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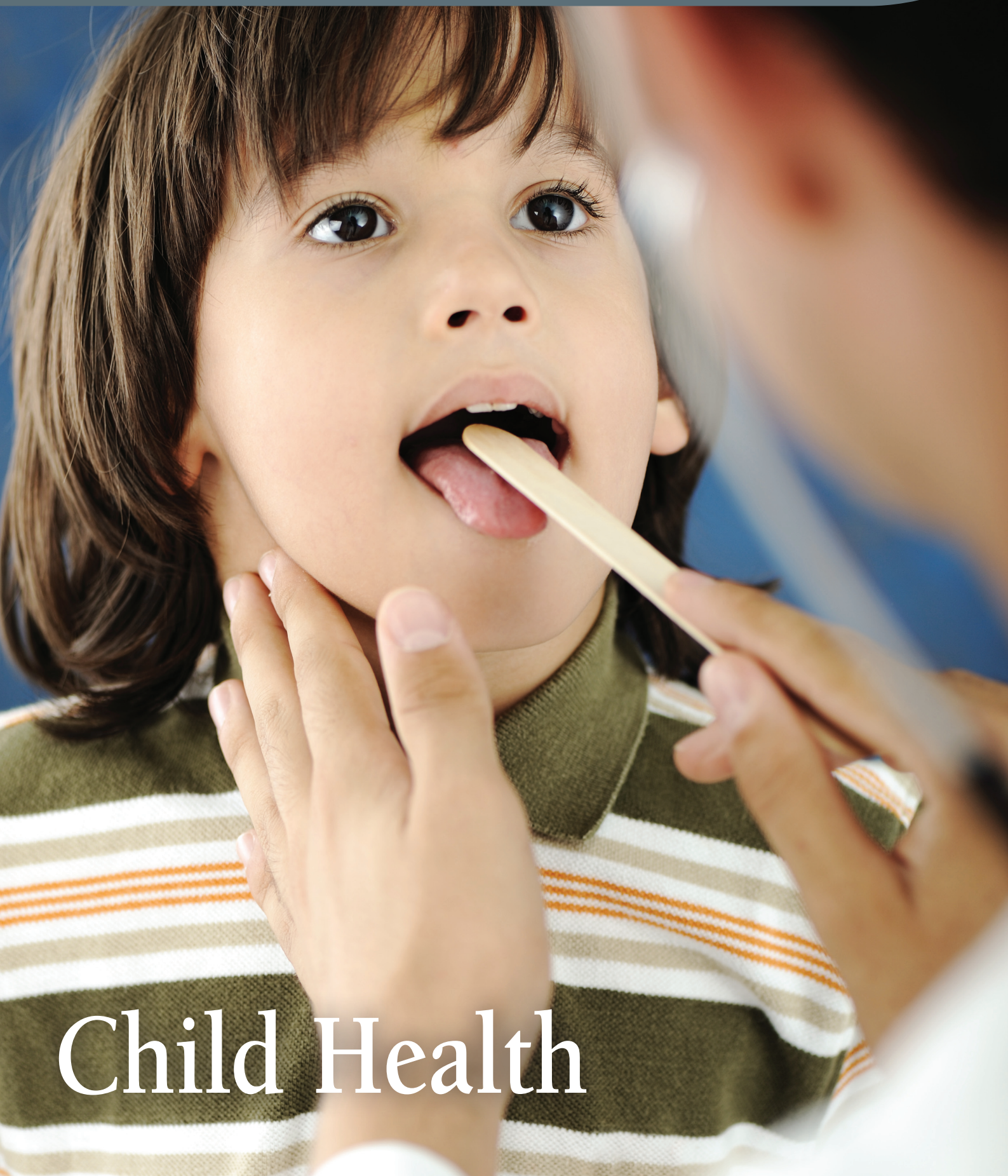

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Journal of the Malta College of Family Doctors

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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President's address at the MMCFD graduation of vocational trainees, 25 March 2014

Prof Pierre Mallia

Esteemed guests,

This is the second graduation I am presiding over but the fourth in a row of graduations. Ten years ago we started along a path to obtain a recognised qualification for family doctors which confirms the graduands as specialists in family medicine. Our natural path was to go through the Royal College of General Practitioners as Malta has a long standing relationship to medicine in the UK and especially to qualifying from Royal Colleges.

Our goal, as voted for through the AGM was to obtain MRCGP(INT) for members. At that time many of us qualified through a grandfather clause, after fulfilling several criteria, to become registered with the Specialist Accreditation Committee. But this did not automatically give us the right to become members of the Royal College of General Practitioners.

Rather the College focussed on its young doctors to establish vocational training and to have a rigorous assessment at the end to obtain MRCGP(INT), which I am sure graduands present know exactly what I am talking about,.

The preparation for the exam is not however a piece of cake. Questions have to be written according to a procedure; clinical cases need actors and training, and there are many pains along the way and difficult council decisions which may bring about considerable tension, especially for those at the helm. It is not the first time that one is tempted to resign and I would like to thank the Vice-President Philip Sciortino, and the Hon Secretary Jason Bonnici, for their considerable support, but also Jean Pierre Cauchi for his wisdom and the other members Daryl Xuereb and Adrian Micallef. Nevertheless it is important to never put in doubt the quality of our exam. In this regard I would like to thank the examiners Drs. Doreen Cassar, and Marco Grech in particular for their rigorous work, present here today and all the others who contribute towards this important endeavour – not least Tanya van Avendonk, who is responsible for your comfort and excellent environment today. A special thanks to the support of the Post Graduate committee, and Mr. Ray Galea in particular. Also thanks to the postgraduate training coordinators Drs. Mario Sammut and Gunther Abela. Last but not least Dr. Neville Calleja, acting Director General, on whose support the tripartite agreement depends. The Minister of Health, the Hon. Dr. Godfrey Farrugia, could not be here today but he reassures us of his continued help and support.

Our next goals are two-fold, God willing.

The first is to obtain the possibility of MRCGP(INT) for existing members. This is not an easy task but we want an assessment which is fair and conducive to experienced doctors.

Next year we will have our 25th Anniversary and we hope to give the Fellowship to those who have contributed substantially to the college and a pathway for those who wish to obtain fellowship. We expect the good doctor to have an interest in the development of family medicine beyond their personal practice. It is only with the Fellowship of the Malta College that those who have the Membership of the Royal College can obtain the Fellowship, which I am sure in time they would want. Therefore my advice to these graduands and those before them is to get involved in the Malta College.

Finally I have to say that we are beginning to be recognized as a hub for training. Libya wishes its doctors to obtain the MRCGP as well and we have already been approached to provide services including training trainers, and preparation for the exams. Should they remain interested, this will be done and we will have an interesting year ahead of us.

With this I congratulate all the graduands and their families and partners, for their support and patience. It was not an easy path, but all the better once you have made it. The value and merit are greater when the path is not easy.

Ethical principles in paediatric practice

Prof Simon ATTARD MONTALTO

INTRODUCTION

Clinical problems with significant ethical implications pose an ever increasing dilemma in everyday medical practice in the 21st century and rarely present a simple solution. This is particularly the case with ethical issues involving children and those unable to take their own decisions. Whilst the patients' interests should come first and all personal, cultural and religious bias eliminated, the impact of costly treatment for the individual patient on the available healthcare resources must also be taken into account. Hence, it is essential to establish an ethically acceptable code of practice which will allow doctors to provide an objective approach to management that is rational and consistent, both for the patient as well as society at large regardless of creed or culture. An equally important code of practice is required for medical research, whether this involves clinical trials on children, laboratory and animal studies. Although the same general principles are applied to guide all medical ethical problems, these may be adjusted to different research scenarios. Particularly difficult issues relate to research involving subjects who are unable to fully comprehend the ethical issues at stake, especially the embryo, children and those with a disability, as well as issues relating to the initiation of intensive care or 'extraordinary' measures and, finally, issues relating to the discontinuation of care and the dying process.

A. GENERAL ETHICAL PRINCIPLES

The ideal code of ethically-acceptable practice may be approached, if not fully achieved, by applying the following accepted principles in the decision-making process.

1. Respect of the individual's autonomy

Autonomy implies that all are free to take an active and totally independent role in the decision-making process. For this to occur, patients and study participants must be fully informed and understand the implications of their medical condition or involvement in research, any treatment, complications and outcome (De Lourdes, et al., 2003). In practice, however, many including young children do not have the ability to be truly informed, and may rely on others for guidance. *Informed consent* is not necessary simply to satisfy medico-legal requirements, but is indeed a pivotal issue with regard to patients' 'free choice' and active participation in their own management. It is fraught with problems in the competent adult, and is doubly more difficult to achieve in minors. *Truly informed* consent can only exist when patients are sufficiently informed to weigh up all the pros and cons of treatment, and their consent is given *freely* without coercion, vested interest or bias from physicians, researchers or third parties. If anything, the situation relating to children heightens the doctors' and/or researchers' responsibility to ensure true *informed consent*, albeit through third parties (Parekh, 2007; Smith-Tyler, 2007).

2. Respect of the individual's competence

Competence implies the patient's level of understanding that allows him or her to weigh up the ethical issues posed by a clinical situation, assimilate these and reach a rational decision (Parekh, 2007; Larcher and Hutchinson, 2010). This degree of comprehension is often a problem with young children and those with developmental disabilities, thereby increasing the responsibility of parents and the medical team to assume the role of competent advocates on their behalf (Cherry, 2010).

