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The diversity of family medicine

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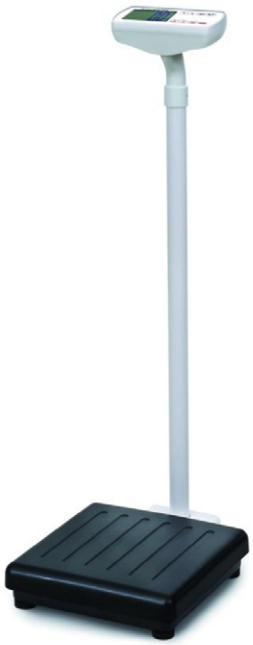

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The mission of the Journal of the Malta College of Family Doctors (JMCFD) is to deliver accurate, relevant and inspiring research, continued medical education and debate in family medicine with the aim of encouraging improved patient care through academic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

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Editor
Prof. Pierre Mallia

Members
Dr Mario R Sammut, Dr Anton Bugeja, Dr Glorianne Pullicino

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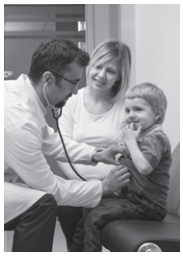

The diversity of family medicine

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Summative assessment and the new council

Prof. Pierre MALLIA

PREPARATIONS FOR THE SUMMATIVE ASSESSMENT OF VOCATIONAL TRAINING

The recent election of the new MCFD council was immediately followed by the preparations for the summative assessment of vocational training which this year has the External Development Advisor visit and the renewal of the RCGP-MCFD-DH contract which we are proud to announce that the Parliamentary Secretary for Health and the Ministry have approved.

The Summative Assessment has become a reality which has put Family Medicine on a specialist status not only in word but in the deed of specialisation. Vocational training in this country does not merely follow that in some other European states whereby trainees spend three years as apprentices in a practice. There is a lot to say for this as well; but our contention is that from the start we wanted the word 'specialist' to be on par with other specialities. Our vocational training programme has a Work-Based Assessment and weekly half-day release course sessions. It culminates in a high profile Applied Knowledge Test in the form of a best-of-five MCQ which is marked via an approved psychometric method of peer review known as the Angoff score. This is followed by a Clinical Skills Assessment on par with that held at the RCGP in which candidates sit in a consulting room with thirteen rotating cases, each consisting of an examiner and an actor of a particular case. The exam is contextual for the local scenario and what indeed makes Family Medicine a speciality is this contextual sense. The same exam in the UK will not give the equivalent of the exam held in another country.

Unfortunately we still face questions every time the contract comes up for signing. This of course signifies the cultural change that has occurred and not everyone will indeed recognise the difficulty to move through the VT programme and hence not everyone may still wish to 'see' us as a speciality. Be that as it may, a speciality we have constructed, not least because we have sought the external review of the RCGP which has the best and first specialisation programme in Europe, and indeed follows the 'Royal College culture' we have in Malta. Although the RCGP do not like to see this as a sort of rubber stamp, in our country that word may hold true.

AIMS AND OBJECTIVES OF THE NEW COUNCIL

I feel that every president should have two roles. In the first instance he or she should be a person who at least tries to reach compromise within council. Whether one's ideas pass or not, the council have to feel that decisions are theirs. Secondly, one has to elect oneself on at least one vision for the next term.

This term I have recommended that the College not remain solely a CPD collegiate activity, but follow the example of other international colleges and associations to interact more with patient groups. To this end we will establish contact with the Malta Health Network (MHN) and see how we can collaborate and moreover examine the possibility of having a patient portal and an education system on our website. In this regard we must tap into EU and other funds. This patient network can also be of mutual benefit for research activities. Whilst patients have shown in the UK that they can indeed be helpful in generating research questions, the portal will help local GPs doing studies to have access to patient databases and have the protection of their anonymity by the College and the MHN. To this end, the second proposal I wish to pass through council, is to have a set-up which allows our members to apply for EU projects. The College will of course take a management fee for auditing but otherwise it will act as a platform for any member/s to apply for European research funds.

Funds can serve also for the continuing development of our curriculum which will have to take on a wider role. Rather than being a curriculum for trainees, it will be a curriculum for continuing development and will guide

CME activities and indeed be a foundation for the day when medical council introduces a revalidation system. To this end one would hope that revalidation would not be merely following a CPD activity but following a CPD programme which has been validated as a curriculum. This will avoid tests which many may fear but it will bring about a closer following of our own activities. Accrediting CME activities which do not follow our curriculum has already been frowned upon by many people both inside and outside the college and indeed, in my humble opinion, following a talk promoted by a drug company is not exactly professional development, no matter how interesting the talk is. We are also pleased to announce that GlaxoSmithKline have offered to sponsor a system whereby we can have immediate questionnaires during a CPD course. Tapping into EU funds such as Erasmus will give us the necessary impetus to move forward in this direction of excellence in medical education.

Council now has a great team of people who have either been tutors or (the majority in fact) have been through the VT programme and obtained their MMCFD/MRCGP(INT). This is a great honour indeed for everyone and I cannot but augur a successful three years ahead.

Prof. Pierre MALLIA
MD PhD CBiol MPhil MA(Law) DipICGP MMCFD MRCP FRCGP

Editor, Journal of the Malta College of Family Doctors
President, Malta College of Family Doctors
Email: pierre.mallia@um.edu.mt

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The management of nocturnal enuresis in children

Dr Marthese GALEA, Dr Christopher SCIBERRAS, Mr Keith GALEA

ABSTRACT

Introduction

Nocturnal enuresis is more prevalent in the male gender. Studies such as that by Butler & McKenna (2002) show how nocturnal enuresis is hereditary, with approximately 50% of the children affected if one parent has suffered from it. The main cause for nocturnal enuresis can be drinking late in the evening or not passing urine before going to sleep, resulting in excessive urine volume. A detailed history needs to be taken, eating and drinking habits should also be assessed, and any drinks or food that can increase the chances of bedwetting should be removed or reduced.

Management

Management has to be adapted to the child and his/her family requirements. Prescribing the right medication and ensuring compliance is important but is only part of the management plan. Lifestyle changes should be advised. A very simple bedwetting vibrating alarm can be considered. If symptoms persist, pharmacological treatment should be prescribed together with the bedwetting alarm.

Conclusion

Nocturnal enuresis is a common condition in a young child, however it requires a careful assessment and management in cooperation with the child's parent or carer. Physicians need to be aware of when the child needs to be referred.

Keywords

Nocturnal enuresis, bedwetting, bedwetting alarm.

INTRODUCTION

Butler & Heron (2008) stated that nocturnal enuresis is the involuntary wetting of the bed while sleeping by children that have no inherited or acquired defects of the central nervous system. If left untreated nocturnal enuresis can result in psychological behavioural problems.

According to the NICE clinical guideline (2010) nocturnal enuresis can be classified in two, namely primary or secondary enuresis. Children above the age of 5 years who never had bladder control are diagnosed as having primary nocturnal enuresis. Children who are potty trained and for six months had no bedwetting episodes are diagnosed with secondary nocturnal enuresis if the child starts wetting the bed again.

Nocturnal enuresis is more prevalent in the male gender. Studies such as that by Butler & McKenna (2002) show how nocturnal enuresis is hereditary with approximately 50% of the children being affected if one parent has suffered from it.

The main cause for nocturnal enuresis can be drinking late in the evening or not passing urine before going to sleep resulting in excessive urine volume. Another cause may be a low amount of antidiuretic hormone during the night which controls the production of urine.

The aim of this article is to review the assessment and management of this condition.

METHODS OF ASSESSMENT

For an accurate diagnosis a good history and examination needs to be carried out and a fluid balance chart used. An ultrasound of the bladder can also be an option.

A detailed history needs to be taken, including if the child is currently on any medications and if he or she used any medication for nocturnal enuresis. Eating and drinking habits should also be assessed, and any drinks or food that can increase the chances of bedwetting should be removed or reduced.

The pattern of when the child wets the bed is important. It is also important to identify causes and / or emotional triggers and the volume of urine passed also needs to be measured.

Identifying important symptoms such as daytime symptoms and frequency of passing urine also need to be

considered. Consider the frequency of going to the toilet. More than seven times a day is considered too frequent while less than four times a day is infrequent. Check for symptoms such as urgency, daytime wetting or dysuria. The pattern of enuresis in different settings, such as in school, should also be taken into account.

MANAGEMENT

Management has to be adapted to the child and his/her family requirements. Parents should have a positive approach when dealing with a child suffering from nocturnal enuresis. The physician needs to tell the carers that the child has no control over the condition, therefore punishing the child should not be considered. This approach can also reduce the psychological impact on the child according to NICE (2010). Wetting the bed is common under the age of 5 (21%) and if during the day there are no symptoms, there is no need to alarm the parents according to Butler & Heron (2008).

In children over the age of 5 years the physician should try to reduce bedwetting episodes and try to ease the psychological impact that nocturnal enuresis can have on the child.

Prescribing the right medication and ensuring compliance is important but is only part of the management plan. Behavioural changes are also needed, such as ensuring the right daily fluid intake, and passing urine before the child goes to bed.

The treatment for nocturnal enuresis is continuous and can take years; therefore the physician should make this clear with the carers of the child. This information should reduce the pressure on the child.

Lifestyle changes should be advised. The child's bed should be placed close to a toilet so he/she has easy access. One should also encourage diet change, going to the toilet before sleeping and using mattress protection that can be easily washed.

Following a pre-set time frame agreed with the parents, if lifestyle changes have not worked a very simple bedwetting vibrating alarm that has a very small sensor inserted in the child's underwear should be recommended as these have a very good success history (Wang *et al.*, 2009). A bedwetting alarm can help the child identify a bladder that is full resulting in the child waking up to pass urine.

A review is suggested after around 6 weeks of alarm use. Improvement can be characterized by having smaller patches, reduction in the number of alarm episodes during the night and the occurrence of alarm episodes later on at night. Once there are 15 days of no bedwetting episodes the alarm can be stopped.

If after three months bedwetting has not stopped, parents can be given the choice to continue and reassess after another 3 months or start pharmacological treatment for 4 weeks if the child is over 5 years of age. Ideally the pharmacological treatment should be prescribed together with the bedwetting alarm and obviously lifestyle changes.

