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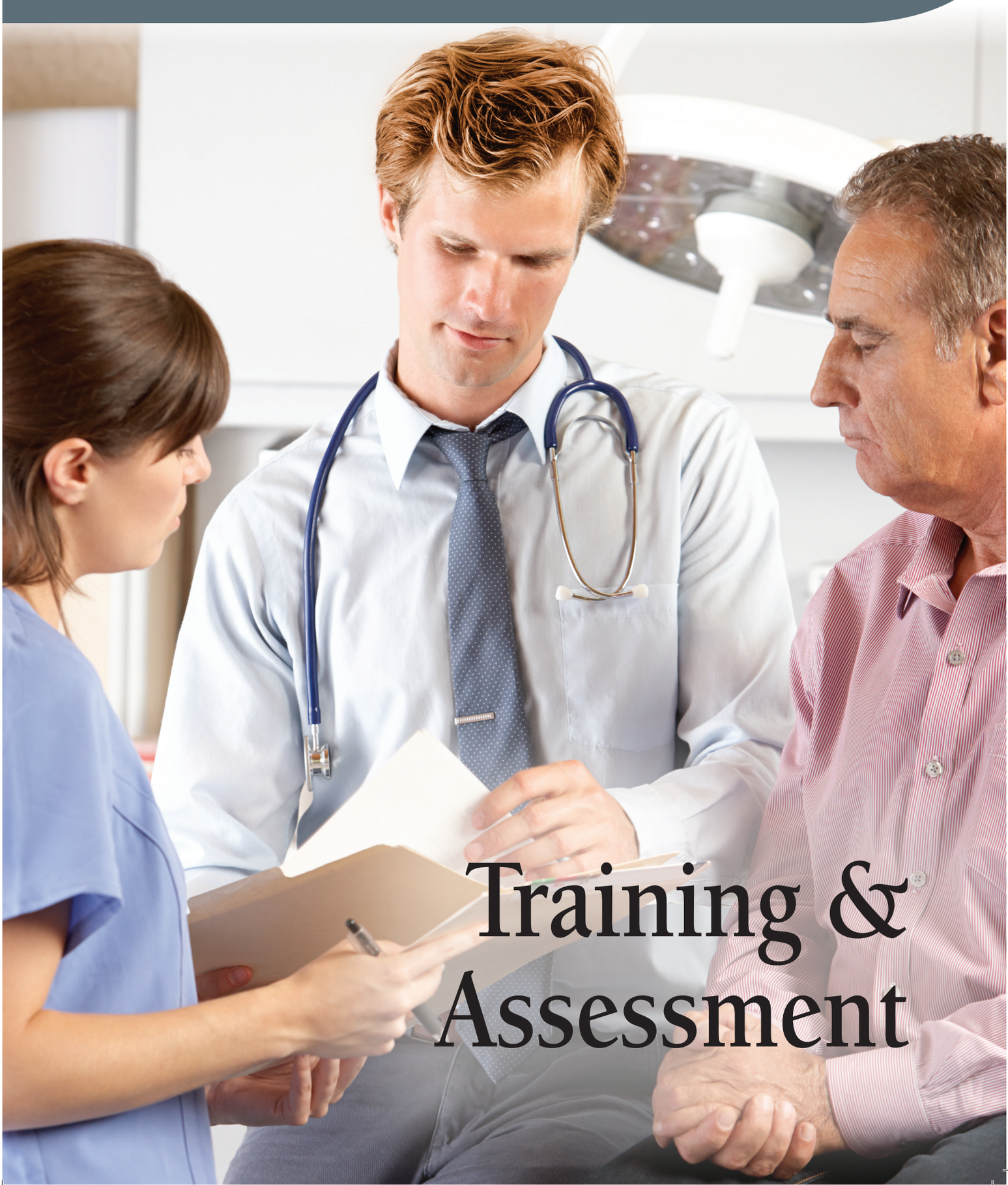

Training & Assessment

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▼This medicinal product is subject to additional monitoring. This will allow quick identification of new safety information. Healthcare professionals are asked to report any suspected adverse reactions. Refer to section 4.8 of the SmPC for how to report adverse reactions. **PRESENTATION:** Each capsule contains 143 µg of indacaterol maleate equivalent to 110 µg of indacaterol and 63 µg of glycopyrronium bromide equivalent to 50 µg of glycopyrronium. Each delivered dose (the dose that leaves the mouthpiece of the inhaler) contains 110 µg of indacaterol maleate equivalent to 85 µg of indacaterol and 54 µg of glycopyrronium bromide equivalent to 43 µg of glycopyrronium. **INDICATIONS:** Ultibro Breezhaler is indicated as a maintenance bronchodilator treatment to relieve symptoms in adult patients with chronic obstructive pulmonary disease (COPD). **DOSAGE AND ADMINISTRATION:** The recommended dose is the inhalation of the content of one capsule once daily using the Ultibro Breezhaler inhaler. Ultibro Breezhaler is recommended to be administered at the same time of the day each day. If a dose is missed, it should be taken as soon as possible on the same day. Patients should be instructed not to take more than one dose in a day. Ultibro Breezhaler can be used at the recommended dose in elderly patients (75 years of age and older). Ultibro Breezhaler can be used at the recommended dose in patients with mild to moderate renal impairment. In patients with severe renal impairment or end-stage renal disease requiring dialysis it should be used only if the expected benefit outweighs the potential risk. Ultibro Breezhaler can be used at the recommended dose in patients with mild and moderate hepatic impairment. There are no data available for the use of Ultibro Breezhaler in patients with severe hepatic impairment, therefore caution should be observed in these patients. There is no relevant use of Ultibro Breezhaler in the paediatric population (under 18 years) in the indication COPD. The safety and efficacy of Ultibro Breezhaler in children have not been established. No data are available. Method of administration For inhalation use only. The capsules must not be swallowed. The capsules must be administered only using the Ultibro Breezhaler inhaler. Patients should be instructed on how to administer the product correctly. Patients who do not experience improvement in breathing should be asked if they are swallowing the medicine rather than inhaling it. **CONTRAINDICATIONS:** Hypersensitivity to the active substance or to any of the other excipients. **WARNINGS/PRECAUTIONS:** Ultibro Breezhaler should not be administered concomitantly with medicinal products containing other long acting beta adrenergic agonists or long acting muscarinic antagonists, the pharmacotherapeutic groups to which the components of Ultibro Breezhaler belong. Asthma: Ultibro Breezhaler should not be used for the treatment of asthma due to the absence of data in this indication. Long acting beta2 adrenergic agonists may increase the risk of asthma related serious adverse events, including asthma related deaths, when used for the treatment of asthma. Not for acute use: Ultibro Breezhaler is not indicated for the treatment of acute episodes of bronchospasm. Hypersensitivity related to indacaterol Immediate hypersensitivity reactions have been reported after administration of indacaterol, one of the components of Ultibro Breezhaler. If signs suggesting allergic reactions (in particular, difficulties in breathing or swallowing, swelling of tongue, lips and face, urticaria, skin rash) occur, treatment should be discontinued immediately and alternative therapy instituted. ***Paradoxical bronchospasm:*** In clinical studies with Ultibro Breezhaler, paradoxical bronchospasm was not observed. However, paradoxical bronchospasm has been observed with other inhalation therapy and can be life threatening. If this occurs, treatment should be discontinued immediately and alternative therapy instituted. *Narrow-angle glaucoma:* No data are available in patients with narrow angle glaucoma, therefore Ultibro Breezhaler should be used with caution in these patients. Patients should be informed about the signs and symptoms of acute narrow angle glaucoma and should be informed to stop using Ultibro Breezhaler should any of these signs or symptoms develop. *Urinary retention:* No data are available in patients with urinary retention, therefore Ultibro Breezhaler should be used with caution in these patients. Patients with severe renal impairment: These patients should be monitored closely for potential adverse reactions. ***Cardiovascular effects:*** Ultibro Breezhaler should be used with caution in patients with cardiovascular disorders (coronary artery disease, acute myocardial infarction, cardiac arrhythmias, hypertension). ***Hypokalaemia:*** Beta2 adrenergic agonists may produce significant hypokalaemia in some patients, which has the potential to produce adverse cardiovascular effects. The decrease in serum potassium is usually transient, not requiring supplementation. In patients with severe COPD, hypokalaemia may be potentiated by hypoxia and concomitant treatment, which may increase the susceptibility to cardiac arrhythmias. Clinically relevant effects of hypokalaemia have not been observed in clinical studies of Ultibro Breezhaler at the recommended therapeutic dose. ***Hyperglycaemia*** Inhalation of high doses of beta$_2$ adrenergic agonists may produce increases in plasma glucose. Upon initiation of treatment with Ultibro Breezhaler plasma glucose should be monitored more closely in diabetic patients. Ultibro Breezhaler should be used with caution in patients with convulsive disorders or thyrotoxicosis, and in patients who are unusually responsive to beta$_2$ adrenergic agonists. Patients with rare hereditary problems of galactose intolerance, the Lapp lactase deficiency or glucose galactose malabsorption should not take this medicine. ***Pregnancy and Lactation:*** There are no data from the use of Ultibro Breezhaler in pregnant women available. Indacaterol may inhibit labour due to a relaxant effect on uterine smooth muscle. Therefore, Ultibro Breezhaler should only be used during pregnancy if the expected benefit to the patient justifies the potential risk to the foetus. It is not known whether indacaterol, glycopyrronium and their metabolites are excreted in human milk. The use of Ultibro Breezhaler by breast feeding women should only be considered if the expected benefit to the woman is greater than any possible risk to the infant. **INTERACTIONS:** Information on the potential for interactions is based on the potential for each of its two components. Beta adrenergic blockers Therefore Ultibro Breezhaler should not be given together with beta adrenergic blockers (including eye drops) unless there are compelling reasons for their use. Where required, cardioselective beta adrenergic blockers should be preferred, although they should be administered with caution. The co administration of Ultibro Breezhaler with other anticholinergic containing medicinal products has not been studied and is therefore not recommended. Concomitant administration of other sympathomimetic agents (alone or as part of combination therapy) may potentiate the adverse events of indacaterol. 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. Inhibition of the key contributors of indacaterol clearance, CYP3A4 and P glycoprotein (P gp), raises the systemic exposure of indacaterol up to two fold. The magnitude of exposure increases due to interactions does not raise any safety concerns given the safety experience of treatment with indacaterol in clinical studies of up to one year at doses up to twice the maximum recommended indacaterol dose. **ADVERSE REACTIONS:** The presentation of the safety profile is based on the experience with Ultibro Breezhaler and the individual components. Ultibro Breezhaler showed similar adverse reactions to the individual components. As it contains indacaterol and glycopyrronium, the type and severity of adverse reactions associated with each of these components may be expected in the combination. The most common adverse reactions with Ultibro Breezhaler are: Upper respiratory tract infections. Common: Pyrexia, chest pain, musculoskeletal pain, dyspepsia, dental Caries, gastroenteritis, cough, oropharyngeal pain including throat irritation, dizziness, headache, nasopharyngitis, urinary tract infections, sinusitis, rhinitis, chest Pain, oropharyngeal pain including throat irritation, Uncommon: Fatigue, peripheral oedema, muscle spasm, myalgia, pain extremity, bladder obstruction and urinary retention, dry mouth, pruritis, rash, glaucoma, myalgia, musculoskeletal pain, pruritis/rash, paradoxical bronchospasm, epistaxis, tachycardia, palpitations, hypersensitivity, diabetes mellitus and hyperglycaemia, insomnia Please refer to SmPC for a full list of adverse events for Ultibro Breezhaler. **LEGAL CATEGORY:** POM **PACK SIZES:** Single pack containing 6x1 or 30x1 hard capsules, together with one inhaler. **MARKETING AUTHORISATION HOLDER:** Novartis Europharm Limited, Wimblehurst Road, Horsham, West Sussex, RH12 5AB, United Kingdom. **MARKETING AUTHORISATION NUMBERS:** EU/1/13/862/001 - EU/1/13/862/003 **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 4, Marsa, MRS 1000 Malta. Tel: +356 +35621222872 2014-MT-ULT-28-MAY-2014

