www.mcfd.org.mt

VOLUME 05 ISSUE 03
DECEMBER 2016

ISSN: 2304-8387

JMCFD

JOURNAL OF THE MALTA COLLEGE OF FAMILY DOCTORS

MMCFD and Teachers' Course Graduation

22 NOVEMBER 2016

Electronic column scale
M304040-01 CE class III approved

Mechanical height measure
MZ10023

Digital height measuring
MZ10033

Electronic professional column weighing scale with 220 kg capacity and 100 g graduation. The heavy duty platform comes with 2 castors for easy moving. Optionally available with ADE electronic or mechanical telescopic height measure. Batteries and a mains adapter are supplied as standard.

Technical specification:

Capacity:	220 kg
Graduation:	100 g
Dimensions:	320 x 320 x 1014 mm
Platform size:	320 x 320 mm
Weight:	8,2 kg

Function: Tare, hold, automatic zero setting, low battery indication, auto switch off, BMI calculation (fully automatic with MZ10033)
Power supply: 6 x AA batteries and mains battery life time approx. 4000 cycles, levelling feet

TECHNOLINE
SERVING MEDICINE & SCIENCE SINCE 1978

51, Edgar Bernard Street
Gzira GZR 1703

Tel: 21 344 345
Fax: 21 343 952

Email: admin@technoline-mt.com
Web: www.technoline-mt.com

JMCFD
JOURNAL OF THE MALTA COLLEGE OF FAMILY DOCTORS

Journal of the Malta College of Family Doctors

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

Volume 5 • Issue 3 • December, 2016

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

Email: mcfdjournal@mcfd.org.mt
www.mcfd.org.mt/jmcfd

Published by: Malta College of Family Doctors
Design and Production: www.outlook.coop

MMCFD and Teachers' Course Graduation 22 November 2016

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

CONTENTS

Guidelines for authors: mcfd.org.mt/resources/documents?did=8

Graduation, specialisation and future initiatives

Prof. Pierre MALLIA

During November we had our annual graduation ceremony. As time goes on this is becoming a main event every year. It is a time for celebrating several things. First and foremost of course a celebration for the graduands, who, after three years of training and an intense assessment have graduated. But more importantly it is a reminder of where we are coming from. More than a decade ago we opted to put Family Medicine on the Specialist Register and soon afterwards we decided that specialisation should come with a well-recognised specialized programme which is externally reviewed. It was natural, as I usually point out, following our 'Royal college' culture, that we should follow the path of the MRCGP(INT).

We now have more than fifty members with this qualification and the qualification process for existing members is in process. This is certainly a cause for celebration. Being called a speciality, for us, is not merely a term which is deserving of the speciality; it also follows a path of appropriate specialisation. As some of the graduates, who had done also the MRCP, realise, this exam is of an equivalent standard.

During the ceremony, I elaborated on what this specialisation means for us. I explained, as I have often done in this journal, that being listed on the specialist register is not an automatic process. Even doctors coming from the European Union cannot automatically apply. They can, as doctors who graduate here, be recognised to practice by the medical council. Due to the collective agreement that health centre doctors have with the Medical Association of Malta, only those on the specialist register can work in these places. Therefore EU doctors cannot automatically work in the government health sector. They can of course work in the private health sector – even those which are outsourced by the government; such as the new Gozo system being proposed. If a specialist register exists in the country from which the doctor comes, then we would have to accept him or her. But having a vocational training programme on its own which does not lead to being registered as a specialist, such as the system that exists in Italy, is not sufficient. This is important to maintain our standards.

We introduced a ceremony which is appropriate for a collegiate and educational body. The graduations at the RCGP are done with robes. The significance of a robe is that of showing a higher educational level. And therefore we are proud to carry out the ceremony with robes which reflects the well-earned reputation. Those who worked hard to establish the vocational training programme, especially the exam, will hopefully all soon be recognised by the Royal College.

POLICY COMPENDIUM

During last council we recognised that the College is often called by the Parliamentary Social Affairs committee to give its position on various issues being discussed. This was done recently on the issue of emergency contraception and on the euthanasia debate. It would be appropriate that these issues are discussed in time and that the College has official positions on various issues. Slowly we will build a compendium of policies of the College for the public to be able to refer to.

Another important issue discussed during the last council was the younger generation of doctors who are becoming members (through the vocational training programme). These members come from the information technology (IT) age – something which for many of us was built during our careers. These doctors grew up in this age and we have recognised that their 'world-view' is rather different. Luckily we have many young doctors on council who have pointed this out and together we will create opportunities which will be attractive to them. More IT use is important but social activities which meet their needs are also important. It is for this reason that I suggest that we form a group of young doctors to design programmes ranging from continuing professional development activities to social activities which are attractive to this younger generation of doctors.

We are looking also into the curriculum which will guide future continuing medical education (CME). In this way, when the medical council decides to introduce re-validation, one need not fear doing extra evaluations other than attending a recognised CME programme which follows a curricular design. This way one would ensure that doctors are kept up-to-date without the need for exams. I believe that we should be giving members value-for-money. CME is only a small part. We have now introduced the opportunity to support research initiatives for those who wish to apply for EU projects. Those who are interested may contact me on bioethicscentre@onvol.net. But I would also ask those who have ideas for the College to come forward. One cannot expect that council does everything and one must be willing also to help find the manpower for initiative. But the more we build the collegiality, the stronger will be our College.

Prof. Pierre MALLIA
MD PhD CBiol MPhil MA(Law) DipICGP MMCFD MRCP FRCGP
President, Malta College of Family Doctors
Email: bioethicscentre@onvol.net

GUEST EDITORIAL

The interphase between family medicine and mental health

Dr Anton GRECH, Ms Sally AXIAK, Prof. Clare GERADA

DeGruy (1996) stated that "*it is fundamentally wrong to speak of mental health as if it is distinct from physical health or health in general*". Generally speaking, and across the world, primary care clinicians deal with mental symptoms as part of a larger more general problem and conversely mentally distressed patients often present with increased physical symptoms. However, and more so within Malta, whilst most patients with common mental illnesses (depression, anxiety, adjustment disorder, alcohol dependence) attend their general practitioner (GP) for help, the more severe and enduring end of the psychiatric spectrum is largely addressed by specialist services, with GPs acting largely only as conduits for referral (McDaid, 2013).

De Hert et al. (2011) reported that the rates of undiagnosed and untreated medical illnesses are higher in individuals with a serious mental illness (SMI) when compared to the general population. In many instances the only contact of SMI patients with health services is through specialised mental health services, and by virtue of their condition they are less able to recognise their own signs of physical illness, solve their problems or care for themselves. Extant literature acknowledges a higher rate of morbidity and mortality in SMI patients (Bailey et al., 2012) but, as DeHert et al. (2011) observed, this is mostly due to modifiable health risk factors.

Wittchen et al. (2003) asserted that primary care doctors are the cornerstone of recognition, diagnosis, treatment and specialist referral for all types of disorders, be they of a somatic or psychological nature. McDiad (2013) stated that *"the best use of both specialist and primary mental health services occurs when an individual can get the help they need at the lowest level of support appropriate for them"*. This is a view that has been gaining ground in recent years with an increasing international trend towards integrating mental health services into primary care services. The World Health Organisation (WHO) has stressed the key role that primary care can play in the treatment of mental health conditions (WHO, 2001). GPs have the advantage of knowing their patients holistically, being aware of their interpersonal, social and domestic circumstances, as opposed to addressing a specific disease or condition. This is extremely relevant in the context of dealing with mental disorder which very often is impacted by social factors and family support. Significantly, robust primary care has been correlated with greater organisational efficiency and better patient outcomes, and consequently primary care is acknowledged

as the hub of current attempts to improve the performance and outcomes of healthcare systems (Fleury et al., 2012).

When individuals require specialist mental health services, it is imperative that their care is shared across the primary-secondary care divide; this ensures that specialist services can focus on individuals who need their skills and intensive support and ensures that their continuing care is delivered in the normal, and less stigmatising, environment of primary care. It also ensures that their other health needs are addressed as with other patients in their community (Fleury et al., 2012, McDaid, 2013).

Studies have examined the willingness of GPs to provide care for patients with SMIs and factors which impede participation in such provision. Oud et al. (2009) stated that a clear distinction must be made between the acute and chronic phases of SMIs. They found that GPs saw their role in the acute phase as being one of identification and referral to specialist services; however, their role in the chronic phase was more ambiguous and less easy to clarify. Whilst many of the participants in this study were willing to have a more extensive role in providing care to this patient group, they identified a need for training in areas such as pharmacotherapy and for a more optimal collaboration with mental health services.

In fact, integrating services between the two systems (primary health care and mental health care services) is a complex process, even where this process has been well established as is the UK National Health Service (Lester, 2005). There are certain obstacles to the successful integration of mental health care into the primary care setting such as time limitations associated with the pace of primary care practice, competing demands, lack of availability or access to other essential professionals (such as psychologists and social workers), and inadequate knowledge on the part of primary care clinicians due to the somatic and biological orientation of medical education. This is especially so when addressing the integration of the delivery of services for SMIs (Kelly et al., 2011).

The WHO (2001) set out a number of principles for addressing such barriers to integration. These included: the inclusion of primary care in mental health policy and planning; appropriate training and support of staff; information technology infrastructure; provision of financial support; a team based approach with an emphasis on communication; the provision of a mental health coordinator to drive integration and the acknowledgement that integration is a process not an event.

Current restructuring of national health care systems in Malta, especially as regards to mental health services, provides an excellent opportunity to weave mental health care into the fabric of primary health care. With this in mind, the government mental health services have recently launched a scheme of collaboration between GPs and the government services' mental health multidisciplinary teams, in the follow up of stable psychiatric patients suffering from psychosis or affective disorder within the community. Training of GPs interested in joining the scheme has already started and is planned to be an ongoing process. This scheme is far from being all-inclusive, but is just the initial step in what would hopefully be a fruitful collaborative process between Maltese GPs and Maltese psychiatrists and their teams, with the ultimate aim being the holistic wellbeing of Maltese sufferers of mental illness.

REFERENCES

Bailey, S., Gerada, C., Lester, H. and Shiers, D., 2012. The cardiovascular health of young people with severe mental illness: addressing an epidemic within an epidemic. *The Psychiatrist,* 36(10), pp. 375 -378.

DeGruy, F., 1996. *Mental Health Care in the Primary Care Setting. Primary Care: America's Health in a New Era*. [online] Available at: <https://www.nap.edu/read/5152/chapter/16> [Accessed 22 November 2016].

De Hert, M., Cohen, D., Bobes, J., Cetkovich-Bakmas, M., Leucht, S., David, M., Ndetei, D. and Correll, C., 2011. Physical illness in patients with severe mental disorders. II. Barriers to care, monitoring and treatment guidelines, plus recommendations at the system and individual level. *World Psychiatry*, 10(2), pp. 138–151.

Fleury, M., Imboua, A., Aube, D., Farand, L. and Lambert, Y., 2012. General practitioners' management of mental disorders: A rewarding practice with considerable obstacles. *BMC Family Practice,* 13(19).

Kelly, B.J., Perkins, D.A., Fuller, J.D. and Parker, S.M., 2011. Shared care in mental illness: A rapid review to inform implementation. *International Journal of Mental Health Systems,* 5, p. 31.

Lester, H., 2005. Shared care for people with mental illness: a GP's perspective. *Advances in Psychiatric Treatment,* 11(2), pp. 133-139.

McDaid, S., 2013. *Mental Health in Primary Care in Ireland: A briefing paper*. Mental Health Reform. Dublin.

Oud, M., Schuling, J., Slooff, C., Groenier, K., Dekker, J. and Meyboom-de Jong., B., 2009). Care for patients with severe mental illness: the general practitioner's role perspective. *BMC Family Practice*, 10(1), p. 29.

Wittchen, H.U., Mühlig, S. and Beesdo, K., 2003. Mental Disorders in Primary Care. *Dialogues in Clinical Neuroscience*, 5(2), pp.115-128.

World Health Organisation, 2001 *The World Health Report 2001 – Mental Health: New Understanding, New Hope*. [pdf] Available at: <http://www.who.int/whr/2001/en/whr01_en.pdf> [Accessed 22 November 2016].

Dr Anton GRECH
MD, PhD (Maas.), MSc (Psych) (Lond), FRCPsych (U.K.)
Mental Health Services, Mount Carmel Hospital, Attard, Malta; Department of Psychiatry, Medical School, University of Malta, Msida, Malta
Email: anton.grech@gov.mt

Ms Sally AXIAK
MSc HSM (Melita), BSc (Hons) Mental Health Nursing, RMN, RNMH
Mental Health Services, Mount Carmel Hospital, Attard, Malta

Prof. Claire GERADA
MBE FRCGP FRCPsych
General Practitioner, Hurley Group, London SE11 4HJ , U.K.

