Implementing guidelines on acute maxillary sinusitis in general practice—a randomized controlled trial

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Background. Management of acute maxillary sinusitis (AMS) is not optimal; antibiotics are often prescribed for viral sinusitis, which leads to many problems including those with antimicrobial resistance. Guidelines have been proposed as a means to change the professional practices.

Objective. Our aim was to study whether a nationwide guidelines implementation programme has an effect on the management of AMS in primary care.

Methods. A multi-centre randomized controlled trial was conducted in 30 health centres (HCs) covering a population of 819,777 people from 1998 to 2002. The participating HCs were randomized to implement guidelines either according to a problem-based learning (PBL) or an academic detailing (AD) method facilitated by local GPs. Data were gathered during 1 week in November in all study years and also from external control HCs in 2002. The main outcome measure was compliance with the key points of AMS management in national Current Care guidelines.

Results. Implementation of guidelines produced minor changes towards the recommended practices in the management of AMS. Use of the first-line drug amoxicillin increased slightly (from 39% to 48% in AD centres and from 33% to 45% in PBL centres, controls 40%). Proportion of courses of antibiotics with recommended duration increased in MIKSTRA study centres (from 34% to 40% in AD centres and from 32% to 47% in PBL centres, controls 43%).

Conclusions. A nationwide guidelines implementation project produced modest changes in the management of AMS. There were no significant differences between AD and PBL education methods. Less than half the HCs were able to realize the project as intended, which decreases the internal validity of the study. The guidelines implementation might have benefited from more focused targets and approaches that took into account the problems and practices of each HC.

Keywords. Drug utilization, implementation, maxillary sinusitis, practice guidelines, primary health care.

Introduction

Acute maxillary sinusitis (AMS) is defined as the situation where the paranasal sinuses develop infection, and most often this occurs as a complication of common viral upper respiratory tract infections (URTs). While the early stage of sinusitis is most often viral and best handled with symptomatic medications, bacterial origin is considered important in AMS, and it is often treated with antibiotics. However, research evidence on the
effectiveness of antibiotics for AMS is limited\textsuperscript{1} and side effects may equal or exceed the marginal treatment benefits.\textsuperscript{2}

For GPs differentiating the bacterial or viral origin of sinusitis is challenging if not impossible. The exact diagnosis would require bacterial sample from paranasal sinuses, which is not feasible in primary care. Diagnostic imaging methods produce many false-positive diagnoses. In computed tomograms, abnormalities of the sinuses can be seen in 90\% of healthy adults with URTIs, and only 2\% of these patients develop bacterial sinusitis.\textsuperscript{2} GPs tend to prescribe antibiotic treatment for AMS to relieve symptoms and to prevent complications and the possible progression of acute infections to chronic sinus disease. However, there is insufficient evidence to prove that antibiotics prevent complications or progress to chronic sinusitis.\textsuperscript{3}

On population level, the wide use of antibiotics for AMS and other URTIs leads to increased risk of bacterial resistance.\textsuperscript{4} It also causes waste of resources in health care and modifies patient expectations towards the unnecessary use of antibiotics for viral diseases. There is evidence that guidelines can be used to change the process and outcome of care.\textsuperscript{5} However, guidelines do not change practice if they are not implemented effectively.\textsuperscript{6,7}

Our aim was to study whether guidelines implementation in a nationwide programme is effective in changing prescribing patterns for acute infections. The participating health centres (HCs) were randomized to implement the national Current Care guidelines\textsuperscript{8} either according to a problem-based learning (PBL) method or an academic detailing (AD) method. The key points in the guidelines were the use of diagnostic imaging methods (either sinus radiography or ultrasound) to verify retention in sinuses, focus on duration of symptoms (antimicrobials not recommended if symptoms lasted less than 1 week), choice and duration (7 days) of first-line antimicrobial: amoxicillin recommended and macrolides not recommended.\textsuperscript{8} In this paper we report the findings on the management of AMS before and after guidelines implementation.

