ORIGINAL ARTICLE

What is the role of quality circles in strategies to optimise antibiotic prescribing? A pragmatic cluster-randomised controlled trial in primary care

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Objective: To evaluate the effect on antibiotic prescribing of an intervention in existing local quality circles promoting an evidence-based guideline for acute rhinosinusitis.

Design: A pragmatic cluster-randomised controlled trial comparing standard dissemination of the guideline by mail with an additional strategy using quality circles.

Setting: General practice in Flanders, Belgium.

Participants: General practitioners (GPs) in 18 local quality circles were randomly allocated to two study arms. All GPs received the guideline by mail. GPs in the nine quality circles allocated to the intervention arm received an additional group intervention, which consisted of one self-led meeting using material introduced to the group moderator by a member of the research team.

Main outcome measures: Adherence to the guideline was measured as differences in the proportion of antibiotic prescriptions, including the choice of antibiotic, between the two study arms after the intervention period. GPs registered their encounters with patients presenting with signs and symptoms of acute rhinosinusitis in a booklet designed for the study.

Results: A total of 75 doctors (29% of GPs in the participating quality circles) registered 408 consultations. In the intervention group, 56.9% of patients received an antibiotic compared with 58.3% in the control group. First-choice antibiotics were issued in 34.5% of antibiotic prescriptions in the intervention group compared with 29.4% in the control group. After adjusting for patient and GP characteristics, the ORadj for antibiotics prescribed in the intervention arm compared with the control arm was 0.63 (95% CI 0.29 to 1.37). There was no effect on the choice of antibiotic (ORadj 1.07, 95% CI 0.34 to 3.37).

Conclusion: A single intervention in quality circles of GPs integrated in the group's normal working procedure did not have a significant effect on the quality of antibiotic prescribing. More attention to the context and structure of primary care practice, and insight into the process of self-reflective learning may provide clues to optimise the effectiveness of quality circles.

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Peer-review groups or quality circles have become an important instrument for the improvement of the quality in primary care.^{1–3} These small groups of doctors are based on voluntary participation and are continuously assessing and improving their own performance in patient care. Mutual respect, commitment and continuity are thought to provide the strong base required for change.² Considering these characteristics, they can have an important role in the implementation of evidence-based guidelines. Quality circles are established in many European countries in various settings.¹ Although widely adopted, evidence for their effectiveness as a tool to promote evidence-based practice is scarce.⁴

High consumption of antibiotics and alarming antimicrobial resistance rates are a growing concern.^{5–6} Most antibiotics are prescribed for respiratory tract infections in primary care, in spite of the evidence that many patients will not benefit from antibiotic treatment.^{7–9} Belgian doctors often prescribe antibiotics, mostly with a broad spectrum.⁵ Public campaigns^{10–11} aimed at the general public and evidence-based guidelines for doctors on rational use of antibiotics have been developed to address this problem.^{12–15} There is evidence that merely distributing guidelines does not affect prescribing, and more complex interventions are necessary.^{16–17} Within the framework of promoting rational use of antibiotics, quality circles could have a role. A recent Cochrane review found only six studies

from industrialised countries comparing small group educational meetings aimed at improving antibiotic prescribing of doctors with a control group.¹⁸ Only two trials involved established quality circles.^{19–20} Given the specific features of quality circles, their potential impact on quality of antibiotic prescribing needs further evaluation.

This study is part of an implementation programme accompanying publication of a guideline on rational use of antibiotics for acute rhinosinusitis in ambulatory care. In this paper, we report the results of a randomised controlled trial evaluating the effect of a group intervention for local quality circles.

MATERIALS AND METHODS

From November 2004 to March 2005, quality circles of general practitioners (GPs) participated in a two-arm cluster-randomised controlled trial (fig 1). The study was approved by the ethics committees of the Ghent University Hospital, Ghent, Belgium and Antwerp University Hospital, Antwerp, Belgium.

Sample size

Research in Belgian general practice has shown that approximately 50% of patients presenting with symptoms related to

Abbreviations: GP, general practitioner; UTI, urinary tract infection

Figure 1 Flowchart of the study design. GP, general practitioner. *Median 5 patients registered per GP (range 1–15). †Median 4 patients registered per GP (range 1–13).

