but was ineffective in moderate depressive illness (Hypericum Depression Trial Study Group, 2002). No proof was found during trials that Evening Primrose Oil is effective for premenstrual syndrome or menopausal symptoms (National Center for Complementary and Alternative Medicine, 2011). More research is needed to determine whether cranberry can help prevent urinary tract infections; it has not been proven effective in the treatment of established infection (Jepson and Craig, 2007).

### **Safety Issues**

“Natural” does not imply “safe”. The belief that herbals are generally safe is based mostly on tradition. Clinical trials of herbals may not have included laboratory monitoring to detect adverse effects, and manufacturers were not required to report severe adverse effects to the Food and Drug Administration (FDA) before December 2007 (U.S. Food and Drug Administration, 2011).

Allergic reactions can occur with commonly used plants like chamomile (National Institutes of Health, 2011). Many plants contain harmful toxins (datura, hemlock), while others can cause dangerous interactions with conventional drugs (e.g. St John’s Wort with warfarin) (Medsafe, 2011). St John’s Wort or garlic can interact with anti-HIV drugs to lower their efficacy (Ladenheim et al., 2008). Herbal medicines can be dangerously contaminated; adulteration by heavy metals and over-the-counter or prescription medications is common, especially in “all-natural” remedies for sexual dysfunction and weight loss (Smolinske, 2005).

Occasionally, serious outcomes have been linked to herb consumption; black cohosh has been implicated in a case of liver failure (Lynch, Folkers and Hutson, 2006). Another identified adverse effect is the nephrotoxicity and carcinogenicity of herbals containing extracts of Aristolochia plants. More than 100 women in Brussels developed nephropathy and consequent renal failure after consuming a herbal weight loss product containing Aristolochia fangchi; almost half developed carcinomas of the urothelial tract (Nortier et al., 2000; Vanherweghem et al., 2003).

In a 2010 survey of 1000 plants, 356 had clinical trials published evaluating their “pharmacological activities and therapeutic applications” while 12% of the plants, although available in the Western market, had “no substantial studies” of their properties (Cravotto et al., 2010). Another issue is lack of quality control of products. Standardization of purity and dosage is not required by law in the United States, as the FDA classifies herbal medicines as “dietary supplements” (Dietary Supplement Health and Education Act, 1994). In the EU, herbal medicines are regulated by the European Directive on Traditional Herbal Medicinal Products (European Commission, 2004).

Proper double-blind clinical trials are needed to determine the safety and efficacy of each plant before it can be recommended for medical use. Without establishing efficacy, useless remedies may be used instead of effective conventional medicines, to the detriment of patient outcomes (Ernst, 2007a).

## **MANIPULATIVE AND BODY BASED THERAPIES**

This group of therapies incorporates chiropractic, osteopathy and massage therapy. The first two will be discussed.

### **CHIROPRACTIC**

This alternative therapy was founded in 1895 by the American Daniel D. Palmer, a former grocer with a belief in vitalism, or “spark of life”. He hypothesized that vertebral “subluxation” interfered with the body’s “innate intelligence” (intrinsic ability to heal itself) and was the root of most diseases (Keating, 2005); this theory is not based on scientific principles. Subluxation in this context does not correspond to vertebral body displacement which can be visualized on X-rays. Manipulation of the spine, joints and soft tissues forms the basis of treatment, together with rehabilitative exercises, complementary procedures, health promotion and lifestyle counselling (Mootz and Shekelle, 1997).

There are two schools of thought in chiropractic: “straights” (minority) adhere to the original Palmer philosophy, while “mixers” (majority) incorporate conventional techniques like exercise and massage, use X-rays and are more open to mainstream views (Murphy et al, 2008; Tyler, 1990). Mixers also advocate use of nutritional supplements, acupuncture, homeopathy and herbal medicine. Chiropractic methods share common features with many other manual-therapy professions, such as massage therapy, osteopathy, physical therapy, and sports medicine.

### **Prevalence of Use**

Chiropractic is very popular in developed countries such as the United States and Canada, where 6-12% of the population makes use of it, mostly sufferers from low back pain or those having neurological or musculoskeletal complaints (Barnes et al., 2004).

### **Evidence for Efficacy**

#### **Low back pain and radiculopathy**

A review carried out in 2008 found strong evidence that spinal manipulation therapy (SMT) is similar in effect to medical care combined with exercise (Bronfort et al, 2008). A 2010 systematic review found that spinal manipulation can achieve equivalent or superior improvement in pain and function when compared with other interventions (Dagenais et al., 2010). In 2011, strong evidence was found that there is no clinically

significant difference between spinal manipulation and other treatments for reducing pain and improving function for chronic low back pain. Further controlled studies were suggested comparing with sham SMT (Rubinstein et al, 2011).

The use of SMT for the treatment of acute lumbar disc herniation with associated radiculopathy is supported by moderate quality evidence (Hahne, Ford and McMeeken, 2010). There is little evidence for chronic cervical and lumbar spine-related extremity symptoms and no evidence exists for the treatment of thoracic radiculopathy (Leininger et al., 2011).

#### **Neck pain (including whiplash)**

Only low level evidence for effectiveness of SMT in neck pain was found in reviews published in 2010 and 2011 (Gross et al., 2010; Cross et al., 2011). Mixed results were obtained for whiplash injury: a 2009 systematic review (Ernst, 2009f) produced no evidence, while low level evidence was found in a review published in 2010 (Shaw et al., 2010).

#### **Headache**

A 2004 Cochrane review found evidence that suggests spinal manipulation may be effective for migraine, tension headache and cervicogenic headache (Bronfort et al., 2004). Two systematic reviews published in 2011 are conflicting, one finding evidence that spinal manipulation might be as effective as propranolol or topiramate in the prevention of migraine headaches (Chaibi, Tuchin and Russell, 2011), the other concluding that evidence does not support the use of SMT (Posadzki and Ernst, 2011). Due to methodological shortcomings present in studies included in the first systematic review, more randomised controlled trials were suggested.

