

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

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## 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 1<sup>st</sup> line antibiotic regimen for uncomplicated cases was recorded. The prescriptions that were evaluated were those for 1<sup>st</sup> 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 =*

$$\left[ \frac{\text{number of compliant prescriptions}}{\text{number of compliant} + \text{non-compliant}} \right] \times 100$$

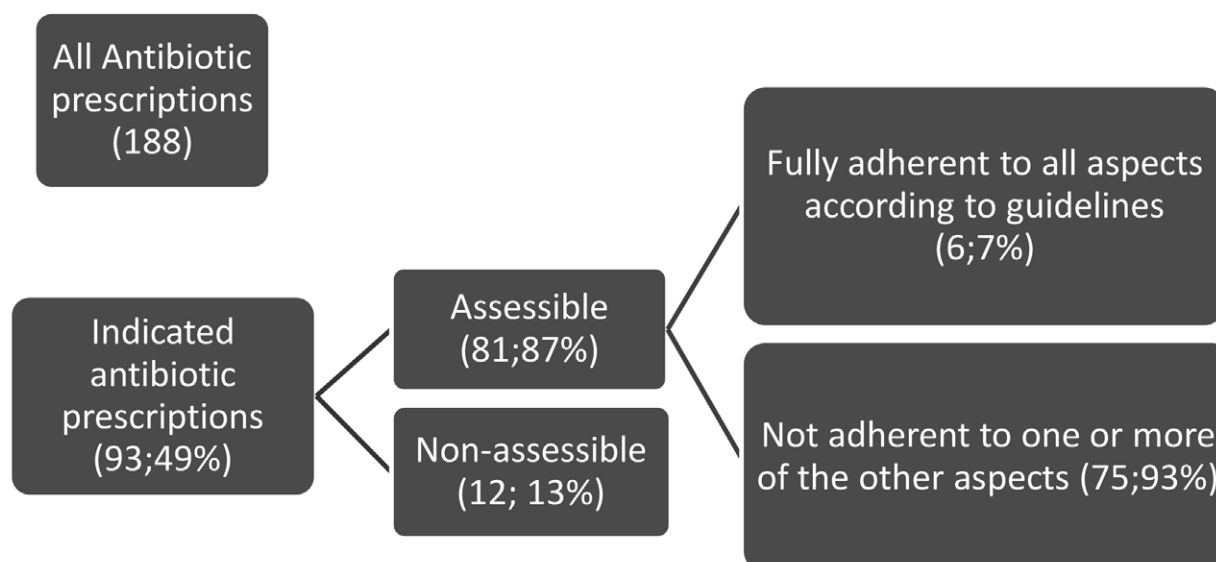
### Processing of data

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		
	Co-amoxiclav	625	PO	tds	7	6	
PRESCRIBED	Co-amoxiclav	625	PO	bd	7	2	14
	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		
	Ciprofloxacin	2 drops	Ear drops	tds	7	1	
	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	
PRESCRIBED	Co-amoxiclav + Chloramphenicol	625mg+ 2 drops	PO +ear drops	tds	7	1	31
	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		
	Co-amoxiclav	625	PO	tds	7	8	
	Co-amoxiclav	1000	PO	bd	7	8	
	Co-amoxiclav	1000	PO	tds	7	2	
PRESCRIBED	Co-amoxiclav	1000	PO	bd	5	2	
	Clarithromycin	500	PO	bd	7	10	36
	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