*Median 5 patients registered per GP (range 1–15)

†Median 4 patients registered per GP (range 1–13)

acute rhinosinusitis receive an antibiotic prescription.²¹ Sample size calculations were based on the ability to measure a 20% reduction in antibiotic prescriptions by means of the intervention, which was considered as a relevant effect. On the basis of the experiences of a previous trial with a similar design and in a comparable setting, a correction factor of 1.5 was applied to control for clustering of patients within GPs.²² A total of 135 patient registrations per study arm were required for 80% power and a 5% significance level. To collect enough patient registrations and counting on a GP participation rate of 25% with an average of 4–5 registrations per GP,²³ 9 quality circles consisting of 12 GPs were needed to be recruited in each study arm.

Recruitment of GPs

Local quality circles in Belgium have been part of a national accreditation programme for doctors since 1996 and consist of 8–25 members practising in the same geographical area, who meet at least four times a year. All 202 local quality circles in three Flemish provinces were eligible to participate in a cluster-randomised controlled trial if they had not participated in the validation process of the guideline on acute rhinosinusitis. Groups were contacted through the representatives listed by the national council for accreditation.

Randomisation

In all, 18 quality circles agreed to participate and were randomly allocated to two study arms (nine in the intervention arm and nine in the control arm) after stratification by geographical location. Researchers performing the outcome assessment were blinded for the allocation.

Intervention

The quality circles in the intervention arm were invited to dedicate one of their scheduled meetings to a discussion of the new guideline on rational use of antibiotics for treating acute rhinosinusitis.¹⁵ The main messages of this guideline are that a clinical case definition without further technical investigations is, in most cases, sufficient and that antibiotics are generally not needed to treat this condition. Amoxicillin is the

recommended first-choice antibiotic if one is required. The diagnostic recommendation corresponds with actual clinical practice. However, the use of antibiotics for acute rhinosinusitis is, in reality, very different from what the guideline recommends. Treatment, and not diagnostics, requires behavioural change in our GPs. Therefore, the intervention mainly emphasised rational use of antibiotics. The guideline was disseminated by mail to all GPs in November 2004. In the preceding month, a national public campaign had addressed the need for rational use of antibiotics in general.¹¹ Following dissemination of the guideline, moderators of the quality circles in the intervention arm received a visit from a trained academic detailer belonging to the research team. During this visit, the material for the group meeting was presented—that is, a presentation of the main recommendations and the scientific evidence underpinning them, flowcharts, research evidence on patient expectations concerning antibiotics, patient information leaflets and clinical case vignettes for discussions in small groups. All the information was available on slides for overhead or LCD (liquid crystal display) projection. The group meetings were scheduled as a regular quality circle session without the presence of an external expert to avoid interference with the peer-review process. The quality circles in the control arm were asked to schedule a group meeting on the guideline after the registration period.

Outcome measures

To minimise potential confounding over time and to measure the “optimal” effect of the intervention, outcome data were collected for 2 months after the intervention. In this period, GPs were asked to record patients consulting with signs and symptoms suspicious of acute rhinosinusitis (according to the definition in the guideline) in a booklet designed for the study. Information was obtained on patients’ demographic characteristics, clinical presentation of symptoms, diagnostic strategies and prescribed drug. Booklets were collected by mail after the registration period. The primary outcome was the difference in proportion of antibiotics prescribed between both study arms. The difference in proportion of first-choice antibiotics (ie,

amoxicillin) was the secondary outcome. Data on characteristics of GPs and their practices were collected through separate anonymous coded questionnaires that were returned by mail.

Analysis

Analysis was based on the registrations of individual doctor-patient consultations for acute rhinosinusitis. Characteristics of the participating GPs and patients in the two groups were described and compared. Cluster-specific methods were applied to estimate the effect of the group intervention. We used a hierarchical generalised linear mixed model approach to explore statistical variance at each of the three levels in the study design (quality circle, GP and patient).²⁴ For both outcomes, as the variance at the level of the quality circles was neither relevant nor significant, we developed and tested models including only two levels (GP and patient). We estimated the population-averaged effect by means of generalised estimated equations using an exchangeable correlation matrix and robust standard error estimates. We tested the following model: $\text{logit}(y) = \text{constant} + \beta_1 \text{intervention}$.^{25, 26} Crude odds ratios (ORs) were calculated in a bivariate model and adjusted ORs in multivariate models adjusting for GP and patient characteristics with STATA V.9 software. Significance was calculated at a 5% significance level. The analysis was performed on an intention to treat basis—that is, all patients registered by GPs were included in the analysis regardless of whether the GP had attended the meeting of his quality circle.