#### **Other conditions**

Very weak or no evidence has been found for a myriad other conditions, among them scoliosis, ADHD/learning disabilities, gastrointestinal disorders and hypertension (Hawk et al., 2007), infant colic (Ernst, 2009a), fibromyalgia (Ernst, 2009b), asthma (Ernst, 2009d), dysmenorrhoea (Proctor et al., 2006) and back pain during pregnancy (Pennick and Young, 2007).

#### **Safety Issues**

Although chiropractic care is generally safe when employed skilfully and appropriately, adverse effects can occur. Absolute contraindications include rheumatoid

arthritis and conditions known to result in unstable joints; osteoporosis is a relative contraindication (World Health Organization (WHO), 2005). Mild temporary worsening of stiffness or pain can occur in up to two thirds of patients (Gouveia, Castanho and Ferreira, 2009). Rarely, spinal manipulation, especially in the cervical region, can result in permanent disability or death (Ernst, 2007b); it has been implicated in vertebrobasilar artery stroke in persons less than 45 years of age (Miley et al., 2008). A review carried out in 2010 concluded that there is a negative risk-benefit balance for cervical spinal manipulation (Ernst, 2010).

Some chiropractors habitually X-ray their patients several times a year, exposing them to unnecessary and harmful ionizing radiation (Singh and Ernst, 2008). There is also a propensity to oppose vaccination (Campbell, Busse and Injeyan, 2000) and water fluoridation (Conser, 2012), a view not shared by all practitioners.

## OSTEOPATHY

Osteopathy was originally conceived in 1874 by Dr Andrew T. Still, from Missouri (University of Maryland Medical Centre, 2011). It is based on the interrelationship between structure and function of the body, with an emphasis on self-healing (American Association of Colleges of Osteopathic Medicine, 2011). Despite initial claims that many diseases including childhood infections, could be cured by manipulation (Barrett, 2003), osteopathy today tends to be more mainstream. However, certain practitioners still carry out osteopathic manipulative treatment (OMT) for asthma (Hondras, Linde and Jones, 2005), otitis media (Mills et al., 2003) and dysmenorrhea (Pirritano, 2004). More controversial are the practices of cranial osteopathy and chelation therapy. In the former, the skull is manipulated to “restore the rhythm of flow of cerebrospinal fluid” to help diagnose and correct diseases. Chelation therapy with ethylenediaminetetraacetic acid (EDTA) is claimed to be effective against various serious conditions including atherosclerosis (Barrett, 2003).

There are two different branches to this discipline: osteopathic medicine is practised by qualified doctors whose degree, Doctor of Osteopathy (D.O.), is equivalent to M.D., while osteopaths are non-physicians who carry out manipulative therapies. In the U.S. only the former are licensed to practise (AOA House of Delegates, 2010). Regulations for registration of osteopaths vary in different E.U. countries.

## Evidence for Efficacy

A 2005 meta-analysis of six randomized controlled trials of OMT in low back pain, concluded that OMT was generally effective for at least three months and this efficacy could not be explained by placebo effects alone (Licciardone, Brimhall and King, 2005).

NCCAM states that most studies have shown that OMT can provide mild to moderate relief from low-back pain, appearing to be at least as effective as conventional medical treatments (Rubinstein et al., 2011). In 2007 guidelines, the American College of Physicians and the American Pain Society included OMT as a recommended treatment option to be considered when pain does not improve with self-care (Chou et al., 2007). Recent research into OMT for low-back pain is looking into different forms of manipulation, as well as treatment duration and frequency; spinal manipulation may provide relief from low-back pain for up to 1 year (NCCAM, 2011c).

## Safety issues

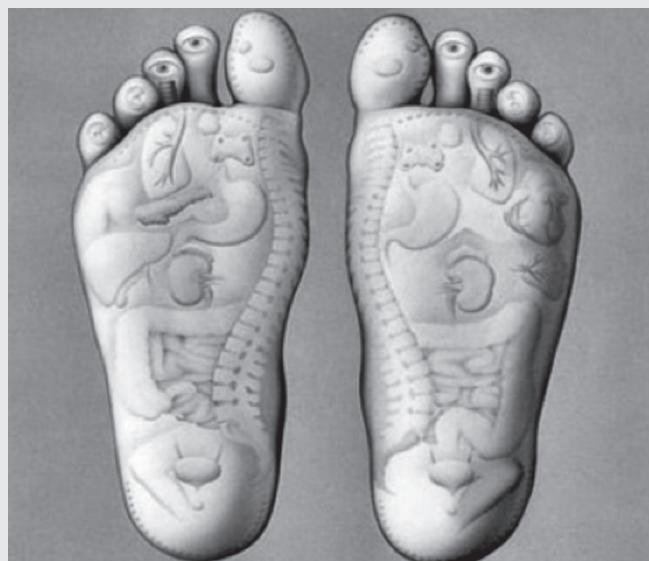
Osteopathy has the same contraindications and potential adverse effects as chiropractic. The commoner adverse effects (25-50% of all patients) are transient: mild pain or discomfort at the site of manipulation, slight headache, and fatigue. More serious potential consequences are rare; stroke and spinal cord injury after cervical manipulation occur in 1 in 20 000 patients to 1 per million procedures (Vickers and Zollman, 1999).

Controversial procedures such as cranial osteopathy and chelation therapies are only carried out by a minority of practitioners; unsubstantiated claims are made that diverse conditions can be cured including Meniere's, hypertension, angina and asthma (Barrett, 2003). As in all CAM practices, delaying diagnosis and treatment of medical conditions by replacing conventional medicine with unproven procedures (opportunity cost) can have serious consequences for patients.