RESEARCH ARTICLE

Imaging of low back pain in a public health centre. A study of test request behaviour of doctors

Dr Glorianne PULLICINO, Ms Jessica PAVIA, Dr Stuart ZINTILIS, Dr Sean FRANCALANZA, Mr Paul SCIORTINO, Dr Philip SCIORTINO

ABSTRACT

Background

Lumbosacral spine radiography is a proven and valuable procedure for evaluating the vertebrae, disk spaces, facet and uncovertebral joints, neural foramina and paravertebral soft tissues. The purpose of radiographic examinations is to identify or exclude anatomic abnormalities or disease processes of the spine and related tissues. The written or electronic requests should provide the necessary information to show the medical need for the examination and allow for its appropriate performance and interpretation.

Objective

Our study was conducted to evaluate the appropriateness of lumbar spine radiography requests for low back pain in a public health centre. The benchmarks used were the 2009 NICE guidelines on the management of persistent non-specific low back pain and the 2011 Royal College of Radiologists' referral guidance.

Method

A descriptive, retrospective, cross-sectional study design was applied. A random sample of 100 lumbosacral spine radiographs was analyzed as recommended by the Royal College of Radiologists guideline tool and the 2009 NICE guidelines. Data was obtained from the Radiology Information System (RIS) and the Picture Archiving and Communication System (PACS).

Results

Sixty-four percent (n=64) of lumbar radiographs performed for low back pain were indicated and judged as appropriate as per existing guidelines. One radiograph (1%) was performed for non-specific low back pain.

Conclusion

This study reached its objectives of evaluating the appropriateness of lumbar spine radiography requests for low back pain. It was noted that there is a need to increase awareness of the Royal College of Radiologists guidelines to enhance appropriate use of lumbosacral spine radiography to ensure more efficient resource utilisation.

Keywords

Health services research; primary health care; community health centers; quality of health care; clinical audit

INTRODUCTION

Radiography of the spine is a proven and useful procedure for evaluating the vertebrae, disk spaces, facet and uncovertebral joints, neural foramina and paravertebral soft tissues. The goal of radiographic examinations is to identify or exclude anatomic abnormalities or disease processes of the spine and related tissues (Reinus, Strome and Zwemer, 1998).

Non-specific back pain is a common problem for primary and secondary care. It is defined as back pain lasting longer than 6 weeks and less than 12 months with no specific cause suspected such as a fracture, infection, malignancy or inflammatory disorder (National Collaborating Centre for Primary Care, 2016). Back pain is a major cause of sickness and absence from work. Much lumbar spine radiographs undertaken for back pain contribute significantly to the radiation burden of the population. The radiation dose of a simple single lateral spine x-ray is the equivalent to 50 chest x-rays (Department of Clinical Radiology, 2016).

NICE Guidelines advised not to offer x-ray of the lumbar spine for the management of non-specific low back pain (National Collaborating Centre for Primary Care, 2016). The latter guidelines stated that MRI should

be considered when a diagnosis of spinal malignancy, infection, fracture, cauda equina syndrome, ankylosing spondylitis or another inflammatory disorder is suspected (National Collaborating Centre for Primary Care, 2016).

In 2007 the Royal College of Radiologists issued guidelines for imaging non-specific back pain suggesting that x-rays would be only indicated if presentation suggested osteoporotic collapse in the elderly and for suspected spondylo-arthropathies in young patients" (The Royal College of Radiologists, 2016). It is important to note that the guidelines conceded that patients gain satisfaction from having information needs met by the x-ray (National Collaborating Centre for Primary Care, 2016; Department of Clinical Radiology, 2016).

Randomised unblinded controlled trials by Kendrick et al. (2001) and by Kerry et al. (2002) showed that lumbar spine radiography in primary care patients with acute low back pain were not associated with improvement in physical function, pain or disability. On the other hand, it is associated with enhanced patient satisfaction and an increase in GP workload (Kendrick et al., 2001). The authors comment that guidelines on the management of low back pain in primary care should be consistent about not recommending radiography of the lumbar spine in patients with low back pain in the absence of indicators for serious spinal disease, even if it has persisted for at least six weeks.

Consistent with this, a systematic review and meta-analysis conducted by Chou et al. concluded that lumbar imaging for low back pain without indications of serious underlying conditions does not improve clinical outcomes. Therefore, clinicians should refrain from routine, immediate lumbar imaging in patients with acute or subacute low-back pain and without features suggesting a serious underlying condition (Chou, Fu, Carrino and Deyo, 2009). The written or electronic requests should provide the necessary information to show the medical need for the examination and allow for its appropriate performance and interpretation (Reinus, Strome and Zwemer, 1998).

Our study was conducted to evaluate the appropriateness of lumbar spine radiography requests for low back pain in a public health centre with reference to the 2009 NICE guidance on the management of persistent non-specific low back pain and the 2011 Royal College of Radiologists' referral guidance.

METHOD

A descriptive, retrospective, cross-sectional study design was applied. All requests for lumbosacral spine radiographs taken in a primary healthcare centre in Mosta, Malta, between January and December 2014 were obtained from the Radiology Information System (RIS) and the Picture Archiving and Communication System (PACS). A random sample of 100 radiographs was analyzed as recommended by the Royal College of Radiologists guidelines. The data was obtained in an anonymous manner.

The patients' demographic and clinical characteristics were recorded. The clinical details presented on the request forms were reviewed and evaluated to determine as to which of the following outcome groups the requests could be classified in:

- Radiograph performed for non-specific low back pain;
- Radiograph performed for low back pain; clinical details reviewed and showed that the radiograph request was appropriate;
- Radiograph performed with insufficient clinical information provided to classify.

Radiographs reviewed as appropriate were those performed for low back pain in the presence of red flag symptoms, and those suggestive of "osteoporotic collapse in the elderly", as per the 2009 NICE guidance and the Royal College of Radiologists guideline tool (National Collaborating Centre for Primary Care, 2016; The Royal College of Radiologists, 2016). Data analysis was subsequently carried out using the Statistical Package for Social Sciences Version 20.

Patients who underwent lumbosacral spine radiography in a public hospital, or in the private sector were excluded from this study. Ethical approval was obtained from the University of Malta Research Ethics Committee.

RESULTS

There were 1877 lumbosacral spine radiographs performed in 2014 in the primary healthcare centre. The majority of patients were females (51%, n=1021). The sample population had an age distribution of 8-96 years with a mean of 55 years. The mode and median age were 65 years and 58 years respectively. The ratio of public to private GP referral for lumbosacral spine radiographs was 3:1.

Sixty-four percent (n=64) of lumbar radiographs performed for low back pain were indicated and judged as appropriate according to existing guidelines. Thirty-five per cent (n=35) of lumbar spine radiographs was carried out with insufficient clinical details. One radiograph (1%) was performed for non-specific low back pain.

DISCUSSION

Most patients referred for lumbosacral spine radiographs were females. This might reflect the fact that females have higher GP service utilisation rates (Wong et al., 2010; Pullicino et al., 2015). The ratio of public to private GP referral for lumbosacral spine radiographs was 3:1 since patients who warranted or expected such radiographs

might have attended the public sector directly. Primary care patients might be responding to what is available in each sector.

The Royal College of Radiologists recommends targets for lumbar spine radiography for low back pain (Table 1). There is a need to boost awareness of these guidelines to enhance appropriate use of lumbosacral spine radiography to ensure more efficient resource utilization (Culleton, O'Keefee and Quinn, 2016). Moreover, by minimising the number of lumbar radiographs performed inappropriately for non-specific low back pain, patients can reach important points in the care pathway more rapidly (National Collaborating Centre for Primary Care, 2016).

Table 1: The targets for lumbar spine radiography for low back pain recommended by the Royal College of Radiologists

Assessing local practice	
Indicators for lumbar spine radiographs for low back pain	**Targets (%)**
Non-specific low back pain	0
Low back pain judged as indicated appropriate with reference to existing guidelines i.e. osteoporotic collapse in the elderly	100
Insufficient clinical details	0

Furthermore, a reduction in unnecessary x-rays is desirable since this reduces costs (Department of Clinical Radiology, 2016). One might consider enhancing clinical information on referrals by designing a new lumbar spine referral form. This might help enhance the vetting and reporting of radiographs (Culleton, O'Keefee and Quinn, 2016).

An audit performed in the Rotherham NHS Foundation Trust by the Department of Clinical Radiology showed that only 22% of lumbar spine radiographs undertaken met either the 2007 Royal College of Radiologists (RCR) guidelines or the 2009 NICE guidelines (Department of Clinical Radiology, 2016). Another audit undertaken in Letterkenny General Hospital amongst patients aged 65 and over showed that 18% of referrals were deemed appropriate according to RCR guidelines (Culleton, O'Keefee and Quinn, 2016).

Patients gain satisfaction from having information needs met by the X-ray investigation. The challenge for primary care physicians is to increase satisfaction without resorting to radiography (Kendrick et al., 2001). Therefore, it is legitimate to conclude that the possibility of minor psychological improvement should be balanced against the high radiation dose involved.

This study reached its objectives of evaluating the appropriateness of lumbar spine radiography requests for low back pain in a public health centre. Therefore, it provides a systematic examination of current practice to assess how well primary care practitioners are performing against set standards. This helps to enhance safe care and efficiency by ensuring a better use of resources. On the other hand, several limitations were identified in the present study. Due to time and resource constraints, radiographs carried out in the public hospital and in the private sector were not captured. This study did not assess whether these imaging services were cost-effective and whether patient expectations were met. Future research can address these limitations.

CONCLUSION

This study provides information for primary care clinicians to improve patients' outcomes. Such findings are also useful to policy makers, educators and researchers who aim to improve the primary health care system to enhance resource allocation and utilisation.

Dr Glorianne PULLICINO
MD MSc (Public Health Medicine) MRCGP (Int) MMCFD
General Practitioner, Primary Health Care Department, Malta
Department of Family Medicine, University of Malta
Email: glorianneb@gmail.com

Ms Jessica PAVIA
Medical Student, University of Malta

Dr Stuart ZINTILIS MD
Foundation Doctor, Mater Dei Hospital, Msida, Malta

Dr Sean FRANCALANZA MD
General Practitioner Trainee,
Primary Health Care Department, Malta

Mr Paul SCIORTINO
Medical Student, University of Malta

Dr Philip SCIORTINO
MD MSc (Public Health Medicine) MRCGP FMCFD
Head of Department, Department of Family Medicine,
University of Malta

REFERENCES

Chou, R., Fu, R., Carrino, J.A. and Deyo, R.A., 2009. Imaging strategies for low-back pain: systematic review and meta-analysis. *Lancet*, 373(9662), pp.463–472.

Culleton, S., O'Keefee, P. and Quinn, C., 2016. *Imaging of low back pain in older people. An audit of current practice.* Electronic Presentation Online System. European Society of Radiology.

Department of Clinical Radiology, 2016. *Imaging for Back Pain. An audit of Practice.* The Rotherham NHS Foundation Trust.

Kendrick, D., Fielding, K., Bentley, E., Kerslake, R., Miller, P. and Pringle, M., 2001. Radiography of the lumbar spine in primary care patients with low back pain: randomised controlled trial. *BMJ (Clinical research ed.)*, 322(7283), pp.400–405.

Kerry, S., Hilton, S., Dundas, D., Rink, E. and Oakeshott, P., 2002. Radiography for low back pain: a randomised controlled trial and observational study in primary care. *The British Journal of General Practice*, 52(479), pp. 469–474.

National Collaborating Centre for Primary Care, 2016. *Low back pain: early management of persistent non-specific low back pain.* Full guideline May 2009. [online] Available at: <https://www.nice.org.uk/guidance/cg88/evidence/full-guideline-243685549> [Accessed 2 October 2016].

Pullicino, G., Sciortino, P., Calleja, N., Schäfer, W., Boerma, W. and Groenewegen, P., 2015. Comparison of patients' experiences in public and private primary care clinics in Malta. *European Journal of Public Health*, 25(3), pp. 399–401.

Reinus, W.R., Strome, G. and Zwemer, F.L., Jr., 1998. Use of lumbosacral spine radiographs in a level II emergency department. *American Journal of Roentgenology*, 170(2), pp. 443–447.

The Royal College of Radiologists, 2016. *The Royal College of Radiologists Imaging Referral Guidelines 2011.* [online] Available at: <https://www.rcr.ac.uk/clinical-radiology/being-consultant/rcr-referral-guidelines/about-irefer> [Accessed 2 October 2016].

Wong, S.Y.S., Kung, K., Griffiths, S.M., Carthy, T., Wong, M.C.S., Lo, S.V., Chung, V.C.H., Goggins, W.B. and Starfield, B., 2010. Comparison of primary care experiences among adults in general outpatient clinics and private general practice clinics in Hong Kong. *BMC Public Health*, 10(1), p. 397.

RESEARCH ARTICLE

Patient satisfaction in Maltese public health centres

Dr Kirsten SCHEMBRI

ABSTRACT

Background

Patient-centred care is a core value in family medicine. Patients have a right to receive high quality health care taking into account the individual's biopsychosocial problems.

Objective

To assess patient satisfaction in north and central Maltese public health centres and identify areas for improvement.