References: 1. Novartis Europharm Ltd. Ultibro® Breezhaler® Summary of Product Characteristics. 2. Vogelmeier CF, Bateman ED, Pallante J, et al. Efficacy and safety of once-daily QVA149 compared with twice-daily salmeterol-fluticasone in patients with chronic obstructive pulmonary disease (ILLUMINATE): a randomised, double-blind, parallel group study. Lancet Respir Med. 2013;1:51-60. 3. Bateman ED, Ferguson GT, Barnes N, et al. Dual bronchodilation with QVA149 versus single bronchodilator therapy: the SHINE study. Eur Respir J 2013; 42(6): 1484-1494 doi: 10.1183/09031936.00200212. Epub 2013 May 30. 4. Wedzicha JA, Decramer M, Ficker JH, et al. Analysis of chronic obstructive pulmonary disease exacerbations with the dual bronchodilator QVA149 compared with glycopyrronium and tiotropium (SPARK): a randomised, double-blind, parallel-group study. Lancet Respir Med. 2013;1:199-209.

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JMCFD
JOURNAL OF THE MALTA COLLEGE OF FAMILY DOCTORS

Journal of the Malta College of Family Doctors

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

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Specialisation and training

Prof Pierre MALLIA

Going through the proceedings of conferences we had organised through the Bioethics Consultative Committee in the past when I was honorary secretary, I came across the conference of 2003 which was about Ethical Issues for Nurses, Midwives and Family Medicine (Mallia, 2003). During that period we were on the eve of becoming a specialty and were working out details on how to qualify for the specialist register. Being president at the time I was also facing a lot of issues with how to deal with skepticism from our colleagues about family medicine becoming a specialty. The College itself was passing through some turbulent times; new organizations were being created and we seemed more divided than ever. I thought that one thing which could bring us together with a common goal in mind was to focus on working for the International Membership of the Royal College of General Practitioners for our members. This would mean that we do not become specialists merely by 'grandfather clause', but we would have something to work for as well. We created a Diploma in Family Practice at the time which was very successful and more than 40 doctors participated for eighteen months and can now use the designation DFP.

There were also other postgraduate courses being offered, from diplomas of the Irish College of General Practitioners to a Masters degree from the University of Ulster. The DFP was the first *Maltese* postgraduate qualification in family practice however and we had to work for its recognition on the Medical Council as well. Being of an island disposition in character, we tend to assume that foreign qualifications are good and somehow, to quote one person at the time, what is done locally is done the 'Maltese way'. It turned out that there was no 'Maltese way' and participants who tried to take short cuts or pleaded for exemption soon found out they could not qualify. It was a serious diploma with eighteen modules - one every month. We received help from both the Royal College of GPs and the Irish College with setting it up to a postgraduate diploma standard.

At the same time we were heading however for the MRCGP(INT.). We were dividing doctors into two groups - those who qualified by the grandfather clause, and those who would be commencing training in family practice. Then I lost the election for a second term as President and things were put on hold for a while but thanks to Presidents and other members, the College continued to work in that direction. Unfortunately the College never got down to obtain the MRCGP(INT.) for members (we are working on it!) but a strong Specialist Training (ST) Programme was offered with the collaboration of the Department of Health. The rest is history. To become a member of the MCFD you now have to do your specialist training and pass the summative and work-based assessments. Through the MMCFD + ST examination you qualify for MRCGP(INT.).

We now boast almost one third of our members as having passed through a true training programme specialising in family medicine. We have about another third who are indeed trainers. In this issue of the JMCFD we look at some of the experiences of those involved in examination and training. Hopefully next year, when we celebrate our 25th anniversary we will continue to produce such articles which I hope to put into a book which can be used to disseminate our philanthropic work towards society.

But the College is not only about Specialist Training and CME. It is an educational body and we need to continue developing training courses. Towards this end, I feel that the council has to relinquish some of its powers and allow duly qualified members to take over some training programmes such as diplomas and certificates. Of course the council must see to standards but we must move away from the idea that only council does the work. Council members are busy with work and my hat goes off to each and every member for the amount of voluntary work that is done. I can only hope that those who have completed ST and obtained MRCGP(INT.) will recognise that doctors of my generation have unrolled the red carpet for them; we have literally contradicted the Maltese expression saying that no-one will ask you to wash your face so that you are better or nicer than he or she. These people did not get MRCGP(INT.) but they have a good feeling in their hearts that as part of their life goals they have made family medicine in Malta better and Malta can now boast of better primary health care not through a system but through a specialist training programme.

Reference

Mallia, P., 2003. Ethical Issues in Maltese General Practice. In Cauchi, M., ed., 2003. Ethical Issues in Practice for Nurses, Midwives and Family Medicine, The Bioethics Consultative Committee, Malta, pp. 121-127.

My experience as a GP Trainer: some reflections

Dr Jason J. BONNICI

INTRODUCTION

Some friends of mine who are teachers, possibly in off-hand moments of cynicism, say that "if you do not know what to do, you should become a teacher". Meaning, I take it, that as a teacher you are to say what should be done rather than have to do it yourself. Of course this is not the holistic picture as teaching is a vocation and there is much, much more to it. And it is so much, much further from the reality of GP Training! Not least of all because a GP Trainer continues to do the "bread and butter" consultations of everyday general practice/family medicine in the clinic while taking on the hat of a GP Trainer.

REWARDS

For me, what comes out most with GP Training is that it is professionally and personally very rewarding. The GP who is a trainer benefits as a GP because s/he keeps abreast of what is going on in the specialty, uses communication skills to bring this knowledge and a variable degree of experience across to the GP trainee, and endeavors to fill in lacunae in skills and/or knowledge. The GP Trainer benefits as a person because one of the essences of teaching is that a teacher gets to know him/herself. But it is not the GP Trainer only who benefits. It is also the whole practice that benefits, be it as a solo GP but possibly even more so within a group practice. This is the result of a regular injection of enthusiasm and input of new ideas and new ways of doing things that GP Trainees bring.

ASSESSMENT PROCESSES

The Specialist Training Program in Family Medicine has been ongoing for a number of years now, and another number of years have gone beforehand onto its making.

The backbone remains the GP Trainee's formative and summative assessments. The GP Trainer develops and/or acquires through courses the tutorial skills and the steps in the cycle of reflection, the problem-based video consultation / case-based discussion skills and the steps in analyzing them, the assessment of performance and the skills to tackle issues of a GP Trainee in difficulty, and consultation skills teaching. The possibility to involve oneself in small group teaching as when a number of GP Trainees are allocated to a group practice and even more during the teaching sessions of the Half-Day Release Course is an experience on its own, different in many ways to the regular one-to-one teaching.

There is nothing mystic about the assessment process (although I remember myself taking a deep breath in when I first saw the whole lot): there are various useful tools to make sure that both the GP Trainer and the GP Trainee get the most from the assessments. Based on the assessments and feedback, the GP Trainer and the GP Trainee can produce education plans which challenge the GP Trainer and interest and enthuse the GP Trainee, while making sure that the road ahead is in the right direction to successfully sit for the GP Licensing Examination that confers the Certificate of Completion in Specialist Training. The satisfaction is there when the GP Trainee gets the MRCGP(Int). The glee in the eyes of a GP Trainer is there when the GP Trainee graduates in the yearly graduation ceremony organized by the Malta College of Family Doctors and is officially welcomed into the community of general practitioners/family doctors.

CHANGES, PAST AND FUTURE

Despite its infancy, the role of the GP Trainer has seen its changes. The GP Trainer accommodates the changes in the curriculum of GP Training, has had to learn to use the various evolving tools employed in workplace-based assessment, has recently had to come to grips with the e-portfolio and has to abide by a substantial number of deadlines for satisfactory completion of training.

And further change is the catalyst for possible future improvement. I look forward to the coming of training practices, where a group practice provides training for GP Trainees, medical students and foundation doctors according to national standards of training. I look forward to the coming of a support structure so that once a GP Trainer has completed a trainers' course, the GP Trainer will be followed up in the development of a the skills and competencies as a GP teacher. I look forward to a structure of continued professional development that provides workshops where GP Trainers can share ideas and gain support from others, both new trainers and those with more experience.

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The Applied Knowledge Test – theory and practice

Dr Marco GRECH

ABSTRACT

The Applied Knowledge Test (AKT) forms part of the summative assessment for the Membership of the Malta College of Family Doctors (MMCFD). Candidates who are successful in the summative assessment and who have successfully finished the Specialist Training Programme in Family Medicine are awarded the MMCFD and the MRCGP[Int] on the basis of a tripartite agreement in place between the Government of Malta, the Malta College of Family Doctors and the Royal College of General Practitioners. This article looks at the local setup of the AKT. It explains the whole process from item writing, to piloting, blueprinting and standard setting. The article also attempts to explore the theory behind the AKT that underpins it as a reliable, valid, educational, cost-effective and acceptable mode of assessment within Miller's pyramid of clinical competence.