## REFLEXOLOGY

Reflexology, also called zone therapy, is described as a “natural healing art based on the belief that there are reflexes in the feet, hands and ears and their referral areas, which correspond to every part, gland and organ of the body. Through application of pressure... reflexology is claimed to relieve tension, improve circulation and help promote the natural function of the related areas of the body” (Reflexology Association of Canada, 2005) – see Figure 1. The principles of reflexology are shown in Table

**Figure 1:** Foot Reflexology Chart (reproduced by kind permission of Ted Pollard, Health 911, 2012. <http://www.health911.com/reflexology>)



1. Postulated mechanisms of action include obstruction of pain transmission through the dorsal horn of the spinal cord and crushing of lactic acid microcrystals by the application of pressure on the feet (CAM-Cancer, 2012). There is no scientific basis for these claims (Ernst, 2009c).

Reflexology was introduced into the United States in 1913 by William H. Fitzgerald, M.D. (1872-1942), an ear, nose, and throat specialist and modified some 20 years later by Eunice D. Ingham (1889-1974), a nurse and physiotherapist

### Prevalence of Use

Reflexology is very popular in Northern Europe. A 2005 national survey in Denmark showed a 21.4% life-long use and a 6.1% 12 month use (Knowledge and Research Centre for Alternative Medicine, 2011). A Norwegian study done in 2007 showed that 5.6 % of the population had used reflexology within the previous 12 months (National Information Centre for

Complementary and Alternative Medicine, 2011).

### Evidence for Efficacy

A 2009 systematic review of randomised controlled trials concludes that: “The best evidence available to date does not demonstrate convincingly that reflexology is an effective treatment for any medical condition” (Ernst, 2009c).

### Safety Issues

Reflexology has not been demonstrated to affect the course of any illness. Done gently, reflexology may be considered as a form of relaxing foot massage (Stephenson, Weinrich and Tavakoli, 2000), with hardly any documented adverse effects (Ernst et al., 2007). Reflexologists are not qualified to make competent diagnoses (White et al., 2000), making opportunity cost a relevant issue.

### IRIDOLOGY

Iridology (also known as iridodiagnosis) is an alternative practice whose proponents claim that examination of patterns, colours, and other characteristics of the iris can determine a patient’s state of health (LindlahrTake, 2010). Practitioners employ magnifying glasses, cameras or slit-lamps to determine the state of health of individuals by comparing their observations to iris charts: the iris is divided into 80 to 90 zones that are said to correspond to specific parts of the human body (Jensen, 1980) – see Figure 2.

The practice was initiated by Ignaz von Peczely, a 19<sup>th</sup> century Hungarian physician, who reportedly noted similar streaks in the eyes of a man he was treating for a broken leg and the eyes of an owl whose leg he had broken many years before. Iridology became better known in the United States in the 1950s, when Bernard Jensen, an American chiropractor, began giving classes in his own method (Barrett, 2008).

**Table 1:** The Principles of Reflexology (Wills, 1995)

The body is divided into 10 longitudinal zones—five on each side of the body.
Each organ or part of the body is represented on the hands and feet.
The practitioner can diagnose abnormalities by feeling the hands or feet.
Massaging or pressing each area can stimulate the flow of energy, blood, nutrients, and nerve impulses to the corresponding body zone and thereby relieve ailments in that zone.

Figure 2: Iridology chart (reproduced by kind permission of Sarah Burt N.D. [http://www.sarahburtnd.co.uk/iridology\\_3.html](http://www.sarahburtnd.co.uk/iridology_3.html))



## Evidence for Efficacy

No clinical data exists to correlate illness with coinciding visible changes in the iris. The iris may only undergo some pigment changes in the first year of life, and thereafter remains unchanged. In fact, this stability is the foundation of biometric technology which uses specific iris morphology for identification purposes (Chellappa, Tistarelli and Li, 2009).

A study published in the Journal of the American Medical Association showed that three different iridologists were unable to correctly identify kidney disease in photographs of irises and even disagreed with one another. It was concluded that iridology was neither selective nor specific and that the odds of accurate diagnosis were statistically no better than chance (Simon, Worthen and Mitas, 1979).

The British Medical Journal also published a study where a group of five iridologists could not correctly identify which subjects had gall bladder problems and which were the healthy controls (Knipschild, 1988).

## Safety Issues

Iridologists are usually not medical practitioners. Patients put their trust in them for diagnosis, management or prevention of diseases which may or may not be present. Delaying diagnosis or conventional treatment for actual illnesses would jeopardise the safety of patients.

## DISCUSSION

If clients express high satisfaction rates when using CAM, why should its use matter to conventional medical

practitioners? With most CAM practices risks are small and costs can be modest. Is it important whether illness is cured by conventional methods or by placebo? Should we actually promote the use of placebo? There are no easy answers to these questions, especially if patients feel healthier and happier with their alternative choices (Ernst, 2009e). However, it should be kept in mind that an increase in patients' trust and reliance on CAM practices may adversely affect outcomes if conventional therapy is eventually partially or completely replaced (Kruglyakov, 2004). For their own safety, patients should also be made aware of what is scientifically sound and what isn't. Lack of public awareness of scientific methods makes many people unquestioningly accept untested herbal remedies, colonic cleansing and magnetic therapy, but worry about the safety of extensively tested conventional drugs.

Osteopathy and chiropractic have been proven effective in low back pain, beyond placebo effect, making them genuine CAM practices in this regard. Herbal medicine is still classified as experimental (London, 2001). Although phytochemicals with proven efficacy are routinely utilised in many conventional pharmaceuticals, research into many commonly used herbal medicines has mostly produced negative results.