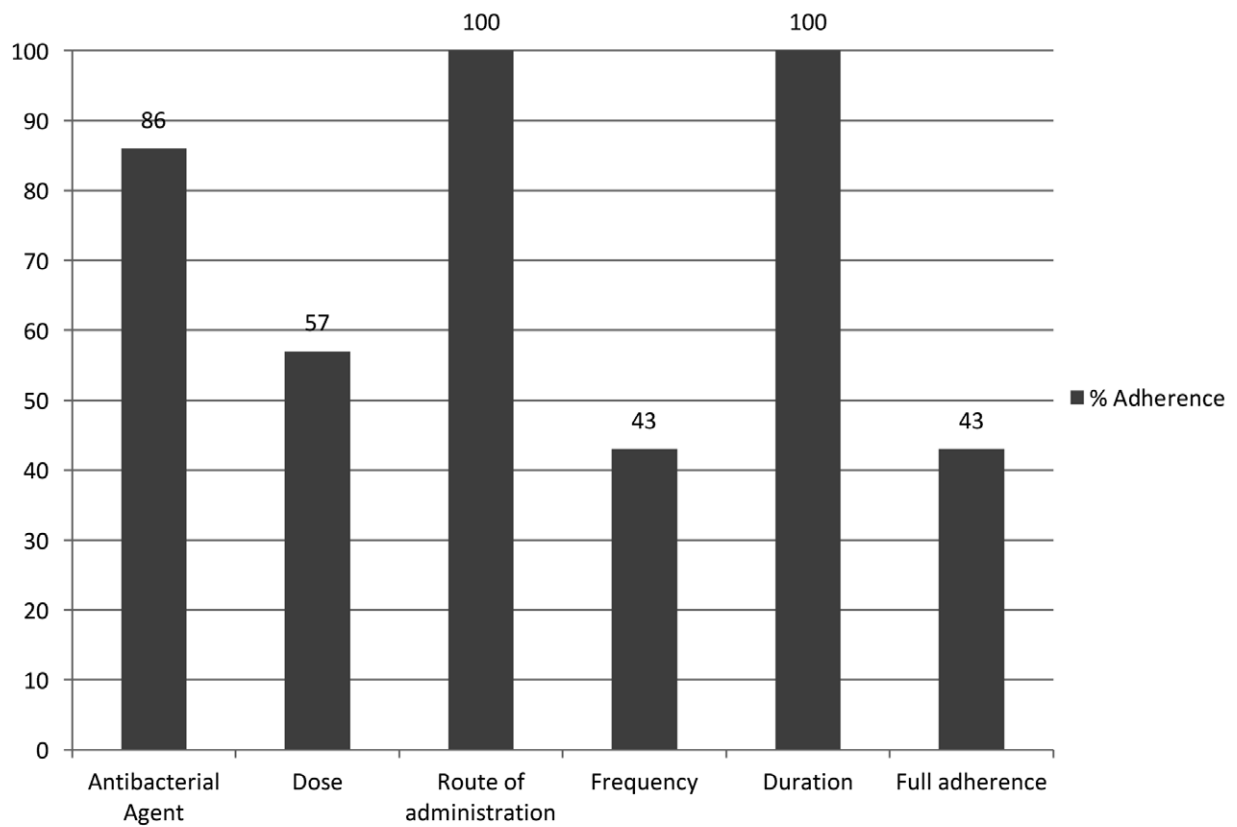


Figure 3: Clinicians' adherence to the treatment guideline in acute otitis media

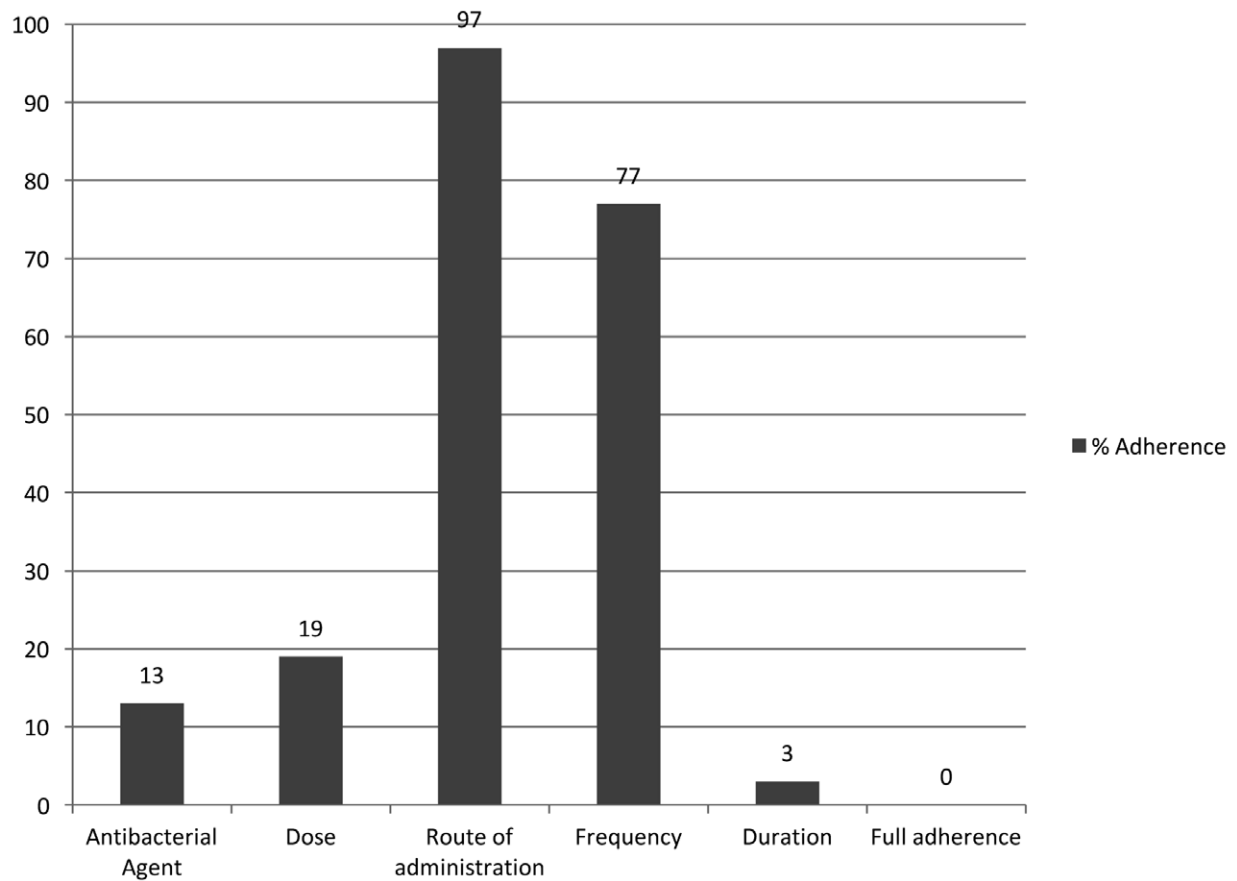


Figure 4: Clinicians' adherence to the treatment guideline in acute tonsillitis