Method

A total of 120 patients were included. Prior authorisation from the Primary Health Care Department and from the data protection office was acquired. Patients who visited the health centre for the general practitioner (GP) service and accepted to take part in the questionnaire were required to sign a consent form. A questionnaire was then given to each of these patients on which they had to mark their level of satisfaction in each of the following areas: waiting time, making appointments, speaking with a doctor on the phone, doctor-patient communication, patients' privacy and dignity, and overall satisfaction.

Results

From a total of 120 patients, 39.2% (n=47) stated that they were not at all satisfied with waiting times at health centres. 49.2% (n=59) were "very satisfied" with the overall service given at health centres. Patients suggested increasing the number of doctors in health centres and having a more organised system whilst waiting at the GP clinic. The Diabetes and Chronic Disease Management Clinics received very positive feedback from patients.

Conclusion

This survey has helped to gauge patients' perceptions of primary care delivered in Maltese public health centres. More research in this area should be carried out possibly using a larger number of patients to obtain more representative results.

Key words

Patient satisfaction, primary care, health-centres

INTRODUCTION

Patient-centred care is "acknowledged as a core value" in family medicine. The aim of this study was to assess patient satisfaction in public primary care and identify areas for improvement (White, 1999) in order to deliver high quality health care and ensure a positive overall biopsychosocial experience for patients and their relatives. Good care of patients in primary care will help to prevent complications in secondary care. This will in the long term decrease population morbidity and lead to better equity and health outcomes (Mallia, 2006).

METHODOLOGY

A total of 120 patients were included in this survey carried out at health centres in the north and central regions of Malta between March and October 2016. Authorisation from the Primary Health Care Department and from the data protection office was acquired beforehand. Patients who visited the health centre for the GP service were invited to carry out this survey. Inclusion criteria were Maltese patients (males and females) who were deemed competent to fill in the survey and who accepted the invitation. In certain cases, patients required further explanation and assistance to fill in the questionnaire. Patients with visual and hearing impairments as well as those with learning disabilities were excluded from the survey. After the GP consultation, patients who accepted to take part in the questionnaire were required to sign a consent form. A questionnaire was then given to each of these patients on which they had to mark their level of satisfaction in each of the following areas: waiting time, making appointments, speaking with a doctor on the phone, doctor-patient communication, patients' privacy and dignity, and overall satisfaction. The questionnaire which was used is shown in Figure 1.

RESULTS

From a total of 120 patients, 39.2% of them (n=47) stated that they were not at all satisfied with waiting times at health centres. 38.3% of patients (n=46) were very satisfied when they made appointments at the health centre for clinics run by either doctors or allied health professionals. 49.2% (n=59) were very satisfied with the overall service given at health centres. None of the patients claimed that they were "not at all satisfied" with respect to doctor-patient communication and respect to patients' privacy and dignity (Figure 2).

When asked whether they would recommend the health centre to a family member or friend, all patients replied in the affirmative. The commonest remark written by participants was that there should be a greater number of doctors in health centres primarily in order to decrease waiting times. In fact, 10.8% of the patients in the survey (n=11) specified that more GPs should be available in health centres. Other comments that were mentioned were:

- A more organised system whilst waiting in the GP clinic;
- Patients commended the Diabetes and Chronic Disease Management Clinics since they felt that their chronic conditions are being monitored more closely, rather than having to wait to be seen only in secondary care. They were particularly satisfied with the appointments given for these clinics (i.e. appointments were "not too far away" compared to appointments given in secondary care).

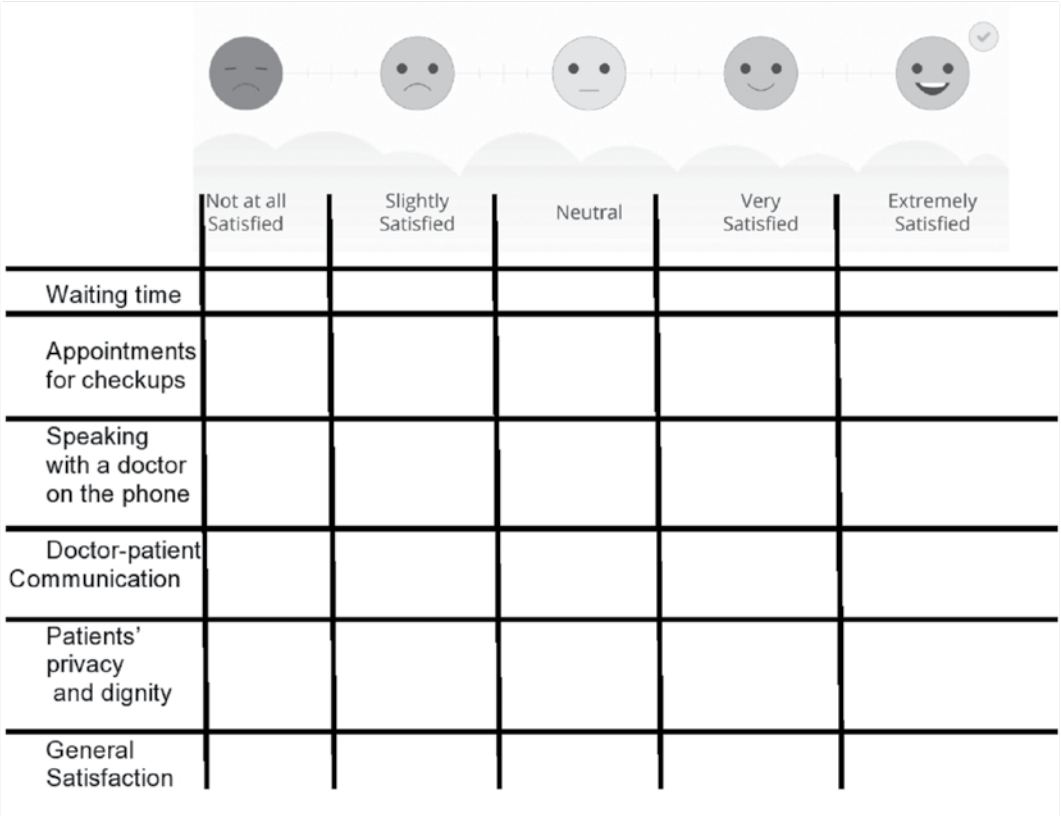
DISCUSSION

Primary health care as stated by the Alma-Ata Declaration "is the first level of contact of individuals, the family and community with the national health system bringing health care as close as possible where people live and work, and constitutes the first element of a continuing health care process" (Declaration of Alma-Ata, 1978). Since primary care is the individual's first contact with health care, its foundation lies in the adoption of a good doctor-patient relationship, continuity and coordination of care (Sammut, 2003).

According to the Institute of Medicine (Institute of Medicine (US) Committee on Quality of Health Care in America, 2001) patient-centred care is defined as "care that is respectful of and representative to individual patient preferences, needs, and values and ensuring that patient values guide all clinical decisions". The patient-centred approaches incorporated into medical training are key determinants of patient satisfaction and are associated with improved health outcomes. Patient-centred physicians are more sensitive to the perceived

Figure 1: Copy of patient satisfaction questionnaire

Please indicate with a tick (✓) according to whether you are satisfied or not in the following areas



	Not at all Satisfied	Slightly Satisfied	Neutral	Very Satisfied	Extremely Satisfied
Waiting time					
Appointments for checkups					
Speaking with a doctor on the phone					
Doctor-patient Communication					
Patients' privacy and dignity					
General Satisfaction					

Please feel free to write down your suggestions below:

- **Would you recommend this clinic to a family member or friend?** Yes / No
- **What can be done to improve our service?**

(Questionnaire adapted from: American Academy of Family Physicians, 2015. *Patient Satisfaction Survey. Family Practice Management*. Available at: <http://www.aafp.org/fpm/1999/0100/fpm19990100p40-rt1.pdf>. [Accessed October, 2016].)

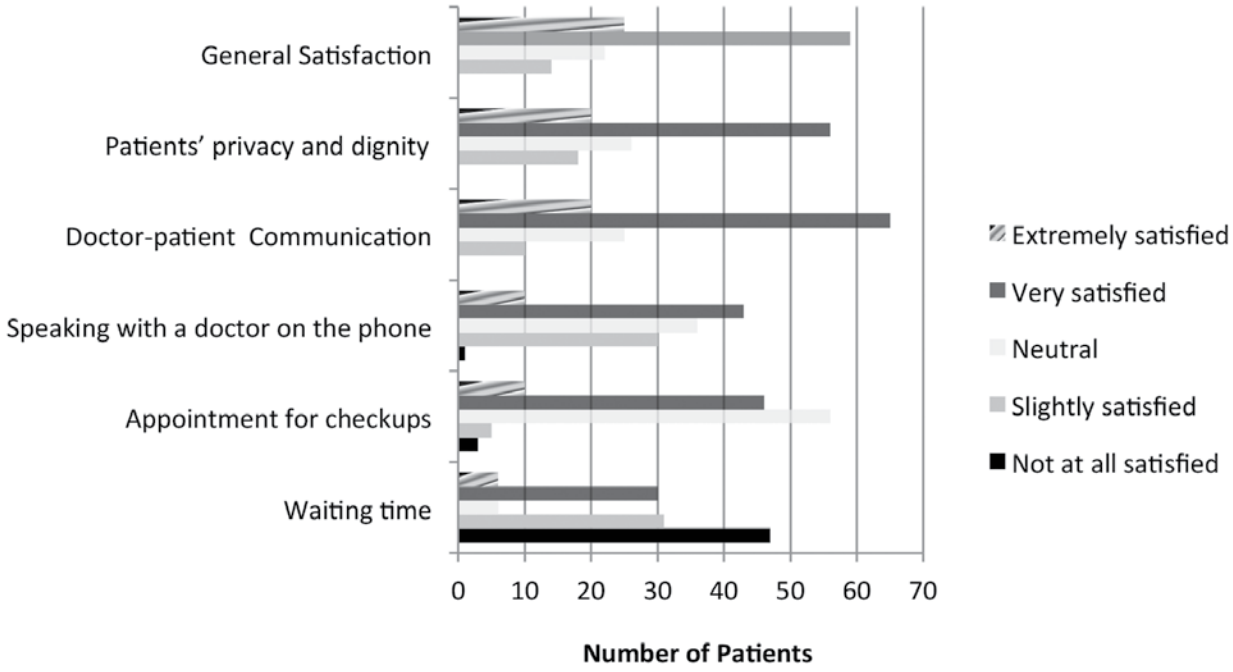
needs of their patients and are able to identify the extent to which their patients want to receive information and to be involved in decision making (Krupat et al., 2000).

Patient satisfaction is therefore of great significance to patient-centred care. The latter has been associated with several positive outcomes including reduction of malpractice complaints and improvements in physician satisfaction, consultation time, patients' emotional state, and medication adherence (Hudon et al., 2011).

Previous studies such as that carried out by Bezzina (2013) have shown that general levels of satisfaction with primary care are high. The strongest predictor for patient satisfaction was that the GP listens carefully to the patient during the consultation. In fact, when doctors listened carefully to the patients during the consultation, patients were 31 times more likely to be satisfied with the consultation (Bezzina, 2013).

Good communication skills play a considerable role in patient satisfaction and in the delivery of high-quality health care. Haskard Zolnierek and DiMatteo (2009) showed that there is a 19% higher risk of non-adherence to treatment among patients whose physician communicates poorly compared to patients whose physician communicates well. Training

Figure 2: Bar graph showing results of patient satisfaction survey



physicians in communication skills therefore results in substantial and significant improvements in patient adherence. In fact, when a doctor receives training in communication skills, the odds of patient adherence are 1.62 times higher than when a physician receives no training (Haskard Zolnierek and DiMatteo, 2009).

Rakel (1995) recognises the doctor-patient relationship as a central principle in family medicine. The family physician has an interest in providing ethical and humane care within the boundaries of the doctor-patient relationship (Mallia, 2006) and can act as an advocate on the patient's behalf. The doctor-patient relationship is established on the belief that a patient is an individual shaped by biological, personal, family, environmental, cultural and social dimensions (Mallia, 2006).

It was interesting to note that from the above results that none of the patients were dissatisfied with the doctor-patient relationship and with respect to patients' privacy and dignity in Maltese public health centres. Having said that, one must point out that there was possibly a degree of bias when answering this survey given by the doctor after a consultation. Patients who took part in this survey commented favourably with regards to the Diabetes and Chronic Disease Management Clinics (CDMC) in health centres. Diabetes is a major health problem in Malta, affecting 10.1% of all 20-79 year olds according to data from the International Diabetes Federation (Calleja et al., 2014). Moreover, this condition still carries significant stigma which would need to be explored by the patient's family doctor. The main aims of diabetic care and regular follow-up is to prevent macrovascular (coronary artery disease, peripheral arterial disease, and stroke) and microvascular complications (diabetic nephropathy, neuropathy, and retinopathy). The general practitioner who cares for his patients holistically therefore plays a strategic role in diabetes management since both the biological and psychosocial aspects of the condition can be addressed. Moreover, the primary care physician is usually the one who treats diabetic emergencies in the community such as hypoglycaemias (Mallia, 2006).