Questionable practices described in this article include reflexology and iridology. These systems have shown no evidence of efficacy and have no scientific basis. Although practices like manipulative and body-based therapies do contain some elements based on scientific principles, they still retain elements of pseudoscience e.g. cranial osteopathy.

Research in CAM is hampered by the fact that rigorous studies require consistent standards which CAM practices often lack. Another factor deterring research, particularly in herbal medicine, is lack of regulation and standardisation; an investigation of the composition of packaged herbal medicines revealed a significant variance in presence of plant extract (WHO, 2004). Many of these products are not patentable, and therefore industry does not invest in research for efficacy or safety levels since this would reduce profits.

Criticism is directed at NCCAM in America about research being carried out on complementary and alternative practices. Some scientists feel that a budget of \$123 million yearly, with hardly any positive results, makes it "politically correct to investigate nonsense" (Barker Bausell, 2007). They feel that this funding should be directed into more deserving projects.

Safety issues have already been highlighted. Besides the presence of opportunity cost where diagnosis and proper treatment are delayed, there is also the issue of safety in children. A study on paediatric vaccination carried out in 2010 found that sole use of CAM leads to lower immunization rates and an increased rate of infectious diseases (Downey et al., 2010). Another study carried out in 2010 presented adverse events in children linked to CAM practices: most were minor e.g. constipation, bleeding and allergies, although the latter 2 can be potentially life-threatening. More serious consequences occurred secondary to failure to use conventional medicines, changes in medication by CAM practitioners or due to dietary restrictions; seizures

and even fatalities were reported (Lim, Cranswick and South, 2010).

In these two articles, not all existing complementary and alternative therapy modalities have been dealt with, the subject being too vast. Other examples of CAM practices not described include massage, yoga, aromatherapy and dietary regimens like the Atkins diet and Blood Type diet.

## CONCLUSION

Scientific research has in many cases failed to provide a strong evidence base for CAM therapies; the majority of claims for efficacy remain unfounded. The positive effects of chiropractic and osteopathic manoeuvres on chronic low back pain were a notable exception; other practices were either disproven or more research is warranted. Safety issues are also an important consideration when dealing with CAM practices.

This subject can create much controversy both in society and even within medical circles. For medical practitioners, the patient's interest should always be a first priority. Keeping this in mind, conventional medical doctors should become knowledgeable about alternative therapeutic options so that they will be in a position to educate and safeguard their patients. This does not mean that doctors should impose their beliefs onto their patients; sensitivity should be exercised especially in the presence of chronic or debilitating illness. Greater awareness of all that CAM practices imply can help improve clinical skills and ameliorate patient outcomes.

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# Dangerous creatures of the Maltese sea: Injuries and treatment - Part 1

**Dr David James SAMMUT**

## ABSTRACT

This article is intended to give information about different organisms which inhabit the Maltese sea and which are potentially harmful. Doctors working in the primary health setup and sometimes also in secondary care are often faced with injuries related to these organisms. The nature of the injury and its treatment is then discussed. Treatment however is not evidenced based as little if any studies have been conducted in this field of medicine. This first of two articles will review the well-known jellyfish stings and other less familiar venomous organisms such as the bristle worm and the sting ray.

## KEY WORDS:

Stings, jellyfish, weever fish, bristle worm, sting rays

## INTRODUCTION

Malta is an archipelago of islands in the centre of the Mediterranean. It is densely populated with many tourists visiting each year, most of them doing activities directly or indirectly related to the sea. It is no wonder that Maltese doctors are often faced with injuries caused by these activities. An important type of injury related to the sea is that caused by dangerous creatures. The most common of these are those caused by jellyfish and weever fish, but these are not the only dangerous animals

which inhabit the sea and are cause of injuries. In this article some of the most common dangerous creatures are described together with the type of injury they inflict and its treatment.

## ORGANISMS AND MECHANISMS OF INJURY

There are more than 300 species of fish which inhabit the central Mediterranean region (Sammut, 2001). To these one has to add the multitude of other species ranging from microscopic organisms to coelenterates and worms. Nature has devised several forms and shapes which have enabled the organisms to survive and evolve. All living creatures have to be able to find or catch food, and to defend themselves against predators and attackers. Man is not spared from these mechanisms and thus is in the same danger of being injured if the marine environment is invaded.

Marine organisms defend themselves by many mechanisms. Sea anemones and jellyfish possess venomous stings which are triggered as soon as the organism is touched, and these cause very painful injuries. Sea urchins possess spines which will penetrate and break into the offending organism. Bristle worms have hairs which contain venom, while weever fish and scorpion fish have venomous spines. The sting ray and eagle ray possess very sharp poisonous barbs in their tail.

**Table 1:** Dangerous creatures divided according to mechanism of injury.

VENOMOUS	BITES	SPINES	ELECTRIC
Anemones	Sharks	Sea urchin	Electric ray
Jellyfish	Moray eel		
Bristle worm	Conger eel		
Greater weever	Barracuda		
Lesser weever			
Scorpion fish			
Sting ray			
Eagle ray			

There are fish such as sharks and the moray eel which possess powerful jaws and/or sharp teeth which will inflict painful bites. The torpedo ray is very peculiar in that it is able to produce electric shocks to stun prey or defend itself. Table 1 gives a list of the organisms which are dangerous together with their weaponry.

Information about the organism together with the injury it inflicts and its treatment will be described. The venomous injuries can all lead to anaphylaxis and shock in rare cases. Obviously, if present, treatment of shock and anaphylaxis should take priority in the management of these injuries. This is beyond the scope of this review and is not dealt with here. It should be pointed out at this stage that treatment of most of the injuries described has little evidence base, as studies are difficult to conduct.