Desmopressin can be useful to reduce bedwetting episodes since it reduces production of night-time urine. Desmopressin can improve confidence and long-term use is considered relatively safe (Evans *et al.,* 2011). According to NICE (2010), anticholinergic medications can also be useful and are often recommended as second line treatment. The most commonly used tricyclic antidepressant is imipramine, but this class of drugs are less used due to a higher incidence of side-effects.

After 4 weeks of taking the medication a review should be done. If found effective the treatment should be continued for 3 months, after which it should be stopped for a week to check if the child still has nocturnal enuresis without the medication. The medication should be prescribed for another 3 months if bedwetting has not stopped (NICE, 2010).

In a study done by Monda and Husmann (1995) where patients were put either under observation, or treated with imipramine, desmopressin acetate or alarm therapy it was concluded that only the enuresis alarm proved constant effectiveness.

Physicians need to be aware of when the child needs to be referred. As stated in NICE (2010) if the child presents with symptoms such as severe daytime symptoms, if there is suspicion of physical, neurological or emotional problems, learning or developmental problems or suspicion of comorbidities the child needs to be referred to a specialist. Caldwell *et al*. (2013) suggest that consideration should also be given to refer a child should symptoms persist after 6 months of treatment without success.

Referral should also be considered if there is a suspicion of child abuse. Williams *et al*. (1996) concluded that bullying which is a means of child abuse can result in bedwetting. If a child suffers from recurrent urinary tract infections he or she should also be referred as according to Helstrom *et al*. (1996) there is a strong relation between urinary tract infection and abnormal bladder function.

CONCLUSION

It is important to keep in mind that, while nocturnal enuresis is a common condition in a young child, it requires a careful assessment and management in cooperation with the child's parent or carer.

Behavioural changes are important, as giving the right medication is only part of the treatment. The physician should try to keep the pressure off the child by explaining to the parents that this is a long term process and that the child has no control over it.

A bedwetting vibrating alarm for 3 months can be introduced before pharmacological treatment. After the 3 months adding desmopressin together with the bedwetting alarm can be useful. Referring the child should also be considered if the symptoms persist, or if one suspects co-morbidities.

Dr Marthese GALEA
MD, MRCPCH
Resident Specialist, Paediatrics Department, Mater Dei Hospital, Msida, Malta

Email: akgalea@maltanet.net

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

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

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An evaluation of referral tickets for acute psychiatric admissions

Dr Ian BALDACCHINO, Dr Edith SCIBERRAS, Dr Simon MICALLEF

ABSTRACT

Background

Tickets of referral assist in clerking and the enforcement of the Mental Health Act. Initial reviewers of the patient who may be more aware of his/her background may provide this information when transferring a patient to Mount Carmel Hospital, Malta's psychiatric hospital.

Objectives

The aims of this study were to assess whether key information on referral tickets was lacking as well as to justify the importance of such information when referring a new case and raise awareness on appropriate referral.

Methods

Permission to review the tickets of referral for new admissions from the community to Mount Carmel Hospital during the month of June 2015 was obtained from the Chairman of Psychiatry. The files of new admissions were assessed to see if the following were present: official referral ticket; drug history; next of kin details; handover to staff at Mount Carmel Hospital. The place of initial assessment was also noted. All data was anonymised and data input was done using a prepared proforma. Patients referred from the civil prison and by the caring consultant's firm were not included.

Results

Seventy admissions were assessed. Eighty-nine per cent ($n=62$) of these admissions included an official ticket of referral. Most referrals came from health centres: 31% ($n=22$). Seventy-four per cent ($n=51$) had a drug history present. Seventy-six per cent ($n=53$) were lacking next of kin details. Forty per cent ($n=28$) of the cases had documentation of a handover to a senior on call.

Conclusions

Poor quality referral tickets with missing information are often present which makes it difficult for the on-call staff at Mount Carmel Hospital to clerk the patient and come up with a provisional treatment plan.

Key words

Referral and consultation, mental health, patient admission, psychiatry, hospitals

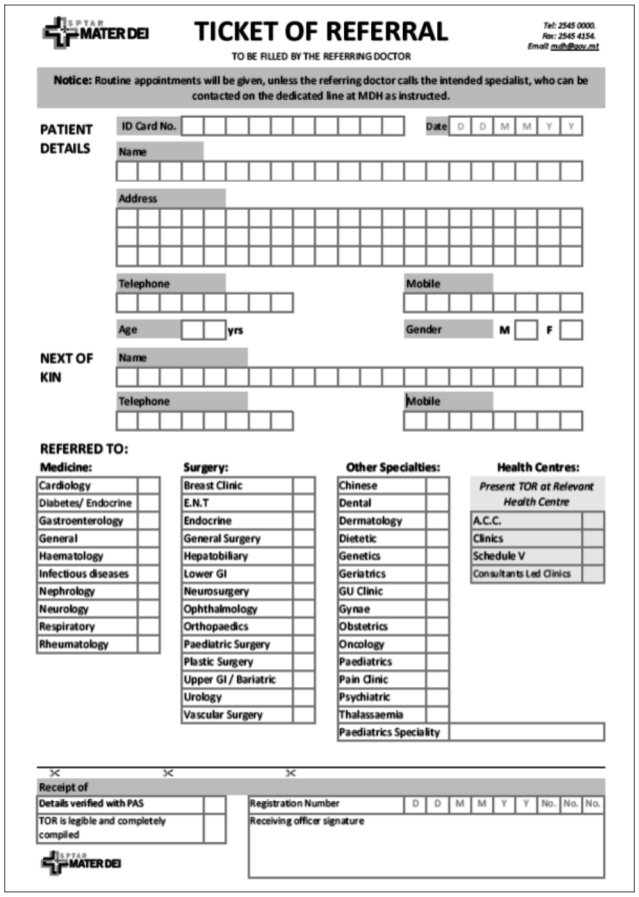
INTRODUCTION

The aim of this study is to emphasize the importance of appropriate referral practices in the acute psychiatric setting to Mount Carmel Hospital (MCH), Malta's psychiatric hospital. Referrals are mainly done from the GP (general practitioner) clinic, psychiatric outpatient department or even an elderly home. Referral tickets should accompany all new admissions. These are written on site and should contain information on symptom presentation, contact details of next of kin and current treatment.

The standard referral ticket supplied by the Department of Health which is used for all the specialties provided by the national health service is made up of 4 main sections to be filled in by doctor doing the referral. The first page (Figure 1) is comprised of a section for: patient's details (ID Card No., Date, Name, Address, Patient Telephone number, Patient Mobile number, Age), next of kin's details (Name, Telephone, Mobile) and 3 tables to tick the specialty where the referral is being made. On the second page (Figure 2) the patient's history is written and, in order to do so, it is split into 5 subsections: reason for referral, past history, current treatment & any allergies, clinical examination findings and investigations done by referring doctor. On the second page the referring doctor should also write his details: full name, registration number, signature and rubber stamp. On this page the referring doctor can write in a specifically dedicated box if the case was discussed with a consultant.

Ideally, the case is discussed with the psychiatrist trainee / psychiatrist at MCH prior to transfer to confirm

Figure 1: Ticket of Referral - first page



TICKET OF REFERRAL

TO BE FILLED BY THE REFERRING DOCTOR

Notice: Routine appointments will be given, unless the referring doctor calls the intended specialist, who can be contacted on the dedicated line at MDH as instructed.

PATIENT DETAILS

ID Card No. | Date D D M M Y Y

Name

Address

Telephone | Mobile

Age yrs | Gender M F

NEXT OF KIN

Name

Telephone | Mobile

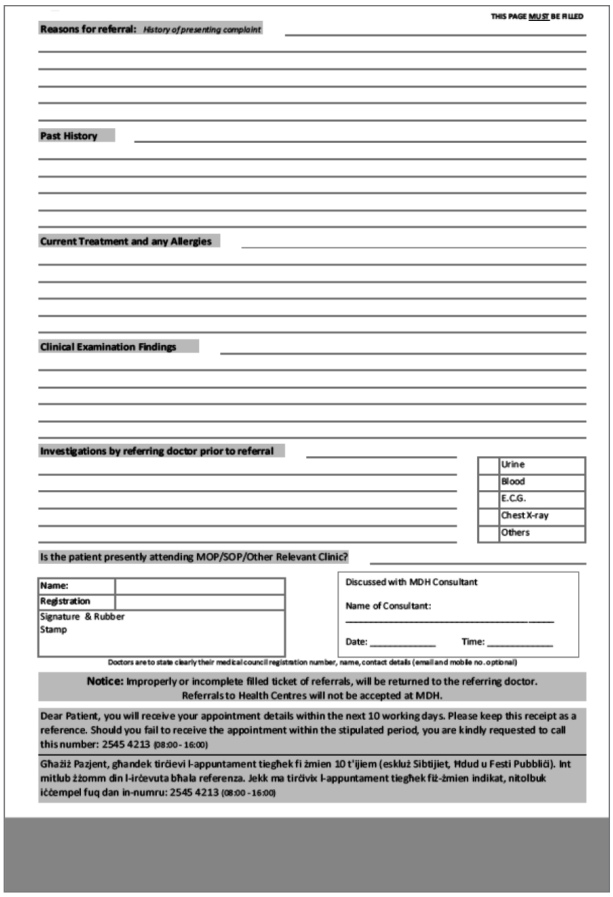
REFERRED TO:

Medicine:	Surgery:	Other Specialties:	Health Centres:
Cardiology	Breast Clinic	Chinese	*Present TOR at Relevant Health Centre*
Diabetes/ Endocrine	E.N.T	Dental	A.C.C.
Gastroenterology	Endocrine	Dermatology	Clinics
General	General Surgery	Dietetic	Schedule V
Haematology	Hepatobiliary	Genetics	Consultants Led Clinics
Infectious diseases	Lower GI	Geriatrics	
Nephrology	Neurosurgery	GU Clinic	
Neurology	Ophthalmology	Gynae	
Respiratory	Orthopaedics	Obstetrics	
Rheumatology	Paediatric Surgery	Oncology	
	Plastic Surgery	Paediatrics	
	Upper GI / Bariatric	Pain Clinic	
	Urology	Psychiatric	
	Vascular Surgery	Thalassaemia	
		Paediatrics Speciality	

Receipt of

Details verified with PAS		Registration Number	D D M M Y Y	No. No. No.
TOR is legible and completely compiled		Receiving officer signature		

Figure 2: Ticket of Referral - second page



THIS PAGE MUST BE FILLED

Reasons for referral: *History of presenting complaint*

Past History

Current Treatment and any Allergies

Clinical Examination Findings

Investigations by referring doctor prior to referral

	Urine
	Blood
	E.C.G.
	Chest X-ray
	Others

Is the patient presently attending MOP/SOP/Other Relevant Clinic?