Methods

The MIKSTRA study (the name coming from the Finnish version of Antimicrobial Treatment Strategies Program)\textsuperscript{9,10} was a nationwide research initiative that assessed the management of primary care infections. From November 1998 to November 2002, yearly surveys were conducted in 30 HCs in Finnish primary care with a population base of 819 777. The included HCs were chosen from the volunteering HCs so that all parts of Finland and both rural and urban areas were represented. All consecutive patients consulting the HCs for any infectious disease during a 1-week period in November in all study years were included in the analysis. To study the overall effects of the MIKSTRA programme, we later included additional 20 volunteering external control HCs with a population base of 545 098 and gathered information in them in 2002.

The MIKSTRA study focused on six common primary care infections. After retrieving baseline information in 1998, the participating HCs were randomized two times by drawing lots: first to two groups (groups A and B) and next to two educational methods, PBL and AD (Fig. 1). Half the HCs (the A HCs)
started the programme with otitis media, tonsillitis and urinary tract infections, and the other half (the B HCs) with bronchitis, sinusitis and skin infections. In the beginning of 2001, the HCs were instructed to start the implementation of the other set of three guidelines in a crossover manner, and during the study years, all HCs were supposed to implement all six guidelines. They were instructed to keep to the educational method they were initially randomized to.

PBL was chosen as the educational method as there was local experience of it in continuing professional development. Literature searches showed that AD might be a method with comparative efficacy and it was chosen as the comparator. PBL was defined here as a method based on group work facilitated by a local GP tutor that utilized case scenarios, information retrieval and reflection. Our modification of AD included use of information sources, feedback of own practices and visits of external experts.

We focussed the educational intervention on the GP facilitators in each HC. During the intervention period from 1999 to spring 2001 the physician facilitators were gathered together twice a year to learn about the educational methods, guidelines and MIKSTRA’s aims. The MIKSTRA study group also provided HCs with educational tools, such as Power Point presentations, case scenarios for PBL, patient leaflets and feedback information from MIKSTRA surveys on local level. The GP facilitators were responsible for the training at worksite of their colleagues and nurses. For follow-up we gathered information in 2002 in all study HCs and in the 20 external control HCs.

Doctors and nurses in the study HCs recorded the age, gender, diagnosis, duration of symptoms, investigations and treatments for each patient. The patients filled in a questionnaire on their symptoms before the consultation. For the analysis of changes in diagnostic strategies, we included a spectrum of patients with possible AMS and studied how often either sinus ultrasound or radiography was applied to diagnose AMS as recommended by the Finnish guidelines. We included patients with at least one of the following symptoms referring to sinusitis: rhinitis, cough or maxillary pain and with a final clinical diagnosis of either AMS or URTI by the GP. For the analysis of antimicrobial choices, we used the AMS diagnoses given by the physicians in HCs. Because our focus was on practices for acute sinusitis, we only included in these analyses the patients who consulted for the first time during this episode of illness.

The main outcome measure was compliance to the key points in national Current Care guidelines on AMS: use of diagnostic devices (either sinus ultrasound or radiography), amoxicillin as first-line treatment, percentage of macrolides prescribed for AMS (common, but not a recommended option) and percentage of antibiotic courses with recommended duration (7 days).

Statistical methods

Percentages were used to describe the occurrence of each outcome. We randomized HCs, not patients, and utilized therefore parameters that measured the trends in practices in each HC. The proportions of patients treated compliant to guidelines in each HC was calculated. We calculated HC-specific differences of the proportions for each of the measured treatment practices to describe the change in each HC and present the median and range of these HC-specific differences within each group. We studied odds ratios (ORs) with 95% confidence intervals for the change within a group during the five study years to measure the change in each situation. Mixed-effects model with the HC and GP as a random effect was used when calculating the ORs. A P-value of 0.05 was used as the significance level. Data were analysed using the SPSS 12 for Windows software and the mixed models were fitted using The SAS system for Windows, version 8, and the GLIMMIX macro.