3. Respect beneficence

Beneficence defines the medical principle of 'do no harm', a hallmark of the Hippocratic oath, and should apply in all cases. Medical practice frequently entails a compromise between benefit and harm, especially with regard to interventional procedures and drug therapy, but should always be biased toward 'benefit'. Hence, in practice, it may be perfectly acceptable to embark on high-risk therapy in a fully informed individual (or his/her advocate), provided there is a *realistic* chance of *reasonable* benefit.

4. Respect of the truth

There is never a case for wilfully lying to patients. Similarly, there is rarely any justification in withholding or omitting information from patients, unless this is deemed to be against their best interests, and this option only adopted after considerable in-depth reflection and broad consultation. For those whose ability to comprehend the nuances of complex medical issues is limited by their tender age, then this responsibility is passed on to third parties.

5. Respect of patient confidentiality

All patients have a right to confidentiality. However, disclosure of confidential information without consent may be justified in situations where failure to report may lead to greater disadvantage to the patient, e.g. in some cases of child abuse.

6. Avoidance of paternalism and bias

Practitioners should strive to remain truly objective and avoid all personal, racial, cultural, religious or other bias when counselling or treating patients. Personal prejudice and preconceived ideas must never influence the provision or withholding of medical care to children, regardless of whether they are disadvantaged, have a pre-existing disability or otherwise. The wishes of parents and guardians must also be respected, again regardless of any personal bias.

7. Avoidance of all conflicts of interest

The child must always come first, before any vested interest of any third party including physicians, parents, guardians, extended family and society (Cherry, 2010; Chen and Fan, 2010). Numerous conflicts of interest may be associated with research activities (e.g recruitment in clinical trials, treatment arms, outcomes, pharmaceutical support), and cannot be allowed to influence any decisions whatsoever. It is 'good practice' and, indeed, should now be mandatory for all 'interests' to be declared by all co-workers and co-authors involved in any given research project. Special attention is required in the formulation of letters of instructions and consent forms dealing with research studies, such that these are specially designed to be 'child-friendly' and also account for the ultimate responsibility being taken by third parties.

8. Respect the limitations of medical care

Medical care should strive to support the patient, and should be tailored to the needs of the individual. It is ethically appropriate to appreciate realistic goals which medical care can achieve, and wrong to aim toward exaggerated or impossible expectations. Hence, it is equally unacceptable to 'treat at all costs', as it is to 'play god'.

Ethics in the decision-making process

Given the above accepted guidelines, ethically acceptable decisions can only be based on:

- *omniscience* - knowledge of all the facts
- *omnipercipience* - consideration for all the points of view
- *disinterest* - absence of any vested interest in the various parties
- *dispassion* - avoidance of any emotional bias
- *consistency* - management that is reproducible for all similar cases

In practice, many of the above ideals may not fully apply to a particular case. For example, it is often difficult to completely separate disinterest and dispassion from children with whom an attending paediatrician has built a close, professional relationship. For these reasons, it is not just desirable but essential to establish **independent ethics committees** to oversee particularly difficult decisions (both with regard to clinical medicine and research). These should be composed of medical, nursing, paramedical and legal experts, laypersons and representatives of various support groups.

Conclusion

Medicine is never a pure science and contentious issues in management abound. Although 'best interest' should be taken as the standard for decision-making (Spence, 2000), in practice a single, simple solution to a given ethical problem in medicine is extremely unlikely, particularly in those patients who are either too young or incapable of grasping the nuances of treatment. These patients rely on third parties for their decision making, and this adds a further dimension to an already complex situation. It is only by careful attention to a strict code of ethics based upon respect and tolerance of other persons, whether 'competent' or not, that decisions can be taken which are truly in the best interest of patients and society at large.

B. ETHICAL ISSUES RELATING TO CHILDREN AND THE DISABLED

Introduction

Ethical issues in child care are often complicated by the child's inability to take responsibility in their own management decisions and, therefore, their reliance on third parties. This situation is further complicated in those children who have an underlying disability which may influence judgment decisions of the child's surrogate guardians, both toward over or under treatment. This is particularly the case with regard to decisions relating to life support, ongoing and quality of life, appropriate use of limited healthcare resources, and medical research (Smith-Tyler, 2007; Luce, 2003).

The area of disability raises its own special ethical problems, particularly where there is total or near-total reliance on third parties, with their own personal bias and agenda that may not always be in the patient's best interests. Dilemmas are common, especially in situations of initiation or discontinuation of therapy, particularly if this involves intensive or extraordinary measures and where 'best interest' is not always easy to define (Armstrong, et al., 2011; Bellieni and Buonocore, 2009).

Life support and critical intervention

A competent person has an almost unquestionable right to decide what to do with his/her own body, even when this may entail the refusal of curative or life-saving care (e.g. blood products and competent, consenting Jehovah witnesses). This 'choice' cannot apply to children, the dependent disabled and those who are unconscious, and this great responsibility is usually taken over by parents/guardians/relatives who may have widely differing views (Michelson, et al., 2009) and who must be supported by detailed, informed discussion(s) with the caring professionals (Bellieni and Buonocore, 2009). Although the vast majority of parents act in accordance with their relative's best interests this is, at times, not perceived to be the case by the professional team and the issue may need to be resolved through legal procedures (Cherry, 2010). Differences of opinion stem from several differing fundamental values including cultural and religious beliefs that, although not strictly essential to the ethico-legal principles of medicine should, if at all possible, be considered and respected in all cases. Finally, good practice would entail the clear documentation in the child's case file of all critical decisions taken by those interested parties (e.g. paediatrician, parents/guardians, nursing staff, etc), and any subsequent changes to the plan of management again documented accordingly.

Quality of life

Ultimately, therapy whether curative or palliative, strives toward achieving 'quality of life' (QOL). Although quality of life is highly subjective, it is consistently cited as a major priority by parents in, for example, situations where withdrawal of therapy is being contemplated (Meyer, et al., 2002). What is acceptable QOL to one individual or a particular society may be abhorrent to another (Lam, et al., 2009). Although it is ethically wrong to withhold therapy simply on the basis of 'a perceived disadvantage' (e.g. a disability), it is often very difficult to predict the degree of disadvantage and, as a rule, the benefit of the doubt should be given to the patient (Kluge 2009). In the critical care setting, although it may be acceptable to withhold therapy at the outset, it may be easier to initiate and withdraw treatment at a later date (Hussain and Rosenkrantz 2003). The latter allows for a trial period during which time the child's response, severity and irreversibility of their disease can be established beyond doubt. Indeed, both under- or over-treatment is wrong and a modus operandi which balances the two should apply in all cases.

Healthcare and resource constraints

In an ideal world, all treatments should be available to all patients a t all times, regardless of age, gender, race, creed, social status and pre-existing disease or disability (co-morbidity). Modern medical care, and especially intensive and high dependency therapy, is extremely expensive and in limited supply, even in developed countries. In practice, this inevitably leads to an overt or covert system of health care rationing which, in the context of society at large, is ethically reasonable (Sabik and Lie, 2008). However, it may lead to negative discrimination against those who, for whatever reason be it medical, social, cultural or otherwise, may be considered to be 'less deserving' (Zlotnik Shaul and Vitale, 2009; Antommaria, Sweney and Poss, 2010). Hence great care is required to ensure that any rationing is reasonable and that any inclusion/exclusion criteria for these patients are fair and ethically acceptable (Kluge, 2009; Antommaria, Sweney and Poss, 2010; Miljeteig, et al., 2010).

Euthanasia

Passive euthanasia allows patients to die naturally of their underlying disease and is generally acceptable in those with irreversible disease. Although this does not include active intervention, passive euthanasia ensures supportive and palliative care at all times. Furthermore, it does not justify a decision not to treat on the basis of an underlying disability. *Active euthanasia*, by positively helping a patient to expedite his/her demise, is considered unlawful in most but not all countries (Kon, 2009). Indeed, although prosecuted, individuals have been found not guilty to the charge of assisted murder after they have admitted to help a loved one take their own life, even in countries where this provision is not empowered by law. The Dutch protocol goes further in that it lays down criteria for legitimately euthanizing neonates whose medical condition falls within three defined categories and is incompatible with sustained life (Kon, 2009). Although gaining wider support and acceptance, such active euthanasia is generally difficult to accept by third parties. It remains, therefore, more difficult to apply to neonates, children and dependent individuals who are unable to make an informed request for this to be carried out. Furthermore, it allows no room for error and further obscures the cut-off limits of what is and what is not ethically acceptable practice.

Medical research and children

A significant proportion of the benefits resulting from biomedical research will help future patients rather than those directly involved in the research (Matutina, 2009). Given that patients should never be used as a means to an end, and difficulties with informed consent in the non-competent child or disabled person (Parekh, 2007; Larcher and Hutchinson, 2010), it is hard to reconcile the participation of these groups in active research. However, a total ban on such research activity will restrict other children and disabled patients from benefiting from any potential advances. 'Good practice' research involves randomisation, use of placebos, and similar concepts that may be very difficult if not impossible for many, but especially for children, to comprehend (Matutina, 2009). Research trials must be unbiased, and avoid any discrimination whilst protecting all participants (Diekema, 2008). 'Negative' findings may be equally if not more important than 'positive' results in research that aims to add to dependable, evidence-based medical practice (Henschel, Rothenberger and Boos, 2010). To this end, therefore, clear ethical, legal and methodological guidelines are essential in the design and conduct of clinical trials involving all subjects, but especially children (Henschel, Rothenberger and Boos, 2010; Burns, 2003; Coleman, 2007).