Name:	
Registration	
Signature & Rubber Stamp	

Discussed with MDH Consultant

Name of Consultant:

Date: Time:

Doctors are to state clearly their medical council registration number, name, contact details (email and mobile no.-optional)

Notice: Improperly or incomplete filled ticket of referrals, will be returned to the referring doctor. Referrals to Health Centres will not be accepted at MDH.

Dear Patient, you will receive your appointment details within the next 10 working days. Please keep this receipt as a reference. Should you fail to receive the appointment within the stipulated period, you are kindly requested to call this number: 2545 4213 (08:00 - 16:00)

Ghażiż Pazjent, għandek tirċievi l-appuntament tiegħek fi żmien 10 t'ijiem (eskluż Sibtijiet, Hdud u Festi Pubbliċi). Int mitlub żżomm din l-irċevuta bħala referenza. Jekk ma tirċivix l-appuntament tiegħek fiż-żmien indikat, nitolbuk iċċempel fuq dan in-numru: 2545 4213 (08:00 - 16:00)

the details of the admission and whether it is warranted. The patient is then transferred to MCH where the on call doctor decides, according to the facts of the referral, the location where to admit a patient and under what level of supervision. Apart from this information, doctors may also speak with the firm caring for the patient and hand over the case details to them.

This study has 3 main aims: to assess whether key parts of the referral tickets are lacking information during referral, to raise awareness on the areas that are lacking on referral, and to justify their importance when referring a new case.

METHODOLOGY

This prospective study prospectively reviewed patient referral tickets of cases that were newly-admitted during the month of June 2015. All data that was kept was anonymised. Permission to review patient files was obtained from the Chairman of Psychiatry before the study began.

Table 1: Details documented in referral tickets

	Percentage of details present or not (n=70)	
	Present	Not Present
Is a referral ticket present?	89%	11%
Are next of kin details written?	24%	76%
Is a drug history present?	74%	26%
Was verbal handover with senior staff documented in the referral?	40%	60%

Referral tickets in files of new admissions were assessed individually for: the presence of a referral ticket, location of assessment, drug history, next of kin details, reason for referral and documented handover to staff at MCH. Data input was done using a prepared template.

Cases where files were not available were not included in the study. Patients referred from the Corradino Correctional Facility (Malta's civil prison) and by the same caring consultant's firm of the forensic branch of MCH were not included in the study.

RESULTS

Seventy cases fitted criteria for inclusion in this study. Eleven per cent (n=8) of admissions were referred to MCH without an official referral ticket (Table 1).

Seventy-four per cent (n=52) of the admissions sent with a referral ticket had a drug history written (Table 1). With regards to next of kin details these were written in only 24 % (n=17) of the admissions sent with a formal referral ticket. Apart from filling in the formal referral ticket we also looked into whether verbal handover was done with the senior staff at MCH. With regards to those patients referred with a formal referral ticket, verbal handover was documented in 40% (n=28).

The majority of the admissions had the location of the assessment clearly written (Figure 3). Health centres were the prime location of assessment - 31% (n=22). Only 6% (n=4) had the location of assessment unknown. The majority of the referral forms had the reason for referral clearly written but in 3% (n=2) the reason for referral was unknown (Figure 4).

DISCUSSION

Not much information is available on the epidemiology leading to acute psychiatric referrals to psychiatric hospitals. In a study conducted in the United States (Larkin *et al*., 2005) the prevailing reasons for psychiatric emergency department visits were substance-misuse and related disorders (30%), mood disorders (23%), anxiety disorders (21%), psychoses (10%) and suicide attempts (7%).

Research undertaken in England (Foot, Naylor and Imison, 2010) shows the importance of high quality referral. Elements worth focusing on for a good referral include:

- The necessity of referring patients when appropriate and without delay;
- The identification of the destination at the end of the referral: the emergency department; the outpatient setting; the acute psychiatric hospital;
- The practice of the referral: what investigations are ordered; the referral ticket details; the awareness about the condition between the GP and patient.

Figure 3: Site of referral as percentage of cases

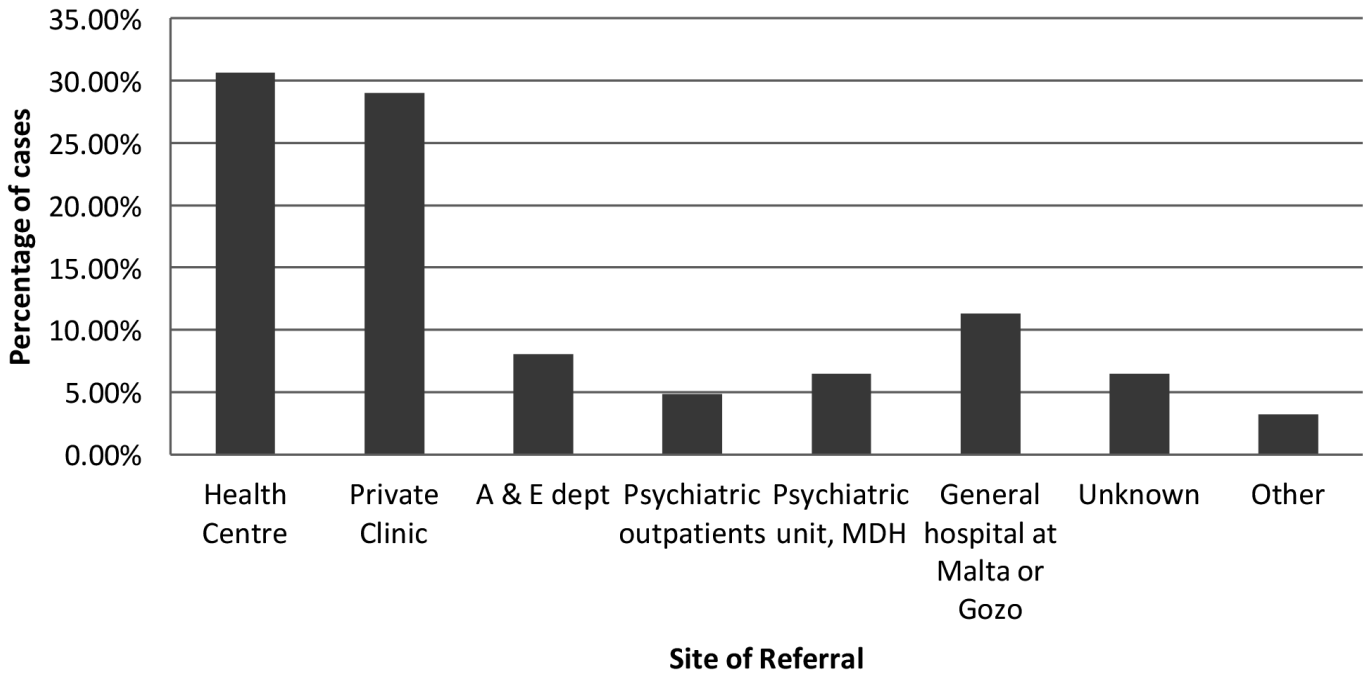
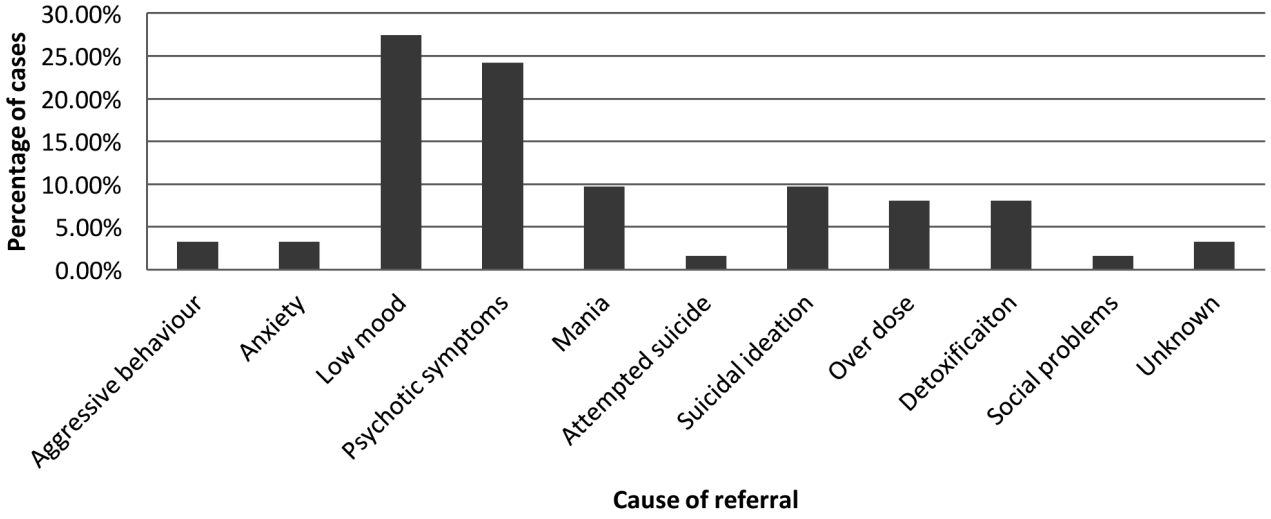


Figure 4: Reason for referral as percentage of cases



Taking the above into consideration, one cannot appropriately refer without the correct patient details, understanding the pathophysiology, the patient's background, the system of psychiatric care in Malta, appropriate documentation and referral. The latter is highly researched as Bodek *et al*. (2006) found that it can make the difference in appropriate triage and prioritisation as well as the destination for the referral and assist the psychiatrist in determining whether to enforce the Mental Health Act.