RESULTS

A total of 75 GPs registered 408 patient encounters for acute rhinosinusitis. Their quality circles had a mean (SD) of 15 (2.9) members with 28% (16%) women and 66% (24%) GPs in solo practice. Tables 1 and 2 show the characteristics of the doctors and their patients. Both groups were similar. GPs in the intervention arm prescribed antibiotics for 56.9% of their patients compared with 58.3% in the control arm. The proportion of first-choice antibiotics was 34.5% in the intervention arm compared with 29.4% in the control arm.

The intracluster correlation coefficient (95% CI) for clustering of patients within GPs was estimated at 0.27 (0.09 to 0.36) for the effect on antibiotic prescriptions and 0.51 (0.40 to 0.63) for the choice of antibiotic. After adjusting for patient and GP characteristics, the OR (95% CI) for antibiotics prescribed by GPs in the intervention arm compared with the control arm was 0.63 (0.29 to 1.37; table 3). There was no significant effect on the choice of antibiotic (adjusted OR 1.07, 0.34 to 3.37).

DISCUSSION

Our pragmatic study in primary care shows that a single quality-circle session on a new guideline did not result in a significant change in antibiotic prescribing.

A limitation of our study was that only 29% of the GPs in the participating quality circles actually registered their patient

encounters. It is possible that only the most motivated GPs participated and this may jeopardise generalisability of the results. The participating quality circles were similar to the non-participating groups with regard to mean number of members, mean proportions of female GPs and GPs working in group practices. It is possible that the participating GPs are more open to interventions aimed at behaviour change than their colleagues who did not participate. Using patient-recruitment rates as a proxy for motivation and considering “low recruiters” to be more like non-participants, we found no significant differences between low and high recruiters for antibiotic prescribing rates, nor for prescribing rates of the first-choice antibiotic. But even if the participating GPs were more motivated, this would not change our conclusion. As the intervention was not effective in this selected group of potentially more motivated GPs, we can assume that it will not work in a less-motivated group either. In contrast, the participating GPs could have reacted similarly to the intervention and control condition. Knowing that they were taking part in a study on rhinosinusitis, they could have read the guideline and consequently changed their prescribing behaviour. In that case, the group session would have no additional effect. Voluntary participation will always introduce this potential bias. There is, however, adequate evidence that merely distributing a guideline without any additional intervention does not have an effect on prescribing behaviour.^{16, 17} Other studies exploring the effect of group sessions (with or without distribution of a guideline) show how difficult it is to change behaviour. It is unlikely that one quality-circle session would be more effective in the general population of GPs than in our selected group of participating GPs. It is also possible that for all GPs in both study arms, merely registering each patient contact influenced their prescribing behaviour.²⁷ If in our study self-registration was a powerful driver, it is possible that the group session did not have any measurable additive effect. There is always a risk of such a bias in studies based on self-registration. It can only be overcome by collecting data through a uniform electronic data retrieval system, but this is not available in Belgium. On the other hand, another study using electronic data retrieval did not find an effect of a peer group session on prescribing.²⁸ It would be interesting to study the effect of self-registration. If it proves to be a powerful driver, this would be an interesting approach to change the doctors' prescribing behaviour. Experiences from audit projects, however, show that registration alone is not enough to achieve meaningful and sustainable change.²⁹

Another point of concern is that participating GPs could have registered only a selection of eligible patients. However, antibiotic prescription rates are similar to other registrations in Flanders,^{21, 23} and other studies in the same region with GPs in similar settings showed that inclusion by GPs does not necessarily mean that selection took place. In a placebo-controlled trial, there was no important bias due to non-inclusion with regard to clinical

Table 1 Characteristics of general practitioners who registered patient encounters for complaints of acute rhinosinusitis*

	Intervention arm, n=30	Control arm, n=31
Mean (SD) group size	15 (3.6)	15 (2.3)
Female (%)	9 (30)	11 (35.5)
Solo practice (%)	18 (60)	16 (53.3)
Involved in practice training programme (%)	9 (29.9)	11 (35.5)
Use of computerised medical records (%)	24 (80)	29 (93.5)
Use of prescription software (%)	16 (55.2)	19 (61.3)
Mean (SD) age in years	45.1 (11.0)	47.5 (8.9)
Mean (SD) number of years in practice	18.8 (11.1)	21.5 (9.9)

*Data were available for 61/75 (81%) participating general practitioners.