Conclusion

In many ways, the ethics which govern the management of those with a disability are no different to those which apply for children. The respect for autonomy and confidentiality, avoidance of conflict and paternalism whilst aiming for acting in the child's interests with honesty should apply for all. However, the disabled subgroup with its inherent potential for negative discrimination when it comes to healthcare support does need greater attention particularly in the areas of critical care where the issue of realistic goals is paramount. The problem of defining quality of life is highlighted in this subgroup, and it is important that physicians accept that others including relatives, may have widely differing views on this definition and should strive to respect their divergent views, provided it is ultimately in the patient's interest. Finally, an effort to respect children and the disabled as individuals with an equal right to healthcare, will facilitate acceptance of their position and/or disability and ensure fairness in their management.

C. ETHICAL ISSUES RELATING TO THE DYING PROCESS IN CHILDREN

Introduction

Despite the application of robust ethical principles, complex issues in patient care commonly result in ethical dilemmas with no clear answers. This is especially so in those 'life and death' decisions relating to continuing curative therapy or opting for palliative care (Spence, 2000; Lam, et al., 2009). As with many situations in medicine, and probably more so in paediatrics, these decisions are complicated by difficulties in establishing clear prognostic outcomes both in terms of disease progression and timescales, patient's reliance on third parties, and appropriate use of resources (Kluge, 2009; Sabik and Lie, 2008; Brook and Hain, 2008). Great efforts are required to ensure family members are fully informed of the evolving clinical situation relating to their loved one, and helping them to accept the inevitability of death. Whenever possible, they should be encouraged to plan for their relative or child's death in a manner that is most appropriate for them as an individual family. This section will explore the ethical principles which offer guidance in these situations, and strives toward: i) establishing

the acceptance of death by the patient and family, ii) ensuring 'quality time' for both family and their dying relative or child and, iii) safeguarding every person's right to die with dignity.

The dying process in children

Fortunately, most childhood illness is curable and, indeed, death in childhood is an unlikely event in 2011. Often death is not a totally unexpected event but can usually be anticipated after a short or long term illness (Brook and Hain, 2008). For these children, a point is reached when cure is no longer possible and is replaced by palliative care. Not uncommonly, this transition can be complicated by ethical dilemmas. Many of the decisions relating to the dying child are complex, and invariably have a significant impact on the child as an individual, his/her family and friends, as well as society at large. If this transition is to be appropriate and acceptable, a code of practice based on sound ethical values is essential.

When to opt for care and not cure?

This difficult milestone requires a multidisciplinary decision involving the patient, whenever possible, the family, relatives, friends and the entire team of carers (Hechler, 2008; Brien, Duffy and Shea, 2010). Stopping curative therapy will depend on medical considerations such as patient viability, futility of further aggressive therapy, and the exhaustion of all reasonable, potentially curative options. The patient must be 'ready' for the transition (with appropriate, sensitive discussion in competent adults and the older child). The importance of family acceptance of palliation versus cure cannot be stressed enough and requires frank discussion, often over several hours (Hechler, 2008). Finally, but equally important, the acceptance of carers must never be overlooked and the personal view of each individual should be actively explored (Duffy and Shea, 2010; Floriani, 2010). Ultimately, a unified team decision is required to avoid conflict that will only add to the distress of the patient and his/her family.

Medical ethics that apply to palliative care

The transition to palliation in critically ill children does not involve a special set of medical ethics. Indeed, the appropriate application of basic principles provides the platform on which difficult issues can be discussed and ethically acceptable decisions taken. Hence, carers should strive toward the patient's best interests whilst respecting the patient's autonomy within the confines of his/her competence. They should respect confidentiality, avoid being paternalistic, anticipate and avoid conflict (Masri, 2000). All issues should be aired realistically, honestly and sympathetically, with due consideration for the patient's/family's views, beliefs and wishes. As with other ethical dilemmas, for medical decisions to be ethically acceptable, they should be based on *all the facts* and *points of view*, free of *bias* and *emotional overtones*, and consistent from one patient to another.

Despite this ideal, the decision making process is rarely straightforward in practice. Often an accurate prediction of outcome (and time-scales) may be difficult in the critically ill, and especially children. Prolongation of life through palliative care raises the issue of quality of life (Michelson, et al., 2009; Meyer, et al., 2002), an extremely subjective issue dependent on personality, inherent expectations (realistic or otherwise), cultural background, religious beliefs and pressure from third parties. Nevertheless, the caring team have a primary duty to maintain the quality of life at all times of, firstly, the child and, secondly, that of the family. In addition, they must present an honest assessment of the medical condition with realistic goals and argue toward the reasonableness, or otherwise, of continuing support. In practice, this cannot be done without taking account of available resources, although healthcare 'rationing' in the terminally ill child can pose a great challenge.

Moreover, these problems are made doubly difficult in patients and children who are unable to grasp the complex issues involved and, therefore, cannot participate in the decision process and depend on third parties, usually their immediate family members (Moro, et al., 2006). In the vast majority of cases, the latter correctly decides what is right for their loved one and for them as a family, and the role of the caring team is essentially to support and facilitate their decisions. Rarely family members may, knowingly or unwittingly, hold strong views that may be biased by their own fears/beliefs and may not be in their relative or child's interest. At this point the caring professionals may be required to gently redress any misguided views to ensure that the dying person is not put through any unnecessary suffering. Once a decision for palliative and not curative care is taken, the unified focus should be toward support, quality and not quantity of life.

The final stages

Toward the later stages of palliative care respect must be shown for the wishes of the patient, the family and carers in the light of their background, culture and creed. Throughout the dying process, great attention must be paid to the child and his family's needs, both physical and emotional (Moro, et al., 2006). Whenever possible, decisions relating to *Where to die?, With whom?* and *How?* should be planned with the family (Floriani, 2010). What may be the ideal for one family may be abhorrent for another. Every effort should be made to enroll all support services (e.g. Hospice movement, social workers, friends, etc) in order to fulfill the patient's and the family's wishes. Certainly in the majority of expected deaths (e.g. cancer relapse) this is eminently feasible, but it is extremely difficult with sudden, unexpected deaths (e.g. post-accidental).

The fact that each child will die only once and that this is invariably a major event for loved ones should form the basis for a modus operandi that strives to ensure that death is as 'acceptable' as possible. A concerted drive to respect the patient's and family's wishes, to ensure 'quality time', and 'humanize' the dying process can help enormously in allowing loved ones to 'let go with resigned acceptance'. In this re gard, the spiritual needs of the family must be taken into consideration (Feudtner, Haney and Dimmers, 2003; Fleischman, et al., 1994), and a conscious effort made to ask the family if they would like the appropriate religious counsellor to attend. Equally, it is important to respect the wishes of those who do not hold any particular religious beliefs and it is wrong to attempt to introduce this, in whatever guise, during the final moments. It is entirely appropriate to decide, together with the family, against active resuscitation and the initiation of further extraordinary (but futile) measures. Indeed, there is little to compare death after a frantic resuscitative attempt often in the absence of family or friends, with the peaceful death of a child in his/her mother's arms or an adult in tranquil surroundings offering sufficient privacy, quietly surrounded by loved ones. Finally, the needs of the surviving family members must not be underestimated and addressed appropriately (Meert, et al., 2007).

Conclusion

For critically ill patients, cure should not be pursued at all costs and there may come a time when cure is impossible and palliative care is in the patient's best interest. Certainly, appropriate supportive care should continue at all times and must include the patient's family and friends. Acceptance of death is very important, particularly for the family, and can only be achieved after sympathetic, often prolonged and repeated discussion with loved ones. Palliation should provide 'quality time' for both family and their dying relative and, ultimately, strive for one overriding goal: namely, to safeguard the patient's right to die with dignity.

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Nutrition in childhood

Dr Marie-Claire BARTOLO

INTRODUCTION

Childhood is the stage in a human's life associated with growth and development. Growth proceeds rapidly in early life, slows down in middle childhood and accelerates at puberty before linear growth ceases. With increasing age there is also physical and psychomotor maturation, which influences activity, body composition, feeding skills and food choices (Geissler, 2011). Adequate nutrition is essential for growth, health and development of children. Poor nutrition increases the risk of illness, and is responsible directly or indirectly for one third of the estimated 9.5 million deaths that occurred in 2006 in children less than 5 years of age. Inappropriate nutrition can also lead to childhood obesity (WHO, 2009a).

Key words

Childhood, Nutrition, Breast feeding, Growth and Development, Serving sizes

BODY COMPOSITION IN CHILDHOOD

After birth the total body water decreases, and the percentage body weight that is fat increases rapidly to peak at around 6 months of age. Early infancy is then followed by a period of natural slimming until around 5 years of age. This is typically followed by a second phase of relatively rapid fat deposition, the adiposity rebound, which continues almost unabated in girls until growth ceases. In boys the adiposity rebound reverses with rapid lean tissue deposition of late puberty (Geissler, 2011).