Doctors and other health care workers face the challenge of transferring a patient suffering from acute mental illness to a safe place where he can receive better care. The more developed the general practitioners' role is the easier it is for them to serve as gatekeepers (Deraas *et al*. cited in Uden *et al*., 2003). Whether such admissions were indicated was not the aim of this study; however the input of trainees and specialists prior to referral should see to them being made appropriately. Public health centres and private physician clinics together accounted for more than half of referrals in this study, showing that first point of contact mainly occurred in the community (Figure 3). Half of admissions were in view of low mood or psychosis (Figure 4).

Almost 1 out of 10 admissions was without a referral ticket (11.43%) (Table 1). Such cases were either referred with a simple note from a physician, or had an accompanying emergency order only, or no note at all. Regrettably there are also individuals who present themselves under extraordinary circumstances to the hospital, for example complaining of suicidal intent, and these cannot be taken lightly.

The environment and pressures under which these referrals were made could not be assessed. Admissions involving aggressive persons, self-harming individuals and people actively under the influence of a substance already pose a struggle to the referring doctor and psychiatric team at MCH. In fact Hunt, Marsden and O'Connor (2011, p. 316) go on to state that it is in fact more troublesome and time consuming to interact with patients and that most information could be on prior medical records. Unfortunately Chetcuti, Farrugia and Cassar (2009, p. 28) pointed out that missing referral information is not just limited to psychiatry but also other specialities.

Verbal handover with the caring team or on-call doctor was not documented in the referral in 60% of cases (Table 1). Perhaps doctors were confident that the patient would be accepted without documentation of this after handover over the phone. Twenty-six per cent of referrals regrettably did not have a treatment list written down, and next of kin details which could be used to trace back treatment were absent in 76% of cases (Table 1).

Substance misusers being followed up at the substance-misuse out-patients unit at St. Luke's Hospital could have their treatment confirmed during first medical contact with the latter only during limited opening hours. Substance misuse related admissions are surely underrepresented in this study since they themselves carry a higher tendency of psychiatric co-morbidity

as well as an aptitude for earlier discharge against medical advice. Norwegian studies demonstrated that substance-misuse related co-morbidities accounted for 54% of admissions (Helseth *et al.* cited in Deraas *et al.*, 2006) compared to 16% of combined detoxification and overdose scenarios during this review.

LIMITATIONS

Files of patients that were discharged early on were not available and information was manually collected. Cases brought under police custody were not documented as such in this study.

The referral tickets drawn up by public GPs were not compared with those of private GPs to see whether they were statistically different regarding details on referral ticket.

The referral tickets drawn up by GPs were not confronted with those drawn up by psychiatry specialists (for patients from Corradino) to see whether they were statistically different.

CONCLUSION

This small study shows that the majority of acute psychiatry referrals are done in the community by GPs. Despite contacting the psychiatric trainee at the hospital prior to transfer, details on the referral form are still left missing, including documentation of verbal handover. Sources of information such as next of kin details are not written down in the majority of referrals.

It is proposed that, in the case of drug misusers, the detoxification centre should be contacted early to confirm current treatment. Also, a plan could start to be considered at prima facie in discussion with the psychiatric team, such as at which ward the patient should be admitted to and under what level of supervision. Considering that the referral ticket is used for admission, such details could be documented in the referral: this would save time and be safer for both the reviewing doctor and patient.

Dr Ian BALDACCHINO MD
Foundation Programme, Mater Dei Hospital, Msida, Malta

Email: ian.baldacchino@gov.mt

Dr Edith SCIBERRAS MD
Foundation Programme, Mater Dei Hospital, Msida, Malta

Dr Simon MICALLEF MD
Foundation Programme, Mater Dei Hospital, Msida, Malta

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Clinicians' adherence to local antibiotic guidelines for upper respiratory tract infections in the ear, nose & throat casualty department of a public general hospital

Dr Clayton John FSADNI, Dr Sarah CARUANA GALIZIA

ABSTRACT

Background

In Malta, resistance to antibiotics constitutes a major threat to public health. This study aims to assess clinicians' adherence to local antibiotic guidelines when treating cases of acute otitis media, acute tonsillitis and rhinosinusitis, that present to the ear, nose and throat (ENT) casualty department in Malta's public general hospital, as well as to recommend methods for improving adherence and minimising overprescribing.

Methodology

Data on first line antibiotic prescribing regimens was retrieved from ENT casualty sheets between February and March 2015 for adult patients (>12years) diagnosed with acute otitis media, acute tonsillitis and persistent rhinosinusitis. On an audit form, aspects of the prescribed antibiotic were benchmarked to local infection control antibiotic guidelines of 2011 to evaluate adherence.

Results

From 1010 casualty records, 188 were antibiotic prescriptions, of which 93 (49.4%) were correctly indicated as per guidelines. From the indicated prescriptions 81 (87%) were assessable, out of which full adherence was only observed in 6 (7%) of prescriptions. All of these were for rhinosinusitis. Full adherence in rhinosinusitis was found to be 43%, whilst no adherence was found in the other infections. The most prescribed antibacterial for all three infections was co-amoxiclav.

Conclusion

The current antibiotic guidelines have not been adequately implemented as adherence to antibiotic choice alone was low in all infections. This may have an impact on antibiotic-resistant rates and infection incident rates. Hence to improve adherence to local antibiotic guidelines, it is recommended that these should be clear, regularly updated, well disseminated and reinforced. The addition of a care pathway may further improve appropriate antibiotic use.

Key words

Antibacterial agents; antibiotic guidelines; respiratory tract infections.

INTRODUCTION

The role of antibiotic policies is to guide physicians to prescribe antibiotics appropriately so as to avoid unjustified prescription, reduce the emergence of antibiotic resistance, support high-quality clinical practice and minimize unnecessary expenses (Aly *et al.*, 2012). A considerable number of upper respiratory tract infection cases, treatable at primary care level, are still being encountered at the ear, nose and throat (ENT) casualty department in Mater Dei Hospital, Malta's public general hospital. Uncomplicated upper respiratory tract infections still remain the most common cases that are channelled to ENT via casualty.

Antibiotic resistance is a major concern both locally and globally. In Malta, resistance to antibiotics constitutes a major threat to public health, and ought

to be recognised as such more widely than it is at present (Borg, 2009). In view of this, infection control has established evidence based guidelines aimed at reducing spread of infections.

The successful implementation of such guidelines is as important as the development of the guidelines themselves. The guidelines are accessible at http://health.gov.mt/en/nac/Pages/guidelines.aspx. There is still no evidence that the antibiotic guidelines have been effectively applied in clinical practice.

The aims of this study were:

- To assess clinicians' adherence to the local community-based guidelines when prescribing for acute otitis media, acute tonsillitis and rhinosinusitis;
- To list recommendations so as to improve adherence to guidelines.

METHODOLOGY

Design and setting

The study is of a retrospective nature. This was done internally as the first part of a standards-based audit of antibiotic prescribing regimens for acute otitis media, acute tonsillitis and rhinosinusitis. It was conducted over a 2 month period (February 2015 to March 2015) at the ENT ward of Mater Dei Hospital. Records selected for review pertained to patients that were referred to the ENT ward by the Accident & Emergency (A&E) department. Data was retrieved and recorded from casualty sheets.

Selection criteria and sampling

Sampling units consisted of adult patients (>12 years of age) diagnosed with otitis media, persistent rhinosinusitis and acute tonsillitis. Only the 1st line antibiotic regimen for uncomplicated cases was recorded. The prescriptions that were evaluated were those for 1st line antibiotic agents prescribed by medical officers covering ENT casualties at the ENT Department of Mater Dei Hospital. Patients who were already taking antibiotics prior to being seen by the medical officer at the ENT ward, or who were penicillin allergic, were excluded from the study.

Audit form

An audit collection form was designed by the researchers and an infection control pharmacist. It was then discussed with a microbiologist. For each of the infections stated above, the factors that make up the antibiotic regimen were recorded. These included the antibiotic name, dose, route of administration, frequency, duration and comments. The reason / indication for the prescription was stated in the comments column of the form. This column was also used to give the clinician sufficient space for any further information regarding the history of presenting complaint and drug allergies. This made it possible to evaluate whether antibiotics were indicated and to identify patients who had already been started on antibiotics.

Assessment of adherence to guidelines

For each infection, performance was measured by first identifying the reason for antibiotic prescribing if any, checking indications and evaluating the appropriateness of the agent. Prescription analysis was based on recommendations of the local infection control antibiotic guidelines (Malta National Antibiotic Committee, 2011) accessible from the government health website. When an antibiotic was prescribed as per guidelines, it was considered appropriate (indicated) and then its dose, route of administration, frequency and duration were further evaluated. In cases where more than one agent was prescribed for that specific infection, the antibiotic regimens were evaluated separately.

Full adherence (compliance) was defined as a prescription that fulfils all aspects of an antibiotic regimen as per guidelines that is in terms of agent, dose, route, frequency and duration. Non-adherence to the guidelines was considered when there was divergence from recommended antibiotic, or failure to have full concordance with the regimen.

In the case of incomplete regimens or when the diagnosis was unclear in the casualty form, evaluation for adherence could not be performed and hence such prescriptions were considered as non-assessable.