Results

Study HCs, patients and weekly incidence of sinusitis

The baseline characteristics of study HCs are presented in Table 1. Overall, 29 043 patients consulted the MIKSTRA HCs during the study weeks for infectious diseases and 3514 (12%) of them were diagnosed as having sinusitis. The percentage of patients diagnosed as having AMS of all patients with infectious diseases varied from 11% to 14% during years 1998–2002, and AMS was the third commonest infectious

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>AD/group B (n = 7)</th>
<th>PBL/group B (n = 8)</th>
<th>Group A (internal control) (n = 15)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Rural/urban HCs</td>
<td>4/3</td>
<td>5/3</td>
<td>8/7</td>
</tr>
<tr>
<td>Population/physicians</td>
<td>99 795/69</td>
<td>203 596/125</td>
<td>516 386/278</td>
</tr>
<tr>
<td>Use of sinus ultrasound or X-ray to diagnose AMS (%)</td>
<td>42</td>
<td>50</td>
<td>46</td>
</tr>
<tr>
<td>Use of amoxicillin as first-line treatment for AMS (%)</td>
<td>36</td>
<td>35</td>
<td>35</td>
</tr>
<tr>
<td>Use of macrolides as first-line treatment for AMS (%)</td>
<td>10</td>
<td>14</td>
<td>18</td>
</tr>
<tr>
<td>Percentage of 7-day courses for AMS</td>
<td>38</td>
<td>35</td>
<td>30</td>
</tr>
</tbody>
</table>

Percentages are proportions of all patients in the group.
disease encountered by the GPs, while acute URTI and otitis media were the two most common ones. Calculated from these figures, the weekly incidence of AMS in the MIKSTRA study was 0.08%.

The spectrum of patients with diagnosed AMS was similar during all study years: 71% were female and 19% were aged under 18. Recurrent or chronic cases of AMS were a minority: most patients (73%) consulted for the first time for this disease.

**Diagnostic strategies**

The use of diagnostic imaging methods for sinusitis was similar in the intervention and internal control groups in 2000 (Table 2) and compared to the external control HCs at the follow-up in 2002 (Table 3), i.e. the use of diagnostic devices did not change significantly during the MIKSTRA study years.

**Use of the first-line antibiotic: amoxicillin**

In the national guidelines, amoxicillin was recommended as the first-line antibiotic for AMS. The use of amoxicillin for AMS increased slightly in MIKSTRA HCs (Table 3) during the five study years, but there were no significant differences between the AD and PBL study groups or in comparison to the external controls (Tables 2 and 3). The use of amoxicillin increased during the intervention years but decreased during follow-up and was at the same level as in control HCs in 2002 (Fig. 2).

**Use of macrolides for AMS**

The national guidelines recommended macrolides only as second-line drugs for AMS. At baseline, there was remarkable variation in the proportion of macrolides prescribed for AMS as first-line therapy (from 10% to 18%, Table 1). The use of macrolides as first-line therapy for AMS did not change significantly in MIKSTRA HCs (Tables 2 and 3). In 2002 it was on a lower level than in control HCs (AD 9%, PBL 16% and control 20%) but the difference was not statistically significant (Table 3).