The Diabetes Shared Care programme between the Primary Health Care Department and the Department of Endocrinology and Diabetes in Mater Dei Hospital upholds the Saint Vincent Declaration and offers continuity of care and holistic support for patients with diabetes in Malta (Government of Malta, 2016).

With regards to the CDMC, this functions to improve integration of services for patients suffering from other chronic conditions such as hypertension and hyperlipidaemia, hence reducing fragmentation of care.

One of the limitations of this survey was that the sample size used was rather small considering the large amount of patients who visit Maltese public health centres. This was mainly because the response rate was low. Patients were selected using convenience sampling and therefore there might have been a high level of sampling error. Also, the demographic details (such as age and gender) of each patient taking part in the survey were not recorded. There was possibly a significant degree of recall bias and selection bias with respect to the type of patients who accepted to take the time to answer questions and add their own comments.

Another major limitation of this survey was that patients' experience in the private sector was not assessed given that the Maltese system is a dual private-public system. A study by Pullicino et al. (2014) showed that there is a significant degree of overlap between the two systems, i.e. public patients also use private GP services and vice versa. Also, there was no significant difference in patients' self-reported health improvement between the public and private primary care clinics (Pullicino et al, 2014).

ACKNOWLEDGEMENTS

The author wishes to express sincere thanks to Dr Gunther Abela and Dr Mario Sammut who encouraged her to develop her ideas and thoughts into this article. She would also like to thank Dr Anthony Livori and Dr Charmaine Cremona for their advice during the initial phase of the survey.

Dr Kirsten SCHEMBRI

GP Trainee, Primary Health Care Department, Malta

MSc in Internal Medicine student, University of Edinburgh, Scotland, U.K.

Email: kirsten.schembri@gov.mt

CONCLUSION

This survey has helped to gauge patients' perceptions of primary care delivered in Maltese public health centres. Following the results from this survey, recommendations for administrators include a more organised system particularly to decrease waiting times and possibly better triage of patients. The Diabetes and Chronic Disease Management Clinics are an important means of achieving integration of health services and therefore more input should continue to be invested in these clinics. Carrying out more research in this area and using a larger number of patients would possibly obtain more representative results.

REFERENCES

American Academy of Family Physicians, 2015. Patient Satisfaction Survey. *Family Practice Management*. Available at: <http://www.aafp.org/fpm/1999/0100/fpm19990100p40-rt1.pdf>. [Accessed October, 2016].

Bezzina, G., 2013. The quality of primary care in Malta: patients' experiences, views and actions. M.Sc. Public Health thesis, University of Malta, Malta.

Calleja, N., Azzopardi Muscat, N., Reiff, S., Fava, S., Vassallo, J., Torpiano, J. et al., 2014. *Diabetes: A National Public Health Priority. Proposal for a National Strategy for Diabetes (2015-2020).* Consultation on Diabetes Strategy, Ministry for Energy and Health (Health), Malta.

Declaration of Alma-Ata, 1978. International Conference on Primary Health Care. Alma-Ata, USSR.

Government of Malta, 2016. *Diabetes Shared Care Programme Overview* [online]. Available at: <https://health.gov.mt/en/phc/Pages/Services/Diabetes-Shared-Care-Programme/Diabetes-Overview.aspx>. [Accessed 23 October 2016].

Haskard Zolnierek, K. B., and DiMatteo, M. R., 2009. Physician Communication and Patient Adherence to Treatment: A Meta-Analysis. *Medical Care*, 47(8), pp. 826-834.

Hudon, C., Fortin, M., Haggerty, J.L., Lambert, M. and Poitras, M.E., 2011. Measuring patients' perceptions of patient-centred care: a systematic review of tools for family medicine. *Annals of Family Medicine*, 9(2), pp. 155-64.

Institute of Medicine (US) Committee on Quality of Health Care in America, 2001. *Crossing the Quality Chasm: A New Health System for the 21st Century.* Washington, DC: National Academy Press.

Krupat, E., Rosenkranz, S.L., Yeager, C.M., Barnard, K., Putnam, S.M. and Inui, T.S., 2000. The practice orientations of physicians and patients: the effect of doctor–patient congruence on satisfaction. *Patient Education and Counseling,* 39(1), pp. 49-59.

Mallia, P., 2006. *You & Your Doctor*, Malta: Agenda.

Pullicino, G., Sciortino, P., Calleja, N., Schäfer, W., Boerma, W. and Groenewegen, P., 2015, Comparison of patients' experiences in public and private primary care clinics in Malta. *The European Journal of Public Health*, 25(3), pp. 399-401.

Rakel, R.E., 2015. *A Textbook of Family Practice,* 9th edition. New York: Saunders.

Sammut, M., 2003. State primary health care: addressing medical manpower needs. M.Sc. Health Services Management thesis, University of Malta, Malta.

White, B., 1999. Measuring patient satisfaction: How to do it and why to bother. *Family Practice Management*, 6(1), pp. 40-4.

Evidence-based smoking cessation and the family doctor

Dr Mario R SAMMUT

ABSTRACT

Background

In Malta smoking is widespread and associated with significant morbidity and mortality. Family doctors are well-placed to provide smoking cessation advice to their patients.

Objective

The aim of this review is to assist family doctors in helping their patients quit smoking by informing them of evidence-based therapies.

Method

The online Cochrane Database of Systematic Reviews within the Cochrane Library was searched for meta-analyses and systematic reviews related to various smoking cessation interventions.

Results

Effective non-pharmacological interventions include individual counselling (face to face and over the telephone), text-messaging and group therapy. Smoking cessation medications that are successful and licensed comprise nicotine replacement therapy, bupropion and varenicline. Combining behavioural support and pharmacotherapy increases smoking cessation success.

Conclusion

By following the 5As technique for smoking cessation based on evidence-based interventions, family doctors can have a considerable influence on the health of smokers by helping them to quit.

Key words

Evidence-based medicine; smoking cessation; family practice.

INTRODUCTION

To ensure that clinical practice today provides effective health care, it should be based on evidence, with the latter being attained from scientific knowledge, research / audit findings and verified experiences (Kernohan, 2006). In 1996, Sackett and colleagues defined evidence-based medicine (EBM) as the conscientious, explicit and judicious use of current best evidence in making decisions about the care of individual patients. They went on to specify that successful EBM must comprise the best available external clinical evidence, clinical expertise and the involvement of patient choice, with best evidence provided by research that is clinically relevant and carried out using sound methodology (Sackett et al., 1996).

The practice of EBM thus involves a process of methodically locating, appraising, and making use of recent research findings in order to inform the taking of clinical decisions (Rosenberg and Donald, 1995). As the above may prove to be a laborious process for busy clinicians, the latter initially may refer to clinical guidelines drawn up by reputable organisations. If a guideline relevant to a certain clinical topic is not found, one may then search in online databases for systematic reviews (of quality studies with sound methodology) and/or meta-analyses (systematic reviews where data from quality studies are pooled and re-analysed as if one large study). (Sandholzer, 2004; Duke University, 2013)

BACKGROUND

In 2008, the European Health Interview Survey revealed that one third of the Maltese population had smoked daily or almost daily for at least one year. Males were approximately two times more likely than females to smoke daily, with occasional smokers being slightly more likely to be female than male. Passive smoking was a problem, with about a quarter of the respondents claiming to be somewhat exposed at home or in public. (Department of Health Information and Research, 2008)

The average annual smoking-attributable mortality in Malta during 1999-2013 was estimated to be 396 deaths in males (42% from cancer, 40% due to cardiovascular disease and 18% from respiratory diseases) and 111 deaths in females (37% due to cancer, 47% from cardiovascular disease and 16% due to respiratory diseases). (Department of Health Information and Research, 2014)

Therefore smoking is a widespread problem in Malta associated with significant morbidity and mortality. As patients see their family doctor four times a year on average, the latter has ample opportunities to practice preventive medicine in daily practice (McWhinney, 1997). The promotion of health and well-being by applying the appropriate strategies in fact is one of the core competences of the family doctor (WONCA Europe, 2005). The aim of this review thus is to assist family doctors in providing smoking cessation advice consisting of interventions that have been proved to work.

METHOD

As meta-analyses and systematic reviews are considered to be at the top of the hierarchy of study designs (Duke University, 2013), the online Cochrane Database of Systematic Reviews (CDSR) within the Cochrane Library (http://www.cochranelibrary.com) was searched for such designs related to various smoking cessation interventions. The Cochrane Library is maintained by a global independent network of researchers, professionals, patients, carers, and people interested in health, that gathers and summarises the best evidence from research to help make informed choices about treatment (Cochrane Library, 2016).

The CDSR systematic reviews are of randomised controlled trials (RCTs) or quasi-RCTs that test the efficacy of a drug or service where subjects are randomly allocated to receive one or other of alternative interventions. These reviews provide the risk ratio (RR), which gives the risk of a certain event happening in one group compared to the risk of the same event happening in another group, and the confidence interval (CI) within which results of a trial fall given a set probability (usually taken as 95%).

RESULTS

Eighty-two reviews related to 'tobacco' were found in the CDSR. Limiting this scrutiny to reviews of treatment modalities that can be used by family doctors to help otherwise-healthy adults in the community quit smoking, 29 different interventions were identified and classified as follows for ease of reference: what doesn't work, what makes no difference, what's still uncertain, and what works.

1. WHAT DOESN'T WORK

(a) Non-pharmacological

As anxiolytics may assist anxiety associated with smoking, Hughes, Stead and Lancaster (2000) identified and reviewed 6 trials of the effect of anxiolytic drugs on smoking cessation for at least six months, but concluded that none showed strong evidence that they were effective.

Aversion therapy (such as rapid smoking) was reviewed by Hajek and Stead (2001), who, after identifying 25 relevant RCTs, concluded that there is insufficient evidence regarding its efficacy.

Hypnotherapy is supposed to help cessation by abating the craving to smoke or strengthening the determination to quit. However there is not enough evidence from 11 RCTs that hypnotherapy could be as effective as counselling in this regard (Barnes et al., 2010).

Although internet-based interventions are popular in this information technology age, when compared with self-help or usual care such interventions did not show consistent effects from 28 quasi/RCTs which were found to be at risk of bias (Civljak et al., 2013).

Acupuncture, acupressure, laser therapy and electrical stimulation have not been found to result in smoking cessation in the long term (for at least six months) from 38 identified RCTs that only provided inconsistent and biased evidence (White et al., 2014).

Exercise programmes were not found to aid smoking cessation in the long term in an analysis of 20 trials by Ussher, Taylor and Faulkner (2014) who identified problems with study design, bias risks and study differences.

(b) Pharmacological

Nicobrevin, a product containing quinine, menthyl valerate, camphor and eucalyptus oil, had been promoted in the past as a smoking cessation aid. However, as no RCTs with long term follow-up were found, there is no evidence that it works (Stead and Lancaster, 2006).

Cannabinoid type 1 receptor antagonists (rimonabant and taranabant) restore the balance of the endocannabinoid system and were developed for the treatment of weight gain. Their mode of action was thought to perhaps be of help with smoking cessation, but a review of 3 RCTs concluded that, while rimonabant may increase the quit-rate by 50%, the evidence for

maintaining abstinence was uncertain. Both rimonabant and taranabant were withdrawn in 2008 due to their side-effects. (Cahill and Ussher, 2011)

Lobeline, an alkaloid produced from Indian tobacco leaves, was not found to help people stop smoking in a review by Stead and Hughes (2012), who could identify no adequate long-term trials.

Silver acetate, in the form of lozenges, gum and spray, produces an unpleasant metallic taste with smoking and thus was intended to help smokers to quit. However there is little evidence from 2 RCTs that it does result in cessation of smoking (Lancaster and Stead, 2012).

Nicotine vaccines have been designed to reduce effects of nicotine on the brain, with less reward from smoking. Four RCTs comparing nicotine vaccines to placebo showed that the former did not result in long-term quitting (Hartmann-Boyce et al., 2012), with the authors of the analysis recommending that further trials of such vaccines are needed.

The long-acting opioid antagonist, naltrexone, was not found to assist smoking cessation in the long term from 8 trials with over 1200 participants (David et al., 2013).

2. WHAT MAKES NO DIFFERENCE

Studies comparing cutting down the number of cigarettes before quitting to the traditional abrupt quitting 'cold turkey' gave similar cessation rates (10 RCTs; number of participants [N] = 3760; RR= 0.94; 95% CI 0.79 to 1.13), with the authors of the analysis (Lindson-Hawley, Aveyard and Hughes, 2012) advising that further studies needed to be carried out regarding the most effective method of cutting down before quitting.

3. WHAT'S STILL UNCERTAIN

(a) Non-pharmacological

Stage-based interventions for smoking cessation are based on the transtheoretical model of behaviour change that suggests that advice to smokers should be tailored to their stage of readiness to quit (precontemplation, contemplation, preparation, action and maintenance). From a review of the evidence from 41 stage-based trials of over 33,000 smokers measuring long-term quit rates, Cahill, Lancaster and Green (2010) found that "providing self-help or counselling support to smokers trying to quit is more effective than 'usual care' or simple observation. However, the extra value of fitting that support to the smoker's stage of change is currently unclear".