## VENOMOUS ORGANISMS

Part one of this article will discuss the venomous organisms while the other organisms will be discussed in part two. Venomous organisms are divided into four groups for easier discussion:

- The Bristle Worm
- Jelly Fish and Sea Anemones
- Weever Fish and Scorpion Fish
- Sting Ray and Eagle Ray

A short description of the organism is first given followed by the type of injury and its treatment. As marine organisms are cold blooded, excluding the mammals, their venom is thermo labile, i.e. it is deactivated by heat, and so heating the area by immersing it in hot water will minimize the trauma (Auerbach, 1999).

### 1. The Bristle Worm

#### The Organism

The bristle worm (Figure 1, Table 2) is a common bottom-dwelling organism which lives on rocky bottoms.

Figure 1: Bristle Worm / Fireworm



Table 2: Information about the Bristle Worm / Fireworm

Family	Ampinomidae
Scientific name	<i>Hermodice carunculata</i>
English name	Bristle worm / Fireworm
Maltese name	Busuf
Maximum length	30cm
Habitat	Rocky Bottom

It is a scavenger and eats any dead fish or debris which it can find. This worm has a bright red colour with rows of fine white hairs along its sides (Sultana et al., 1995). These venom-containing bristles are fired into any offending organism when it is disturbed or handled.

#### Nature of Injury

Injury often occurs when the worm is touched by bare hands, when curious divers pick up the organism unaware of its danger. Spear fisherman can also get hurt when they accidentally touch the organism while fishing beneath boulders or crevices. The injury is easily prevented by wearing a wet suit or vest which protects against these hairs penetrating the skin. When one touches this worm the hairs stick into the skin and cause intense itching at the site. An instinctive urge to rub the affected area ensues. One should refrain from doing so as this pushes the venom deeper into the skin. If the hairs are seen attached to the skin while diving, it is best to remove them cautiously by grasping them between the thumb and index finger and pulling them out. This greatly reduces the intense stinging pain which follows. This pain lasts for up to four hours after the contact.

#### Treatment

The area should be heated by either pouring or immersing it in hot water. One should be careful not to scald the skin (Auerbach, 1999). After this, the application of ice will numb the area and provide immediate relief. Applying adhesive tape followed by acetic acid (vinegar) or isopropyl alcohol is also advocated (Haines, 2006). Oral analgesia is also helpful. The injury is self limiting and does not lead to infection or scarring.

### 2. Jellyfish and Sea Anemones

#### The Organisms

The jellyfish (Figure 2, Table 3) and the anemones are coelenterates. They possess millions of venom filled nematocysts on their tentacles which fire as soon as anything touches them (Sultana et al., 1995). This is their

Figure 2: Jellyfish

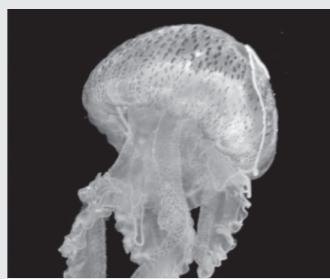


Table 3: Information about the Jellyfish

Family	Polagiidae	Actiniida
Scientific name	Pelagia noctiluca	Anemonia viridis
English name	Common Jellyfish	Sea Anemone
Maltese name	Brama Komuni	Artikla
Maximum length	20cm	15cm
Habitat	Free Swimming	Rocky Shore

mechanism to capture food and to defend themselves.

The jellyfish are free swimming organisms that can occur in large numbers during times of blooming. No one is spared when the sea is full of them. Blooming is a natural phenomenon which occurs in a cyclical fashion. The thick tentacles are not more than 20 cm in length and contain the greater number of nematocysts. The narrow tentacles, which may be more than two meters in length, have fewer nematocysts and thus produce less intense injuries.

The sea anemones are related to the jellyfish but are sedentary. They live on rocky shores in very shallow water. Anemones have much more tentacles which are narrower. The tentacles are coloured yellowish-green and violet and thus often attract the attention of young children who touch them unaware of the danger. Their venom is less potent and so they only cause mild irritation to the victim, if any.

### Nature of Injury

Jellyfish stings are by far the commonest of injuries which will be described in this article. Anyone who goes into the sea during times of blooming can be a victim of them. Injuries occur on any part of the body. Stings are worse where the skin is more sensitive like the flexure areas and the face, and when the thick tentacles are involved. Stings cause an immediate intense, sharp, burning pain at the site. Some people can be at risk of drowning if they panic or have multiple stings on their body. When stings affect the face, especially when somebody dives head first or when scuba divers jump in the water, they can cause difficulty with breathing. Wearing a vest protects against jellyfish stings.

Immediately after the sting there is an intense acute inflammatory response with swelling, redness, pain and warmth of the area which can last for up to a week after the contact. Some doctors wrongly assume this to be an infective process and give antibiotics. However this is rarely the case and the inflammation is a direct reaction to the venom. Intense itching develops after a few days with a scab developing along the scars left by the tentacles. If the scab is scratched it will leave a permanent scar.

A delayed inflammatory reaction may develop in some people, whereby an apparently healed injury starts to itch and blister months after the contact. This is a cell mediated immune response.

### Treatment

A multitude of first aid treatments has been advocated for jellyfish stings ranging from sweeping the area with a credit card, applying vinegar, hot and cold water to the area, and covering it with talcum powder. There is no evidence-based treatment for jellyfish stings, despite them being very common.

First and foremost, one should not do the following actions:

- Do not wash the area with fresh water. Through osmolarity this causes the breakdown of intact nematocysts thus spreading the venom (Drobina, 2008).
- Do not rub the area or apply any creams. Doing so will massage the venom deeper into the skin and spread it further (Drobina, 2008).