Keywords

Applied knowledge test, assessment

INTRODUCTION

The Applied Knowledge Test (AKT) forms part of the summative assessment for the Membership of the Malta College of Family Doctors (MMCFD). The overall purpose of this final summative assessment is to assess the competence of general practice (GP) trainees who have finished or are in the last six months of the Specialist Training Programme in Family Medicine (STPFM). Having achieved this level of competence, candidates are awarded the Membership of the Malta College of Family Doctors. This, together with the certification of completion of training, enables the candidates to apply to the Specialist Accreditation Committee for listing as Specialists in Family Medicine. It also enables candidates to be awarded with Membership of the Royal College of General Practitioners (MRCGP [Int]) according to a tripartite agreement currently in place between the Government of Malta, the Royal College of General Practitioners (RCGP) and the MCFD.

THE APPLIED KNOWLEDGE TEST

The AKT is a 3-hour 200 multi-choice question examination aimed at testing the application of knowledge in the context of Maltese Family Medicine. There are no true-or-false questions and therefore negative marking is not applied. The AKT attempts to assess both clinical and non-clinical aspects of family medicine, with assessment of medicine related to general practice such as general medicine & surgery, medical specialties (e.g. dermatology, psychiatry, geriatrics), surgical specialties (e.g. ENT, ophthalmology), women's health and paediatrics. Critical appraisal and research methodology related questions are also included. Each question is intended to explore a topic about which an ordinary general practitioner (GP) in Malta is expected to have a working knowledge.

The questions in the AKT are designed to assess knowledge about evidence-based current best practice rather than local practices. Questions are written by a group of practising local GPs who are offered training in AKT writing by the MCFD. These writers bind themselves by a confidentiality agreement. All test items in the AKT are based on the MCFD Curriculum blueprint. All questions have to be referenced. This facilitates the verification of answers and the updating of the questions in the future. After an initial feedback by the AKT lead, all questions are peer reviewed within the AKT writers' group and refined as necessary. Renowned reference sites are used when writing questions. These include the National Institute for Health and Care Excellence (NICE) and Scottish Intercollegiate Guidelines Network (SIGN) guidelines, the British Medical Journal (BMJ), the British Journal of General Practice (BJGP), Medline, and the British National Formulary (BNF). Use is also made of a number of online resources such as the RCGP Essential Knowledge Updates, BMJ Learning, and the Clinical Knowledge Summaries (now clarity.com). Following this process, questions are stored in a bank ready for selection and inclusion in an exam paper.

Questions in the AKT take one of two forms: the Single Best Answer (SBA) or the Extended Matching Question (EMQ). In SBA questions, a stem presents a clinical scenario or a factual statement. This is then followed by a list of five possible options. Only one option can be chosen and the candidate will have to decide on the "most appropriate answer". (Elfes, 2011)

An Extended Matching Question is a selected response item in which the item stem has been extended, usually, to a short clinical vignette or scenario and the choices have been extended to include all potentially acceptable ones for the clinical problem or issue that is being addressed by the item (Jolly, 2014). Pictures may form part of either of the two types of question.

All GP Trainees who

- have successfully completed the three-year Specialist Training Programme in Family Medicine (STPFM),
- will be completing the three-year STPFM programme within 6 months from the date of the examination, or
- have failed previous sittings of the AKT component as stipulated by the regulations

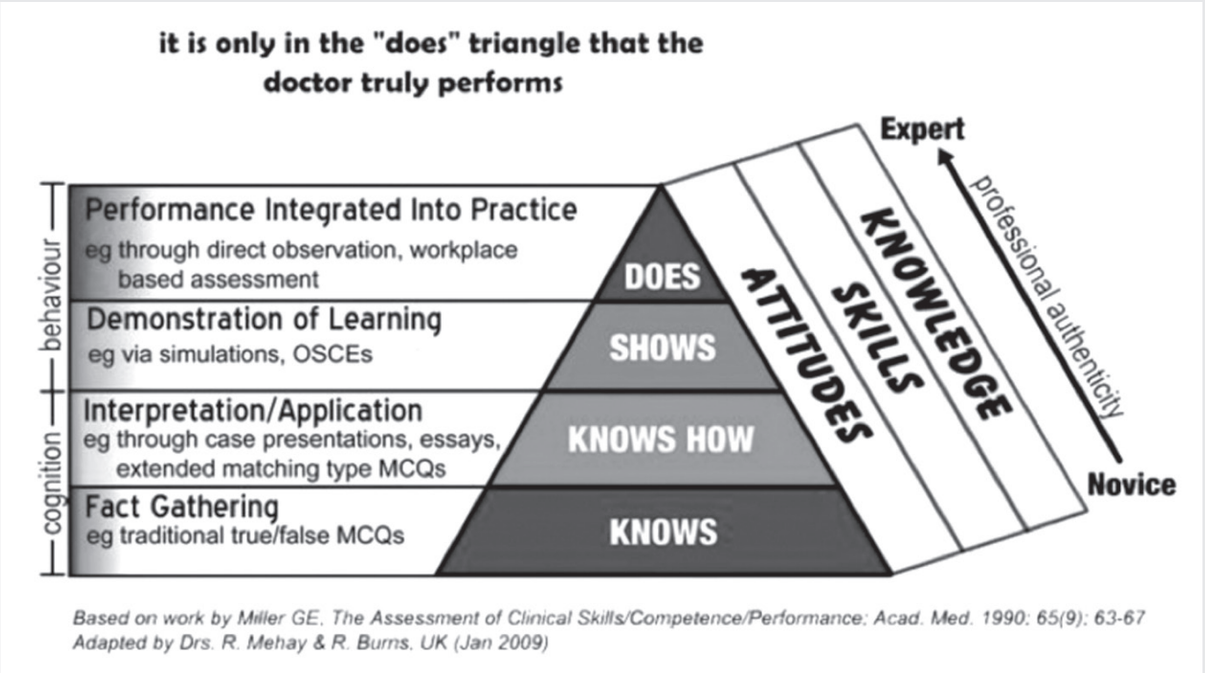
are eligible to sit for the AKT and Clinical Skills Assessment (CSA) components of the MMCFD examination. (Malta College of Family Doctors, 2013)

The examination is usually held at the Malta Medical School. The whole process is monitored by the MCFD's Quality Assurance officials. This ensures transparency and that the correct procedure (e.g. that the paper is sealed before being opened) is being followed throughout.

Standard setting involves the definition of a clear standard below which a trainee GP would not be deemed fit to practice independently (Wass et al., 2001). Such a standard is set locally using the Angoff method wherein a group of 9 practising GPs, comprising a healthy mix of experienced and newly qualified GPs, come up with the cut-off point after analyzing every question in the AKT paper in detail. These GPs are reminded in every session that the established cut-off point would identify the "minimally competent GP". Essentially this group is asked to individually rate the probability of a borderline candidate passing an individual question in the test. Any wide variations are resolved after discussion within the group. This is a very laborious process which takes a number of sessions but is essential in producing a fair outcome for all parties. The Angoff group sessions are held before the sealed papers from the AKT exam are corrected, thereby eliminating the possibility of the introduction of bias in the standard setting procedure.

The correction of the paper is done by hand using answer sheet templates after the Angoff procedure has

Figure 1: Miller's prism of clinical competence (aka Miller's Pyramid)



been finalised. Each paper is corrected by two separate examiners and any discrepancies in the marks awarded by the two examiners are reviewed by a third examiner. Both the standard-setting Angoff group sessions and the correction of the papers are closely monitored by the College's Quality Assurance officials.

The pass mark is then set using the cut-off score that is the product of the Angoff process and the Standard Error of Measurement that is a statistical function of the set of scores obtained by the candidates in the AKT examination.

THE THEORY OF ASSESSMENT AND THE AKT

Assessment drives learning (Wass et al., 2001). Formative assessment is used to promote learning. The feedback received by trainees during their training should be aimed to build their knowledge and skills. Assessment needs also to have a summative function. It is only thus that a doctor can be certified as being fit to practise, thereby satisfying the demand by the profession and the public for assurance that doctors are competent.

The AKT aims to assess the application of knowledge, not just the recall of knowledge, in a wide variety of scenarios. This would correspond to the "knows how" level in the Miller's Prism of Clinical Competence (see Figure 1) (Wass et al., 2001). The other components of assessment leading to the MMCFD cover other levels of this pyramid. The Clinical Skills Assessment covers the "shows how" level, whereas the Workplace-Based Assessment covers the "does" level of competency.

In his seminal work, van der Vleuten (Van der Vleuten, 1996) looks at the characteristics of a good assessment system. Van der Vleuten suggested that reliability, validity, educational impact, cost effectiveness and acceptability are to be considered in the construction of an assessment system.

Reliability

Reliability refers to the reproducibility or the consistency of a test. (Wass et al, 2001). It indicates the ability of a test to be replicated under the same conditions. Reliability can be seen as the ratio between subject variance (what we are trying to measure in an exam) and the subject + error variance. The reliability coefficient measures what percentage of the variance is due to true differences between candidates and what percentage is due to error (General Medical Council, 2010). It can therefore be improved by increasing the variance between candidates relative to error variance. Cronbach alpha is the most widely used reliability measure. The coefficient gives a value between 0 and 1; the latter value would reflect the perfect test. A cut-off of 0.8 is traditionally taken as a benchmark of reliability. All assessments have an inherent element of error which can never be removed completely, though much can be done to reduce this level of error to the minimum possible e.g. by eliminating ambiguous questions and by intensive examiner training (Tighe et al., 2010).

One can also calculate the effect of any error that remains. The Standard Error of Measurement (SEM) provides the confidence interval around the pass mark. The smaller the SEM, the more accurate is the assessment that is being made. Some have suggested that the SEM is a more appropriate measure of quality for postgraduate medical assessments than reliability (Tighe et al., 2010). This is because the reliability coefficient can be artificially inflated by having a greater number of very weak or very strong candidates sit for the exam. This will increase the standard deviation and as a result the reliability will apparently be higher. When examinations have a very small number of candidates the risk that reliability is distorted by an unusually high, or low, spread of candidate ability is greater. The SEM's main use is in the proper identification of borderline candidates – those whom the examination has not been able to confidently place on one side or the other of the pass mark (Postgraduate Medical Education and Training Board, 2007 cited in Tighe et al., 2010). A low SEM would indicate a higher accuracy achieved in the classification of the cut-off point.