(b) Pharmacological

Mecamylamine (developed as an antihypertensive) is a nicotine antagonist and a review was carried out to see if it was of use as an aid to long-term smoking cessation. As only 2 small trails (N=128) were identified that suggested that mecamylamine in combination with nicotine may be superior to nicotine alone in helping smokers quit, the authors of the review recommended that larger studies are required (Lancaster and Stead, 1998).

Cytisine is a natural nicotine receptor partial agonist extracted from seeds of the Golden Rain acacia that aims to reduce withdrawal symptoms and smoking satisfaction. Two RCTs (N=937) found that it increases the chances of quitting, although absolute quit rates were modest at around 9% (Cahill et al., 2016).

Electronic cigarettes (ECs) are electronic devices that produce an inhalable aerosol through heating a liquid usually composed of propylene glycol and glycerol, with or without nicotine. Two RCTs (N=662) have found that ECs delivering nicotine help smokers to quit long-term compared with placebo ECs. However, confidence in the result is rated 'low' by standards developed by the Grading of Recommendations, Assessment, Development and Evaluations (GRADE) Working Group due to the small number of trials, low event rates and wide confidence intervals (Hartmann-Boyce et al., 2016).

4. WHAT WORKS

(a) Non-pharmacological interventions

The provision of printed self-help materials without any other contact was found by Hartmann-Boyce, Lancaster and Stead (2014) to increase quit rates compared to no intervention by about 20% from 11 RCTs with 13,241 participants (RR 1.19; 95% CI 1.04 to 1.37).

Motivational interviewing (MI) is a style of counselling that is directive and patient-centred and aims to explore and overcome ambivalence about change in behaviour. A meta-analysis of 28 RCTs (N=16,803) of MI compared to usual care or brief advice showed an increase of about 25% in quitting (RR 1.26; 95% CI 1.16 to 1.36). The authors (Lindson-Hawley, Thompson and Begh, 2015) however advised caution in interpreting these results because of differences between studies regarding their features and treatment delivery.

Individual counselling compared to minimal behavioural intervention in 22 quasi/RCTs (RR 1.39; 95% CI 1.24 to 1.57) was found to increase the rate of quitting by 40% (Lancaster and Stead, 2005). Telephone counselling through calls to a helpline was also found

to increase the quit rate by 40% in a review of 9 quasi/RCTs (N>24,000; RR 1.37; 95% CI 1.26 to 1.50) by Stead, Hartmann-Boyce et al. (2013). Mobile phone text-messaging in high-income countries increases long term quit rates by nearly 70% compared with control programmes according to 12 quasi/RCTs (N= 11,885; RR 1.67; 95% CI 1.46 to 1.90) reviewed by Whittaker et al. in 2016.

While brief advice intervention from a medical practitioner versus usual care or no advice increases the rate of quitting long term by nearly 70% (17 RCTs; RR 1.66; 95% CI 1.42 to 1.94) (Stead, Buitrago et al., 2013), group therapy compared to self-help was found to double the chances of quitting from 13 RCTs (N=4375, RR 1.98; 95% CI 1.60 to 2.46) analysed by Stead and Lancaster (2005).

(b) Pharmacological interventions

Clonidine is a centrally-acting antihypertensive that was found to increase the rate of quitting by 60% from 6 RCTs (RR 1.63; 95% CI 1.22 to 2.18). However, due to the limited number of studies with potential biases, and the drug's important side-effects, its use for smoking cessation is limited (Gourlay, Stead and Benowitz, 2004).

Nicotine replacement therapy (NRT) aims to help the shift from smoking to quitting by replacing nicotine from cigarettes and thus decrease both the stimulus to smoke and the symptoms resulting from nicotine withdrawal. Such therapy is available in different forms (patch, gum, spray, inhaler and lozenges/tablets). Stead et al. (2012) established that NRT increase quit rates by 50-70% from 117 RCTs with over 50,000 total participants (RR 1.60; 95% CI 1.53 to 1.68).

The tricyclic antidepressant nortriptyline was found to double the chances of long term cessation, but from only 6 RCTs with a total of 975 participants (RR 2.03; 95% CI 1.48 to 2.78). Due to adverse effects, nortriptyline is not licensed as a smoking cessation medication. There is more evidence available regarding bupropion, another antidepressant which inhibits norepinephrine-dopamine reuptake and is licensed also to treat smoking cessation. Forty-four RCTs (N=13,728; RR 1.62; 95% CI 1.49 to 1.76) showed that it increases the rate of long term cessation by 60% (Hughes et al., 2014).

Varenicline, a synthetic nicotine receptor partial agonist, was specifically developed and approved as a smoking-cessation therapy in 2006. It has been ascertained from 27 RCTs (N=12,625) that varenicline increases the chances of successfully quitting long-term by two to three-fold compared with placebo (RR 2.24; 95% CI 2.06 to 2.43) (Cahill et al., 2016).

(c) Pharmacological and behavioural interventions together

Adding behavioural support (face to face or by telephone) to pharmacotherapy may increase the chance of successful quitting by 10 - 25% as a result of pooling of results by Stead, Koilpillai and Lancaster (2015) from 47 quasi/RCTs (N>18,000; RR 1.17; 95% CI 1.11 to 1.24).

Combined behavioural support (such as brief advice and counselling) and pharmacotherapy (e.g. NRT, varenicline and bupropion) increases smoking cessation success by over 80% compared to minimal interventions or usual care. This conclusion is based on high quality evidence from 52 quasi/RCTs (N=19,488) with a RR of 1.83 and a 95% CI of 1.68 to 1.98 (Stead et al., 2016).

CONCLUSION

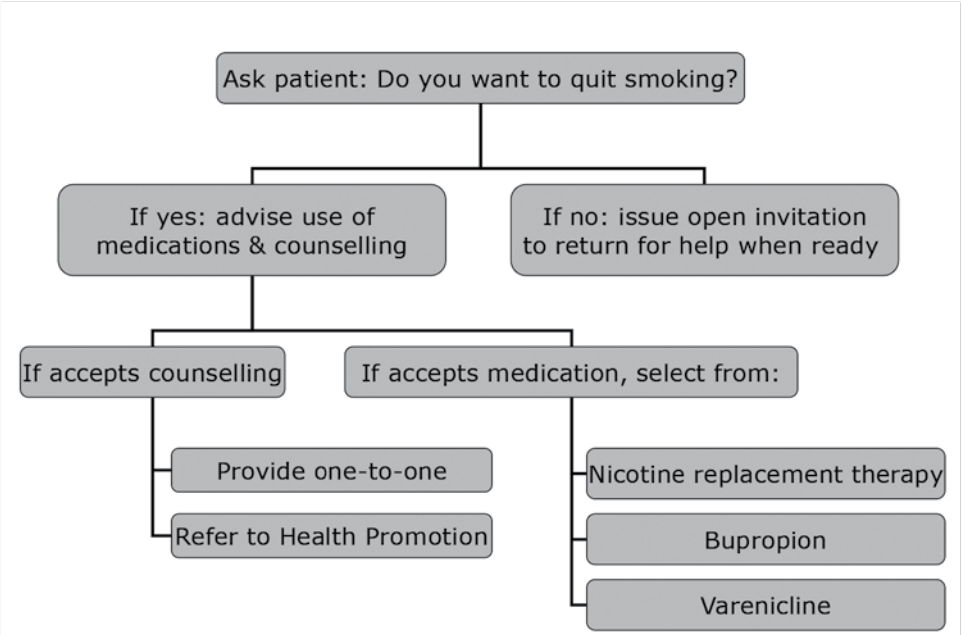
The website BMJ Best Practice (http://bestpractice.bmj.com) provides access to the latest research evidence, guidelines and expert opinion to aid diagnosis and treatment decisions. Regarding smoking cessation, it recommends the following 5-step technique for clinicians to follow (Best Practice, 2016):

- **Ask**: patients if they smoke;
- **Advise**: smokers on how quitting can help them achieve their goals;
- **Assess**: whether the patient is ready to attempt to stop and, if ready, how confident he/she is about success;
- **Assist**: if not ready to quit, inform the smoker that help is always available when he/she is ready; if willing to stop, provide a menu of pharmacotherapy / counselling;
- **Arrange** follow-up through a telephone counselling line, group or individual counselling, return visits and telephone calls.

Individual counselling and group therapy clinics are available in Malta from the Health Promotion Unit within Malta's Ministry for Health that may be contacted as follows:

- website: https://health.gov.mt/en/health-promotion/Pages/home.aspx;
- email: health.pro@gov.mt;
- telephones: 23266000 (main), 23266116 (tobacco support officer), 80073333 (quitline).

Figure 1: Smoking cessation flowchart for the clinician



(Adapted from BMJ Best Practice, 2016)

Preventive measures in tobacco control involves knowing which diseases are related to smoking, informing patients on the dangers of smoking and the benefits of quitting, and advising all patients who smoke to quit and how (Sammut, 2006). Giving up smoking is probably the biggest single thing smokers can do in their life to improve their health, and the intervention of family doctors in this respect (see Figure 1) will probably be the most important single influence they can have on the health of patients who smoke (Raw, 1988).

Dr Mario R SAMMUT
MD, DipHSc, MScH, MScPC&GP(Ulster), FMCFD
Specialist and Lecturer in Family Medicine
Email: mrsammut@rocketmail.com

REFERENCES

Barnes, J., Dong, C.Y., McRobbie, H., Walker, N., Mehta, M. and Stead, L.F., 2010. Hypnotherapy for smoking cessation. *Cochrane Database of Systematic Reviews*, Issue 10. Art. No.: CD001008. DOI: 10.1002/14651858.CD001008.pub2.

BMJ Best Practice, 2016. *Smoking cessation.* [online] Available at: <http://bestpractice.bmj.com/best-practice/monograph/411.html> [Accessed 21 October 2016).

Cahill, K., Lancaster, T. and Green, N., 2010. Stage-based interventions for smoking cessation. *Cochrane Database of Systematic Reviews*, Issue 11. Art. No.: CD004492. DOI: 10.1002/14651858.CD004492.pub4.

Cahill, K., Lindson-Hawle, N., Thomas, K.H., Fanshawe, T.R. and Lancaster, T., 2016. Nicotine receptor partial agonists for smoking cessation. *Cochrane Database of Systematic Reviews*, Issue 5. Art. No.: CD006103. DOI: 10.1002/14651858.CD006103.pub7.

Cahill, K. and Ussher, M.H., 2011. Cannabinoid type 1 receptor antagonists for smoking cessation. *Cochrane Database of Systematic Reviews*, Issue 3. Art. No.: CD005353. DOI: 10.1002/14651858.CD005353.pub4.

Civljak, M., Stead, L.F., Hartmann-Boyce, J., She, A. and Car, J., 2013. Internet-based interventions for smoking cessation. *Cochrane Database of Systematic Reviews*, Issue 7. Art. No.: CD007078. DOI: 10.1002/14651858.CD007078.pub4.

Cochrane Library, 2016. *About Cochrane*. [online] Available at: <http://www.cochranelibrary.com/about/about-the-cochrane-collaboration-and-how-to-get-involved.html> [Accessed 12 October 2016].

David, S.P., Lancaster, T., Stead, L.F., Evins, A.E. and Prochaska, J.J., 2013. Opioid antagonists for smoking cessation. *Cochrane Database of Systematic Reviews*, Issue 6. Art. No.: CD003086. DOI: 10.1002/14651858.CD003086.pub3.

Department of Health Information and Research, 2008. *European Health Interview Survey 2008 Summary Statistics*. [pdf] Available at: <http://health.gov.mt/en/dhir/Documents/ehis_eight__summ_stats.pdf> [Accessed 12 October 2016].

Department of Health Information and Research, 2014. *Smoking attributable deaths. Factsheet 01/2014*. [pdf] Available at: <http://health.gov.mt/en/dhir/Documents/dhir_fact_sheet_smoking_attributable_deaths.pdf> [Accessed 12 October 2016].

Duke University Medical Centre Library & University of North Carolina Health Sciences Library, 2013. *Introduction to Evidence-Based Practice*. [online] Available at: <http://guides.mclibrary.duke.edu/ebmtutorial> [Accessed 12 October 2016].

Gourlay, S.G., Stead, L.F. and Benowitz, N., 2004. Clonidine for smoking cessation. *Cochrane Database of Systematic Reviews*, Issue 3. Art. No.: CD000058. DOI: 10.1002/14651858.CD000058.pub2.

Hajek, P. and Stead, L.F., 2001. Aversive smoking for smoking cessation. *Cochrane Database of Systematic Reviews*, Issue 3. Art. No.: CD000546. DOI: 10.1002/14651858.CD000546.pub2.

Hartmann-Boyce, J., Cahill, K., Hatsukami, D. and Cornuz, J., 2012. Nicotine vaccines for smoking cessation. *Cochrane Database of Systematic Reviews*, Issue 8. Art. No.: CD007072. DOI: 10.1002/14651858.CD007072.pub2.

Hartmann-Boyce, J., Lancaster, T. and Stead, L.F., 2014. Print-based self-help interventions for smoking cessation. *Cochrane Database of Systematic Reviews*, Issue 6. Art. No.: CD001118. DOI: 10.1002/14651858.CD001118.pub3.