Table 2 Characteristics of the patients with complaints of acute rhinosinusitis

	Intervention arm, n = 204	Control arm, n = 204
Female (%)	125 (62.2)	119 (58.9)
Mean (SD) age in years	38 (14.8)	37 (14.8)
Clinical presentation		
Purulent nasal secretion (%)*	79 (40.5)	80 (41.0)
Two-phased illness course (%)	85 (50.3)	96 (53.0)
Mean (SD) pain score†	1.6 (0.75)	1.6 (0.75)
Fever $\geq 38^{\circ}\text{C}$ (%)	35 (17.2)	54 (26.5)
History of recurrent acute rhinosinusitis (%)	69 (33.8)	52 (25.5)
Median symptom duration (days)	5	5

*Scored as "moderate" or "much" on a 4-point Likert scale.

†Composite of scores on facial pain, pain in upper teeth, headache, pain on bending, tender sinuses; all were scored on a 4-point Likert-scale.

features of patients with signs and symptoms of acute rhinosinusitis.³⁰ Another trial, with a design similar to that of ours, on the effect of academic detailing on prescribing for acute cough found no important differences between patients who were included and those eligible for inclusion.²² Data from a regional registration network show that on an average 4–6 patients with sinusitis could be expected to consult their GP during a month in the "cold season".²³ The median number of patients per GP in our study was five over a period of 6–8 weeks. Considering the slightly lower than usual incidence of respiratory infections in the late winter of 2005, we believe that selection of patients did not have an important role. If, in spite of these experiences, selection did occur, it is probable that GPs included patients with less severe symptoms. GPs are aware of the "desired behaviour" promoted by the available practice guidelines on upper respiratory tract infections—that is, not to prescribe antibiotics, and for patients with mild symptoms, it would be easier to comply. If our patients are a selected group of "less ill" patients, the antibiotic prescribing rates in a "real life" population might be higher. If we cannot find an effect of the intervention in patients with a low risk of serious complications, it is very unlikely that an effect is present in a population of patients with more severe symptoms of rhinosinusitis.

The study was powered to demonstrate a difference of 20% in the proportion of prescribed antibiotics. Other studies have shown that such an effect was feasible in primary care settings.^{22–31} It was also considered relevant and meaningful for tackling antimicrobial resistance and public spending on antibiotics. A smaller effect could still have an impact on national drug expenses,^{18–32} but to improve antimicrobial resistance rates, larger reductions in the use of antibiotics are needed.³³ We collected twice the number of registrations required for non-clustered trials, but it is possible that this was not sufficient to detect the desired difference in prescribing proportions. However, given the fact that this large effect was found in studies with more intensive interventions, such as individual academic detailing visits²² or multiple contacts,³¹ it is

probable that the true effect of unsupported group interventions is lower than desired. Moreover, our findings confirm the lack of effect in the only other pragmatic trial studying the effect of a similar peer-group intervention.²⁸

The intervention in our study took place immediately after a national campaign aimed at the public and GPs. As evaluation of a previous campaign has shown an overall reduction in antibiotic consumption,³⁴ this could have reduced the potential impact of our intervention. In the general population, an opinion shift favouring rational use was found shortly after the campaign, but how this could have influenced GPs' prescribing needs further investigation.³⁵ It had no impact on prescribing in an earlier study on acute cough.²²

The main strength of our study is that it makes use of existing local quality circles and reflects the way they function outside of a study context. The meetings on the guideline were integrated in the existing schedule and managed by members of the quality circles. Absence of an external "expert" is a core feature of this type of peer-review.³⁶ This allows us to evaluate the effectiveness of a tool for quality improvement that is integrated in many European accreditation systems.¹