### Table 2 Primary outcome measures

<table>
<thead>
<tr>
<th>Outcome</th>
<th>Intervention group</th>
<th>Internal control group</th>
<th>P-value for the difference between groups</th>
</tr>
</thead>
<tbody>
<tr>
<td>Use of sinus ultrasound or X-ray to diagnose AMS</td>
<td>AD/group B: 23.2% (–42 to 39), OR (95% CI): 1.29 (0.73–2.27)</td>
<td>PBL/group B: –5.1% (–64–20), OR (95% CI): 1.12 (0.79–1.58)</td>
<td>0.716</td>
</tr>
<tr>
<td>Use of amoxicillin as first-line treatment&lt;sup&gt;a&lt;/sup&gt;</td>
<td>AD/group B: 3.3% (–42 to 33), OR (95% CI): 1.82 (0.76–4.37)</td>
<td>PBL/group B: 13.2% (–24 to 73), OR (95% CI): 1.58 (0.99–2.52)</td>
<td>0.965</td>
</tr>
<tr>
<td>Use of macrolides as first-line treatment&lt;sup&gt;b&lt;/sup&gt;</td>
<td>AD/group B: 0.0% (–19 to 8), OR (95% CI): 1.26 (0.46–3.35)</td>
<td>PBL/group B: 2.8% (–8 to 12), OR (95% CI): 1.08 (0.64–1.85)</td>
<td>0.997</td>
</tr>
<tr>
<td>Use of 7-day courses</td>
<td>AD/group B: 19.6% (–7 to 50), OR (95% CI): 1.69 (0.97–7.44)</td>
<td>PBL/group B: 15.8% (–13 to 69), OR (95% CI): 1.34 (0.73–2.46)</td>
<td>0.132</td>
</tr>
</tbody>
</table>

Management of AMS in HCs immediately after the intervention in group B HCs (year 2000) as compared to year 1998 and group A HCs. ORs with confidence intervals (95% CIs) and median and range of HC-specific changes.

<sup>a</sup>Recommended treatment by guidelines.

<sup>b</sup>Not recommended treatment by guidelines.

### Table 3 Changes in AMS management towards recommended practices after intervention using two different training methods (AD or PBL) during the study years and comparison to management in the external control HCs in 2002

<table>
<thead>
<tr>
<th>Outcome</th>
<th>AD group</th>
<th>PBL group</th>
</tr>
</thead>
<tbody>
<tr>
<td>Use of recommended diagnostic methods to diagnose AMS</td>
<td>OR 5 years trend: 0.92 (0.85–0.99)</td>
<td>1.02 (0.96–1.08)</td>
</tr>
<tr>
<td>Use of amoxicillin as the first-line treatment for AMS&lt;sup&gt;a&lt;/sup&gt;</td>
<td>OR 5 years trend: 1.11 (0.99–1.24)</td>
<td>1.10 (1.02–1.20)</td>
</tr>
<tr>
<td>Use of macrolides as the first-line treatment&lt;sup&gt;b&lt;/sup&gt;</td>
<td>OR 5 years trend: 1.83 (0.98–3.43)</td>
<td>1.18 (0.67–2.08)</td>
</tr>
<tr>
<td>Use of 7-day courses</td>
<td>OR 5 years trend: 1.00 (0.88–1.14)</td>
<td>0.98 (0.90–1.07)</td>
</tr>
</tbody>
</table>

ORs with confidence intervals (95% CIs).

<sup>a</sup>Recommended by guidelines.

<sup>b</sup>Not recommended by guidelines.
Duration of antibiotic treatment
The courses of antibiotics for AMS became shorter in MIKSTRA HCs as recommended by guidelines: the proportion of 7-day courses increased and that of longer ones decreased (Table 3). The 1- to 5-day courses of azithromycin were excluded from these analyses. The trend lasted during all MIKSTRA study years and was statistically significant (Table 3). However, there was no significant difference to the external control HCs in 2002.

Discussion
Implementation of guidelines produced minor changes in the management of AMS towards the recommended practice. The use of first-line antibiotic for AMS, amoxicillin, increased in MIKSTRA study HCs and the duration of treatment for AMS decreased as aimed. However, the changes were modest and smaller than what the study group expected.

The Current Care guidelines on AMS were written by a group of ear, nose and throat (ENT) surgeons with one GP member. The sinusitis population encountered by ENT specialists differs from the one the GPs treat, and antibiotics may have a larger role in secondary care patients. It is possible that the message to restrict the use of antibiotics for AMS was not emphasized enough in the guidelines. Also, deeper understanding of the factors affecting GPs prescribing might have helped to set the targets better.