Full adherence was calculated from those assessable as the percentage of compliant regimens divided by total number of regimens recorded:

Full Adherence =

[(number of compliant prescriptions)/(number of compliant + non-compliant)] X 100

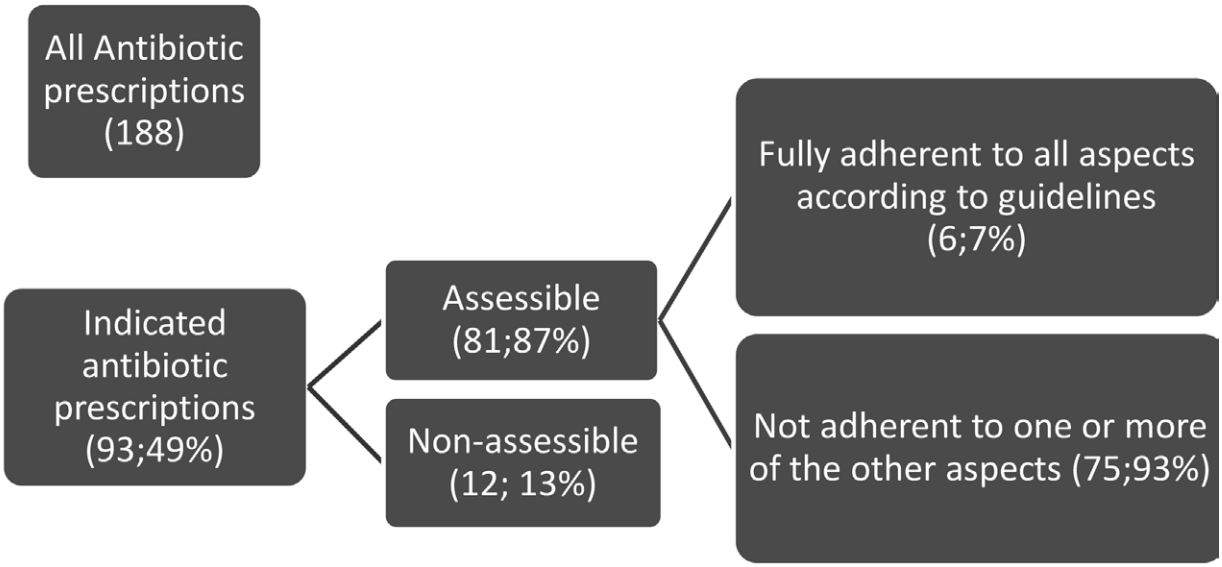
Processing of data

All data was processed and then subsequently analysed using Windows Microsoft Excel® 2007.

Pilot study (10%)

A pilot study was undertaken over a 4 day period prior to the 2 month data retrieval period. The pilot study was aimed to examine the appropriateness of the designed

Figure 1: Situational analysis of antibiotic prescriptions



audit form. No changes were made to the original proforma or sampling method.

Ethical approval and consent

The study was approved by both the Foundation Programme Audit Committee and the Mater Dei Hospital data protection unit. Consent for the study was obtained from the Chairman of the ENT Department, Mr M Said.

RESULTS

Antibiotic prescriptions

During the months of February and March 2015, 1010 casualty records were retrieved from the ENT Department. From these, 188 were antibiotic prescriptions of which 93 (49.4%) were correctly indicated as per guidelines.

From the indicated prescriptions, 81 (87%) were assessable in terms of regimen (refer to Figure 1). Out of these, 14 (17%) were for rhinosinusitis, 31 (38%) were for acute otitis media and 36 (44%) for tonsillitis.

Antibiotic choice

The antibiotic regimens, the total number of prescriptions and respective number of indicated regimens for each infection are represented in Tables 1-3. The mostly prescribed antibacterial agent was co-amoxiclav in all the three infections – 86% of prescriptions for rhinosinusitis, 77% for acute otitis media and 56% for tonsillitis.

Antibiotic adherence to local guidelines

The 81 assessable antibiotic prescriptions were evaluated as follows: fully adherent (compliant) in 6 (7%) and non adherent (non-compliant) in 76 (94%). The situational analysis of all antibiotic prescriptions is illustrated in Figure 1. The adherence to the antibiotic agent, dose, route of administration, frequency, duration and full adherence for each infection are represented in Figures 2-4. The total adherence to each aspect of the antibacterial regimen for all infections is represented in Figure 5.

Table 1: Antibacterial regimens for rhinosinusitis

	Antibacterial agent	Dose(mg)	Route	Frequency	Duration (days)	Number of Prescriptions	Total number of prescriptions
STANDARD	Co-amoxiclav	625	PO	tds	7		
PRESCRIBED	Co-amoxiclav	625	PO	tds	7	6	14
	Co-amoxiclav	625	PO	bd	7	2	
	Co-amoxiclav	1000	PO	bd	7	4	
	Cefuroxime	500	PO	bd	7	2	

Table 2: Antibacterial regimens for acute otitis media

	Antibacterial agent	Dose	Route	Frequency	Duration (days)	Number of Prescriptions	Total number of prescriptions
STANDARD	Amoxicillin	500mg	PO	tds	5		
PRESCRIBED	Ciprofloxacin	2 drops	Ear drops	tds	7	1	31
	Co-amoxiclav	375mg	PO	tds	7	2	
	Co-amoxiclav	625mg	PO	bd	7	1	
	Co-amoxiclav	625mg	PO	tds	7	17	
	Co-amoxiclav	625mg	PO	tds	14	1	
	Co-amoxiclav	1000mg	PO	tds	7	1	
	Co-amoxiclav + Chloramphenicol	625mg+ 2 drops	PO +ear drops	tds	7	1	
	Co-amoxiclav + ciprofloxacin	625mg+ 4 drops	PO +ear drops	bd+ tds	7	1	
	Amoxicillin	500mg	PO	bd	7	3	
	Amoxicillin	500mg	PO	tds	7	1	
	Clarithromycin	500mg	PO	bd	5	1	
	Clarithromycin	500mg	PO	bd	7	1	

Table 3: Antibacterial regimens for acute tonsillitis

	Antibacterial agent	Dose (mg)	Route	Frequency	Duration (days)	Number of Prescriptions	Total number of prescriptions
STANDARD	Penicillin V	500	PO	tds	10		
PRESCRIBED	Co-amoxiclav	625	PO	tds	7	8	36
	Co-amoxiclav	1000	PO	bd	7	8	
	Co-amoxiclav	1000	PO	tds	7	2	
	Co-amoxiclav	1000	PO	bd	5	2	
	Clarithromycin	500	PO	bd	7	10	
	Clarithromycin + Levofloxacin	500 + 500	PO	bd +Bd	5 + 10	2	
	Metronidazole + levofloxacin	400+ 500	PO	tds + bd	7	2	
	Azithromycin	500	PO	tds	3	2	

DISCUSSION

Antibiotic prescribing guidelines are aimed to provide a simple, empirical approach to the treatment of common infections. They also reduce the emergence of resistance whilst ensuring cost effective treatment. The implementation of evidence-based guidelines has been shown to improve overall patient outcomes (Aly *et al*., 2012).

The antibiotic guidelines used for this study were formulated by the national antibiotic committee in 2011 (Malta National Antibiotic Committee, 2011). These consist of broad evidence-based guidelines for community acquired infections. Previously, no studies