The most commonly agreed first aid treatment is the use of vinegar on the area affected. As vinegar has an acidic pH this is said to neutralize the alkaline nature of the venom. Immersing the area in hot water will denature the protein of the venom (Mayo Clinic, 2011). The use of topical anaesthetic sprays used for insect bites also relieve the pain. Applying cold compresses to the site numbs the pain.

If the immediate treatment is very varied and sometimes anecdotal, the further management is even less consensual. Several options are advocated. Analgesics are certainly an option. Antihistamines, especially the sedating type, help to decrease the inflammation and control the itching. Systemic steroids could probably have a role in treatment (Mayo Clinic, 2011). The use of topical treatment is not very effective and can actually make it worse.

The author would like to describe a case which he had treated with a transparent, hydrocellular gel dressing. A four year old girl suffered an extensive injury involving

all her thigh causing intense itching and pain. Covering the area with this dressing greatly reduced the symptoms. The injury healed completely without leaving any scar.

### 3A. The Weever Fish

#### The Organism

The weever fish (Figures 3 and 4, Table 4) are the commonest cause of the more serious venomous injuries. They are thin-bodied fish which live on sandy bottoms, spending most of the time buried in sand waiting for smaller fish or crustaceans to pass nearby. The first three dorsal spines and two spines on the side of the head contain very potent venom which is injected into any offending organism (Sammut, 2001).

There are two species of the weever fish: the lesser and the greater weever fish. The lesser weever grows to a

smaller size and lives in shallower waters, and juveniles may be found even at a few feet of depth. The greater weever lives in deeper waters down to 100m depth. As a result it is the lesser weever which causes most of the injuries as it is caught by amateur fishermen who are unaware of its danger. The greater weever is caught offshore by usually more experienced fishermen who know how to handle this fish with due respect.

#### Nature of Injury

There are two mechanisms by which this fish can provoke an injury. The most common is when the fish is caught and mishandled. Amateur fishermen fishing from the shore or from boats by rod or lines catch this fish and are unaware of its potential danger. While unhooking it, the fish will twist about violently stinging the fisherman on the hands. More rarely the weever fish stings bathers who step on it while swimming in sandy beaches.

After the sharp sting, an intense, excruciating pain is felt rushing from the site of the sting centrally, often described as going towards the heart, as the venom spreads via the blood stream. There is an immediate reactive inflammatory response with swelling, redness, pain and warmth at the site of the sting. If left untreated the area around the sting will form blisters which can become gangrenous. It should be noted at this stage that the venom of the weever fish remains active even after the fish is dead. There have also been accidents occurring to people handling fish which had been frozen for weeks.

To prevent injuring oneself by the weever fish it is best to cut the line to release the fish rather than unhooking it. If the fish is being kept the spines on the back and side of head should be immediately cut off with extreme care once the fish is dead. The spines should be thrown away where nobody can come in contact with them as the venom will remain active.

Figure 3: Greater Weever Fish

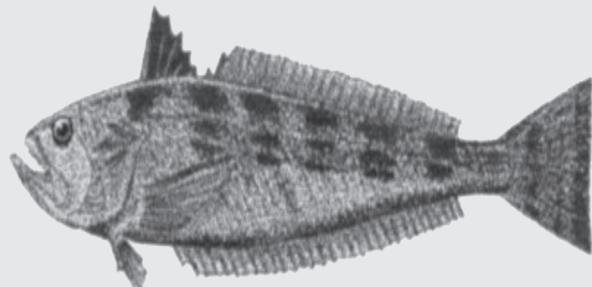


Figure 4: Lesser Weever Fish

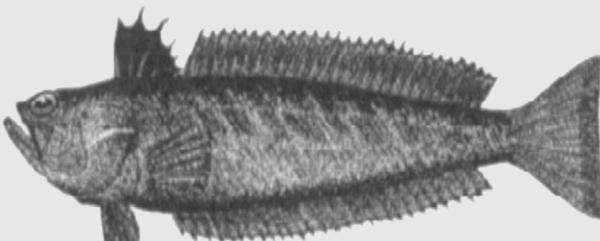


Table 4: Information about the Lesser and Greater Weever Fish

Family	Trachinidae	Trachinidae
Scientific name	<i>Echiichthys vipera</i>	<i>Trachinus draco</i>
English name	Lesser Weever	Greater Weever
Maltese name	Sawt	Tracna
Maximum length	30 cm	50 cm
Habitat	Sandy bottom	Sandy bottom

## Treatment

First aid treatment consists of bleeding the site to minimize the spread of the venom. Heating the area by immersing it in hot water denatures the protein of the venom, further decreasing the pain (Fell, 2012; Gallagher, 2011). However medical care should be sought immediately as a local infiltration of lignocaine acts both as pain relief and as an anti-venom, neutralizing the deleterious effects (Zammit, undated). Tetanus vaccination should be given and antibiotics started if signs of infection commence.

## 3B. Scorpion Fish

### The Organism

The scorpion fish (Figure 5, Table 5) is a bottom dwelling fish which lives in rocky bottoms. There are several species of scorpion fish, the *Scorpaena porcus* being the most common. The scorpion fish have a deeper body with a very large head. These fish live under rocks and crevices in depth ranging from 0.5m to 50m (Sammut, 2001). They are masters of camouflage, waiting immobile for prey to swim past which they then engulf with a sudden snap. Like the weever fish, scorpion fish have venomous spines on the back and sides of the gills. The venom of the scorpion fish is less potent than that of the weaver fish but still causes intense pain and inflammation at the site.