Hartmann-Boyce, J., McRobbie, H., Bullen, C., Begh, R., Stead, L.F. and Hajek, P., 2016. Electronic cigarettes for smoking cessation. *Cochrane Database of Systematic Reviews*, Issue 9. Art. No.: CD010216. DOI: 10.1002/14651858.CD010216.pub3

Hughes, J.R., Stead, L.F., Hartmann-Boyce, J., Cahill, K. and Lancaster, T., 2014. Antidepressants for smoking cessation. *Cochrane Database of Systematic Reviews*, Issue 1. Art. No.: CD000031. DOI: 10.1002/14651858.CD000031.pub4.

Hughes, J.R., Stead, L.F. and Lancaster, T., 2000. Anxiolytics for smoking cessation. *Cochrane Database of Systematic Reviews*, Issue 4. Art. No.: CD002849. DOI: 10.1002/14651858.CD002849.

Kernohan, G., 2006. *Evidence-Based Healthcare: An Introduction*. University of Ulster (online teaching module).

Lancaster, T. and Stead, L.F., 1998. Mecamylamine (a nicotine antagonist) for smoking cessation. *Cochrane Database of Systematic Reviews*, Issue 2. Art. No.: CD001009. DOI: 10.1002/14651858.CD001009.

Lancaster, T. and Stead, L.F., 2005. Individual behavioural counselling for smoking cessation. *Cochrane Database of Systematic Reviews*, Issue 2. Art. No.: CD001292. DOI: 10.1002/14651858.CD001292.pub2.

Lancaster, T. and Stead, L.F., 2012. Silver acetate for smoking cessation. *Cochrane Database of Systematic Reviews*, Issue 9. Art. No.: CD000191. DOI: 10.1002/14651858.CD000191.pub2.

Lindson-Hawley, N., Aveyard, P. and Hughes, J.R., 2012. Reduction versus abrupt cessation in smokers who want to quit. *Cochrane Database of Systematic Reviews*, Issue 11. Art. No.: CD008033. DOI: 10.1002/14651858.CD008033.pub3.

Lindson-Hawley, N., Thompson, T.P. and Begh, R., 2015. Motivational interviewing for smoking cessation. *Cochrane Database of Systematic Reviews*, Issue 3. Art. No.: CD006936. DOI: 10.1002/14651858.CD006936.pub3.

McWhinney, I.R., 1997. *A Textbook of Family Medicine*. 2nd Edition. New York: Oxford University Press.

Raw, M., 1988. *Help your patient stop*. London, UK: British Medical Association and the Imperial Cancer Research Fund.

Rosenberg, W. and Donald, A., 1995. Evidence-based medicine: an approach to clinical problem-solving. *BMJ*, 310, pp. 1122-6.

Sackett, D.L., Richardson, W.S., Rosenberg, W. and Haynes, R.B., 1996. *Evidence-based medicine: how to practice and teach EBM*. New York: Churchill Livingstone.

Sammut, M.R., 2006. Smoking Cessation in Family Practice. *Maltese Family Doctor / It-Tabib tal-Familja*, 15(2), pp. 62-5.

Sandholzer, H., 2004. *Search and appraisal of literature*. EGPRN International Course on Research in Primary Health Care, St. Andrews, Malta, October 2-6.

Stead, L.F., Buitrago, D., Preciado, N., Sanchez,G., Hartmann-Boyce, J. and Lancaster, T., 2013. Physician advice for smoking cessation. *Cochrane Database of Systematic Reviews*, Issue 5. Art. No.: CD000165. DOI: 10.1002/14651858.CD000165.pub4.

Stead, L.F., Hartmann-Boyce, J., Perera, R. and Lancaster, T., 2013. Telephone counselling for smoking cessation. *Cochrane Database of Systematic Reviews*, Issue 8. Art. No.: CD002850. DOI: 10.1002/14651858.CD002850.pub3.

Stead, L.F. and Hughes, J.R., 2012. Lobeline for smoking cessation. *Cochrane Database of Systematic Reviews*, Issue 2. Art. No.: CD000124. DOI: 10.1002/14651858.CD000124.pub2.

Stead, L.F., Koilpillai, P., Fanshawe, T.R. and Lancaster, T., 2016. Combined pharmacotherapy and behavioural interventions for smoking cessation. *Cochrane Database of Systematic Reviews*, Issue 3. Art. No.: CD008286. DOI: 10.1002/14651858.CD008286.pub3.

Stead, L.F., Koilpillai, P. and Lancaster, T., 2015. Additional behavioural support as an adjunct to pharmacotherapy for smoking cessation. *Cochrane Database of Systematic Reviews*, Issue 10. Art. No.: CD009670. DOI: 10.1002/14651858.CD009670.pub3.

Stead, L.F. and Lancaster, T., 2005. Group behaviour therapy programmes for smoking cessation. *Cochrane Database of Systematic Reviews*, Issue 2. Art. No.: CD001007. DOI: 10.1002/14651858.CD001007.pub2.

Stead, L.F. and Lancaster, T., 2006. Nicobrevin for smoking cessation. *Cochrane Database of Systematic Reviews*, Issue 2. Art. No.: CD005990. DOI: 10.1002/14651858.CD005990.

Stead, L.F., Perera, R., Bullen, C., Mant, D., Hartmann-Boyce, J., Cahill, K. and Lancaster, T., 2012. Nicotine replacement therapy for smoking cessation. *Cochrane Database of Systematic Reviews*, Issue 11. Art. No.: CD000146. DOI: 10.1002/14651858.CD000146.pub4.

Ussher, M.H., Taylor, A.H. and Faulkner, G.E.J., 2014. Exercise interventions for smoking cessation. *Cochrane Database of Systematic Reviews*, Issue 8. Art. No.: CD002295. DOI: 10.1002/14651858.CD002295.pub5.

White, A.R., Rampes, H., Liu, J.P., Stead, L.F. and Campbell, J., 2014. Acupuncture and related interventions for smoking cessation. *Cochrane Database of Systematic Reviews*, Issue 1. Art. No.: CD000009. DOI: 10.1002/14651858.CD000009.pub4.

Whittaker, R., McRobbie, H., Bullen, C., Rodgers, A. and Gu, Y., 2016. Mobile phone-based interventions for smoking cessation. *Cochrane Database of Systematic Reviews*, Issue 4. Art. No.: CD006611. DOI: 10.1002/14651858.CD006611.pub4.

WONCA Europe, 2005. *The European Definition of General Practice/Family Medicine*. [pdf] Available at: <http://euract.woncaeurope.org/publications> [Accessed 12 October 2016].

Thumb sucking and transitional objects

Dr Marthese GALEA, Mr Keith GALEA, Dr Christopher SCIBERRAS, Ms Clarissa SCIBERRAS

ABSTRACT

This case study assesses the effects of thumb sucking and transitional object on a 4 year old child while being observed in 3 different environments, for 15 minutes each time for 10 days. Sucking only occurred when the transitional object was with the child. These results are discussed through reference to a literature review. Methods of how to control thumb sucking are proposed.

Key Words

Transitional objects, thumb sucking.

INTRODUCTION

Infants express a number of social responses that are related to the physical vicinity of the baby's mother. Experts such as Bowlby (1969) classify these responses as affectionate behaviour. As discussed by Mahalski (1983), once physical attachment starts to decrease between the infant and mother, around 60% of babies shift their affectionate behaviour to an object mainly a blanket or a soft toy. Litt (1986) concluded that because these objects facilitate the change from dependence to autonomy, these objects are referred to as transitional objects. There are very few studies that have been done about transitional objects. Transitional objects can be associated to typical behaviours in a child. Mahalski (1983) stated that half of the children that use a transitional object also participate in thumb sucking.

CASE STUDY

A case study on a 4 year old boy who was brought up in a normal family environment and having normal cognitive functions will be presented in this article.

This 4 year boy, GL, was breast fed from birth until 3 months. He never used a pacifier. At the age of 16 months he was persistently sucking his left thumb while smelling his favourite soft toy that had a loose cloth hanging from it. It was noted that he sucked his thumb only when he had his soft toy with him.

GL was observed in 3 different environments, for 15 minutes each time for 10 days. He was observed on the sofa while watching television, in the car while strapped to his car seat after school, and in the evening while in bed.

During the period when the transitional object (Teddy) was absent, the consequence was that the child never placed his thumb in his mouth. The child looked visually uncomfortable and asked for the transitional object and still he did not resort to thumb sucking. When "Teddy" was given to the child the thumb sucking immediately started. Two observers were used, each independently confirming the episodes that occurred. It was also noted that thumb sucking always happened with the left thumb.

DISCUSSION

The child's thumb sucking started immediately when the transitional object was held in his hands and did not happen when the transitional object was not in his hands. There was no encouragement for thumb sucking to take place from the 2 observers. Therefore one can say that the child developed a conditioned behaviour i.e. sucking his thumb while holding the transitional object.

Bijou & Baer (1965) concluded that automatic reinforcement is assumed to result from the sucking itself. GL always asked for "Teddy" when it was absent and immediately reached for it when it was within his sight. No data was found addressing how the presence of the transitional object supported thumb sucking behaviour.

As discussed by Firman (1990) a reason can be that, through the pairing of the two sources of stimulation, their purposes became harmonized in ways suggestive of other corresponding activities such as kissing and cuddling. The findings from this case study demonstrate the strong influence of a transitional object on thumb sucking. If there are health issues due to thumb sucking it is important that thumb sucking is stopped; however a question that is often asked is when the parents should intervene. One should consider intervening when the child develops permanent teeth, the reason being that the palate or the line-up of the teeth might become affected. Interventions should also be considered if the child is feeling embarrassed or the front teeth are

moving. Referring the child to the dentist as recommended by the American Dental Association (2016) can also be an alternative to assess what damage is being done and if needed discuss the way of how to stop. According to the American Dental Association if you are dealing with an older child, to increase the chances of success it would be better to involve the child while choosing the method to stop.

According to the Mayo Clinic (2015), if the child uses thumb sucking to draw attention, suggesting to the parents not to take any notice when he/she does it or not mentioning it can be enough to make the child stop.

Research on object manipulation to address these limitations is needed and would require new research that includes data on object manipulation, and the close association between the object and behaviour.

Although thumb sucking and the use of transitional objects are common, the authors did not find any literature with regards to children living in Malta. This case study is the first one of its kind in Malta. A major limitation of this article is that just one child was monitored. Monitoring more children of similar age might result in different conclusions or reinforce these findings. A study to assess the prevalence of thumb sucking in Malta and the use of transitional objects can be done.

Family doctors and paediatricians when faced with parents inquiring about their child sucking his/her thumb or being attached to a specific object can use this article as a reference to what the implications are and how to stop it if needed.

Dr Marthese GALEA
MD, MRCPCH
Resident Specialist, Paediatrics Department, Mater Dei Hospital, Msida, Malta
Email: akgalea@maltanet.net

Mr Keith GALEA
B.Pharm. (Hons), MBA Leic. (UK)
Pharmacist

Dr Christopher SCIBERRAS
MD, MRCPCH, MRCP(UK), MSc. Comm.Paeds (Warwick),
DCH (Dublin), Cert. Dev. Paeds.(London)
Consultant Paediatrician, Community Paediatrics and Disability Services, Department of Paediatrics, Mater Dei Hospital, Msida, Malta

Ms Clarissa SCIBERRAS
Medical Student, University of Malta

CONCLUSIONS

There are a number of suggestions that can be given to parents to help their child stop thumb sucking and the use of transitional objects; however none of them have been clinically proven to work.

One can ask the parents to try to recognize what makes the child suck the thumb. It can be a soft toy or a cloth such as described by this case study. In this case recommending that the cloth or the soft toy be removed gradually might work.

The child might be willing to stop but, as with other behaviours, it can become a habit and he or she might start sucking the thumb without the child realizing it. Reminding the child when he/she does it can also work. It is however important not to scold or embarrass the child in front of other children.

Whatever suggestion the parents will adopt, it is important that the parents reward the child every step of the way and not punish him or her as recommended by the American Dental Association (2007). Ideally methods such as using sour or unpleasant material to cover the thumb of the child should not be used as this can cause unnecessary discomfort for the child. Besides, the child might get used to the bad taste after a while.

For some children, thumb sucking is incredibly difficult to break. In the meantime, the parents should be reassured so they do not worry. Putting too much pressure on the child to stop thumb sucking might only delay the process. More research is required to better understand the connection between the transitional object and thumb sucking and regarding which method can best work for the specific child.

REFERENCES

American Dental Association, 2007. Thumb sucking and pacifier use. *Journal of the American Dental Association,* Vol. 138.

American Dental Association, 2016. Thumbsucking and Pacifier Use. [online] Available at: <http://www.mouthhealthy.org/en/az-topics/t/thumbsucking> [Accessed 20 June 2015].

Bijou, S. and Baer, D.M., 1965. *Child development*. Vol. 2. Eaglewood Cliffs New Jersey Prentice Hall.