Figure 2: Clinicians' adherence to the treatment guideline in rhinosinusitis

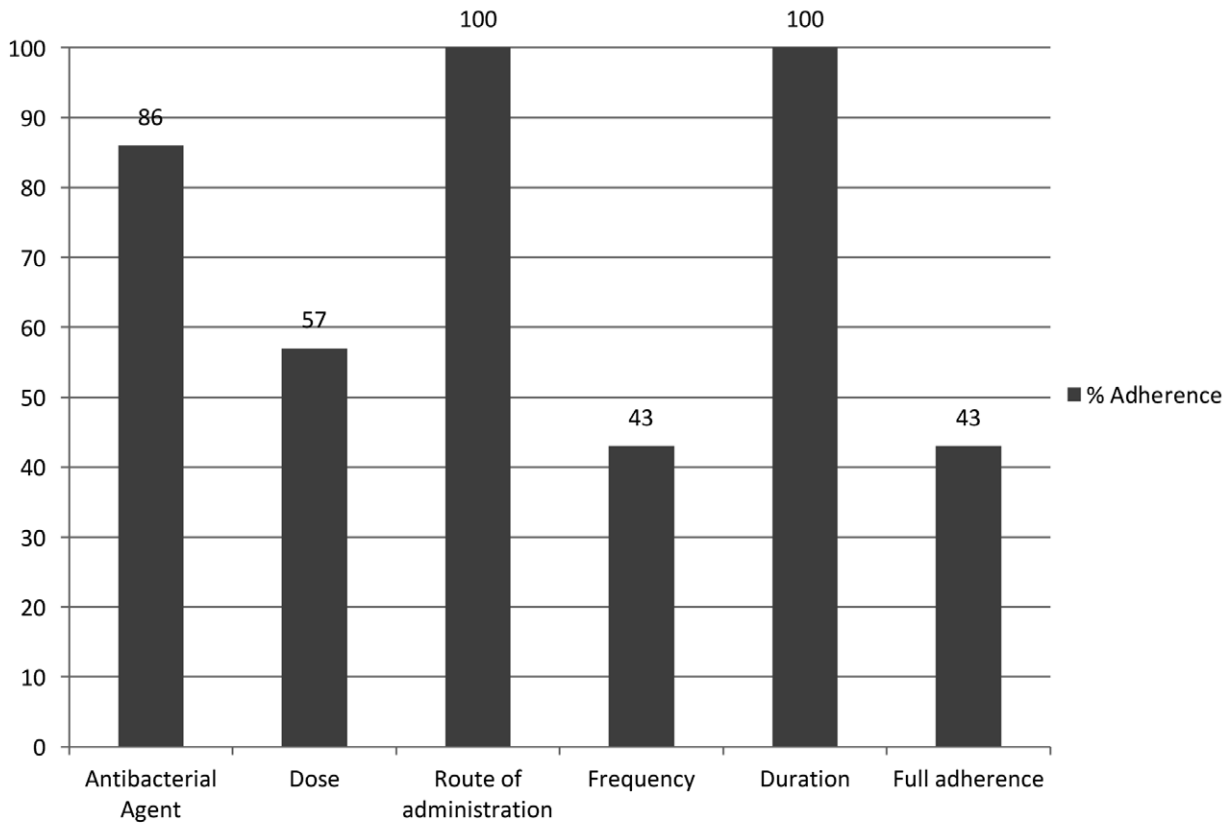


Figure 3: Clinicians' adherence to the treatment guideline in acute otitis media

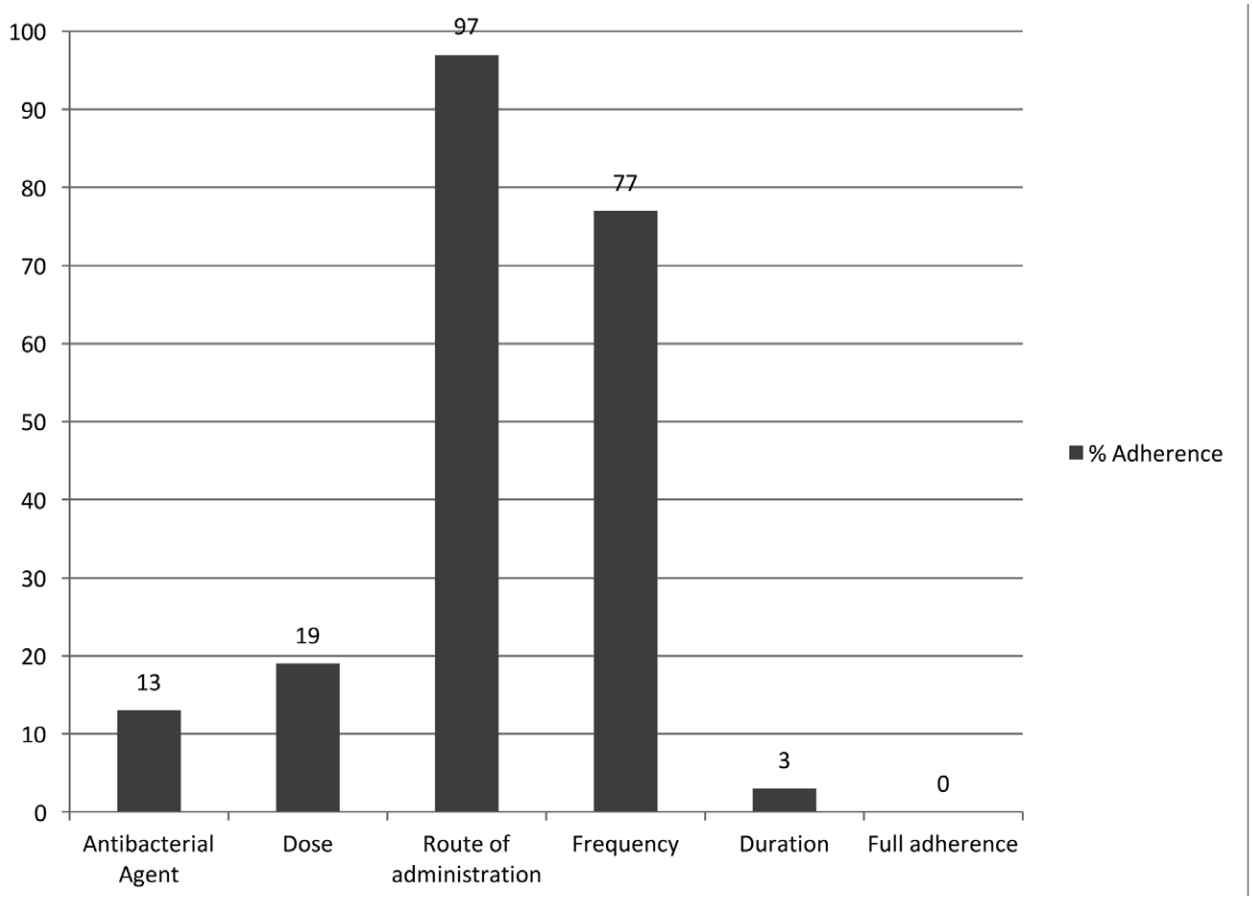


Figure 4: Clinicians' adherence to the treatment guideline in acute tonsillitis

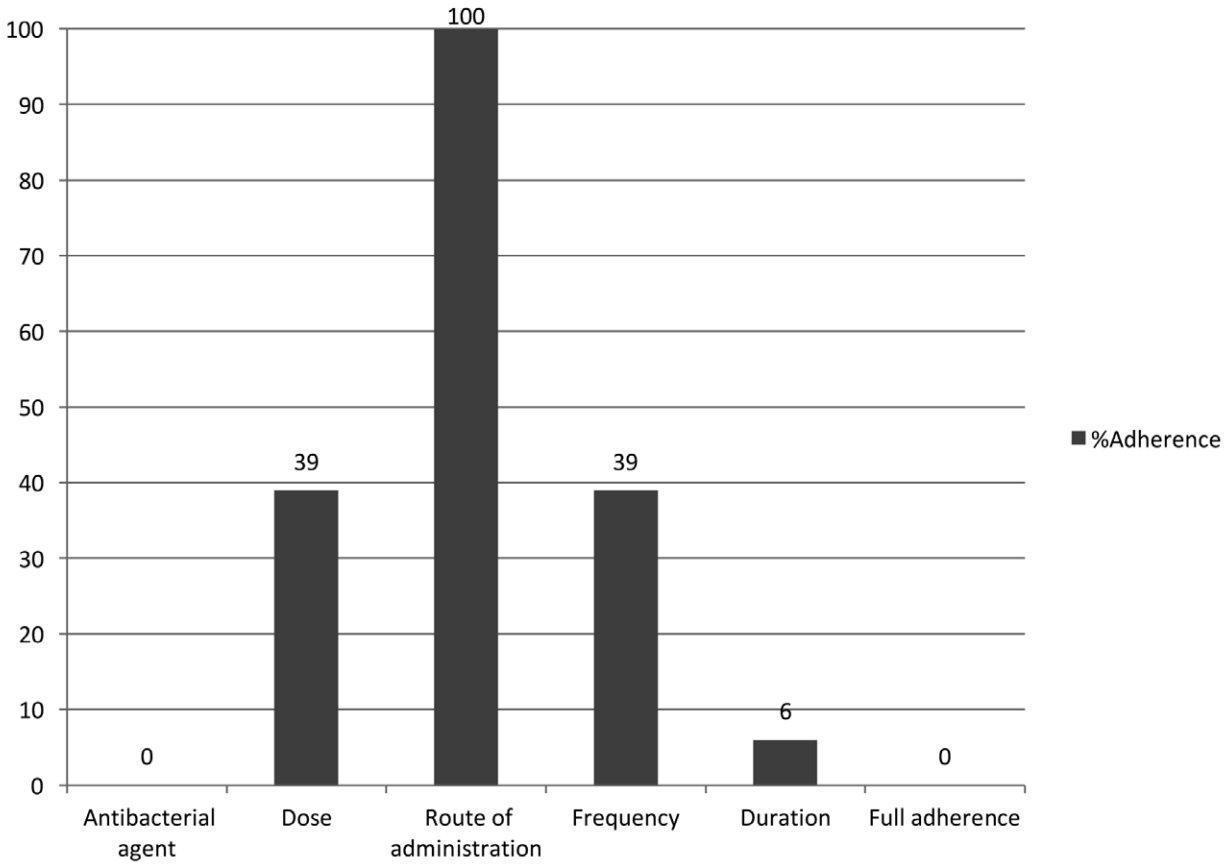
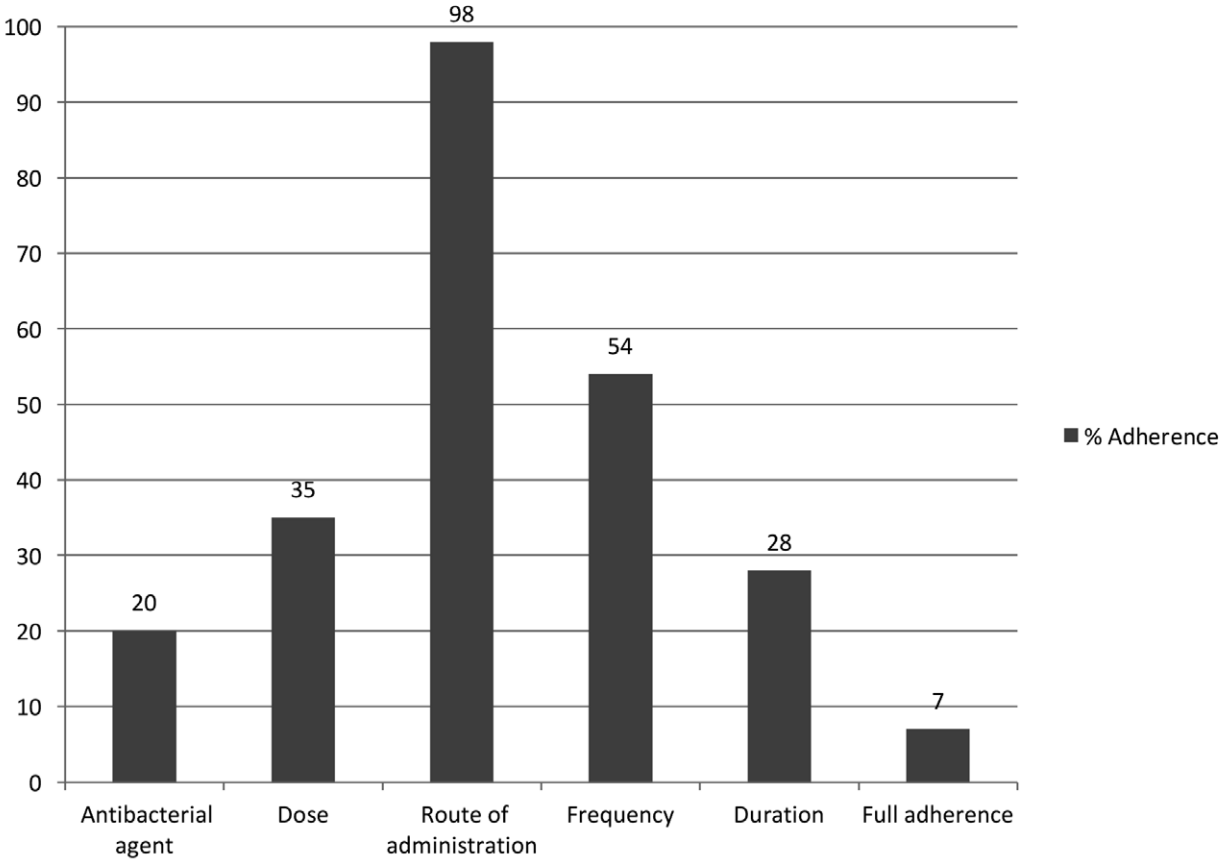


Figure 5: Clinicians' adherence to the treatment guideline in all infections



were carried out on the effective application of these guidelines in treating upper respiratory tract infections (rhinosinusitis, acute otitis media and acute tonsillitis) at ENT Casualty at Mater Dei Hospital.

From this study, 51% of antibiotic prescriptions were not indicated according to the guidelines. Overprescribing of antibiotics amongst clinicians could be due to unawareness of the delayed or no-antibiotic strategy as stated by the guidelines. Another reason could be concern of a poor clinical outcome if an antibiotic is not prescribed. There is also fear of legal action by patients and hence a tendency for the clinician to self-protect (Aly *et al*., 2012). Furthermore, due to lack of patient knowledge and to expectations of being given a prescription, patients often put pressure on clinicians to prescribe antibiotics (Mc Vey, 2012).