Validity

Validity is defined as the extent to which the competence that the assessment claims to measure is actually being measured (Schuwirth and van der Vleuten, 2006). Two main types of validity are considered: content validity and construct validity.

The *content validity* in the AKT relates to whether the assessment covers the whole spectrum of what has to be tested, which in the local scenario is the Curriculum of the MCFD. It is the role of the Assessment Team to ensure that the AKT paper covers the whole blueprint of the curriculum. As assessment drives learning (Eraut, 2004 and van der Vleuten and Schuwirth, 2005) this wide representation of the blueprint conveys an educational message to the trainees of what is needed to master the test.

A *construct* is defined as a personalised psychological characteristic that cannot be observed directly but which

is assumed to exist (Schuwirth and van der Vleuten, 2006). So in construct validity (also known as indirect validity) we are trying to assess whether the assessment scores align with our expectations about the type of competence we are trying to assess. Therefore, in a medical problem-solving test with a good construct validity one would expect that people who solve problems more expertly to outperform those who are less good problem-solvers (Schuwirth and van der Vleuten, 2006).

Other types of validity exist and are sometimes referred to. Perhaps in the future more impressive evidence for the AKT will emerge from studies, which to date are not available, about the extent to which the AKT predicts later performance. (Metcalfe, 2012)

Educational impact

Evidence shows that assessment has a major impact on students' study behaviour (Jolly, 2014). The content, format, scheduling and regulatory structure of assessments can have a positive or negative effect on the intrinsic and extrinsic motivation for learning of trainees (Schuwirth and van der Vleuten, 2006). Some summarise this as "students don't do what you expect, students do what you inspect". Therefore assessment can be used to influence the students' learning in several ways. Having the questions tied to the curriculum blueprint helps ensure that candidates read about a variety of subjects during their studies. Studies may be needed to assess the candidates' reading behaviour when preparing for the AKTs and how this compares to the reading behaviour adopted when preparing for the CSAs, for example.

To be eligible to sit for the AKT in Malta, the GP trainees would have to have finished, or are in the last six months of, the Specialist Training Programme in Family Medicine. One session per calendar year is held locally. This contrasts with the possibility in the UK of GP trainees sitting for the exam in one of three sittings throughout the last two years of training, thereby having the facility to choose the ideal time to sit for the examination (Metcalfe, 2012). It is evident that the MCFD lacks the resources to organise this any time soon. One hopes that the capacity-building exercise being encouraged by the current MCFD Council bears fruit in this respect as well.

Cost effectiveness

The cost effectiveness of an assessment is a compromise between the information gained and the resources required (van der Vleuten, 1996). The cost for the candidate to sit for the MCFD AKT exam in 2014 was set at €500. Costs incurred in running the exam include remuneration of writers, examiners, invigilators, members of the Angoff group and members of faculty, together with printing, secretarial services and other minor sundry expenses.

A difficulty arises in assessing the cost-effectiveness of the AKT exam in isolation. One would rather look at it as part of the whole MCFD exam considering that some of the costs are shared. However it is generally accepted that an MCQ examination is considered as one of the most cost-effective and reliable examinations to assess the "know" and "knows how" levels on the Miller's pyramid (Metcalfe, 2012).

Locally, the examination delivery and correction is still paper-based. Other centres administering similar examinations have switched to computer-based technology (Metcalfe, 2012). The introduction of such technology could introduce a number of advantages such as:

- a reduction in human resources needed, e.g. examiners, invigilators;
- improved efficacy in the marking and analysis of the examination;
- a reduction in the human error possibility, e.g. while correcting;
- feedback for individual candidates and for the whole cohort become easier and quicker.

On the other hand the introduction of such technology might create some disadvantages such as:

- the introduction of bias between candidates on the basis of their technological abilities;
- higher design costs;
- costs of hardware and networks and the maintenance thereof (Metcalfe, 2012);
- the reduction in cost-effectiveness caused by the limited number of local candidates.

Acceptability

Van der Vleuten proposes that the beliefs, opinions, and attitudes of both examiners and examinees must be considered in choosing and designing assessments in order to ensure that there is no threat to the survival of the assessment (Postgraduate Medical Education and Training Board, 2008).

No studies have been conducted locally to assess the acceptability of AKTs to examiners. However it is well known that the AKT process is lengthy, requiring

time to research questions which will then need modification, peer-reviewing, re-modification after reviewing, categorisation before inclusion in the bank and standard setting. Questions also need to be continually updated with the latest guidelines. Item analysis after the exam is also another time-consuming exercise in which all items in the exam are analysed for discrimination and improved as necessary.

On the other hand, evaluation among candidates indicates a general widespread acceptability of the AKT exam. After the 3-hour examination, the candidates dedicate quite some time to fill in the evaluation form. This shows their high degree of interest and appreciation of the exam process as a whole.

The organisational and logistical aspects of the examination process were all highly rated. A marked improvement has also been noted lately regarding the candidates' satisfaction with the quality of the picture booklet – all candidates scored Likert 4 or 5. There was a mixed (but mostly positive) response about the spread of AKT questions as reflecting the breadth and reality of family practice in Malta. Despite all candidates finishing on time, a small minority of candidates felt that not enough time was allocated or considered the paper unfair. (Malta College of Family Doctors – AKT Exam 2014)

CONCLUSION

The strength of the MCFD assessment programme stems from combination of the formative assessment in the Work-Place Based Assessment (which promotes continuous learning through continuous feedback) and the use of different summative assessment methods each assessing different competencies in the commonly described educational theory model of Miller's pyramid. This triangulation helps increase the usefulness of AKTs in assessment as part of a complete picture of the performance of the trainees. (van der Vleuten and Schuwirth, 2005)

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EDUCATION ARTICLE

Work-Based Assessment within Malta's Specialist Training Programme in Family Medicine

Dr Mario R SAMMUT, Dr Günther ABELA

ABSTRACT

The Specialist Training Programme in Family Medicine (STPFM) – Malta was drawn up by the Malta College of Family Doctors in 2006, approved by Malta's Specialist Accreditation Committee, and launched in 2007 by the Primary Health Care Department and the Malta College of Family Doctors. This article regarding the work-based assessment of specialist training in family medicine in Malta was prepared by consulting various local / international documents and publications that are related to general practice / family medicine and its teaching, appraisal and assessment. Assessment of family doctors should consider their actual performance of different tasks in diverse settings of daily practice; this is carried out on-site by direct observation of the practitioner at the work-place (work-based assessment) using different methods.

To successfully complete Malta's STPFM, a GP trainee needs to pass the summative assessment, consisting of an applied knowledge test, a clinical skills assessment and a work-based assessment (WBA). The latter is carried out through an annual appraisal of an educational portfolio, which also provides formative assessment. WBA undergoes quality management to verify the areas where consolidation is needed and identify other areas where corrective actions are required. While the annual appraisal process has shown that significant quality work is being carried out by the GP trainees under their trainers' supervision, further collaboration between the stakeholders involved would further improve the quality of specialist training in family medicine in general and of WBA in particular.

KEY WORDS

Education, specialisation, family practice, work-based assessment, Malta

INTRODUCTION

After the Specialist Training Programme in Family Medicine (STPFM) – Malta was drawn up by the Malta College of Family Doctors in 2006 (Sammut et al., 2006) and approved by Malta's Specialist Accreditation Committee, the programme was launched in Malta on the 9th July 2007 by the Primary Health Care Department (PHCD) and the Malta College of Family Doctors (MCFD).

The three-year programme consists of designated training posts, divided fifty-fifty between family practice and hospital placements, which are supervised by GP trainers and hospital consultants respectively. These work placements are complemented by weekly 4-hour academic group activities within a Half-Day Release Course (HDRC) (Sammut and Abela, 2012).

BACKGROUND

General practitioners / specialists in family medicine (GPs) were defined by WONCA Europe (the European Society of General Practice/ Family Medicine) in 2002 as 'specialist physicians trained in the principles of the discipline.They are personal doctors, primarily responsible for the provision of comprehensive and continuing care to every individual seeking medical care irrespective of age, sex and illness. They care for individuals in the context of their family, their community, and their culture, always respecting the autonomy of their patients. They recognise they will also have a professional responsibility to their community' (WONCA Europe, 2005).

In the EURACT Educational Agenda of General Practice / Family Medicine issued in 2005, EURACT (the European Academy of Teachers in General Practice / Family Medicine) stated that the assessment of the knowledge, attitudes and skills required by family doctors to provide such primary care management requires

diverse assessment methods. These include knowledge-based tests such as MCQs, tests of competence such as exams with simulated patients, assessment of attitudes through observation (e.g. sitting-in, video recordings), and assessment of performance in daily work using repeated checklists and global ratings. (Heyrman, 2005). The latter (work-based assessment) targets what occurs in practice, or the 'does' level at the top of a pyramid devised by Miller to assess clinical competence, with the lower levels ('knows', 'knows how' and 'shows how') being measured in an artificial environment (Norcini, 2003).