The modest results may also be explained by the problems that the MIKSTRA study faced. First, after the beginning of the study, a trend began in Finnish health care where GPs started to leave their jobs. Especially, the rural HCs faced serious problems with shortage of physicians. When even a quarter of GP posts were not filled and half the doctors were replaced during the five study years, the implementation of new guidelines by means of training at worksite was severely violated.

Second, there were problems in the study group itself. The key person involved in the educational intervention became seriously ill and was replaced only after half a year’s break in the educational intervention. Because of this, the HCs received the educational tools, the Power Point presentations and the case scenarios to aid the local educational activities not until summer 2000, almost 1 year delayed from the beginning of the intervention. As a consequence, 13 of the study HCs realized the programme as recommended by MIKSTRA study group, 14 of them modified the strategy, and 3 HCs were not able to start the programme at all.

Third, the HCs had problems to follow the protocol as expected. The educational method that they were randomized to did not always fit the local needs and it needed modifications. Even more than that, the order of guidelines to implement was violated. For example, if the HCs had a genuine local interest on the management of otitis media, they sometimes started with that topic, although they were supposed to start with sinusitis, or vice versa. All but 1 of the 15 HCs in group B correctly implemented the guideline for sinusitis during 1999–2000, 7 of the 15 HCs in group A also did so, which was against the recommended, and partly violated the internal control setting. For this reason and delays in providing the educational tools, the A and B structure did not hold, as it should have.

The study group was not adequately prepared for these problems. The study might have needed a new strategy and better resources; however, we did not want to change the original protocol while the study was already set going. More support and more specific interventions would have been needed for many HCs; however, we did not want to ruin the design of the randomized controlled trial. One lesson of the MIKSTRA study is the importance of risk management in large and long-lasting trials: risks in resources, personnel and society should all be monitored.

One teaching is the importance of relevant goal setting in guidelines implementation. Many practices in the management of AMS were on a satisfactory level at the baseline: the diagnostic devices were used as recommended in guidelines and the first-line antibiotic amoxicillin was prescribed in more than one-third of the cases. It is difficult to achieve large changes in a practice that is already on a moderate level. Also, the key points and targets were not clearly set by the guidelines group as the current practices were not known exactly when the guidelines were published. Nowadays, the key messages of guidelines and the quality criteria have a much larger role in new Current Care guidelines.

The fact that the results in the study group HCs did not differ statistically from those of the external control group HCs at follow-up may have several
optimal circumstances. It has been debated whether a single or a multifaceted intervention produces better results in guidelines implementation and the question still remains unanswered. Guidelines implementation is a complex process with many, also unexpected, variables. Careful modelling of the process might help in planning the guidelines implementation strategies.

As a consequence of varying situations in HCs, some of the HCs achieved good results while the practices deteriorated in others. The problems encountered by HCs and the study group itself decrease the study ability to find a difference between control and intervention groups. It is possible that our finding is a false-negative one that could have been avoided in optimal circumstances and with better resources.

The strength of the MIKSTRA study is the extent of the project: it covered a sixth part of the population of one country and gives an exact picture of the current management of AMS. Other strengths of the study include that the analysis was by intention-to-treat and that we measured clinical outcomes. Although our study did not bring a convincing positive result, it has given a lot of useful information and experience for guidelines production and implementation in our country.

Conclusions

Guidelines implementation in MIKSTRA study produced modest changes towards the recommended practices in the management of AMS. There were no significant differences between AD and PBL education methods; however, the implementation of these methods in HCs was less than optimal. Less than half of the HCs were able to realize the project as intended, which decreases the internal validity of the study. The guidelines implementation might have benefited of more focussed targets and approaches that took into account the problems and practices of each HC.

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Declaration

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Conflicts of interest: None.

References