The most commonly prescribed antibacterial agent for all the infections under study was co-amoxiclav. According to the guidelines, this was only appropriate for rhinosinusitis. In the case of acute otitis media and tonsillitis amoxicillin and penicillin V were recommended respectively. This shows that prescribers opted for a broader spectrum antibiotic. Hence prescribers need to be aware that a more broad-spectrum empirical treatment does not result in more effective treatment, but does increase the selection of antimicrobial resistance. (Van Der Veiden *et al*., 2011).

Full adherence was 43% for persistent rhinosinusitis whilst 0% adherence was recorded for both acute otitis media and acute tonsillitis. The most probable reason for this could be that since antibiotics for rhinosinusitis were prescribed in persistent cases, clinicians referred to guidelines for optimisation of treatment.

With regards to other aspects of antibacterial regimens the results for all infections showed that the correct route of administration was used 98% of the time whilst the correct antibacterial agent was chosen only in 20% of cases.

Acute otitis media

According to the guidelines an antibiotic is indicated for the adult population only if:

- Fever is ≥ 39°C and / or evidence of systemic toxicity;
- Otorrhoea is present.

In acute otitis media, 13% (n=4) prescribed the correct antibacterial agent, that is amoxicillin. Out of these 75% (n=3) prescribed a twice daily dose instead of the recommended TDS dose and in all the prescriptions, the prescribed duration was 7 days instead of the suggested 5 days. From previous studies, it has been shown that inappropriate dosing frequency and treatment duration encourages the emergence of antibiotic–resistant mutants (Olofsson and Cars, 2007).

Rhinosinusitis

The cases under study were all cases of persistent rhinosinusitis. In this case the guidelines suggest that an agent with anti-anaerobic activity (co-amoxiclav) is to be prescribed. Most prescriptions (86%) were for the correct antibacterial agent. Out of the 86%, non-compliance to guidelines was observed in terms of dose (33%) and frequency (50%). As pointed out previously this may increase the emergence of resistance.

Acute tonsillitis

The guidelines use the pharyngitis score to assess the likelihood of Group A streptococcal infection and hence to determine whether an antibiotic is indicated or not. In this study there was no adherence to the recommended antibacterial, that is penicillin V in oral form. Penicillin V is not available in community pharmacies. Hence, this may be the main reason why prescribers opted for an alternative penicillin, mainly co-amoxiclav (56%). Whenever a non-penicillin was prescribed, this may have been due to penicillin hypersensitivity or due to unawareness of the guidelines.

Reasons for non-adherence

There are many possible reasons why the clinicians did not adhere to the guidelines. There are three main factors that may contribute to non-adherence. These may be classified under patient factors, clinician factors and factors related to the guidelines themselves.

Patient factors

Lack of patient knowledge of the difference between viral and bacterial infections, and of the resistance problem, may lead to the patient putting excess pressure on the physician to prescribe an antibiotic. Furthermore, specific notions on the effectiveness of antibiotics and expectations in terms of being given a prescription may also contribute to this external bias (Mc Vey, 2012).

Clinician factors

Guidelines may be perceived by clinicians as a threat to professional autonomy and as interfering with daily clinical practice (Mol *et al*., 2004). One of the main clinician factors that lead to non-adherence is 'clinician

inertia'. This is the tendency for physicians to adhere to their own habitual prescribing pattern rather than referring to guidelines. Due to the continuous change in resistance patterns habitual prescribing may not only be ineffective but may also promote the emergence of resistant strains. Clinician inertia may also lead to overprescribing and its already discussed repercussions (Haggard, 2011).

Many doctors are uncertain about the diagnosis and the best way forward, especially if the symptoms have not cleared up after a few days (Alweis *et al*., 2014). They prefer to take the certain route than the less clear one and may have quite unrealistic expectations about what antibiotics can do. For example, many clinicians tend to prescribe broader spectrum antibacterials. Doctors are often afraid of complications if they do not treat the patient, whilst at the same time they are not fully aware of the risk of antibiotic resistance (Mc Vey, 2012).

Guideline factors

For physicians to comply with guidelines, ease of access, clarity, regular updates and enforcement are essential, which were lacking in the guidelines used in this study - the only antibiotic prescribing guidelines available locally.

With regards to dissemination of these guidelines, accessibility is only available on the government health website. This is the main attributor to the lack of awareness of these guidelines.

The guidelines are also unclear especially when it comes to adult dosing in acute otitis media. Practicality was also an issue with regards to the recommendation of penicillin V for acute tonsillitis. Penicillin V is only available at Mater Dei Hospital's inpatients pharmacy and therefore this may lead to problems when it is prescribed in primary care or patients seen at ENT casualty. This is because in this case the patient is forced to buy the medication from the inpatient pharmacy which causes much inconvenience. Hence this leads to non–compliance.

The local guidelines were last updated in 2011. Guidelines need to be regularly updated for the simple reason that they need to comply with the continuous change in local resistance patterns. This also promotes their credibility and hence increases adherence by physicians.

Another reason for non–adherence may be due to lack of enforcement of the guidelines as no form of academic teaching is carried out and no electronic clinical decision support tool has been implemented.

Recommendations for improving adherence to local antibacterial guidelines

Patient factors

Various education campaigns on both national and international levels, such as the European Antibiotic Awareness Day may help improve public knowledge on antibiotic prescribing (Haggard, 2011).

The dissemination and easy access of patient information leaflets can provide sufficient basic knowledge to the patients that will allow them to comprehend the reason why the use of such drugs requires specific indications for their use. Antibiotic campaigns can further enhance in a more practical manner such understanding.

Guideline Factors

To improve adherence to local antibiotic guidelines, it is recommended that these should be clear, regularly updated, well disseminated and enforced. Repeating audits is also a good way of reinforcing the current guidelines.

Clarity can be achieved by clearly stating doses for subcategories of the population and for patients that suffer from co-morbidities. Nonetheless, no clinical guidelines will be specific enough for all patients under all situations; therefore a need to deviate from guideline recommendations for clinical reasons will always remain (Hecker *et al*., 2003). To ensure patient compliance, the antibiotics chosen and their respective regimen should be practical. For example, for acute tonsillitis, instead of recommending penicillin V, it would be more practical to recommend amoxicillin or co-amoxiclav as these are available in community pharmacies and at the same time provide similar antibacterial coverage for the most common upper respiratory tract infection pathogens (Kinlay *et al*., 2003). Another alternative is to make penicillin V available also in community pharmacies.

From a retrospective study, conducted in 2005 by Mol *et al*., it was found that updating the guidelines in close collaboration with the specialists involved (hence giving them a sense of 'ownership' of the guidelines) followed by active dissemination, proved to be an efficient way of improving compliance with guideline recommendations (Mol *et al*., 2005). Hence the current local guidelines which were produced in 2011 require many revisions which should involve a pharmacist, a medical microbiologist and several clinical specialists (Van Der Veiden *et al*., 2011).

The guidelines should be made available on the Mater Dei intranet (KURA). A hard copy should be made available in each ward. A downloadable digital version should also be available (Haggard, 2011) for smartphones. More effort

to familiarise physicians with the guidelines needs to be made. This involves strengthening physician education, training and promoting continued professional education by means of seminars, conference, lectures and if possible by setting up an Active Outreach Committee. These should also involve junior doctors, as most of the prescribers under study were foundation doctors. Any updates to the previous version should be notified to the prescribers either through meetings or more conveniently by electronic notifications of updates (Mol *et al*., 2004).

A new habit may be more readily adapted when supported by a facility that solves an acknowledged problem. Evidence on reminders and prompts built into computerised decision support systems suggests at least short-term reductions in antimicrobial use and improved appropriateness of antimicrobial selection (Lu *et al*., 2008).

It is also recommended that local guidelines should include a care pathway similar to that employed for respiratory infections by the NICE guidelines (NICE Clinical Guideline 69, 2008). This is intended to further control antibacterial use through appropriate antibacterial prescribing. In view that the most of the upper respiratory tract infections are viral in origin clinicians may opt for three prescribing options:

1. *No antibiotic prescribing*
   Patients are offered reassurance that antibiotics are not needed immediately because they will make little difference to symptoms and may have side effects, for example diarrhoea, vomiting and rash. A clinical review should also be offered if the infection worsens or becomes prolonged.
2. *Delayed antibiotic prescribing*
   Patients are offered reassurance as explained above, as well as advised to use a delayed prescription if symptoms do not settle or get significantly worse.
3. *Immediate antibiotic prescribing*
   This is offered in patients that:-
   a. Are systemically very unwell
   b. Have symptoms and signs suggestive of serious illness or complications (e.g. peritonsillar abscess in tonsillitis and mastoiditis in acute otitis media)
   c. Are at high risk of complications because of pre-existing comorbidity. This includes patients with significant heart, heart, lung, renal, hepatic or neuromuscular disease and immunosuppression.

Whichever prescribing option the clinician opts, it is vital that all patients are offered advice about the usual natural history of the illness and average total illness length as follows:

- Acute otitis media: 4 days
- Tonsillitis: 1 week
- Acute rhinosinusitis:2 ½ weeks

This provides the patient with an indication of infection persistence that, when exceeded, would require referral.

Clinician factors

The best way to avoid clinician inertia and defensive medicine is to provide a reliable system that will automatically provide the best antibacterial choice for that particular clinical scenario. Here we are referring to computerised clinical decision support systems which are intended to provide to the prescriber a tool that is both reliable and practical to use.

Computerised clinical decision support systems (CDSSs) are information systems designed to improve clinical decision making. Characteristics of individual patients are matched to a computerised knowledge base, and software algorithms generate patient–specific recommendations (Garg *et al*., 2005). These systems provide several modes of decision support including alerts of critical values, reminders of overdue preventive health tasks, advice for drug prescribing, critiques for existing health care orders, and suggestions for various active care issues. As with any health care innovation, CDSSs should be rigorously evaluated before widespread dissemination into clinical practice. A study performed by Garg *et al*. in 2005 showed that many CDSSs improve practitioner performance. Incorporation of the local guidelines within a CDSS would therefore be a useful way to directly enforce the local guidelines.