PSYCHOMOTOR MATURATION RELEVANT TO FEEDING

Table 1 outlines some of the important developmental milestones that occur with age, related to a child's ability to feed.

Infancy is associated with almost total dependency on carers for the provision of nutritional needs. As children grow they begin to understand the implications of choices and make their wishes understood. They also use food to manipulate those around them. Once at school children take their cues for food preferences from their friends besides their families. They are also influenced by media. In adolescence peer approved fashions for certain diets come into play and this could lead to haphazard eating and bizarre diets (Geissler, 2011).

INFANCY

Optimal infant and young child feeding practices rank among the most effective interventions to improve child health. The WHO and UNICEF's global recommendations for optimal infant feeding state that an infant should be exclusively breastfed for the first 6 months of life. Nutritionally adequate complementary feeding should start from the age of 6 months with continued breastfeeding up to 2 years of age or beyond (WHO, 2009a).

Poor breastfeeding and complementary feeding practices are however widespread. Worldwide it is estimated that only 34.8% of infants are exclusively breast fed for the first 6 months of life, the majority receiving some other food or fluid in the early months (WHO, 2009b). Several studies suggest that obesity in later childhood and adolescence is less common amongst breastfed children, and that there is a dose response effect with a longer duration of breastfeeding associated with a lower risk of obesity (Harder et al., 2005; Burke et al., 2005).

WHY "BREAST IS BEST"

Human breast milk is specifically designed for the requirements of a human baby. Breast milk contains all the nutrients that an infant needs in the first 6 months of life, including fat, carbohydrates, proteins, vitamins, minerals and water (Butte et al., 2002).

Carbohydrates

Lactose is the main carbohydrate (80%) in milk. It is well designed to fit its role in providing the infant's nutritional requirements since it is highly soluble, promotes growth of protective intestinal flora and facilitates calcium absorption through the relative solubility of calcium lactate. Other carbohydrates in milk include monosaccharides, oligosaccharides and protein-bound carbohydrates. These provide important protection against infection (Riordan, 2004).

Table 1: Age at average development of feeding/ nutrition skills

Age	Feeding skills acquired
36 weeks gestation to birth	Integrated sucking and swallowing reflexes
3 months	Conveys bolus of food from front of mouth to back of mouth
5 months	Conveys objects placed in hand to mouth Drinks from hand-held cup with biting movements
5 to 6 months	Reaches out for objects and conveys them to mouth
6 to 7 months	Begins to make chewing movements Feeds self with biscuit, rusk or other small item Transfers object from one hand to the eater
7 months	Learns to shut mouth, shake head and indicates no
9 months	Picks up raisin-sized object with thumb and forefinger Throws food to ground with great enthusiasm and expects someone else to pick it up
10 months	Holds beaker of liquid but drops it when finished
12 months	Tries to spoon feed but unable to stop rotation of spoon before it reaches mouth
15 months	Manipulates spoon and food on spoon to mouth
18 months	Determined to be independent at meal times
2 years	Expresses own self and independence in often irrational food refusal. This spell may last some years
5 years	Eating in company with peers may lead to eating a greater variety of foods then previously accepted. May also lead to strong preferences for 'popular' foods

Proteins

Breast milk protein differs in both quantity and quality from animal milks and it contains a balance of amino acids which makes it much more suitable for a baby. Human milk protein is 30 to 40% casein and 60 to 70% whey. Human milk casein forms smaller micelles with looser structure than the casein of cow's milk. The structure facilitates enzymic action. Precipitation of tough, undigested casein curds in the stomach is less likely than with cow's milk or unmodified cow's milk formula. Moreover the concentration of protein in breast milk is lower than in animal milks. The much higher protein in animal milks can overload the infant's immature kidneys with waste nitrogen products. Human milk contains alpha-lactalbumin whilst cow's milk contains beta-lactalbumin, to which infants can become intolerant (Riordan, 2004).

Fat

Although the quantities of fat in human and cow's milk are not very different, the component fatty acids differ greatly. Human milk fat is higher in unsaturated fat, particularly the essential fatty acids linoleic and alpha-linolenic acid and also contain the long chain polyunsaturated fatty acids (LCPUFA). These fatty acids are important for the neurological development of a child. LCPUFA are added to some varieties of infant formula but this does not confer any advantage over breast milk, and may not be as effective. The fats in human milk are more readily digested and absorbed than those in cow's milk.

Micronutrients

Breast milk normally contains sufficient vitamins for an infant (besides vitamin D which the infant produces on exposure to sunlight). Breast milk contains lactoferrin

and other micronutrient binding compounds. These facilitate absorption of iron, folic acid, vitamin B12, zinc and other micronutrients.

Anti-infective factors

Breast milk contains many factors that help to protect an infant against infection (Hanson, 2004) including:

- immunoglobulin, principally secretory immunoglobulin A (sIgA), which coats the intestinal mucosa and prevents bacteria from entering the cells;
- white blood cells which can kill micro-organisms;
- whey proteins (lysozyme and lactoferrin) which can kill bacteria, viruses and fungi;
- oligosacccharides which prevent bacteria from attaching to mucosal surfaces.

INFANT FORMULA

Infant formula is usually derived from industrially modified cow's milk or soy products. During the manufacturing process the quantities of nutrients are adjusted to make them more comparable to breast milk. However the qualitative differences in the fat and protein cannot be altered and the absence of anti-infective and bio-active factors remain (WHO, 2009a). Soy formula contains phyto-oestrogens which could potentially reduce fertility in boys and bring early puberty in girls (Setchell et al., 1997).

COMPLEMENTARY FEEDING

From 6 months of age, an infant's need for energy and nutrients start to exceed what is provided by breast milk. Complementary feeding therefore becomes necessary. Ideally parents wait till the baby is 6 months old, since the renal and digestive systems are not fully developed at an earlier age and to decrease the risk of food allergies and choking. Complementary foods need to be nutritionally adequate, safe and appropriately fed. The child should initially be given small amounts of food which increase as the child gets older. The most suitable consistency for an infant's or young child's food depends on age and neuromuscular development (WHO/UNICER, 1998). Beginning at 6 months an infant can eat pureed, mashed or semi-solid foods. By 8 months most infants can also eat finger foods. By 12 months, most children can eat the same types of food as consumed by the rest of the family. There is evidence of a critical window for introducing lumpy foods; if these are delayed

Table 2: Practical guidance on the quality, frequency and amount of food to offer children between 6-23 months of age

Age	Texture	Frequency	Amount of food an average child will usually eat at each meal
6-8 months	Start with thick porridge, well mashed foods Continue with mashed family foods	2-3 meals per day Depending on the child's appetite 1-2 snacks may be offered	Start with 2 -3 tablespoonfuls per feed, gradually increasing to ½ of a 250ml cup
9-11 months	Finely chopped or mashed foods, and foods that baby can pick up	3-4 meals per day Depending on the child's appetite 1-2 snacks may be offered	½ of a 250 ml cup/bowl
12-23 months	Family foods, chopped or mashed if necessary	3-4 meals per day Depending on the child's appetite 1-2 snacks may be offered	¾ to full 250 ml cup/bowl

Table 3: Characteristics of good complementary foods

Rich in energy, protein and micronutrients (particularly iron, zinc, calcium, vitamin A, vitamin C and folate)
Not spicy or salty
Easy for the child to eat
Liked by the child
Locally available and affordable

beyond 10 months of age, it may increase the risk of feeding difficulties later on. Although it may save time to continue feeding semi-solid foods, it is important to gradually increase the solidity of food with increasing age, for optimal child development (WHO, 2009a). Table 2 summarizes the quality, frequency and amount of food that children between 6 and 23 months should be offered (WHO, 2009a). The characteristics of good complementary foods are highlighted in table 3.

Parents and carers should be advised to give the baby one new food at a time and for three to five days before adding another new food. This will tell what foods the baby might be allergic to or can't tolerate. Carers should begin with small amounts of new solid foods. A teaspoon would be enough at first and slowly this would increase to a table spoon. The infant can be started on dry infant rice cereal, mixed as directed, followed by vegetables, fruits and then meats. When preparing infant foods, salt or sugar should not be added. Canned foods may contain large amounts of salt and sugar and are therefore best avoided. Cow's milk should not be introduced until the baby is 1 year old. The American Academy of Paediatrics recommends not to give fruit juices to infants younger than 6 months of age. Only pasteurized, 100% fruit juices, without added sugar may be given to older infants and children and this should be limited to 180ml a day. The juice should be diluted with water and offered in a cup with a meal (Johns Hopkins Medicine, Health library, 2014).

Another issue which needs to be tackled with parents is to avoid the "clean plate syndrome". Forcing a child to eat all the food on a plate when he or she is full will lead to over eating and it teaches the child to eat just because the food is there not because he or she is hungry. Parents should also be advised to expect a reduction in appetite and the child might become pickier since the growth rate slows down around the first birthday. Carers should offer a wide variety of foods at this stage to pave the way for good eating habits later on in life. Fat and cholesterol shouldn't be restricted in the diets of very young children. Children need calories, fat and cholesterol for the development of their brains and nervous systems and for general growth (Johns Hopkins Medicine, Health library 2014). After the age of 2 it is recommended that the diet is moderately low in fat, as diets high in fat at a later stage may contribute to cardiovascular disease and obesity later in life (Stettler, 2011). Adult recommendations of fibre intake should not be applied in early childhood. A high fibre content would lead to decreased energy density in foods, and high phytate levels could interfere with micronutrient absorption (Geissler, 2011).