Bowlby, J., 1969. *Attachment and loss*. Vol. 1. Attachment. London: Hogarth.

Friman, P.C., 1990. Concurrent habits: What would Linus do with his blanket if his thumb sucking were treated? *American Journal of Diseases in Children,* 144, pp. 1316–1318.

Litt, C.J., 1986. Theories of transitional object attachment: An overview. *International Journal of Behavioral Development,* 9, pp. 383–399.

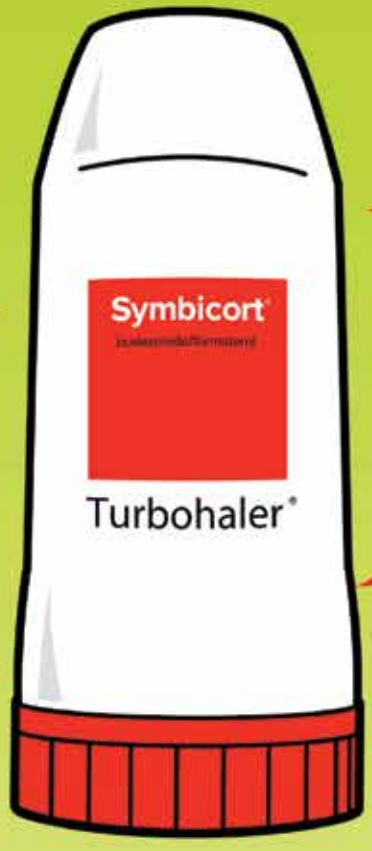
Mahalski, P.A., 1983. The incidence of attachment objects and oral habits at bedtime in two longitudinal samples of children. *Journal of Child Psychology and Psychiatry,* 24, pp. 283–295.

Mayo Clinic, 2015. Healthy Lifestyle Children's health. [online] Available at: <http://www.mayoclinic.org/healthy-lifestyle/childrens-health/in-depth/thumb-sucking/art-20047038?pg=2> [Accessed 29 June 2015].

Symbicort® Turbohaler®

(budesonide/formoterol)

Easy to use[1]



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

Patients do not need to hold their breath after inhalation

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

Symbicort® Turbohaler® – For Asthma and severe COPD

Consult SmPC for full information

Symbicort Turbohaler

ABRIDGED PRESCRIBING INFORMATION. Consult Summary of Product Characteristics before prescribing. SYMBICORT© TURBOHALER© 100 micrograms/6 micrograms/inhalation, inhalation powder. SYMBICORT© TURBOHALER© 200 micrograms/6 micrograms/inhalation, inhalation powder (budesonide/formoterol fumarate dihydrate). **Indication:** Indicated in adults, adolescents aged 12 -17 years and children aged 6 years and older (100/6 only), for the regular treatment of asthma where use of a combination (inhaled corticosteroid and long-acting β_2 adrenoceptor agonist) is appropriate: 1) patients not adequately controlled with inhaled corticosteroids and 'as needed' inhaled short-acting β_2 adrenoceptor agonists or 2) patients already adequately controlled on both inhaled corticosteroids and long-acting β_2 adrenoceptor agonists. Symbicort 100/6 is not appropriate for patients with severe asthma. **Symbicort 200/6 only:** Indicated in adults aged 18 years and older for the symptomatic treatment of patients with COPD with FEV_1 <70% predicted normal (post-bronchodilator) and an exacerbation history despite regular bronchodilator therapy. **Presentation:** Inhalation powder. **Symbicort 100/6:** Each metered dose contains budesonide 100mcg/inhalation and formoterol fumarate dihydrate 6mcg/inhalation. **Symbicort 200/6**: Each metered dose contains budesonide 200mcg/inhalation and formoterol fumarate dihydrate 6mcg/inhalation. **Dosage and administration: Symbicort maintenance therapy:** Patients should be advised to have their separate rapid-acting bronchodilator available for rescue use at all times. **Adults (18 years and older):** The recommended dose is 1-2 inhalations twice daily. Some patients may require a maximum of 4 inhalations twice daily. **Adolescents (12-17 years):** The recommended dose is 1-2 inhalations twice daily. **Children 6-11 years (100/6 only):** The recommended dose is 2 inhalations twice daily. **Children under 6 years:** Not recommended. **Symbicort maintenance and reliever therapy:** . **Adults (18 years and older):** The recommended maintenance dose is 2 inhalations per day, given either as one inhalation in the morning and evening or as 2 inhalations in either the morning or evening. 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. No more than 6 inhalations should be taken on any single occasion. A total daily dose of more than 8 inhalations is not normally needed, a total daily dose of up to 12 inhalations could be used for a limited period. Patients using more than 8 inhalations daily should be strongly recommended to seek medical advice. **Children and adolescents under 18 years:** Not recommended. **COPD (200/6 only):** The recommended dose in adults is 2 inhalations twice daily. **Elderly:** No special dosing requirements required. **Patients with hepatic or renal impairment:** Increased exposure is expected in patients with severe liver cirrhosis. **Contraindications:** Hypersensitivity to active substance(s) or excipients. **Warnings and precautions:** Recommended that the dose is tapered when the treatment is discontinued and should not be stopped abruptly. If treatment is ineffective, or exceeds the highest recommended dose, medical attention must be sought. Sudden and progressive deterioration in control of asthma or COPD is potentially life threatening and patient should undergo urgent medical assessment. Consideration should be given for increased therapy with corticosteroids, e.g. orally, or antibiotic treatment if infection present. Patients should be reminded to take their maintenance dose as prescribed, even when asymptomatic. The reliever inhalations should be taken in response to asthma symptoms but are not intended for regular prophylactic use e.g. before exercise, separate rapid-acting bronchodilator should be considered. Once asthma symptoms are controlled, consideration may be given to gradually reducing the dose. Patients should not be initiated on Symbicort during an exacerbation or if they have significantly worsening or acutely deteriorating asthma. Paradoxical bronchospasm may occur with an immediate increase in wheezing and shortness of breath after dosing. Symbicort should be discontinued immediately and an alternative therapy instituted if necessary. Systemic effects may occur, particularly at high doses prescribed for long periods e.g. Cushing's syndrome, Cushingoid features, adrenal suppression, growth retardation in children and adolescents, decrease in bone mineral density, cataract and glaucoma, and more rarely, a range of psychological or behavioural effects including psychomotor hyperactivity, sleep disorders, anxiety, depression or aggression (particularly in children). Recommended that height of children receiving prolonged treatment is regularly monitored and if growth is slowed, therapy should be re-evaluated and consideration given to referring the patient to a paediatric respiratory specialist. If adrenal function is impaired from previous systemic steroid therapy, care should be taken when transferring patients to Symbicort therapy. Patients transferring from oral steroids may remain at risk of impaired adrenal reserve for a considerable time. HPA axis function should be monitored regularly. Prolonged treatment with high doses of inhaled corticosteroids may result in clinically significant adrenal suppression. Additional systemic corticosteroid cover should be considered during periods of stress such as severe infections or elective surgery. Rapid reduction in dose of steroids can induce acute adrenal crisis, symptoms may include anorexia, abdominal pain, weight loss, tiredness, headache, nausea, vomiting, decreased level of consciousness, seizures, hypotension and hypoglycaemia. Treatment with systemic steroids should not be stopped abruptly. Transfer from oral steroid therapy to Symbicort may result in the appearance of allergic or arthritic symptoms such as rhinitis, eczema, muscle and joint pain. Specific treatment should be initiated for these conditions. In rare cases, tiredness, headache, nausea and vomiting can occur due to insufficient glucocorticosteroid effect and temporary increase in the dose of oral glucocorticosteroids may be necessary. To minimise risk of oropharyngeal candida infection, patients should rinse mouth with water after inhaling doses. Concomitant treatment with itraconazole, ritonavir or other potent CYP3A4 inhibitors should be avoided. Observe caution in patients with thyrotoxicosis, phaeochromocytoma, diabetes mellitus, untreated hypokalaemia, hypertrophic obstructive cardiomyopathy, idiopathic subvalvular aortic stenosis, severe hypertension, aneurysm or other severe cardiovascular disorders such as ischaemic heart disease, tachyarrhythmias or severe heart failure. Observe caution when treating patients with prolongation of the QTc-interval. Re-evaluate need for Symbicort in patients with active or quiescent pulmonary tuberculosis, fungal and viral infections in the airways. Hypokalaemia may occur at high doses of β_2 adrenoceptor agonists. Particular caution recommended in unstable or acute severe asthma. Monitor serum potassium levels. As for all β_2 adrenoceptor agonists, consider additional blood glucose monitoring in diabetic patients. The excipient lactose contains small amounts of milk proteins, which may cause allergic reactions. **200/6 only:** An increase in the incidence of pneumonia, including pneumonia requiring hospitalisation, has been observed in patients with COPD receiving inhaled corticosteroids. Physicians should remain vigilant as clinical features of such infections overlap with symptoms of COPD exacerbations. Risk factors include current smoking, older age, low BMI and severe COPD. Potential effects on bone density should be considered especially in patients on high doses for prolonged periods that have co-existing risk factors for osteoporosis. **Drug interactions:** Potent CYP3A4 inhibitors (e.g. ketoconazole, itraconazole, voriconazole, posaconazole, clarithromycin, telithromycin, nefazodone and HIV protease inhibitors) are likely to increase plasma levels of budesonide and concomitant use 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 together with beta-adrenergic blockers (including eye drops) as can weaken or inhibit the effect of formoterol, unless compelling reasons. Concomitant treatment with quinidine, disopyramide, procainamide, phenothiazines, antihistamines (terfenadine) 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 towards β_2 sympathomimetics. Concomitant treatment with MAOIs, including agents with similar properties such as furazolidone and procarbazine, may precipitate hypertension reactions. Elevated 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. Hypokalaemia may increase the disposition towards arrhythmias in patients taking digitalis glycosides. **Pregnancy and lactation:** Use only when benefits outweigh potential risks during pregnancy and breastfeeding. Budesonide is excreted in breast milk; at therapeutic doses, no effects on child are anticipated. Not known whether formoterol passes into human breast milk. **Undesirable events:** Consult SmPC for full list of side effects. **Common:** Headache, palpitations, tremor, candida infections in the oropharynx, coughing, mild irritation in the throat, hoarseness and pneumonia (in COPD patients using Symbicort 200/6) **Uncommon:** Tachycardia, muscle cramps, aggression, psychomotor hyperactivity, anxiety, sleep disorders, nausea, dizziness and bruises. **Rare:** Hypokaelemia, 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:** Depression and behavioural changes (predominantly in children), angina pectoris, prolongation of QTc-interval, hyperglycaemia, taste disturbances, Cushing's Syndrome, Cushingoid features, adrenal suppression, growth retardation in children and adolescents, decrease in bone mineral density, cataract, glaucoma and variations in blood pressure. Paradoxical bronchospasm may occur in very rare cases. **Presentation:** 1 pack x 120 doses. **Legal category:** POM. **Marketing Authorisation Numbers:** MA 046/00901-2. **Marketing Authorisation Holder (MAH):** AstraZeneca AB, Gartunavagen, S-15185 Sodertalje, Sweden. Further information available from Associated Drug Company Limited, Triq l-Esportaturi, Mriehel, Birkirkara BKR 3000, Malta. Tel: (+356) 2277 8000. SYMBICORT and TURBOHALER are trade mark(s) of the AstraZeneca group of companies. **Abridged Prescribing Information prepared:** 11/2016. URN No: 13/0125. Date of Preparation: Dec 2016.

AstraZeneca Respiratory

Reference: 1. Adelphi Respiratory Disease Specific Programme 2008. **2.** Olaf Selroos *et al. Treat Respir Med* 2006; 5 (5): 305-315. **3.** Engel *et al.* Br *J Clin Pharmacol* 1993; 33(4): 439-44.

Suspected adverse reactions and medication errors should be reported. Report forms can be downloaded from **www.medicinesauthority.gov.mt/adrportal** and send by post or email to: **ADR reporting/Sir Temi Zammit Buildings, Malta Life Sciences Park, San Gwann SGN 3000, Malta**. Suspected adverse reactions and medication errors should also be reported to Associated Drug Company Limited on **+356 2277 8115**.