The above mentioned recommendations are all applicable to primary health care systems especially the antibacterial stewardship through the above mentioned CDSS tool.

Strengths of study

The general trend of 1st line antibacterial prescribing at the ENT casualty during the study period is quite reliable as it is based on a large number of prescriptions (n=188) prescribed by a relatively small number of prescribers (n=12). In most cases the whole regimen was stated and hence the extent of non-adherence to the guidelines was evaluated for each regimen parameter.

The infections considered are common community-acquired infections; therefore the study's recommendations are also applicable to primary health care. Synergy with other domains of health care encourages the need for the implementation of such recommendations favouring the proper use of improved guidelines for primary and secondary care settings, thus further enhancing the study's influence for altered clinical practice and improved patient care.

The study is suitable for scaling-up, allowing coverage of other settings apart from ENT casualty such as health

care centres. The study can also be repeated (completing the audit cycle) after the correct implementation of the study recommendations. This would provide prescribers with the evidence base that will help them to identify areas for further continuing professional development in antibacterial prescribing.

Limitations of study

Several limitations were encountered in the study especially when it came to data retrieval of antibiotic regimens from casualty forms. It was assumed that the diagnosis of the prescriber is correct but this was not always made clear as sub-categorization of the condition was rarely stated. Furthermore drug allergies, possible drug interactions or co-morbidities (e.g. renal and liver function) that would have affected the prescribing trend, were never stated and hence not considered in the study.

In order to avoid variation of dosing in the paediatric population, only patients older than 12 years of age were considered in the study. Moreover only first-line treatment regimens were considered, and it was assumed that the antibiotic prescribed is available at the pharmacy. It was also assumed that the patients were compliant to the treatment regimen.

The total number of prescribers assessed within the data retrieval period amounted to twelve, most of which being foundation officers with limited experience in ENT.

CONCLUSION

The current antibiotic guidelines have not been adequately implemented. Adherence to antibiotic choice alone was low in all infections especially in acute tonsillitis. Failure to comply with appropriate dosing, route, frequency and duration of treatment as well as overprescribing were the reasons for poor adherence to the policy as a whole. This low adherence may have an impact on antibiotic-resistant rates and on infection incidence rates. To improve adherence to local antibiotic guidelines, it is recommended that these should be clear, regularly updated, well disseminated and enforced. The addition of a care pathway is also considered to be essential in ensuring appropriate antibacterial prescribing especially at primary care level where continuity of care is provided.

Dr Clayton John FSADNI B.Pharm(Hons) MD
Foundation Year Doctor with main interest in Family Medicine, Mater Dei Hospital, Msida

Email: menturius@gmail.com

Dr Sarah CARUANA GALIZIA MD
Foundation Year Doctor with main interest in Paediatrics Mater Dei Hospital, Msida

Email: sarahannecg@gmail.com

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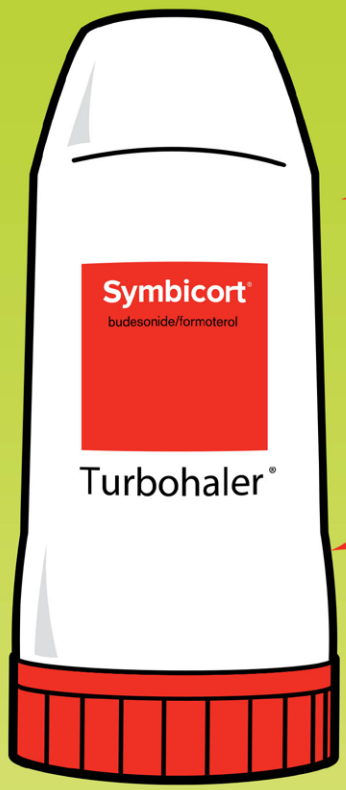

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Symbicort Turbohaler 100/6 is not appropriate for patients with severe asthma. **COPD** ***(Symbicort 200/6 only):*** Symptomatic treatment of patients with COPD with FEV1 <70% predicted normal (post-bronchodilator) and an exacerbation history despite regular bronchodilator therapy. **Presentation** Inhalation powder. ***Symbicort Turbohaler 100/6:*** Each metered dose contains 100 mcg budesonide/inhalation and 6 mcg formoterol fumarate dihydrate/inhalation. ***Symbicort Turbohaler 200/6:*** Each metered dose contains 200 mcg budesonide/inhalation and 6 mcg formoterol fumarate dihydrate/inhalation. Refer to the SmPC for information on the method of administration. Dosage and Administration **Asthma** Not intended for the initial management of asthma. Dose should be individualised. If a patient requires dosages outside recommended regimen, appropriate doses using individual inhalers should be prescribed. When long-term symptoms are controlled, titrate to the lowest effective dose, which could include a once daily dosage. **Symbicort maintenance therapy – regular maintenance treatment with a separate rescue medication:** ***Adults (≥18 years, including elderly):*** 1-2 inhalations twice daily (maximum 4 inhalations twice daily). ***Adolescents (12-17 years):*** 1-2 inhalations twice daily. ***Children 6-11 years (Symbicort 100/6 only):*** 2 inhalations twice daily. ***Children under 6 years:*** Not recommended. **Symbicort maintenance and reliever therapy – regular maintenance treatment and as needed in response to symptoms:** consider for patients with (I) inadequate asthma control and in frequent need of reliever medication (ii) previous asthma exacerbations requiring medical intervention. ***Adults (including elderly):*** 1 inhalation twice daily or as 2 inhalations once daily. 2 inhalations twice daily may be appropriate for some patients (200/6 strength only). Patients should take 1 additional inhalation as needed in response to symptoms. If symptoms persist after a few minutes, an additional inhalation should be taken. Not more than 6 inhalations should be taken on any single occasion. A total daily dose of more than 8 inhalations is not normally needed; however, up to 12 inhalations a day could be used for a limited period. Patients using more than 8 inhalations daily should be strongly recommended to seek medical advice and should be reassessed; their maintenance therapy should be reconsidered. Patients should be advised to always have Symbicort for reliever use. ***Children and adolescents under 18 years of age:*** not recommended. ***COPD (Symbicort 200/6 only): Adults (≥ 18 years):*** 2 inhalations twice daily. Contraindications Hypersensitivity to active substances or excipient. Warnings and Precautions If treatment is ineffective, or exceeds the highest recommended dose therapy should be reassessed. Sudden and progressive deterioration in control requires urgent medical assessment. Treatment should not be stopped abruptly. Patients should have their appropriate rescue medication available at all times i.e. either Symbicort or a separate reliever. If needed before exercise a separate reliever should be used. Therapy should not be initiated during an exacerbation. Serious asthma-related adverse events and exacerbations may occur. If asthma symptoms remain uncontrolled or worsen patients should continue treatment but seek medical advice. If paradoxical bronchospasm occurs Symbicort should be discontinued. It responds to a rapid-acting inhaled bronchodilator and should be treated straightaway. 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, cataract, glaucoma and more rarely a range of psychological or behavioural effects including psychomotor hyperactivity, sleep disorders, anxiety, depression or aggression (particularly in children). Height of children should be monitored. Potential effects on bone should be considered especially in patients on high doses for prolonged periods that have co-existing risk factors for osteoporosis. Prolonged treatment with high doses of inhaled corticosteroids, particularly higher than recommended doses, may also result in clinically significant adrenal suppression. Additional systemic corticosteroid cover should be considered during periods of stress e.g. severe infections or elective surgery. Transfer from oral steroid therapy to Symbicort may result in the appearance of allergic or arthritic symptoms which will need treatment. 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. Observe caution in patients with thyrotoxicosis, phaeochromocytoma, diabetes mellitus, untreated hypokalaemia, or severe cardiovascular disorders. 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. Particular caution recommended in unstable or acute severe asthma. Monitor serum potassium levels. In diabetic patients consider additional blood glucose monitoring. The small amounts of milk proteins present may cause allergic reactions. Drug Interactions Concomitant treatment with potent CYP3A4 inhibitors should be avoided. If this is not possible the time interval between administration should be as long as possible. Symbicort maintenance and reliever therapy is not recommended in these patients. Not recommended with beta adrenergic blockers (including eye drops) unless compelling reasons. Concomitant administration 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. Concomitant administration with MAOIs, including agents with similar properties such as furazolidone and procarbazine, may precipitate hypertension. Elevated risk of arrhythmias in patients receiving anaesthesia with halogenated hydrocarbons. Hypokalaemia may increase the disposition towards arrhythmias in patients taking digitalis glycosides Fertility, Pregnancy and Lactation No data available on the potential effect on fertility. During pregnancy, use only when the benefits outweigh the potential risks. Budesonide is excreted in breast milk, however at therapeutic doses no effects on the child are anticipated.

Undesirable effects ***Common:*** headache, palpitations, tremor, Candida infections in the oropharynx, coughing, mild irritation in the throat, hoarseness. ***Uncommon:*** tachycardia, muscle cramps, nausea, dizziness, bruises, aggression, psychomotor hyperactivity, anxiety, sleep disorders. ***Rare:*** hypokalaemia, cardiac arrhythmias including atrial fibrillation, supraventricular tachycardia and extrasystoles, bronchospasm and immediate and delayed hypersensitivity reactions including exanthema, urticaria, pruritus, dermatitis, angioedema and anaphylactic reaction. ***Very Rare:*** depression, behavioural changes (predominantly in children), angina pectoris, prolongation of QTc-interval, hyperglycaemia, taste disturbance, Cushing's syndrome, adrenal suppression, growth retardation, decrease in bone mineral density, cataract, glaucoma and variations in blood pressure. As with other inhalation therapy, paradoxical bronchospasm may occur in very rare cases. Package Quantities Each Symbicort Turbohaler contains 120 inhalations. Legal Status POM. Marketing Authorisation Numbers MA 046/00901-2. Marketing Authorisation Holder (MAH) AstraZeneca AB, Gartunavagen, S-151 85 Sodertalje, Sweden. Further product information available on request from Associated Drug Company Limited, Triq l-Esportaturi, Mriehel, Birkirkara BKR 3000, Malta. Tel: (+356) 2277 8115. Abridged Prescribing Information prepared 12/15. Symbicort and Turbohaler are trademarks of the AstraZeneca group of companies. URN No: 13/0125 **Date of Preparation:** March 2016

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

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