In 2014 EURACT published the EURACT Performance Agenda of General Practice / Family Medicine to 'close the loop between teaching knowledge, allowing students and trainees to gain competencies, and assessing actual performance of GPs in daily practice … applicable to various tasks and in a wide range of settings'. Such assessment of the whole picture of performance should be carried out on-site by direct observation of the practitioner at the work-place (work-based assessment) using a palette of different methods. (Wilm, 2014)

WORK-BASED ASSESSMENT

For a GP trainee to successfully complete Malta's STPFM, s/he needs to pass the Summative Assessment, consisting of an Applied Knowledge Test (AKT), a Clinical Skills Assessment (CSA) and a Work-Based Assessment (WBA). WBA is carried out through an Annual Appraisal of the Educational Portfolio, which was developed also as a means for the trainees to undergo continuous Formative Assessment. The latter comprises end-of-placement reports from the GP trainer and other-speciality clinical supervisors, multi-source feedback from healthcare professionals and consultation satisfaction questionnaires from patients. While the MCFD is responsible for the AKT and CSA, WBA is coordinated by the Postgraduate Training Coordinators in Family Medicine. (Sammut et al., 2011; Sammut and Abela, 2012)

EDUCATIONAL PORTFOLIO

The GP Trainee Educational Portfolio (popularly known as the logbook) was developed in 2007 for the use of trainees within the STPFM to record learning experiences throughout training, together with the results of various assessments, both formative and summative. While summative assessment is crucial to the certification of completion of training, formative assessment acts as a stimulus to further learning. As explained in the introduction to the Yorkshire Deanery Log Book (Yorkshire Deanery Department for NHS Postgraduate Medical and Dental Education, 2003), the portfolio provides GP Trainees with the opportunity to record "personal gaps" and then, either by themselves, with their trainers or in groups of peers, to set about "plugging the gaps". (Specialist Training Programme in Family Medicine – Malta, 2012)

The Educational Portfolio comprises a number of sections as follows:

- The Learning Record, comprising the educational agreement, trainee self-rating scale, educational plans, tutorial programmes, video analyses in family medicine using the consultation observation tool (COT), and case-based discussions (CBD) of selected cases in family medicine.
- The Formative Assessment, made up of trainee interim reviews by GP trainer, other-speciality clinical supervisor's reports of GP trainee, multi-source feedbacks (MSF): 360° team assessment of behaviour (TAB), and consultation satisfaction questionnaires (CSQ).
- Educational Activities, including teaching and learning within the HDRC, HDRC attendance record, European Resuscitation Council Basic / Automated External Defibrillator (AED) & Advanced Life Support certificates, certificates of attendance to other educational activities, teaching and learning through other educational activities, and any papers published by the trainee.
- Clinical Experience, consisting of logs of cases seen during various attachments, clinical diary for reflective practice, significant event analyses (SEA), emergencies / referrals / acute admissions, child health surveillance at well baby clinics, direct observation of procedural skills (DOPS) and minor surgical procedures.
- Clinical Experience gained in the Accident & Emergency Department, such as managing acute conditions, interpretation of data and performing procedures.
- Trainee's Evaluations of family medicine and other-speciality posts.

(Specialist Training Programme in Family Medicine – Malta, 2012)

Alongside the paper-based portfolio, a web-based electronic portfolio (ePortfolio) was developed for Malta's STPFM by NHS Education for Scotland and soft-launched in October 2013 at **www.nhseportfolios.org**. The ePortfolio is currently being utilised by the

2013-intake GP trainees as part of the User Acceptance Testing (UAT). GP trainees who started training before 2013 continued to use the paper-based format of the portfolio in order to avoid disruption to their training. (Sammut & Abela, 2013a)

ANNUAL APPRAISAL

Appraisal has been defined as 'a process to provide feedback on doctors' performance, chart their continuing professional development, and identify their developmental needs', with educational appraisal described as 'a process, which involves a trainee and an education supervisor, which is personal and reviews progress and plans future training' (NHS Appraisal, 2003).

An annual appraisal of trainees was mandated to be part of the process leading to the award of the Certificate of Specialist Training by Malta's Ministry of Health, the Elderly and Community Care in MHEC Circular 26/2008 dated 22nd January 2008. As a result, '**The GP Trainee's Annual Appraisal**' document was compiled by the training coordinators and the MCFD with the involvement of all stakeholders and approved on 25th November 2008. (Specialist Training Programme in Family Medicine – Malta, 2014)

The annual appraisal process involves the GP trainee and his/her trainer going through the GP Trainee Educational Portfolio to review the progress of the former during the training year in question, while making plans for future training. After they jointly complete and sign the 'One-to-One Appraisal' section of the appraisal report, the training coordinators then review the trainee's One-to-One Appraisal and Educational Portfolio according to a list of objective requirements listed on the form 'Review of the GP Trainee Educational Portfolio'. A satisfactory review results in a recommendation for the trainee to progress to the next year of the programme or in certification (for a third year GP trainee) that s/he has completed the final-year appraisal and the educational portfolio. The Annual Appraisal document also specifies the procedures that need to be followed in cases of unsatisfactory review, namely the request for remedial actions and the involvement as needed of a Progress Review Board and an Appeals Board. (Specialist Training Programme in Family Medicine – Malta, 2014)

In the '**One-to-One Appraisal**', the following twelve competency areas are assessed by the GP trainer as 'needs further development', 'competent' or 'excellent':

1. Communication and consultation skills;
2. Practising holistically;
3. Data gathering & interpretation;
4. Making a diagnosis / making decisions;
5. Clinical management;
6. Managing medical complexity;
7. Primary care administration & Information Management Technology (IMT);
8. Working with colleagues and in teams;
9. Community orientation;
10. Maintaining performance, learning and teaching;
11. Maintaining an ethical approach to practice;
12. Fitness to practice.

(Specialist Training Programme in Family Medicine – Malta, 2014)

The **GP Trainee Educational Portfolio** is reviewed by the postgraduate training coordinators for the following objective requirements:

1. One-to-One Appraisal.
2. Learning Record: the Educational Agreement signed by the trainee and trainer; the GP Trainee Self-Rating Scale; an Educational Plan per placement as agreed by the trainee and trainer/ supervisor; the lists of weekly one-to-one tutorials undertaken by the trainer/trainee and monthly tutorials given in the other speciality placements; four video analyses (using the Consultation Observation Tool - COT) and four Case-Based Discussions (CBDs) per attachment in family medicine (including one mandatory COT and CBD done with another contracted trainer per full-time family medicine placement).
3. Formative Assessment: one trainee interim review by GP trainer per GP post; one report on GP trainee from each hospital clinical supervisor; a set of Multi-Source Feedback questionnaires per full-time post in family medicine (completed by each member of the GP trainee's team); and a set of 10 Consultation Satisfaction Questionnaires per full-time post in family medicine (completed by 10 consecutive adult patients).
4. Educational Activities: record of Half Day Release Course (HDRC) sessions attended (minimum attendance rate of 85%); proof of participation in the delivery of at least one HDRC session in the 3rd year of training; and Basic / Advanced Life Support Certificates.

Table 1: Overview of the Annual Appraisals carried out and evaluated since 2010

Period	Annual Appraisals carried out	Unsatisfactory report	Referred for Remedial Actions by Coordinators (as from 2012)	Referred to In-Programme Appeals Board (Progress Review Board as from 2012)
July 2010 – January 2011	19	5 (26%)	NA	5
February – December 2011	22	6 (27%)	NA	6
January – December 2012	29	13 (45%)	8	5
January 2013 – March 2014	32	8 (25%)	8	0

NA – not applicable

5. Clinical Experience: child health surveillance in well baby clinics; and Direct Observation of Procedural Skills (DOPS).
6. Evaluation of Posts: trainee's evaluations of each hospital and family medicine post.

(Specialist Training Programme in Family Medicine – Malta, 2014)

QUALITY MANAGEMENT

WBA undergoes quality management by the postgraduate training coordinators who regularly monitor feedback received after each placement and carry out any corrective actions that are necessary (Sammut and Abela, 2012). Moreover, a comparison of the trainees' evaluations of the first (2007-8) and fifth (2011-2) years of the training programme was carried out to identify areas where consolidation was needed (Sammut & Abela, 2013b). The study found that placements in family practice were generally deemed very satisfactory, noted an improvement in the overall satisfaction with the hospital placements, and made recommendations to further improve the educational value of training both in family practice and in hospital. The latter included:

- For training in state primary care: arrangements for the GP trainer and trainee to work together in the same clinic.
- For hospital training: the availability of a named clinical supervisor for each trainee in all specialities; the ability to see patients independently and then discussing them with the supervisor; the provision of daily placements that are more GP-relevant and community-oriented; and the continuing enhancement of clinical and formal teaching tailored to the needs of the GP trainee. (Sammut & Abela, 2013b)

The postgraduate training coordinators in family medicine also publish a yearly 'Quality Assurance Report' based on their review of the educational portfolios of the GP trainees as part of the annual appraisal process (Abela & Sammut, 2014). The aim of this report is to analyse the annual appraisal processes, with the objectives of verifying the areas where the WBA is functioning properly within the STPFM as well as to outline other areas which need further development. The production of this annual 'Quality Assurance Report' was suggested in a 2010 report issued by the External Development Advisers of the UK's Royal College of General Practitioners. (Abela & Sammut, 2014)

While the latest report of the annual appraisal processes undertaken during January 2013 to March 2014 highlights a number of good practice points, certain recommendations were made as follows:

- The One-to-One Appraisal: Although the coordinators do provide appropriate feedback regarding the discrimination of score allocation within the 'One-to-One Appraisal' report when meeting each trainee and his/her trainer following the annual appraisal, trainers need regular Continued Professional Development (CPD) training in formative / work-based assessment to improve the proper completion of this report.

- The Educational Portfolio: Not only should the trainees review the work logged in their educational portfolio at least once a week in order to keep on track, but the trainers too should review regularly the portfolio with the trainees to ensure that it reaches the required standard and to inform the completion of the Trainee Interim Reviews by GP Trainer and the One-to-One Appraisal. Moreover the trainees and trainers should properly follow instructions when completing the required forms, and the GP trainers should remember to cross-refer between successive interim reviews and between interim reviews and the annual one-to-one appraisal. (Abela & Sammut, 2014)

Table 1 provides an overview of the Annual Appraisals carried out and evaluated since 2010 in the four quality assurance reports drawn up by the training coordinators to date. It is to be noted that, as from 2012, the facility was introduced for the coordinators to request remedial actions for problems that were not of sufficient severity to require a referral to the Progress Review Board (previously all problems were brought before an In-Programme Appeals Board). In 2013, for the first time since the start of the annual appraisal process, none of the trainees required referral for board review, with all those who had an unsatisfactory annual appraisal report only requiring remedial actions (Abela & Sammut, 2014).

CONCLUSION

A significant amount of quality work is being carried out by the GP trainees under their trainers' supervision as highlighted by the review of the annual appraisal process carried out by the training coordinators (Abela & Sammut, 2014). It is augured that the current collaboration of the coordinators with the MCFD and other stakeholders is maintained in order to further improve the quality of specialist training in family medicine provided in general and of WBA in particular.