GALVUS and EUCREAS

COMPREHENSIVE POWER TO ADVANCE TYPE 2 DIABETES TREATMENT

GALVUS is a DPP-4 inhibitor that improves glycemic control through powerful islet enhancement[1]

EUCREAS is the combination of a DPP-4 inhibitor, GALVUS, and metformin[2]

Eucreas®

PRESENTATION: Each 50 mg/850 mg film-coated tablet contains 50 mg of vildagliptin and 850 mg metformin hydrochloride. Each 50 mg/1000 mg film-coated tablet contains 50 mg of vildagliptin and 1000 mg metformin hydrochloride. **INDICATIONS:** Eucreas is indicated in the treatment of type 2 diabetes mellitus patients, indicated in the treatment of adult patients who are unable to achieve sufficient glycaemic control at their maximally tolerated dose of oral metformin alone or who are already treated with the combination of vildagliptin and metformin as separate tablets. Eucreas is indicated in combination with a sulphonylurea (i.e. triple combination therapy) as an adjunct to diet and exercise in adult patients inadequately controlled with metformin and a sulphonylurea. Eucreas is indicated in triple combination therapy with insulin as an adjunct to diet and exercise to improve glycaemic control in adult patients when insulin at a stable dose and metformin alone do not provide adequate glycaemic control. **DOSAGE:** The dose of antihyperglycaemic therapy with Eucreas should be individualised on the basis of the patient's current regimen, effectiveness and tolerability while not exceeding the maximum recommended daily dose of 100 mg vildagliptin. Eucreas may be initiated at either the 50 mg/850 mg or 50 mg/1000 mg tablet strength twice daily, one tablet in the morning and the other in the evening. For patients inadequately controlled at their maximal tolerated dose of metformin monotherapy: The starting dose of Eucreas should provide vildagliptin as 50 mg twice daily (100 mg total daily dose) plus the dose of metformin already being taken. For patients switching from co-administration of vildagliptin and metformin as separate tablets: Eucreas should be initiated at the dose of vildagliptin and metformin already being taken. For patients inadequately controlled on dual combination with metformin and a sulphonylurea: The doses of Eucreas should provide vildagliptin as 50 mg twice daily (100 mg total daily dose) and a dose of metformin similar to the dose already being taken. When Eucreas is used in combination with a sulphonylurea, a lower dose of the sulphonylurea may be considered to reduce the risk of hypoglycaemia. For patients inadequately controlled on dual combination therapy with insulin and the maximal tolerated dose of metformin: The dose of Eucreas should provide vildagliptin dosed as 50 mg twice daily (100 mg total daily dose) and a dose of metformin similar to the dose already being taken. Eucreas should be taken with or just after food to reduce gastrointestinal symptoms associated with metformin. Patients ≥ 65 taking Eucreas should have their renal function monitored regularly. Eucreas is not recommended for use in patients less than 18 years old. For use in renal or hepatic impairment, see contraindications and precautions below or refer to the SmPC for more information. The safety and efficacy of vildagliptin and metformin as triple oral therapy in combination with a thiazolidinedione have not been established. **CONTRAINDICATIONS:** Hypersensitivity to vildagliptin or metformin hydrochloride or to any of the excipients. Diabetic ketoacidosis or diabetic pre-coma. Renal failure or renal dysfunction defined as creatinine clearance < 60 ml/min. Acute conditions with the potential to alter renal function e.g. dehydration, severe infection, shock or intravascular administration of iodinated contrast agents. Acute or chronic disease which may cause tissue hypoxia e.g. cardiac or respiratory failure, recent myocardial infarction, shock, hepatic impairment, acute alcohol intoxication, alcoholism, lactation. **WARNINGS / PRECAUTIONS:** Eucreas is not a substitute for insulin in insulin-requiring patients and should not be used in patients with type 1 diabetes. Due to the risk of lactic acidosis, renal function could be monitored at least once yearly in patients with normal renal function and at least two to four times/year in patients with serum creatinine at the upper limit of normal and in elderly patients. Eucreas is not recommended in patients with hepatic impairment, including patients with pre-treatment ALT or AST >3x the ULN. LFT's should be performed prior to treatment initiation, at three month intervals during the first year and periodically thereafter. Should an increase in AST or ALT of 3x ULN or greater persist, withdrawal of Eucreas therapy is recommended. Patients who develop jaundice or other signs suggestive of liver dysfunction should discontinue Eucreas. Routine monitoring of diabetic patients for skin disorders such as blistering or ulceration is recommended. As Eucreas contains metformin, treatment should be discontinued 48 hours before elective surgery with general anaesthesia and not usually resumed earlier than 48 hours afterwards. The IV administration of iodinated contrast agents can lead to renal failure. Therefore due to metformin active ingredient, Eucreas should be discontinued prior to or at the time of the test and not reinstituted until 48 hours afterwards and only after renal function has been re-evaluated and found to be normal. Eucreas should not be administered during pregnancy or lactation. Sulphonylureas are known to cause hypoglycaemia. Patients receiving vildagliptin in combination with a sulphonylurea may be at risk for hypoglycaemia. Therefore, a lower dose of sulphonylurea may be considered to reduce the risk of hypoglycaemia. The use of vildagliptin has been associated with a risk of developing acute pancreatitis. If pancreatitis is suspected, vildagliptin should be discontinued; if acute pancreatitis is confirmed, vildagliptin should not be restarted. Caution should be exercised in patients with a history of acute pancreatitis. There may be an increased risk of angioedema in patients concomitantly taking ACE-inhibitors. **INTERACTIONS**: Vildagliptin has a low potential for drug interactions. No clinically relevant interactions with other antidiabetics (glyburide, pioglitazone, metformin), amlodipine, digoxin, ramipril, simvastatin, valsartan or warfarin were observed after co-administration with vildagliptin. Interactions with metformin hydrochloride that are not recommended include alcohol, cationic active substances e.g. cimetidine and intravascular administration of iodinated contrast media. Combinations requiring caution include metformin hydrochloride with medicines tending to produce hyperglycaemic activity e.g. glucocorticoids, beta agonists and diuretics. The dose of antihyperglycaemic medicinal products may need to be adjusted in combination with ACE inhibitors. **ADVERSE REACTIONS:** Rare cases (≥1/10,000 to <1/1,000) angioedema, hepatic dysfunction (including hepatitis) have been reported with vildagliptin. Vildagliptin Monotherapy: Common (≥1/100 to <1/10): dizziness, Uncommon (≥1/1,000 to <1/100): headache, constipation, arthralgia, hypoglycaemia, oedema peripheral. Very rare (<1/10,000): URTI, nasopharyngitis. Metformin monotherapy; Very common (≥1/10) Nausea, vomiting, diarrhoea, abdominal pain and loss of appetite. Common: metallic taste. Combination vildagliptin with metformin; Common: tremor, headache, dizziness, nausea, hypoglycaemia. Uncommon: fatigue. Combination with metformin and sulphonylurea: Common: hypoglycaemia, dizziness, tremor, hyperhidrosis, asthenia, decreased blood glucose, headache, chills. Combination with insulin: Decreased blood glucose, headache, chills, nausea, gastro-oesophageal reflux disease, diarrhoea, flatulence For a full list of Adverse reactions, please refer to the SmPC. **LEGAL CATEGORY:**POM **PACK SIZES:** 30, 60 film-coated tablets **MARKETING AUTHORISATION HOLDER**: Novartis Europharm Limited, Frimley Business Park, Camberley GU16 7SR, United Kingdom. **MARKETING AUTHORISATION NUMBER**: EU/1/07/425/002–003, EU/1/07/425/008-009. Please refer to Summary of Product Characteristics (SmPC) before prescribing. Full prescribing information is available upon request from: Novartis Pharma Services Inc, Representative Office Malta, P.O. Box 4, Marsa, MRS 1000, Malta. Tel +356 21222872 2015-MT-EUC-16-DEC-2015

Galvus®

PRESENTATION: Each tablet contains 50 mg of Vildagliptin **INDICATIONS:** For the treatment of type 2 diabetes mellitus in adults:
As monotherapy in patients inadequately controlled by diet and exercise alone and for whom metformin is inappropriate due to contraindications or intolerance. As dual oral therapy in combination with: metformin in patients with insufficient glycaemic control despite maximal tolerated dose of monotherapy with metformin; a sulphonylurea in patients with insufficient glycaemic control despite maximal tolerated dose of a sulphonylurea and for whom metformin is inappropriate due to contraindications or intolerance; a thiazolidinedione in patients with insufficient glycaemic control and for whom the use of a thiazolidinedione is appropriate. As triple oral therapy in combination with a sulphonylurea and metformin when diet and exercise plus dual therapy with these medicinal products do not provide adequate glycaemic control. Vildagliptin is also indicated for use in combination with insulin (with or without metformin) when diet and exercise plus a stable dose of insulin do not provide adequate glycaemic control. **DOSAGE:** When used as monotherapy in combination with thiazolidinedione, in combination with metformin and a sulphonylurea or in combination with insulin (with or without metformin), the recommended daily dose of Vildagliptin is 100mg, administered as one dose of 50 mg in the morning and one dose of 50 mg in the evening. When used in combination with a sulphonylurea, a lower dose of the sulphonylurea may be considered to reduce the risk of hypoglycaemia. Galvus can be administered with or without a meal. Doses greater than 100 mg are not recommended. Galvus is not recommended for use in children and adolescents (< 18 years). The safety and efficacy of Galvus in children and adolescents (< 18 years) have not been established. No data are available. The recommended dose for patients with moderate/severe renal impairment is 50mg once daily. If a dose of Galvus is missed, it should be taken as soon as the patient remembers. A double dose should not be taken on the same day. No dose adjustments are necessary in elderly patients *(≥ 65 years.* The safety and efficacy of Vildagliptin as triple oral therapy in combination with metformin and a thiazolidinedione have not been established. **CONTRAINDICATIONS:** Hypersensitivity to the active substance or to any of the excipients **WARNINGS / PRECAUTIONS**: Galvus should not be used in patients with type 1 diabetes or for the treatment of diabetic ketoacidosis. There is limited experience in patients with ESRD on haemodialysis. Therefore Galvus should be used with caution in these patients. Galvus is not recommended in patients with hepatic impairment, including patients with pre-treatment ALT or AST >3x the ULN. Liver function tests should be performed prior to treatment initiation, at three month intervals during the first year and periodically thereafter. Should an increase in AST or ALT of 3xULN or greater persist, withdrawal of Galvus therapy is recommended. Patients who develop jaundice or other signs suggestive of liver dysfunction should discontinue Galvus. Clinical experience in patients with NYHA functional class III treated with Vildagliptin is still limited and results are inconclusive. Routine monitoring of diabetic patients for skin disorders such as blistering or ulceration is recommended. Patients with rare hereditary problems of galactose intolerance, the Lapp lactase deficiency or glucose-galactose malabsorption should not take this medicine. Galvus should not be administered during pregnancy or breast-feeding since no studies on the effect on human fertility have been conducted for Galvus. Should be used with caution in patients with renal impairment. Sulphonylureas are known to cause hypoglycaemia. Patients receiving Vildagliptin in combination with a sulphonylurea may be at risk for hypoglycaemia. Therefore, a lower dose of sulphonylurea may be considered to reduce the risk of hypoglycaemia. Use of Vildagliptin has been associated with a risk of developing acute pancreatitis. If pancreatitis is suspected, Vildagliptin should be discontinued; if acute pancreatitis is confirmed, Vildagliptin should not be restarted. Caution should be exercised in patients with a history of acute pancreatitis. **INTERACTIONS**: Vildagliptin has a low potential for drug interactions. No clinically relevant interactions with other antidiabetics (glyburide, pioglitazone, metformin), amlodipine, digoxin, ramipril, simvastatin, valsartan or warfarin were observed after co-administration with Vildagliptin. As with other oral antidiabetic medicines, the hypoglycaemic effect of Vildagliptin may be reduced by certain active substances, including thiazides, corticosteroids, thyroid products and sympathomimetics. There may be an increased risk of angioedema in patients concomitantly taking ACE-inhibitors **ADVERSE REACTIONS:** Rare cases (≥1/10,000 to <1/1,000) angioedema, abnormal liver function tests, hepatic dysfunction (including hepatitis).
Monotherapy: Common (≥1/100 to <1/10): dizziness, Uncommon (≥1/1,000 to <1/100): headache, constipation, arthralgia, hypoglycaemia, oedema peripheral. Very rare (<1/10,000): URTI, nasopharyngitis. Combination with metformin: Common: tremor, headache, dizziness, nausea, hypoglycaemia, hyperhidrosis, asthenia. Uncommon: fatigue. Combination with sulphonylurea: Common: tremor, headache, dizziness, asthenia, hypoglycaemia. Uncommon: constipation. Very rare: nasopharyngitis. Combination with Thiazolidinedione: Common: weight increase. oedema peripheral, Uncommon: headache, asthenia, hypoglycaemia. Combination with insulin: Common: decreased blood glucose, headache, chills, nausea, gastro-oesophageal reflux disease. Uncommon: Diarrhoea, flatulence. Frequency not known: urticaria, pancreatitis, hepatitis and abnormal liver function tests (reversible upon discontinuation of the medicinal product), bullous or exfoliative skin lesions. Combination with metformin and a sulphonylurea: Common: hypoglycaemia, dizziness, tremor, hyperhidrosis, asthenia. **LEGAL CATEGORY**: POM **PACK SIZES:** 7, 28 tablets **MARKETING AUTHORISATION HOLDER**: Novartis Europharm Limited, Frimley Business Park Camberley GU16 7SR United Kingdom. **MARKETING AUTHORISATION NUMBERS:** EU/1/07/414/001, 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 21222872. 2015-MT- GAL-16-DEC-2015

GAL AD1 12/16 MT

NOVARTIS

1. Novartis Europharm Ltd. Galvus®. Summary of Product Characteristics.
2. Novartis Europharm Ltd. Eucreas®. Summary of Product Characteristics.

Galvus vildagliptin

Eucreas vildagliptin/metformin