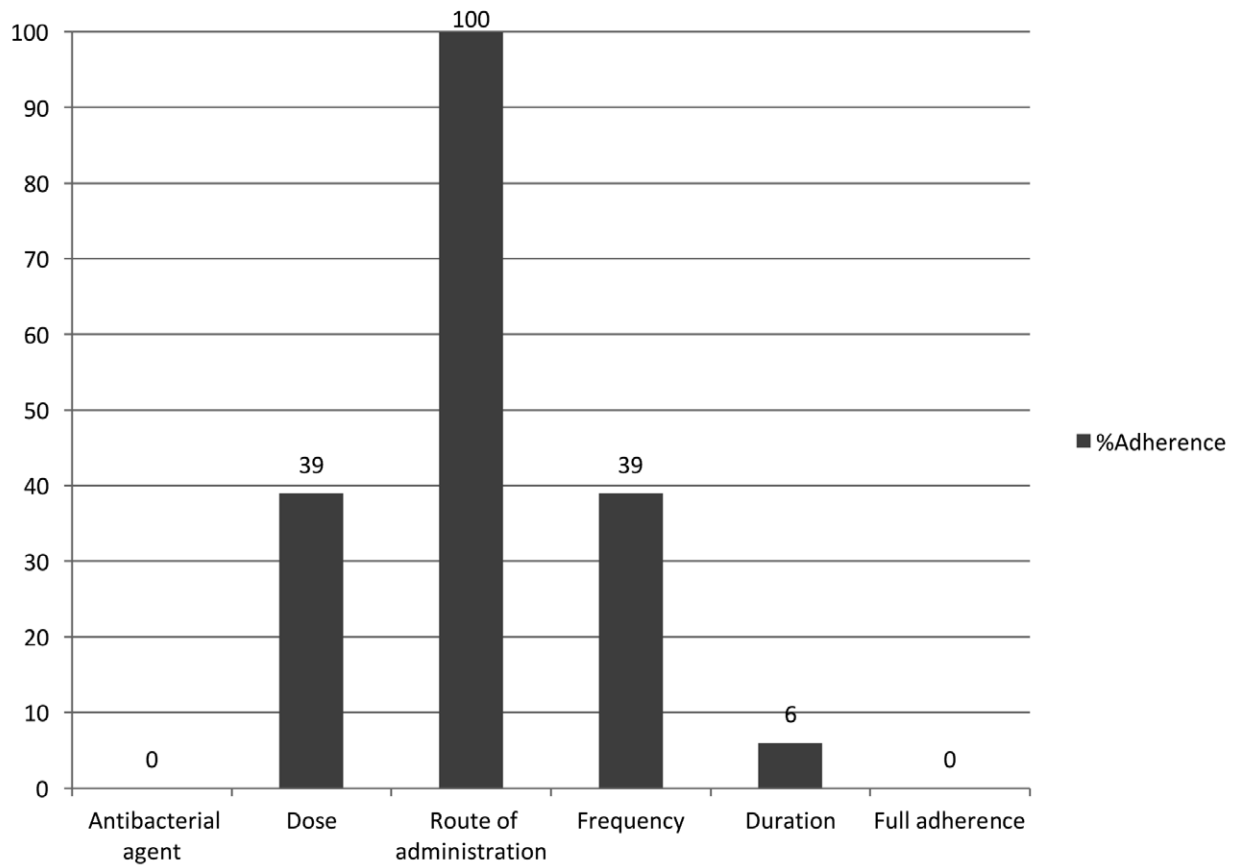
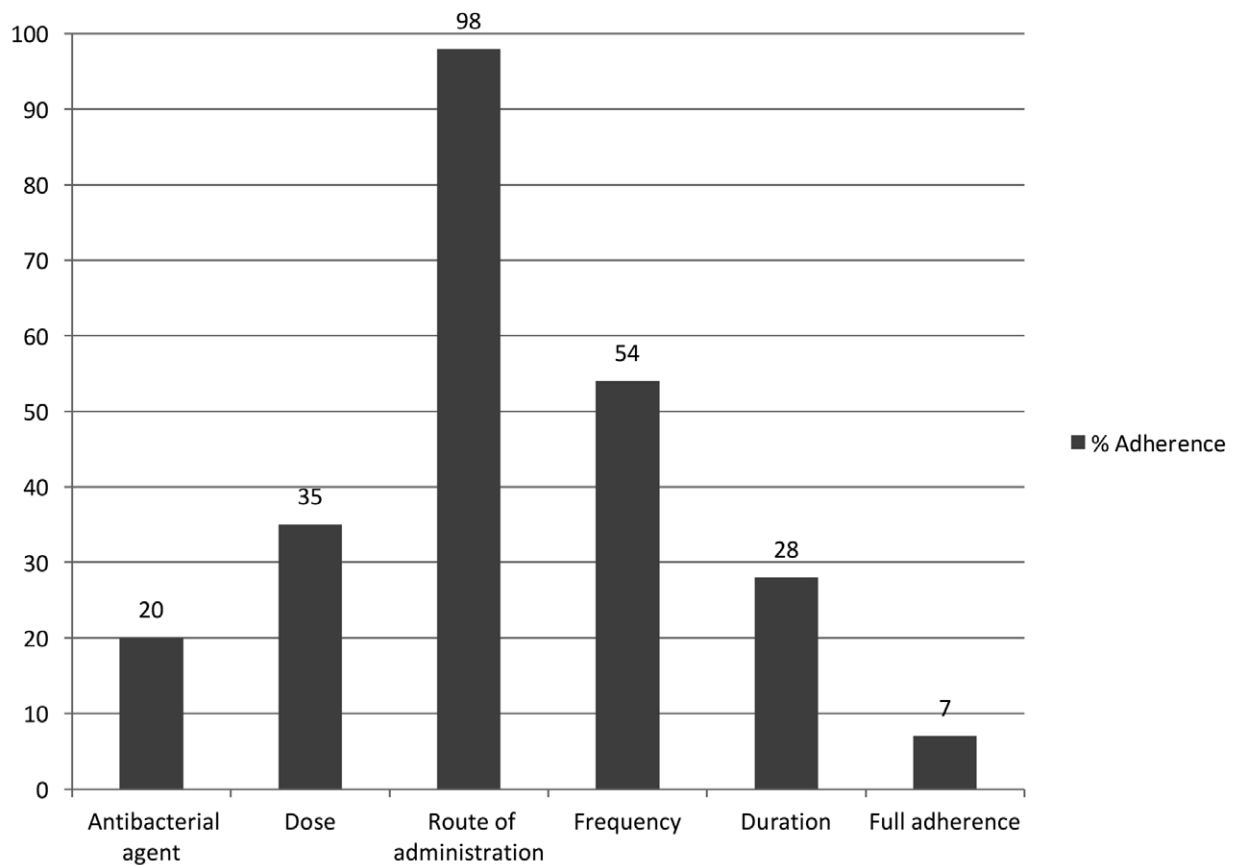


Figure 5: Clinicians' adherence to the treatment guideline in all infections



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  $\geq 39^{\circ}\text{C}$  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 1<sup>st</sup> 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.

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