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REVIEW ARTICLE

Attention Deficit Hyperactivity Disorder – an overview

Dr Christine GALEA, Dr Christopher SCIBERRAS, Dr Marthese GALEA

ABSTRACT

Attention Deficit Hyperactivity Disorder (ADHD) is a neurobehavioural disorder found more commonly, but not exclusively, in school-age children. The hallmarks of the condition are inattention and hyperactivity/impulsivity, which often go together. Although the term ADHD was coined relatively recently, ADHD has in fact been described as early as 1902. This review article will go through the most important historical aspects of the condition, and will also give an account of what is known about the aetiology of ADHD. The diagnostic criteria issued by the American Psychiatric Association in DSM-5, have been last updated in May 2013. This article will highlight the differences between DSM-5 and the previous version, DSM-IV-TR, and will also touch upon the latest developments in electroencephalography-based investigations and imaging studies for ADHD. Although the condition cannot be cured, symptoms can be managed using various modalities such as behaviour intervention strategies and medication, such that the individual affected by ADHD can have the least possible disruption to social and academic functioning.

ABBREVIATIONS

ADHD – Attention Deficit Hyperactivity Disorder
DSM-5 – Diagnostic and Statistical Manual of Mental Disorders, 5th Edition
CDC – Centers for Disease Control and Prevention (US)
FDA – Food and Drug Administration

INTRODUCTION

Attention Deficit Hyperactivity Disorder (ADHD) is characterized by inattention, hyperactivity and impulsivity. It is a common and widely studied neurobehavioural disorder in school age children (Desmond, 2011). Some leading figures in the ADHD field have questioned whether ADHD, as it is being diagnosed today, actually does exist or whether it has become convenient to merely attribute behavioural difficulties to ADHD, resulting in overdiagnosis and inappropriate treatment of children.

HISTORY

The recognition of ADHD as a neurobehavioural disorder goes back over one hundred years, although the term ADHD was only coined in 1987. In 1902, Sir George Frederick Still (1868-1941) published a paper in *The Lancet* entitled, 'Some abnormal psychical conditions in children: the Goulstonian lectures'. He described 43 children who he had come across in his practice, who displayed behavioural features that could today be attributed to ADHD, such as poor attention, difficulty with self-regulation, emotional lability, disinhibited behaviour and normal cognitive functioning. Still chose to call this constellation of features, 'Disorders of Moral Control'.

In 1917, the Romanian psychiatrist and neurologist, Constantin von Economo (1876-1931) described the encephalitis epidemic that was rampant between 1915 and 1926 mainly in Europe and North America. This atypical form of encephalitis was known as encephalitis lethargica or Von Economo disease. Adult survivors often developed a parkinsonian-like post-encephalitic phase, sometimes after a latent period of several years, while children tended to develop behavioural difficulties, including overactivity, impulsivity and poor coordination (Arnold, 1995; Wender, 1995). This was called minimal brain dysfunction-like behaviour. Von Economo also described the histology and showed that encephalitis lethargica mainly affected the dopamine-rich areas of the brain, often with autoantibodies against human basal ganglia antigens. Nowadays, it is widely known and accepted that the dopamine pathway is affected in ADHD sufferers (Dawei et al., 2006).

In 1923, Franklin G. Ebaugh, an American physician, published a paper in the *American Journal of Diseases of Children* entitled 'Neuropsychiatric sequelae of acute epidemic encephalitis in children'. Ebaugh was the

first to realise that ADHD could be the result of brain injury in children who had no prior behavioural issues (Spencer, 2007).

In 1937, Charles Bradley (1902-1979), a Rhode Island paediatrician, made an unexpected discovery when he realised that children who had behavioural difficulties and poor academic performance, showed a marked improvement when given benzedrine, a stimulant. At the time, Bradley was carrying out diagnostic procedures called pneumoencephalographies, where most of the patient's cerebrospinal fluid (CSF) was drained to be replaced by air or helium, thereby obtaining a clearer X-ray image of the brain. Benzedrine was administered so as to increase CSF production and reduce the severe headaches that were so common after this procedure. In 1936, benzedrine was FDA-approved as treatment for ADHD symptoms (CDC, 2014).

EPIDEMIOLOGY AND AETIOLOGY

The American Psychiatric Association reports that 5% of children have ADHD (APA, DSM-5, 2013). However, the CDC data obtained from the National Survey of Children's Health which has been carried out every 4 years from 2003, quotes a much higher figure of around 11% of children aged 4-17 years. The diagnosis is on the increase, 5% per year increase over the period 2003–2011. It is more common in boys (13.2% in boys, 5.6% in girls), with an average age at diagnosis of 7 years (CDC, 2013). Approximately half of all children with ADHD go on to have symptoms in adulthood. The National Resource Centre on AD/HD (2014), quotes a prevalence rate of ADHD in adults in the United States, of 4.4%.

It is widely accepted that ADHD is a neurobiologic disorder primarily affecting the dopamine and noradrenaline pathways in the brain (Medscape Pediatrics, n.d.), with a strong genetic influence (Ross, 2012). There is a 50% concordance in first degree relatives. Several other factors have been attributed to the aetiology of ADHD, especially antenatal complications, prematurity and low birth weight, as well as tobacco smoking and alcohol consumption by the mother during pregnancy. Postnatal injury to the prefrontal areas of the brain has also been implicated (CDC, 2014). It is thought that azo dyes, a type of synthetic food colouring, may have an impact on ADHD behaviours, probably by causing zinc deficiency and, thereby, interfering with the processes that eliminate mercury from the body (Dufault, 2009). To this effect, in July 2008, the European Union ruled that as of July 2010, apart from the relevant E number for the particular azo dye, the product must clearly display the phrase 'may have an adverse effect on activity and attention in children' (McBurney, 2011). Studies show no cause-effect relationship between sucrose ingestion and ADHD (Benton, 2008). However, an important point of consideration is that the sugar that is found ubiquitously in processed foods, particularly sweets and sugary drinks, is not sucrose but high fructose corn syrup (HFCS), and therefore, one can only conclude that a high-sucrose diet, not a high-sugar diet, does not cause ADHD. HFCS is often contaminated with mercury while it is produced, and further studies are needed to determine whether ingestion of HFCS is associated with ADHD (Dufault, 2009).

Exposure to heavy metals from the diet, particularly in the prenatal period and in the first few years of life, has an impact on ADHD. High body lead levels have long been known to cause neurobehavioral problems. Mercury exists in two main forms – the inorganic form that is found mainly in soil and water, and the organomercurials. The earliest evidence that mercury is toxic to humans dates from the 1950s-1960s when mercury-containing industrial effluent from acetaldehyde production, was discharged into Minimata Bay, Japan. The result was that people who consumed fish and seafood caught from the bay in question, developed neurological and developmental disorders. Methylmercury is an organic type of mercury that is concentrated in the aquatic food chain. Current FDA recommendations for pregnant women are to eat no more than two portions (12 ounces or 340g) of fish or seafood per week, and to choose fish that is relatively low in mercury, such as salmon, shrimp, pollock, canned light tuna and catfish. Due to their high mercury levels, shark, swordfish, king mackerel and tilefish should be avoided in pregnancy, so as to reduce exposure of the foetus to the heavy metal (FDA, 2004).

Ethylmercury is another type of organic mercury, which however, appears to be less toxic to humans because it is metabolized and excreted differently to methylmercury. The main way in which humans are exposed to ethylmercury is through thiomersal, a preservative used first in the 1930s in biological products and some vaccines, but is now being phased out (FDA, 2014). Thiomersal is still used in some multi-dose vials of inactivated influenza vaccine, but these are not imported in Malta and Gozo. As a result, all vaccines that are administered to children and pregnant women locally, are thiomersal-free or have a trace amount of thiomersal (<1microgram of mercury per dose).

An interesting study that looked at the effects of mercury (from seafood) and lead (from gunshot pellets in birds and animals that are hunted for food) in Arctic Canada, showed that prenatal methylmercury exposure was linked to ADHD symptoms later in childhood, and that even a low lead level in childhood, is associated with ADHD (Boucher et al., 2012).

DIAGNOSIS

The fifth edition of the Diagnostic and Statistical Manual of Mental Disorders (DSM-5), was issued by the American Psychiatric Association on 18th May 2013 (APA, DSM-5, 2013). This replaced the previous DSM-IV-TR version. Table 1 highlights the changes in DSM-5 as compared to the previous edition. DSM uses the term ADHD, which is then subclassified into three presentations. The World Health Organization's (WHO) International Statistical Classification of Diseases and Related Health Problems, 10th revision (ICD-10), in use since 1992, uses the term Hyperkinetic Disorder (HKD), with ADHD listed as a subcategory. ICD-10 will be superseded by ICD-11 in 2017. The DSM-5 criteria cater for adolescents and adults who have ADHD symptoms, which were not necessarily present in early childhood.

The diagnosis of ADHD is made by obtaining a detailed history from the parents, caregivers and teachers, and from the adolescent or adult patient. Behaviour rating scales, of which there are several available, are the main tools used to diagnose ADHD. Conners Rating scale, perhaps the most well known and widely used system, was devised by Carmen Keith Conners, a clinical psychologist who set up the ADHD program at Duke University, USA. This behaviour rating scale is currently in its third edition, Conners 3™, to reflect

Table 1: ADHD diagnostic criteria, main differences between DSM-IV-TR and DSM-5

DSM-IV-TR (2000) **Criteria now obsolete**	**DSM-5 (2013)** **Criteria currently in use**
ADHD listed under Disruptive Behavior Disorders	ADHD listed under Neurodevelopmental Disorders
9 inattentive & 9 hyperactive-impulsive behaviours listed	
	examples given of behaviours expected in older child/ adolescent
6 symptoms needed to make a diagnosis	
	only 5 symptoms needed to make a diagnosis in >17 years & adults
symptoms which are not in-keeping with child's developmental level, present for 6 months or longer	
symptoms must be present and cause impairment by 7 years of age	symptoms must be present, but not necessarily cause impairment, by 12 years of age
symptoms cause some impairment in at least 2 settings	several symptoms present in two or more settings
'clinically significant impairment in social, academic or occupational functioning'	'clear evidence that the symptoms interfere with, or reduce the quality of, social, academic, or occupational functioning'
3 subtypes: Predominantly Inattentive Type Predominantly Hyperactive-Impulsive Type Combined Type	3 presentations: Predominantly Inattentive Presentation Predominantly Hyperactive-Impulsive Presentation Combined Presentation Can change from one to the other
If symptoms no longer fulfill diagnostic criteria, specify in 'Partial Remission'	
	ADHD diagnosis made as mild, moderate or severe
ADHD cannot be diagnosed with Autistic Spectrum Disorder	Recognizes that ADHD can coexist with Autistic Spectrum Disorder

the new DSM-5 criteria (Conners, 2013). Perhaps the major flaw of such a behaviour rating scale, which is in the form of a questionnaire that requires the person to rate the particular behaviour on a score from 1-5, is its subjectivity. A physical examination, including a vision and hearing test should be done to exclude other conditions. Body lead levels are only indicated if the history is suggestive of a high lead exposure.