Figure 5: Scorpion Fish

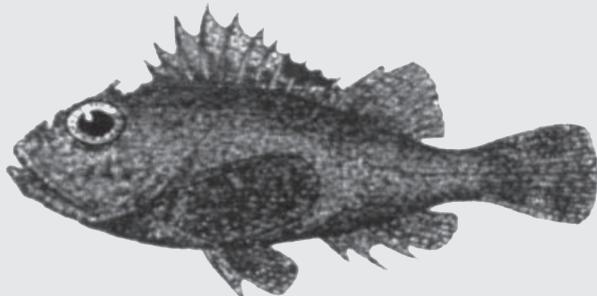


Table 5: Information about the Scorpion Fish

Family	Scorpaenidae
Scientific name	<i>Scorpaena porcus</i>
English name	Scorpion fish
Maltese name	Skorfnna
Maximum length	30cm
Habitat	Rocky Bottom

## Nature of Injury

Injury occurs when the fish is caught and mishandled. Most commonly the injury occurs when the fish is being released from nets. Due to its characteristic large head, deep body and colour it is easily recognizable and less easily confused with other fish. Moreover this fish is less slippery than the weever fish so it is easier to release from hooks. Nonetheless one has to respect this fish and exert the maximum caution while handling it. Caution has to be taken also when the fish is dead, as the venom will remain active even if the fish is frozen. Cutting off the dangerous spines immediately when the fish is dead is recommended.

## Treatment

Treatment is identical to that of injuries by weaver fish. Immersing the area in hot water for about fifteen minutes is the immediate treatment. If pain persists infiltrating the area with lignocaine eases the pain and decreases the complications. Tetanus booster is indicated and any resulting infection should be treated with antibiotics (Zammit, undated; Fell, 2012; Gallagher, 2011).

## 4. Sting Rays and Eagle Rays

### The Organisms

The rays are fish which live on the bottom (Figure 6, Table 6). They are flat with an elongated narrow tail. At the base of the tail the sting and eagle rays possess sharp, pointed venomous barbs which they use as self defence. These fish can bury themselves completely in the sand becoming invisible from above. The common sting ray has a rounded flat shape. The eagle ray has a more kite like shape with a distinct snout and long tail which is very narrow and reaches to double the fish's length (Sammut, 2001). Both are very strong fish capable of swimming gracefully along the sea bed. The eagle ray is more graceful in its movement giving the impression of flying rather than swimming in the sea. It can also be found swimming near the surface in the open water during migration.

Adult specimens of these fish are rare and often found solitary. The common sting ray is the commoner of the two. The adult female gives rise to a litter of about 10 to 15 young rays which are identical to the adult in every way including the potentially dangerous barb. These small rays swim into shallower waters down to few meters in depth to feed and grow. They can often be found in small groups.

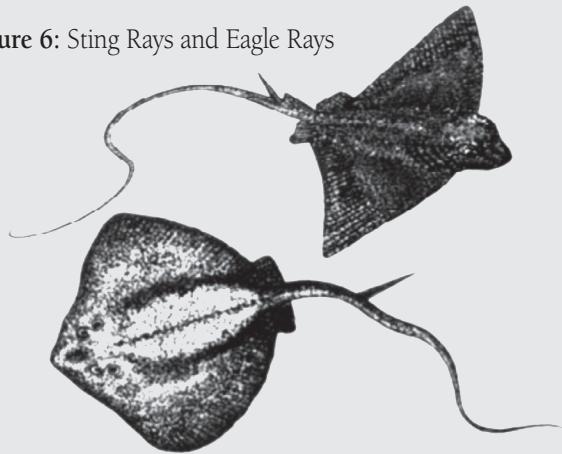
## Nature of Injury

As already mentioned these rays have a very effective means of self defence. When attacked, caught or disturbed they will twist and swirl their tail frantically in an effort to inflict the barb into the aggressor. The barb is extremely

**Table 6:** Information about the Sting Ray and Eagle Ray

Family	Dasyatidae	Myliobatidae
Scientific name	Dasyatis pastinaca	Myliobatis aquila
English name	Common Stingray	Eagle Ray
Maltese name	Boll Komuni	Ajkla, Hammiema Komuni
Maximum length	2.3m x 1.5m	2.0m x 1.2m
Habitat	Sandy/Posedoni	Sandy/Posedonia

**Figure 6:** Sting Rays and Eagle Rays



sharp and will lacerate skin and soft tissues easily. It also contains a potent venom which is injected into the victim often deep into the tissues. The eagle ray also uses its long, narrow tail as a whip, literally whipping its offender.

Most often injury occurs when the fish are caught either with long lines or by spear fishing. The younger sting rays are the commoner culprits because they are often encountered in shallow water and are easily speared. The hands are often the part of the body injured as the fish is being released from the hook or spear. Once the barb penetrates the skin intense pain follows. This may result in hyperventilation, loss of consciousness and rarely fatality. After penetration, extensive inflammation develops at the site which may even lead to areas of gangrene. At a later stage infection may develop.

### Treatment

Emergency treatment consists of stopping the bleeding and of minimizing the damage of the venom. Once again heat denatures the venom but may be difficult to apply because of the open wound which may be quite deep and jagged. The wound should be thoroughly cleaned and cared for. Analgesics are often needed to decrease the pain. Tetanus vaccine should be given and the patient should be prescribed antibiotics (DuBois, 2005).

### CONCLUSION

Knowledge of these creatures and the injuries that they inflict is of essential importance to general practitioners and emergency doctors who need to treat such injuries during their practice.

By understanding the organism, a proper diagnosis can be reached and appropriate treatment started without delay. It should be stressed that some of these injuries may result in shock. This may result either from anaphylaxis or from hypovolaemia through bleeding (especially in severe injuries from rays). Should this be present, treatment of such a complication should take absolute priority.