FEEDING AFTER THE FIRST YEAR

Whilst growth rate slows down at this age, nutrition still remains a top priority. It is also time for parents to start removing bottles and move to a stage where children will eat and drink more independently. Toddler years, especially between 12 and 24 months are considered transition years where children learn to eat at table and accept new tastes and textures. If a child rejects a new food, the best advice would be to remove it without fuss and re-introduce it at a later date. Children will be interested in eating what people around them are having. Parents and carers should therefore set a good example by following a healthy diet.

Between 2 to 5 years children seem to eat less with appetite fluctuations during growth spurts. Parents are often concerned whether their child is eating enough.

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Table 4: Fussy eater – Parental advice

Be patients
Offer variety of bite–sized foods
Offer food in small and interesting shapes
Choose nutrient dense foods e.g. avocado, broccoli, cheese, eggs, fish, red kidney beans
Do not turn each meal into a battle
No force feeding
Do not punish child
Congratulate him or her for what he or she does eat
The lesser the pressure on the child, the more likely that the phase will pass without problems

Practical advice to parents would be to offer a nutritious selection of foods, remain patient and to give the child freedom to choose, within reason. A common clinical scenario would be parents being concerned that their child has become a fussy eater. Table 4 lists some practical advice to help parents deal with this situation better.

Another common clinical scenario is a parent questioning whether the child requires any multivitamin supplements. Both the American Medical Association and the American Dietetic Association recommend that healthy children should get all their nutrients from foods rather than vitamin supplements. The nutrients that are most likely to be deficient in a child's diet are iron, vitamin C, vitamin A, folic acid, and vitamin B6. The American Academy of Pediatrics does not support routine supplementation for normal, healthy children. However, there is no significant risk if a parent wishes to give their child a standard paediatric multivitamin (Medline Plus, 2014).

SCHOOL AGE CHILDREN

At about 5 years of age growth rate picks up and children often become even more active. The eating habits of most 5 year olds will have been shaped largely by those of their family, but as they grow older they will begin to accumulate habits from their friends at school. Popular snack foods such as biscuits and crisps are high in fat and sugar. These are fine from time to time but children need to be guided towards choosing snacks that provide a range of essential nutrients as well as energy such as yoghurts and sandwiches with healthy fillings. Snacks rich in fat and sugar should not be used as a reward.

Breakfast is important to top up children's energy stores for the morning activities. Children who eat a healthy breakfast are less likely to snack on foods that are high in fat and/or sugar later on and tend to have a better nutrient intake across the day. Many studies have also shown that regular breakfast consumption results in children performing better at school, compared to those children who don't eat breakfast (British Nutrition Foundation, 2014a).

Although younger school-age children are often very active, many children are overweight or even obese. In 2008 over a quarter of Maltese children aged 7 years were found to be overweight or obese, with the proportion rising to just over 40% when the same cohort was measured in 2010 at the age of 9 years (Farrugia Sant'Angelo et al., 2011).

It is not usually advisable for children of primary school age to go on a slimming diet as this may interfere with their growth and development. Instead, management usually entails a regimen combining healthy eating and increased physical activity. This needs to be family focused and aims at enabling the child to remain at a constant weight or increase weight slowly, while the height increases. It is also important to review the family's dietary patterns, and to encourage improvement where necessary. Developing a healthy family lifestyle, including a healthy varied diet and regular physical activity is particularly important in the weight management of children (British Nutrition Foundation, 2014a).

Exercise is crucial for health throughout life including

Table 5: Food servings according to age group, including examples of 1 serving from each food group

	Age groups			
Food group	**1-2 years**	**3-5 years**	**6-12 years**	**13-18 years**
Grains/ starchy vegetables	**4 servings** 1 serving = ¼-1/2 slice of bread, 2-4tbsp cooked rice/pasta, 1 small potato	**4 servings** 1 serving = ½-1 slice bread, 4-8tbsp cooked rice/pasta, 1 medium potato	**5 – 11 servings** 1 serving = 1 slice of bread, 3 heaped tbsp cooked rice/pasta, 1 large potato	**5 -11 servings** 1 serving = 1 slice wholemeal bread, 40g high fibre cereal
Vegetables	**2-3 servings** 1 serving = 2tbsp carrots, 2tbsp peas	**2-3 servings** 1 serving = 3 tbsp carrots, 3 tbsp peas	**2-3 servings** 1 serving = medium sized mixed salad, 3 tbsp cooked vegetables	**2-3 servings** 1 serving = medium sized mixed salad, 3 tbsp cooked vegetables
Fruit	**2-3 servings** 1 serving =½ apple, 1 small banana	**2-3 servings** 1 serving = 1 apple/ 1 banana	**2-3 serving** 1 serving = 1 apple, 150ml fresh fruit juice	**2-3 servings** 1 serving = 1 apple, 150ml of fresh fruit juice
Dairy	**2 servings or min of** 350ml milk 1 serving =1 small yoghurt, 30g of cheese	**2 servings or minimum** of 300ml milk 1 serving = 150ml yoghurt, 35 g of cheese	**2-3 servings** 1 serving = 35-40g cheese, 200ml milk	**2-3 servings** 1 serving = 40g cheese, 200ml milk
Proteins	**2 servings** 1 serving =30g chicken. 30g fish, 30g meat, 1tbsp peanut butter	**2 serving** 1 serving = 30-50g chicken, 30-50g fish, 30-50g lean meat, 1 egg	**2 servings** 1 serving =50- 85g chicken, 50-85g fish, 50- 85g lean meat, 2-3 heaped tbsp cooked lentils	**2 servings** 1 serving = 85g chicken, 85g fish, 85g lean meat, 3 heaped tbsp cooked lentils

childhood. It is recommended that children and young people should engage in at least 60 minutes of moderate intensity physical activity each day. This should include activities that improve bone health, muscle strength and flexibility, for example running, cycling or swimming, at least twice a week. Only 70% of boys and 61% of girls meet these recommendations. Boys tend to be more active than girls and it is common to see a decline in physical activity levels as children reach adolescence, which is more marked in girls (British Nutrition Foundation, 2014a).

All children should be encouraged to choose a variety of foods from all the food groups, in order to achieve a healthy varied diet. Table 5 summarizes the recommended serving sizes for different age groups.

ADOLESCENCE

During adolescence the child undergoes major physical and psychological changes, leading to high energy and nutrient needs. Teenage years are associated with a tendency for independence and a phase of experimentation including self imposed dietary restraints which could have detrimental effects on health. There is evidence of inadequate micronutrient intakes among teenagers. For example, many teenage girls (11-18 years) are consuming low amounts of iron (46% below the Lower Reference Nutrient Intake - LRNI) and there is also evidence of low intakes of vitamin A (14% below the LRNI), riboflavin (21% below the LRNI), calcium (18% below the LRNI), magnesium (51% below the LRNI), potassium (31% below the LRNI), selenium (45% below the LRNI), iodine (21% below the LRNI) and zinc (19% below the LRNI). In contrast, micronutrient intakes in younger children are generally not of concern. [The LRNI, lower reference nutrient intake, is the amount judged to be sufficient for only 2.5% of the population](British Nutrition Foundation, 2014b). Adolescence should be counselled regarding healthy nutrition and healthy lifestyle at every opportunity.

CONCLUSION

During early childhood and school-age years, children begin to establish habits for eating and exercise that remain for their entire lives. If children establish healthy habits, their risk for developing many chronic diseases will be greatly decreased. On the other hand, poor eating habits and physical inactivity during childhood set the stage for health problems in adulthood.

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RESEARCH ARTICLE

What General Practitioners need to know about Patent Foramen Ovale

Dr Mario SALIBA

ABSTRACT

Background

A patent foramen ovale (PFO) consists of a hole between the right and left atriums of the heart that did not close the way it should after birth. Twenty five percent of the population have a PFO, but this usually does not cause problems, because the opening is functionally closed by the difference in pressure between the heart and the chest.

Method

This study is a literature review about the clinical significance of PFO and its management in three clinical situations: cryptogenic strokes, migraine with aura and scuba divers who sustained a decompression sickness.

Results and conclusion

PFOs had been linked with various medical conditions such as strokes, migraine, and with certain types of decompression sickness (DCS). In general, this association is not very well established. Young patients who sustain a cardiovascular event without a known cause (cryptogenic stroke) have resulted in the tendency to screen these patents becoming the norm and more PFOs are being closed using standard methods and devices. The association of PFOs and migraine attacks is less clear. In the case of scuba divers the risk of suffering from a decompression accident is increased if one has a PFO. The management of these patients remains difficult.

Keywords

Patent foramen ovale, cryptogenic strokes, migraine, decompression sickness

INTRODUCTION

A PFO is a defect in the septum between the two atrial chambers of the heart. Specifically, the defect is an incomplete closure of the atrial septum that results in the creation of a flap or a valve-like opening in the atrial septal wall. A PFO is present in everyone before birth but seals shut in about 75 to 80 per cent of the population. The cause of a PFO is unknown. There are no known risk factors. PFOs have been found on autopsy in up to 35 per cent of the healthy population (Laskowski, 2012).