Imaging studies, including single-photon emission computed tomography (SPECT), positron emission tomography (PET), and functional magnetic resonance imaging (fMRI), have shown that there is about a 3 year delay in brain maturation and some differences in brain activity in children with ADHD when compared to controls (Watson, 2013). SPECT, a costly procedure, which uses an injectable radioactive substance to measure blood flow and brain activity, is not yet FDA-approved for ADHD diagnosis. In July 2013, FDA approved the first brain imaging test for ADHD diagnosis in patients of 6-17 years of age. This Neuropsychiatric EEG-Based Assessment Aid (NEBA) System is a 15 minute EEG-based test which measures the theta-beta ratio of brain waves emitted (FDA, 2013). This ratio is known to be higher in individuals with ADHD as compared to controls. The procedure, pioneered by Howard Merry, has come under criticism because of the way FDA approved the test based only on Merry's study of 275 individuals, and also because of the cost involved to carry out this test (Brauser, 2014). NEBA is not a stand-alone diagnostic test for ADHD, but should be used in conjunction with the standard behaviour rating scales and fulfilment of DSM-5 criteria. It remains to be seen whether NEBA is useful in distinguishing ADHD from bipolar disorder in adolescents, a distinction that can be very difficult to make accurately.

It is imperative that a diagnosis of ADHD is made accurately by stringent use of the DSM 5 criteria. Otherwise, we run the risk of overdiagnosing and overtreating patients. Some leading figures in the ADHD field have questioned whether ADHD really does exist. To cite one example, reference is made to an opinion piece that was published on *Time* on 14th March 2014 by Dr Richard Saul, a fellow with the American Academy of Paediatrics and an associate fellow of the American Academy of Neurology. 'I've come to believe based on decades of treating patients that ADHD — as currently defined by the Diagnostic and Statistical Manual of Mental Disorders (DSM) and as understood in the public imagination — does not exist' (Saul, 2014).

MANAGEMENT

Apart from the use of medications, the management of ADHD involves behavioural intervention strategies and educating the family on how to deal with the condition. It also has implications on schooling - some children with ADHD may benefit from the help of a Learning Support Assistant.

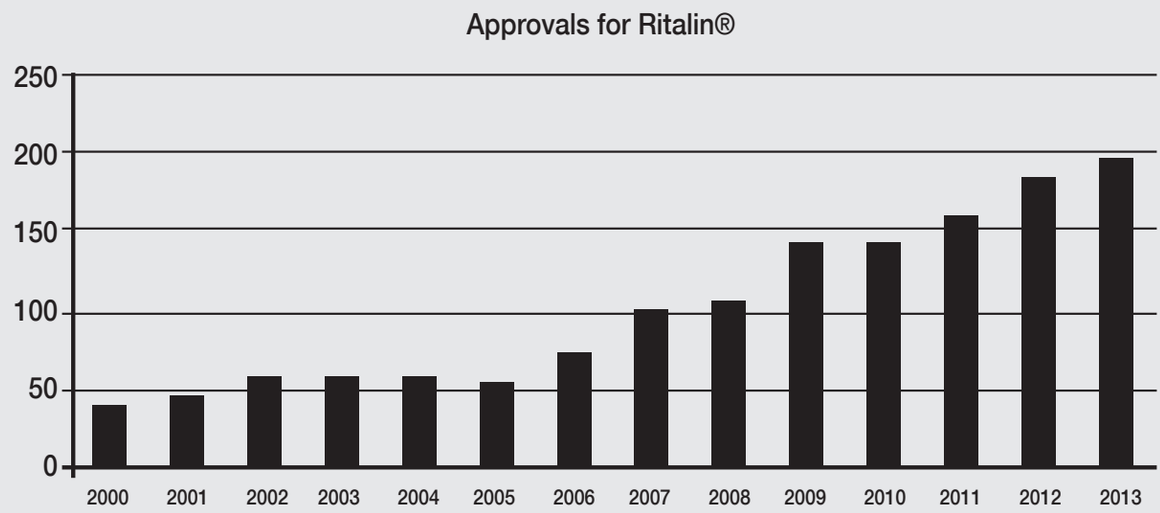
The Feingold® diet is an elimination diet that is free from dyes, artificial flavours, sweeteners and preservatives, and can be used both as a diagnostic tool to determine whether any dietary factors are negatively affecting ADHD behaviours, as well as a treatment modality for ADHD. Using a double-blind randomised controlled trial, Rucklidge et al., (2014), showed that a micronutrient supplement consisting of various vitamins and minerals may have some efficacy in managing adults with ADHD.

Drugs are FDA-approved from 6 years of age, and once started, it is recommended to stop the treatment for a couple of weeks, usually in the summer, so as to determine whether the patient still requires medication or not. Other factors to keep in mind are adverse drug effects, drug interactions, co-morbid conditions and parent and child-preferences.

The two main groups of drugs for ADHD treatment are the stimulants and non-stimulants. The drugs that are available locally are the stimulants Ritalin® and Concerta® (both methylphenidate) and the non-stimulant Strattera® (atomoxetine).

Methylphenidate is a dopamine-reuptake inhibitor, and so increases extracellular dopamine in the striatium. Ritalin® is an immediate-release form with a duration of action of 3-4 hours (SPC Ritalin®, 2013), whereas Concerta®, which is intermediate-release with a duration of action of up to 12 hours (SPC Concerta®, 2014), has the advantage of once daily dosing. The dose is increased in a stepwise fashion over a 4 week period. Around 75% of patients respond to treatment, while the remainder either show no improvement or have side effects which necessitate stopping the drug. The most common side effects are reduced appetite, transient weight loss, irritability and sleep disturbance. In January 2009, the European Medicines Agency (EMEA) issued some recommendations on the safe use of methylphenidate (EMEA, 2009). Because of the cardiovascular and cerebrovascular risks, all patients should have their blood pressure and heart rate measured before starting treatment, and every 3 months while on medication. Prior to starting methylphenidate, one should ask about

Figure 1: Number of patients started on Ritalin® in Malta over the period 2000-2013



a family history of cardiovascular disorders, and in those patients with a positive family or personal history or an abnormal cardiovascular examination, an ECG and cardiology consultation would be warranted. The patient's height and weight should be measured, and one must look out for the development of psychiatric disorders.

The use of methylphenidate locally has shown a 4 fold increase since the year 2000, as shown in Figure 1.

Strattera® is a selective noradrenaline reuptake inhibitor, with a duration of action of 12 hours. It is usually given as a single daily dose in the morning, and the capsule has to be swallowed whole. The most common side effects are sleep disturbances, fatigue, nervousness, dry mouth and stomach upset. Suicidal ideation (0.4% in Strattera-treated group as compared to 0% in the placebo group); severe liver injury, including hepatic failure, which was only picked up in post-marketing surveillance of the drug; and sudden deaths in children who had an underlying structural cardiac abnormality, have been reported (SPC Strattera, 2013).

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ASSOCIATED IMPAIRMENTS

People who suffer from ADHD, may also have associated impairments. The most common problems are difficulty in peer-relationships and an increased risk of injuries. An associated learning disorder is found in approximately half of 6-11 year olds with ADHD. Data from the CDC National Health Interview Survey (2008) shows that in the US over the period 2004-2006, 5% of children aged 6-17 years had ADHD without a learning disability, 5% had a learning disability without ADHD, and 4% had both conditions. Oppositional Defiant Disorder and Conduct Disorder are less common.

The ADHD Family Support Group Malta is a non-governmental organization which holds monthly meetings for families of ADHD-sufferers as well as the public in general.

CONCLUSION

Over the past years, ADHD has been studied closely and much research has been carried out, particularly to elucidate the aetiology of the condition, to make a more accurate and timely diagnosis, and for effective treatments to be made available. However, much still remains to be known.

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INVITED ARTICLE

Hospice Malta

Ms Anna ZAMMIT

HOSPICE MISSION STATEMENT

Hospice Malta is a voluntary organisation inspired by Christian values. It exists to provide and promote the highest standards of palliative care for persons with cancer, motor neurone disease and other terminal disease. It also aims to help and support their families.

PALLIATIVE CARE IN MALTA

Palliative care in Malta is offered free of charge by Hospice Malta in the community, day therapy unit and through hospital support. There is also an in-patient palliative care unit in Boffa Hospital where patients are admitted for symptom control or during the terminal phase.

Hospice has been delivering palliative care support for cancer and motor neurone disease patients and their families for the past 25 years. Since 2010 the criteria for admission has been extended for end life respiratory, cardiac and renal disease.

This support is delivered through a multidisciplinary team consisting of doctors, nurses, social workers, physiotherapist, complementary therapist, chaplain, day therapy coordinator and care assistants. Delivery of services (Table 1) is also made possible with the backup of the council of management, administrative and fund raising team. Additionally, there are around 200 volunteers who, according to their skills, are involved in different departments.

On referral, patients are generally contacted within 24 hours and a primary assessment is carried out within the week. The patient and the family are assessed by the Hospice nurse to identify actual and potential problems from the physical, psycho-social and spiritual perspective. This enables the Hospice team to devise a care plan which needs to be followed up and reviewed according to the circumstances. Discussions regarding the care of the patient and place of death are highly significant as this will enable the hospice team, patients and relatives to plan ahead, thus avoiding crises and multiple admissions to hospitals.

When the patient passes away the relatives are contacted and bereavement support offered. This support is provided through one to one sessions or within a group setting.

CONCLUSION

Effective palliative care in the community will enhance the quality of life of patients and their families, avoid unnecessary hospitalisation and lessen the risk of complicated grief. This will enable people to remember this otherwise traumatic period in their lives with less negativity and more tranquillity.