Systematic reviews report only a limited number of studies comparing a small group intervention with a control group in primary care, and their results vary.^{4, 18–37} In contrast to our pragmatic study, the interventions in most trials consist of multiple sessions on the same topic supervised by a researcher or an expert, a situation usually very different from real life.^{19–20, 38–40} For instance, the international Drug Education Project studied the impact of several small group interventions in the presence of an external expert on asthma and urinary tract infections (UTIs) in various European countries.^{19–20, 39} Lagerlöv *et al*³⁹ showed that two sessions involving local pharmacists could improve prescribing in Norway, and in Sweden two tailored educational sessions resulted in a significant increase in the prescription of first-choice antibiotics for UTI.¹⁹ The Dutch Drug Education Project study found a significant effect on the duration of UTI treatment, but the already high proportion (89%) of first-choice antibiotics in UTI did not change.²⁰ Another study in The Netherlands, offering an intensive interactive group education with four sessions supervised by an experienced GP, could not demonstrate a significant effect on treatment strategies for care of patients with asthma.⁴⁰

A key feature of our study is that we used existing quality circles and integrated the intervention in the groups' normal working procedure. To our knowledge only two other studies applied this pragmatic approach. Kasje *et al*²⁸ did not find a change in prescribing for chronic heart failure or diabetes mellitus type 2 after a single self-supporting peer group intervention. Another study involving Dutch pharmacotherapy counselling groups suggests that combining a group meeting with other interventions may be needed. They found an 11% reduction in antibiotic prescribing after a multiple intervention consisting of a group meeting with a consensus procedure, a communication skills training, involvement of practice assistants and availability of patient leaflets.³¹

Table 3 The effect of the intervention on the proportion of (first-choice) antibiotics prescribed for acute rhinosinusitis

	n	Unadjusted OR (95% CI)*	n	Adjusted† OR (95% CI)*
Antibiotics	408	0.73 (0.39 to 1.35)	306	0.63 (0.29 to 1.37)
First-choice antibiotics	235	1.05 (0.45 to 2.46)	175	1.07 (0.34 to 3.37)

*Based on a generalised estimated equation model.

†Adjusted for all registered variables for general practitioner and patients.
n refers to the number of patient registrations included in the model.

Our study findings confirm the absence of effect found in the only other pragmatic study evaluating the effect of local quality circles of GPs.²⁸ This calls for more attention on the role of local quality circles in the quality debate. In many countries substantial efforts and resources are allocated to the peer-review programme, but evidence supporting their effectiveness is lacking. Studies with small group interventions suggest that by reinforcing groups with external support or multiple guided sessions, a relevant improvement in prescribing can be achieved. Interventions based on academic detailing have shown more promising results, and combining this with group interventions may yield more effect.^{22–31} To integrate quality circles successfully in feasible and sustainable (cost-) effective strategies to improve the quality of prescribing, we need more insight into their process and how they translate evidence-based messages and, also, a wider scope is needed.⁴¹ Our study and others show that focusing on transfer of knowledge is insufficient. We have learned from behavioural science models that knowledge by itself is not the trigger for change in behaviour and that individual doctor's characteristics are also important.^{42–43} A defensive attitude of the GP, for instance, has been linked to overprescribing.^{21–44} Quality improvement requires a reflective attitude of one's own knowledge and performance. This cannot be imposed by regulations and accreditation requirements. Providing the legal framework for quality circles is necessary, but not sufficient. Undergraduate medical education and consecutive vocational training have a crucial role in the shaping of doctors' attitudes and behaviour. The importance of role models and medical leadership in education seems to have been neglected and needs attention.⁴⁵ Clinical practice and actual prescribing takes place in the doctor-patient encounter, where medical evidence competes with contextual factors. Understanding the patient's wishes and needs, and effective communication, for instance, could facilitate evidence-based prescribing.^{46–48} Many of our GPs still work in single-handed practices, an environment with very few reflective stimuli. The new generation of GPs is looking for other practice settings, for partnerships with colleagues and other health professionals.⁴⁹ Several projects have shown that such an approach can be successful.^{50–51} In addition, structural components of the healthcare system, such as (non) existence of gatekeeping, reimbursement and payment have a role.^{41–52} The challenge for improving quality of care in the 21st century is to develop interventions that integrate the experiences derived from behavioural science with the achievements of clinical science and evidence-based medicine, with special attention on the policy environment and the context of the doctor-patient encounter. The functioning of quality circles needs to be reoriented within this broader comprehensive framework and include self-reflective and interprofessional learning, and communication skills. More research is needed into the process of learning and unlearning,⁵³ how (changing) attitudes can be learned and taught, and how quality circles can be deployed to initiate and pursue this process of change.

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