*Part two of this article will deal with other organisms that may injure humans in diverse and imaginative ways.*

### Acknowledgement

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Prof. Pierre Mallia, Bioethics Research Programme  
Prof. Kevin Aquilina, Dean, Faculty of Laws  
Rev. Prof. Emanuel Agius, Dean Faculty of Theology

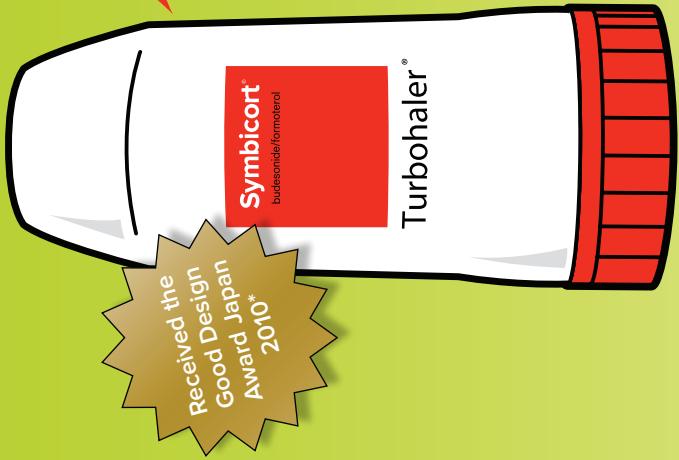
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In case such effects occur, treatment may need to be discontinued. **Hypokalaemia:** Beta<sub>2</sub>-adrenergic agonists may produce significant hypokalaemia in some patients, which has the potential to produce cardiovascular effects. In patients with severe COPD, hypokalaemia may be potentiated by hypoxia and concomitant treatment which may increase the susceptibility to cardiac arrhythmias. **Hyperglycaemia:** Inhalation of high doses of beta<sub>2</sub>-adrenergic agonists may produce increases in plasma glucose. Upon initiation of treatment with Onbrez Breezhaler plasma glucose should be monitored more closely in diabetic patients. During clinical studies, clinically notable changes in blood glucose were generally more frequent by 1-2% on Onbrez Breezhaler at the recommended doses than on placebo. Onbrez Breezhaler has not been investigated in patients with not well controlled diabetes mellitus. **Pregnancy and Lactation:** No data available from the use of indacaterol in pregnant women. Onbrez Breezhaler should only be used during pregnancy if the expected benefits outweigh the potential risks. Not known whether indacaterol / metabolites are excreted in human milk. A decision must be made whether to discontinue breast-feeding or discontinue Onbrez Breezhaler therapy, taking into account the benefit of breast-feeding for the child and the benefit of therapy for the woman. Immediate hypersensitivity reactions have been reported after administration of Onbrez Breezhaler. If signs suggesting allergic reactions (in particular, difficulties in breathing or swallowing, swelling of tongue, lips and face, urticaria, skin rash) occur, Onbrez Breezhaler should be discontinued immediately and alternative therapy instituted. **INTERACTIONS:** Concomitant administration of other sympathomimetic agents may potentiate the undesirable effects of Onbrez Breezhaler. Onbrez Breezhaler should not be used in conjunction with other long-acting beta2-adrenergic agonists or medicinal products containing long-acting beta2-adrenergic agonists. Concomitant hypokalaemic treatment with methylxanthine derivatives, steroids, or non-potassium-sparing diuretics may potentiate the possible hypokalaemic effect of beta2-adrenergic agonists, therefore use with caution. Indacaterol should not be given together with beta-adrenergic blockers (including eye drops) as these may weaken or antagonise the effect of beta2-adrenergic agonists. Where required, cardioselective beta-adrenergic blockers should be preferred, although they should be administered with caution. Inhibition of the key contributors of indacaterol clearance, CYP3A4 and P-gp, does not raise any safety concerns given the safety experience of treatment with Onbrez Breezhaler. Indacaterol has not been shown to cause interactions with co-medications. **ADVERSE REACTIONS:** The most common adverse reactions with Onbrez Breezhaler are: dizziness, nasopharyngitis, upper respiratory tract infection, sinusitis, headache, cough, rhinorrhoea, respiratory tract congestion, muscle spasm, peripheral oedema. Common: Chest Pain, Oropharyngeal pain including throat irritation, Uncommon: Myalgia, Musculoskeletal pain, Pruritis/rash, Paradoxical bronchospasm, tachycardia, palpitations, hypersensitivity, diabetes mellitus and hyperglycaemia, paraesthesia, atrial fibrillation and non-cardiac chest pain, ischaemic heart disease. Please refer to SmPC for a full list of adverse events for Onbrez Breezhaler. **LEGAL CATEGORY:** POM. **PACK SIZES:** Onbrez Breezhaler 150mcg - carton containing 10 or 30 capsules and one Onbrez Breezhaler inhaler. Onbrez Breezhaler 300mcg - carton containing 30 capsules and one Onbrez Breezhaler inhaler. **MARKETING AUTHORISATION HOLDER:** Novartis Europharm Limited, Wimblehurst Road, Horsham, West Sussex, RH12 5AB, United Kingdom. **MARKETING AUTHORISATION NUMBERS:** EU/1/09/593/001, 002, 007. Please refer to Summary of Product Characteristics (SmPC) before prescribing. Full prescribing information is available on request from Novartis Pharma Services Inc, Representative Office Malta P.O Box 124, Valletta, VLT 1000 Malta. Tel: +356 22983217/+35621222872 - 2012-MT-ONB-02-Aug-2012

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1. Cazzola M, Matera MG. Novel long-acting bronchodilators for COPD and asthma. Br J Pharmacol. 2008;155:291-299.  
2. Novartis Europharm Ltd. Onbrez® Breezhaler® Summary of Product Characteristics.

Once Daily  
**onbrez®**  
**breezhaler®**  
indacaterol inhalation powder

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