Table 1: Palliative care services provided by Hospice Malta

Palliative Care Services
Home Care
Day therapy
Hospital support
Loan of specialised equipment
Respite
Physiotherapy
Hydrotherapy
Complementary therapy
Phsycho social support
Spiritual support
Bereavement support

Ms Anna ZAMMIT
Hospice Care Services Manager

Email: info@hospicemalta.org

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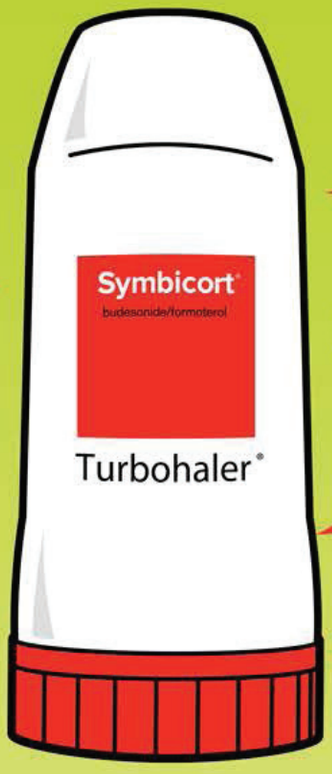

Easy to use[1]

Patients do not need to hold their breath after inhalation

High lung deposition (25-40% of delivered dose)[2]

Peak Inspiratory Flow from around 30 L/min[3]

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Consult SmPC for full information

Symbicort Turbohaler

PRESCRIBING INFORMATION. Refer to full Summary of Product Characteristics (SmPC) before prescribing. Symbicort® Turbohaler® 100/6; 200/6; 400/12; Inhalation Powder (budesonide/formoterol fumarate dihydrate) Presentations: Inhalation powder. ***Symbicort Turbohaler 100/6:*** Each metered dose contains 100mcg budesonide/inhalation and 6mcg formoterol fumarate dihydrate/inhalation. ***Symbicort Turbohaler 200/6:*** Each metered dose contains 200mcg budesonide/inhalation and 6mcg formoterol fumarate dihydrate/inhalation. ***Symbicort Turbohaler 400/12:*** Each metered dose contains 400mcg budesonide/inhalation and 12mcg formoterol fumarate dehydrate/inhalation. **Uses: Asthma:** Treatment of asthma where the use of a combination (inhaled corticosteroid and long acting β_2 adrenoceptor agonist) is appropriate. Symbicort 100/6 is not appropriate for patients with severe asthma. **COPD (Symbicort 200/6; 400/12):** Symptomatic treatment of patients with severe COPD (FEV1 <50% predicted normal) and a history of repeated exacerbations, who have significant symptoms despite regular therapy with long-acting bronchodilators. **Dosage and Administration: Asthma (Symbicort maintenance therapy – regular maintenance treatment with a separate rescue medication): Adults *(including elderly)* 100/6 and 200/6:** 1-2 inhalations twice daily. Some patients may require up to a maximum of 4 inhalations twice daily; **400/12:** 1 inhalation twice daily. Some patients may require up to a maximum of 2 inhalations twice daily ***Adolescents (12-17 years)* 100/6 and 200/6:** 1-2 inhalations twice daily; **400/12:** 1 inhalation twice daily. ***Children 6 years and older* 100/6 only**: 2 inhalations twice daily. ***Symbicort is not recommended for children under 6 years. Symbicort 400/12 is not recommended for children under 12 years.*** Not intended for the initial management of asthma. Dose should be individualised. If an individual patient requires dosages outside recommended regimen, appropriate doses of β_2 adrenoceptor agonist and/or corticosteroid should be prescribed. When long-term symptoms are controlled, titrate to the lowest effective dose, which could include a once daily dosage. **Asthma (Symbicort maintenance and reliever therapy – regular maintenance treatment and as needed in response to symptoms) *for Symbicort 100/6 and 200/6 only (NOT recommended with 400/12 strength):*** especially consider for (i) patients with inadequate asthma control and in frequent need of reliever medication (ii) patients with asthma exacerbations in the past requiring medical intervention. Close monitoring for dose-related adverse effects is needed in patients who frequently take high numbers of Symbicort as-needed inhalations. ***Adults (including elderly) 100/6 & 200/6:*** 1 inhalation twice daily or as 2 inhalations once daily. For some patients a dose of 2 inhalations twice daily may be appropriate (200/6 strength only). Patients should take 1 additional inhalation as needed in response to symptoms. If symptoms persist after a few minutes, an additional inhalation should be taken. Not more than 6 inhalations should be taken on any single occasion. A total daily dose of more than 8 inhalations is not normally needed; however, up to 12 inhalations a day could be used for a limited period. Patients using more than 8 inhalations daily should be strongly recommended to seek medical advice and should be reassessed; their maintenance therapy should be reconsidered. Patients should be advised to always have Symbicort for reliever use. ***Children and adolescents under 18 years of age:*** not recommended. **COPD (200/6): *Adults:*** 2 inhalations twice daily. **(400/12):** 1 inhalation twice daily. **Contraindications, Warnings and Precautions etc.: *Contraindications:*** Hypersensitivity (allergy) to budesonide, formoterol or lactose (which contains small amounts of milk proteins). ***Warnings and Precautions:*** If treatment is ineffective, or there is a worsening of the underlying condition, therapy should be reassessed. Sudden and progressive deterioration in control requires urgent medical assessment. Patients should have their appropriate rescue medication available at all times, i.e. either Symbicort or a separate reliever. If needed for prophylactic use (e.g. before exercise) a separate reliever should be used. Therapy should not be initiated during an exacerbation. Serious asthma-related adverse events and exacerbations may occur and patients should continue treatment but seek medical advice if asthma symptoms remain uncontrolled or worsen after initiation of Symbicort. Paradoxical bronchospasm may occur, with an immediate increase in wheezing and shortness of breath after dosing. This responds to a rapid-acting inhaled bronchodilator and should be treated straightaway. As with any inhaled corticosteroid, systemic effects may occur, particularly at high doses prescribed for long periods. These may include Cushing's syndrome, Cushingoid features, adrenal suppression, growth retardation in children and adolescents, cataract and glaucoma and more rarely a range of psychological or behavioral effects. Potential effects on bone should be considered especially in patients on high doses for prolonged periods that have co-existing risk factors for osteoporosis. Prolonged treatment with high doses of inhaled corticosteroids, particularly higher than recommended doses, may also result in clinically significant adrenal suppression. Therefore additional systemic corticosteroid cover should be considered during periods of stress such as severe infections or elective surgery. Treatment with supplementary systemic steroids or inhaled budesonide should not be stopped abruptly. During transfer from oral steroid therapy to Symbicort, a generally lower systemic steroid action will be experienced which may result in the appearance of allergic or arthritic symptoms which will need treatment. In rare cases, symptoms such as tiredness, headache, nausea and vomiting can occur due to insufficient glucocorticosteroid effect and temporary increase in the dose of oral glucocorticosteroids is sometimes necessary. Observe caution in patients with thyrotoxicosis, phaeochromocytoma, diabetes mellitus, untreated hypokalaemia, or severe cardiovascular disorders. As with other β_2 adrenoceptor agonists, hypokalaemia may occur at high doses. Particular caution recommended in unstable or acute severe asthma as this effect may be potentiated by xanthine-derivatives, steroids, diuretics and hypoxia. Monitor serum potassium levels. Hypokalaemia may increase the disposition towards arrhythmias in patients taking digitalis glycosides. In diabetic patients, consider additional blood glucose monitoring. Symbicort contains lactose monohydrate, as with other lactose containing products the small amounts of milk proteins present may cause allergic reactions. Interactions: Concomitant treatment with potent CYP3A4 inhibitors should be avoided. If this is not possible the time interval between administration should be as long as possible. Symbicort maintenance and reliever therapy is not recommended in patients using potent CYP3A4 inhibitors. Not to be given with beta adrenergic blockers (including eye drops) unless there are compelling reasons. Concomitant administration with quinidine, disopyramide, procainamide, phenothiazines, antihistamines (terfenadine), MAOIs and TCAs can prolong the QTc-interval and increase the risk of ventricular arrhythmias. L-Dopa, L-thyroxine, oxytocin and alcohol can impair cardiac tolerance. Concomitant administration with MAOIs, including agents with similar properties such as furazolidone and procarbazine, may precipitate hypertension. Risk of arrhythmias in patients receiving anaesthesia with halogenated hydrocarbons. Concomitant use of other beta adrenergic drugs or anticholinergic drugs can have a potentially additive bronchodilating effect. **Pregnancy and Lactation:** Should only be used when the benefits outweigh the potential risks. Budesonide is excreted in breast milk, however at therapeutic doses no effects on the child are anticipated. **Undesirable effects: *Common:*** headache, palpitations, tremor, candida infections in the oropharynx, coughing, mild irritation in the throat, hoarseness. ***Uncommon:*** tachycardia, nausea, dizziness, bruises, aggression, psychomotor hyperactivity, anxiety, sleep disorders. ***Rare:*** hypokalaemia, cardiac arrhythmias including atrial fibrillation, supraventricular tachycardia and extrasystoles, bronchospasm and immediate and delayed hypersensitivity reactions including exanthema, urticaria, pruritus, dermatitis, angioedema and anaphylactic reaction. ***Very Rare:*** psychiatric disorders including depression, behavioural changes (predominantly in children), angina pectoris, prolongation of QTc-interval, hyperglycaemia, taste disturbance, Cushing's syndrome, adrenal suppression, growth retardation, decrease in bone mineral density, cataract and glaucoma and variations in blood pressure. As with other inhalation therapy, paradoxical bronchospasm may occur in very rare cases. **Package Quantities:** Each Symbicort Turbohaler 100/6 or 200/6 contains 120 inhalations. Each Symbicort Turbohaler 400/12 contains 60 inhalations. **Legal Category:** Prescription Only Medicine (POM). **Marketing Authorisation Number(s):** MA 046/00901-3. **Marketing Authorisation Holder (MAH):** AstraZeneca AB, Gartunavagen, S-151 85 Sodertalje, Sweden. **Further product information available on request from:** Associated Drug Company Limited, Triq l-Esportaturi, Mriehel, Birkirkara BKR 3000, Malta. Telephone: (+356) 22778000. Fax: (+356) 22778120. **Abridged Prescribing Information prepared:** 04/12. Symbicort and Turbohaler are Trade Marks of the AstraZeneca group of companies. URN: 13/0125 **Date of Preparation:** October 2014.

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