PFOs AND CRYPTOGENIC STROKES

Crytogenic strokes are those cerebrovascular accidents in usually young patients where the cause remains unknown despite extensive diagnostic work up. This type of stroke amounts to forty percent of all strokes (Sacco, et al., 1989). The prevalence of a PFO is approximately doubled among cryptogenic stroke (CS) patients. Regardless of mechanism, nearly 30,000 young patients each year have a cryptogenic stroke and a PFO. This has generally been attributed to paradoxical embolism, and many physicians recommend PFO closure to prevent recurrence (Kent and Thaler, 2010). Since 1988, studies have shown that a PFO is significantly more frequent in young stroke patients (less than 55 yrs) than in matched control subjects, and paradoxical embolism has been suggested as the main mechanism of stroke in these patients (Rodriguez and Homma, 2003). Nonetheless, another study on 68 patients aged less than 55 years concluded that paradoxical embolism is not the primary mechanism of stroke in patients with a patent foramen ovale (Ranoux, 1993).

The association in older patients remains uncertain as only a few studies have included patients more than 55 years old. Nonetheless, one study confirmed the association between the presence of a PFO and CS in both patients younger than 55 years of age and those 55 years of age or older (Handke, 2007).

The question at present is whether we should screen patients for PFOs and what the managment should be when a PFO is discovered. Optimal management at present is still desirable. There are ongoing studies and trials to compare the effectiveness of percutaneous closure of the PFOs with medical therapy and to study the outcomes in the hope of issuing guidelines for the management of these patients. The Randomized Evaluation of Recurrent Stroke Comparing PFO Closure to Established Current Standard of Care Treatment was an industry-sponsored trail (Respect Trial, 2012). This trial, started in 2007, recruited 900 participants aged between 18 and 60 years. The trial was concluded in August 2012. Patients who had a cryptogenic stroke within the last 270 days and patients who have been diagnosed with a PFO were included. Those found to have a PFO had an intervention to close the defect using a Amplatzer PFO Occluder device and later tested to ensure a successful procedure by using transthoracic echocardiography (TTE) and bubble studies. These patients were compared with patients who were treated medically using aspirin alone, Coumadin alone, Clopidogrel alone, or Aspirin combined with Dipyridamole. For carefully selected patients with history of cryptogenic stroke and PFO, the Respect Trial provided evidence of benefit in stroke risk reduction from closure with the Amplatzer PFO Occluder over medical management alone. Stroke risk reduction was observed across the totality of analyses with rates ranging from 46.6% - 72.7%. PFO closure with the Amplatzer PFO Occluder exposed patients to a very low risk of device- or procedure-related complications. RESPECT remains the best trial showing the benefits of PFO closure in reducing the incidence of associated stroke.

Another trail included the Evaluation of the STARFlex Septal Closure System in Patients with a Stroke or TIA due to the Possible Passage of Clot of Unknown Origin through a PFO (Closure 1). Preliminary results from this trial showed that alternative explanation unrelated to paradoxical embolism present in 80 per cent of patients with recurrent stroke or TIA and that percutaneous closure with STARFlex® plus medical therapy does not offer any significant benefit over medical therapy alone for the prevention of recurrent stroke or TIA in patients $\leq$ aged 60 presenting with cryptogenic stroke or TIA and a PFO. The other trial was the PC (Percutaneous Closure-Trial: PFO and Cryptogenic Embolism (Khattab, et al., 2011). However, patients taking part in these trials were all 60 years or younger on enrollment. Further trials with older participants are needed in order to develop diagnostic and therapeutic guidelines. Another trial which can throw some light on this, is the ongoing trial by Kent and Thaler (2011) called the Risk of Paradoxical Embolism (RoPE) Study which is aimed to develop and test a set of predictive models that can identify those patients most likely to benefit from preventive treatments for PFO-related stroke recurrence, such as PFO closure. The study is still ongoing. A study by Akhondi, et al., (2010) which evaluated the relationship between the morphological and functional size of the PFO showed that PFO size or morphology should not be used as the only criteria to decide whether a PFO should be closed.

PFOs AND MIGRAINE

An association between migraine with aura and PFO with shunting has been suggested (Tepper, Sheftfell & Bigal, 2007). An association of migraine with aura and Osler-Weber-Rendu disease has also been proposed, with the mechanism likely to be shunting though pulmonary arteriovenous malformations (Dalla Volta, et al., 2005). This study confirmed previous observations of a link between migraine with aura, cluster headaches and PFO. The study also suggested that such an association was independent to migraine clinical phenotype and was probably unrelated to the pathogenic mechanism of paradoxical embolism.

In a quantitative systematic review, a low to moderate level of evidence for the association between migraine (with or without aura) and PFO was found (Schwedt, Demaerschalk and Dodick, 2008).

Six studies of the effects of PFO closure on migraine showed an improvement but had a very low grade of evidence. The low-to-moderate grade of evidence from observational studies supported an apparent association between PFO and migraine. Although PFO closure seemed to affect migraine patterns favourably, the very low grade of available evidence to support this association precluded definitive conclusions. It has already been stated that prospective, controlled, clinical trials designed to evaluate the efficacy and safety of percutaneous device closure of PFO for migraine prevention were needed (Schwedt and Dodick, 2006).

On the other hand, in a multi-ethnic, elderly, population-based cohort, it was found that the presence of a PFO was not associated with self-reported migraine. This study also showed that the causal relationship between PFO and migraine remained uncertain, and

the role of PFO closure among unselected patients with migraine remains questionable (Rundle, et al., 2008). On the other hand, a case control study showed that compared with medical treatment, closure of PFO brings about a significant overall improvement in migraine. This seems to occur irrespective of migraine type and of previous cerebrovascular disease (Anzola, et al., 2006). In addition to the overall improvement in migraine with aura, the occurrence of aura is dramatically reduced. In a study of 121 patients with migraine it was again found that there is a possible association of migraine with aura and PFO. But it seems that PFO does not influence the type of aura and frequency of attacks of migraine as well as it is not associated with familial occurrence of migraine (Domitrz and Mieszkowski, 2008).

PFOs AND MYOCARDIAL INFARCTION

PFOs have been implicated as being also a risk factor not only for stroke and migraine but also for myocardial infarction and other ischemic vascular events (Diener, Tobias and Dodick, 2007). Although we have this evidence, explanation for these associations remains desirable.

PFOs AND SCUBA DIVERS

Right-to-left shunts are also associated with certain forms of neurological decompression sickness (DCS) in SCUBA (self-contained underwater breathing apparatus) divers (Wilmshurst and Bryson, 2000). The neurological decompression illness can occur after normal dives according to decompression tables, as a result of paradoxical gas embolism. A small number of observations suggested that cutaneous decompression illness was also associated with a right-to-left shunt, although embolic aetiology of a diffuse rash was more difficult to explain (Wilmshurst, et al., 2001). Cutaneous decompression illness has two possible mechanisms. The first mechanism was associated with a large right-to-left shunt, when it seemed that paradoxical gas embolism from peripheral bubble emboli invaded tissues supersaturated with nitrogen. Secondly, cutaneous decompression illness could occur in individuals without a shunt. In these subjects, the mechanism might be bubble emboli passing through an 'overloaded' lung filter or autochthonous bubble formation (Wilmshurst, et al., 2001). PFOs that caused DCS were 8mm in diameter or more (the larger the area the greater the shunting and the greater the chance of a DCS). PFOs which are smaller in diameter are found in about 15 per cent of the general population, but in only about 3 per cent of these did shunt related DCS occur. Also the diameter of a PFO is only partly correlated with propensity to shunt, because additional factors, such as mobility and stiffness of the flap covering the PFO, right atrial pressure that varies with activities, and atrial flow characteristics affect shunting (Wilmshurst, 2012). Today, we know that virtually most types of bends affecting the skin are related to right to left shunts across a PFO. We have more data about PFOs than many other fitness-to-dive issues, so if anyone has a cutaneous decompression illness, this is more likely to be PFO related, and therefore, the diver involved merits to be screened for a PFO (Wilmshurst, 2012).

The United Kingdom Sport Diving Medical Committee (UKSDMC) meeting about screening agreed that it was not reasonable to screen all, but that the potential groups where screening may be appropriate would be those with a previous DCS and those with migraine with aura (UKSDMC, 2001).

The rationale is that a diver who has a documented PFO, theoretically, has an increased risk of DCS. He has to make a more reasonable risk assessment if he wants to do high decompression stress diving. Having the test does not commit him to a closure procedure. He may simply modify his diving. If a diver had a history of migraine with aura, and suffered even once decompression illness, he should be definitely screened for a PFO. Current evidence on the efficacy of percutaneous closure of PFO for the secondary prevention of recurrent paradoxical embolism in divers is inadequate in quality and quantity, and the evidence on safety shows that there is a possibility of serious complications. Therefore, this procedure should only be used with special arrangements for clinical governance, consent and audit or reseach (NICE, 2010).

Screening tests for PFOs and the subsequent closure procedure can be a costly business, so the decision to go ahead is not a light one to take. The patients needing to know whether they have a PFO need to be counselled about why they want to know and what they will do with the information and disadvantages of knowing (such as adverse effects on insurance premiums). This strategy actually takes longer than it takes to close a PFO. So essentially, at present, the criteria for doing a contrast echo include divers with migraine with aura and no history of DCS and divers who are about to go to do some high risk diving in a

place remote from recompression facilities. Otherwise, the only candidates for screening for PFO are divers who have had a DCS and intend to persist with diving, young people who sustained some form of cryptogenic strokes and those patients awaiting posterior fossa neurosurgery Wilmshurst, 2012).

CONCLUSION

For carefully selected patients with history of cryptogenic stroke and PFO, the Respect Trial provides evidence of benefit in stroke risk reduction by closure with the Amplazter PFO Occluder over medical management alone. The PFO size or morphology should not be the only criteria to decide whether a PFO should be closed in case of paradoxical embolism. The link between PFOs and DCS has been amply demonstrated. The closure of the PFO, when it was done well, resulted in a reduction in the risk of a DCS. The occurrence of a PFO in divers who had a DCS may be of consequence and its closure may be contemplated. The association between migraine and PFOs is not well established. No sound evidence exits so far that closure of PFOs will reduce the incidence of migraine.

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A review of certain recent advances in primary health care

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ABSTRACT

Background

A strong primary health care system is the keystone of health care and helps patients manage their health conditions in the community, whilst also providing disease prevention services. Primary care is a continuously evolving specialty, with recent exciting innovations, aiming to improve all aspects of care and to meet people's needs and expectations.

Method

A search for articles focusing on the specific aspects of recent advances in primary health care was done using internet search engines. Articles were selected from primary and secondary literature sources, which included original research articles, review articles and other epidemiological studies.

Results

Recent advances in information technology, services and access, dealing with multimorbidity, academic family medicine, equity and outcome measures have all made an impact on the primary health care system and on meeting the ever-increasing challenges of modern society.

Conclusion

Primary health care is of extreme importance in having an efficient and effective health care system. As primary health care improves with recent advances, a positive effect is seen on the population's health, cost savings and health care disparities.

INTRODUCTION

The WHO Declaration of Alma-Ata represents a major step in the worldwide attention for primary care. This declaration highlighted the importance of developing, implementing and maintaining primary health care throughout the world, particularly in developing countries (World Health Organization, 1978).

The world has been changing since the Alma Ata Declaration of 1978. By contrast with the financial optimism of developing nations in the 1970s, the days of straightforward concerns and priorities have vanished. The pattern of disease, care and treatment options are changing (World Health Organization, 2007). Infectious diseases (such as, for example, tuberculosis or malaria) are no longer the only problems effecting only the poor (Frenk, 2009; Brundtland, 2005) during 1995-2000, the overall tuberculosis rate in Malta increased mainly due to the large influx of migrants from high-prevalence countries and to the increasing ratio of migrant to Maltese TB cases (Pace-Asciak, Mamo and Calleja, 2012).

At a time of financial and economic turmoil, health care needs and demand for public services will increase, colliding with austerity measures and privatisation policies (Kondilis et al., 2013). There are no easy solutions to create health care sustainability across and beyond Europe (Mamo, 2012). In view of these emerging public health challenges, decision makers are looking for solutions to achieve more cost-effective and better-coordinated care. One possible solution is implementing and maintaining high-quality primary care (QUALICOPC Consortium, 2012; Schäfer, 2013).

METHOD

A search for articles focusing on the specific aspects of recent advances in primary health care was done using the internet search engines PubMed, Medline Plus and Google Scholar . The keywords used while searching were 'recent advances', 'primary care', 'information technology', 'services and access', 'dealing with multimorbidity', 'academic family medicine', 'equity' and 'outcome measures'. Articles were selected from primary and secondary literature sources, which included original research articles, review articles and other epidemiological studies.

RESULTS

Primary health care has been facing major challenges including changing demographics, increasing demands and expectations, and rising health care costs. National and international strategies to address population health at primary care level are becoming increasingly important. Several studies have demonstrated that strong primary care systems and practice characteristics such as community orientation, co-ordination, comprehensiveness and continuity of care are associated with improved population health and lower costs (Delnoij et al., 2000; Kringos, 2012; Liss et al., 2011; Macinko et al., 2003; Starfield, 1994). In view of these emerging public health challenges, decision makers are looking for solutions to achieve more cost effective and better-coordinated care. One possible solution is implementing and maintaining high-quality primary care through the use of information technology, providing innovative services, dealing with multimorbidity, ensuring equity, strengthening the academic side of family medicine and measuring outcomes (QUALICOPC Consortium, 2012; Schäfer, 2013).

Information Technology

Information Technology (IT) has become an integral part of the health care system. Advances in IT improve quality and safety by:

a) improving access to reference information (e.g. through the use of mobile apps)
b) increasing adherence to guidelines due to easier accessibility
c) enhancing disease surveillance
d) reducing medication errors through the use of legible and complete computerised prescriptions, as well as calculation aids
e) using programmes that alert abnormal results (e.g. mobile alerts) and
f) improving primary and secondary preventive care (Bates & Gawande, 2003; Chaudry et al., 2006).

The main programmes available for use in primary health care in Malta are:

a) iSoft Clinical Manager, which is a computer program also used at Mater Dei Hospital as an electronic medical record, to send orders for laboratory tests and medical imaging, and to receive results of the laboratory tests and reports on the medical images
b) Picture Archiving and Communications System (PACS) which enables viewing of medical images taken at Mater Dei Hospital and Health Centres
c) Electronic Case Summary which enables viewing of discharge letters done at Mater Dei Hospital
d) myHealth which is the Governement of Malta's portal for online access to health records. The myHealth portal is a service available to all those who have a Maltese e-ID card and they, together with the doctors of their choice, can access health data through this site. As from 2008, the data accessible is the Electronic Case Summaries, Current Pharmacy of your Choice medicine entitlement, laboratory results and medical image reports, and appointments at Government Hospitals and Health Centres. There is also the possibility to set up e-mail notifications or sms reminders for appointments through this portal.

IT systems that were intended for professionals are now being adopted to be used at home by patients. Software is being designed to help patients clarify values and to provide computer-based decision aids, helping them to make informed choices. Electronic health records that are made available to patients empower them and can be used to tailor health information to their specific needs. Internet is a source of education for both patients and professionals, and there is the development of 'cyberlicensed professionals' who are specially trained to counsel patients online, while practice is monitored for quality (Eysenbach, 2000). Electronic referrals are a cheaper and more efficient way of handling outpatient services.

General practitioner (GP) teleconsulting with specialists results in managing problems in primary care instead of referral to secondary care, and this is especially useful to decrease the burden on secondary care and to prevent unnecessary travel in elderly patients. Teleradiology, where specialist opinion is obtained by transmission of digital x-ray images to a radiologist, is being used in primary health care (Wootton, 2001).

Services and Access

There has been a development in the number and types of services offered in primary care. These include minor surgery, radiography, orthopaedic services (including application of plaster), chronic disease follow-up clinics by a multi-disciplinary team (e.g. diabetes clinic), mental health clinics, physiotherapy, podology, ultrasound including echocardiograms, health promotion and prevention and home visits. The 'Patient Access' system (Longman, 2011) was developed for GP practices in the United Kingdom where getting access

to a GP was becoming increasingly difficult. The aim of this system was to transform access to medical care, and the technology used is the telephone. This starts with the patient calling the practice, where the receptionist is trained in taking calls. If the question is an administrative one, the receptionist will deal with it; the receptionist can also advise the patient to visit the practice to be seen by the nurse or else will pass on the details to the GP who will in turn contact the patient within a short time. The GP may then give advice over the phone, or advise the patient to come and see the GP or the nurse. This system was found to be time-saving for patients, who are encouraged to choose the GP to speak to, with more than 80% seen on the day. For doctors this resulted in reduced stress, flexible appointments, fewer 'did not attends' and more control over their working day. Accident & Emergency attendance is reduced by about 20% since it is easier to get access to medical care in the community (Longman, 2013).

Dealing with Multimorbidity

Non-communicable diseases are on the rise and multi-morbidity is becoming more the rule and no longer the exception. Older patients with multiple chronic conditions are at a higher risk of receving poorer overall quality of care compared to those with single or no chronic conditions. Disease-management programmes may have difficulty to achieve comprehensive, personalized care in view of competing guidelines, the burden of numerous recommendations and the difficulty in implementing treatments for multiple conditions (Min et al., 2007). Therefore, a paradigm-shift from 'problem-oriented' towards 'goal-oriented' care is needed, reorienting the care towards the goals formulated by the patient. By doing so, we will avoid care that may lead to 'inequity by disease' (De Maeseneer & Boeckxtans, 2011).

Academic Family Medicine

Family Medicine is a discipline that has only recently joined the academic arena. Medical schools are known to suffer from challenges, mainly that they do not relate to the problems of the modern world. It has largely been argued that the introduction of academic family medicine can solve some of these challenges. One of the main contributions of family medicine is in the innovative methods of education that family medicine can offer. The hallmark is the one-to-one teaching in practice, and other methods include role-playing and small group teaching (Svab, 2012). Local barriers to undertake training were found to be similar to those in UK and include shortage of staff, lack of time and other commitments. UK professionals mentioned time, cover for people to attend, costs and access or locality (Sammut, Bombagi and Cachia Fearne, 2012). Both family medicine and the medical school have a lot to benefit from mutual cooperation (Svab, 2012).

Equity

Whitehead describes equity in health care as the provision of fair means by which each person can access health care services, irrespective of their geographic location, financial means or cultural provenance (Whitehead, 1992). The two governing principles arising from this statement are that health provisions must particularly be made for individuals who are most vulnerable, and individuals who have equivalent needs must all have equal access to health care services (Culyer and Wagstaff, 1993).

An example of equity in our national health system is the presence of Health Centres of particular catchment areas in such a manner as to facilitate access to health care services, which provide not only teams of doctors, but also nursing services, mental health teams, podiatrists, speech language pathologists, physiotherapy services, social workers, visiting consultant services for internal medicine, ophthalmology, orthopaedics and diabetes management. This is an example of decentralisation of services, as well as ease of access to medicines through the option of collecting free medicines from a patient's pharmacy of choice and the provision of ambulatory services such as home vistis by doctors, nurses and social workers. The option of attending a local health centre free of charge helps ensure that even the poorest members of a local community are able to access health services through the availability of salaried professionals and care co-ordinators.

The availability of salaried GPs working in a health centre, should lead to an increased focus on personalized care rather than the provision of services which are determined by how much a patient is ready to pay, a shift in focus from the purse to the person (Campbell, Charlesworth and Gillett, 2001). Of particular concern is the immigrant population, whose care is not usually as good as that of individuals born in a particular country even if they have equal access to health care services (Muggah, Dahrouge and Hogg, 2012).

In 2010, the European QUALICOPC study was designed to provide information regarding the delivery of primary care in Europe. Its much awaited results will provide information regarding quality of care, financial issues, as well as issues of equal access to care (Schäfer et al., 2011).

Equity issues often involve issues of age, race, literacy, gender, stigmatised groups, disability, sexuality, social class and income groups amongst others, as well as differences between urban and rural populations. Evidence shows that patients living in rural areas significantly experienced more difficulty in accessing out-of-hours care as opposed to those in urban areas (Bezzina et al, 2013). In these situations, one must ensure the provision of a number of 'core' provisions, as well as services aimed at the specific needs of the particular community (Carey et al., 2013). An aspect to be commended is the involvement of all stakeholders, including the patient, in processes of quality assurance and planning at an organizational level.

Measuring Outcomes

Outcome measures provide a standard means of measuring and comparing the results of primary care services. These help us evaluate current practice, work towards improved services, make comparisons between the outcomes of different centres so that they can learn from one another and work towards the optimization of services and service delivery (Green et al., 2012; Reed et al., 2011). They also provide an evidence base for the provision of specific services and are a measure of their performance, especially within the context of the health care reform, where such studies can inform the decisions of policy-makers (Furler et al., 2008). These studies involve the use of administrative data, written and electronic patient records, observational studies, surveys, audits, quantitative and qualitative data.

Individual patient outcomes can be measured by means of standardised scales (eg. 'Patient-Specific Functional Scale', 'Kessler Psychological Distress Scale', 'Visual Analogue Scale') and validated questionnaires which are useful in the prevention, diagnosis and management of disease. Regular audit is essential to monitor the performance of a health centre, as well as studies that make use of standard validated tools and performance scores, which account for a variety of care models. Such scales account for a variety of factors including health promotion, disease prevention and management of chronic illness, as well as accessibility, service utilisation, cultural sensitivity, family orientation, communication and development/maintenance of rapport (Dahrouge et al., 2011), whilst taking different primary care models into consideration.

One must also bear in mind the importance of considering the patient's quality of life, which can be more difficult to measure, and where more often a qualitative approach is required, which seeks to encompass the patient's experience of the healthcare system. A number of countries provide incentives for community practice groups to work towards improved outcomes.

A recent innovation in primary care has been the developement of telemonitoring systems, particularly for the improved care of patients whose chronic illnesses make them house-bound, e.g. patients with chronic heart failure or chronic lung disease requiring chronic administration of oxygen. This demands a relatively high degree of patient motivation to carry out self-monitoring of vital parameters, input the data, which is then transferred electronically to a centralised system to provide monitoring of the patient. There is also the provision of telephone contact with the GP or practice nurse, home visits by members of the primary team, who can also liaise regularly with secondary care, in order to optimise management and reduce the number of hospital admissions (Martin-Lesende et al., 2011).

CONCLUSION

This review demonstrates the importance of appropriate resource allocation and optimisation directed towards the changing demands and needs of patients. Recent advances in the system can help to improve the provision of accessible, equitable and comprehensive care in an ambulatory setting to patients.

The available literature provides an evidence base showing that primary health care is a continuously-evolving specialty, with recent exciting innovations. Prioritising the strengthening of primary health care is an important part of the answer to address the emerging public health challenges in a globalising world.

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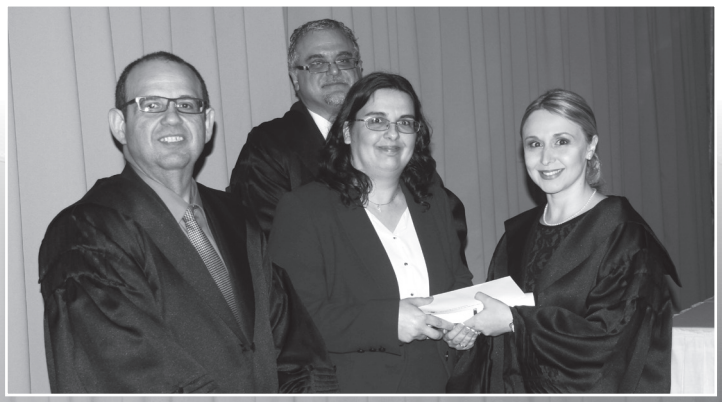
MMCFD Graduation Photos; 25 March 2014



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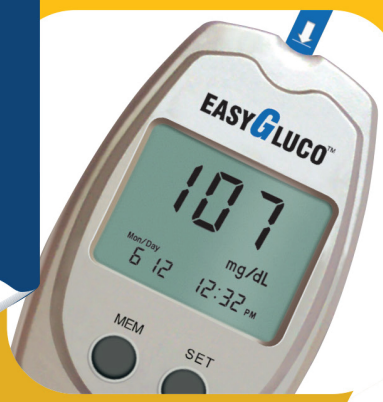

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PRESENTATION:
Each capsule contains 63 micrograms of glycopyrronium bromide equivalent to 50 micrograms of glycopyrronium. The delivered dose (the dose that leaves the mouthpiece of the inhaler) is equivalent to 44 micrograms of glycopyrronium.

INDICATIONS:
Indicated as a maintenance bronchodilator treatment to relieve symptoms in adult patients with chronic obstructive pulmonary disease (COPD).

DOSAGE:
The recommended dose is the inhalation of the content of one capsule once daily. Seebri Breezhaler is recommended to be administered, at the same time of the day each day. If a dose is missed, the next dose should be taken as soon as possible. Patients should be instructed not to take more than one dose in a day.

CONTRAINDICATIONS:
Hypersensitivity to the active substance or to any of the excipients.

WARNINGS/PRECAUTIONS: Seebri Breezhaler is not indicated for the initial treatment of acute episodes of bronchospasm. Paradoxical bronchospasm has been observed with other inhalation therapy and can be life threatening. If this occurs, Seebri Breezhaler should be discontinued immediately and alternative therapy instituted. Caution in patients with narrow angle glaucoma or urinary retention. Patients should be informed about the signs and symptoms of acute narrow angle glaucoma and should be informed to stop using Seebri Breezhaler and to contact their doctor immediately should any of these signs or symptoms develop. In patients with severe renal impairment including those with end stage renal disease requiring dialysis, Seebri Breezhaler should be used only if the expected benefit outweighs the potential risk. Seebri Breezhaler should be used with caution in patients with a history of cardiovascular disease. Patients with rare hereditary problems of galactose intolerance, the Lapp lactase deficiency or glucose-galactose malabsorption should not take this medicine. There are no data from the use of Seebri Breezhaler in pregnant women. Glycopyrronium should only be used during pregnancy if the expected benefit to the patient justifies the potential risk to the foetus. The use of glycopyrronium by breast feeding women should only be considered if the expected benefit to the woman is greater than any possible risk to the infant. Glycopyrronium has no or negligible influence on the ability to drive and use machines.

INTERACTIONS: The co administration of Seebri Breezhaler with other anticholinergic containing medicinal products has not been studied and is therefore not recommended. No clinically relevant drug interaction is expected when glycopyrronium is co administered with cimetidine or other inhibitors of organic cation transport.

ADVERSE REACTIONS: Common (≥1/100 to <1/10): Nasopharyngitis, insomnia, headache, dry mouth, gastroenteritis, urinary tract infection. Uncommon (≥1/1,000 to <1/100): Rhinitis, cystitis, hyperglycaemia, hypoaesthesia, atrial fibrillation, palpitations, sinus congestion, productive cough, throat irritation, epistaxis, dyspepsia, dental caries, rash, pain in extremity, musculoskeletal chest pain, dysuria, urinary retention, fatigue, asthenia

LEGAL CATEGORY: POM

PACK SIZES: Single pack containing 30x1 hard capsules, together with one inhaler.

MARKETING AUTHORISATION HOLDER: Novartis Europharm Limited, Wimblehurst Road, Horsham, West Sussex, RH12 5AB, United Kingdom.

MARKETING AUHORISATION NUMBER:
Seebri Breezhaler 44 micrograms inhalation powder, hard capsules - EU/1/12/788/001-006

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 22983217/21222872

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For information on Seebri Breezhaler dose expression, please refer to full prescribing information.

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