

Communication training and antibiotic use in acute respiratory tract infections

A cluster-randomised controlled trial in general practice

Matthias Briel^a, Wolf Langewitz^b, Peter Tschudi^c, Jim Young^a, Christa Hugenschmidt^a, Heiner C. Bucher^a

^a Basel Institute for Clinical Epidemiology, University Hospital Basel, Basel, Switzerland

^b Division of Psychosomatic Medicine, Department of Internal Medicine, University Hospital Basel, Basel, Switzerland

^c Institute for Primary Care Medicine Basel, University Hospital Basel, Basel, Switzerland

Summary

Background: Physician–patient communication plays a key role in treatment decisions in primary care. We aimed to reduce the antibiotic prescription rate for acute respiratory tract infections using a short training programme in patient-centred communication.

Methods: We conducted a cluster-randomised controlled trial in 45 general practices in Switzerland. Thirty physicians received evidence-based guidelines for the management of acute respiratory tract infections; 15 physicians randomised to the full intervention additionally received training in patient-centred communication. A further 15 physicians, not randomised, served as a control to blind the physicians in the other two groups to the true comparison. The primary outcome was the antibiotic prescription rate reported by pharmacists. Secondary outcomes were patient satisfaction and enablement, re-consultation rates, days with restrictions, and days off work. 1108 adults with acute respiratory infections were screened between January and May 2004. Outcomes were

measured in 837 consultations; 624 patients had follow-up interviews at 7 and 14 days.

Results: The antibiotic prescription rate reported by pharmacists was low in both full and limited intervention groups (13.5% and 15.7% respectively) but only half of the antibiotics were prescribed according to guidelines (53.8% and 53.1%). No significant differences were seen between the two randomised groups in primary and secondary outcomes. In both groups patient satisfaction was high (median score for both 68 out of 70).

Conclusions: In this trial, patient-centred communication training did not reduce the rate of antibiotic prescriptions below an already unusually low level. Even with this low prescription rate, patient satisfaction with received care was high.

Key words: antibiotics; prescribing; respiratory tract infections; primary health care; communication training; cluster-randomised trial

Introduction

The judicious use of antibiotics in primary care is paramount because of increasing antibiotic resistance for common bacteria [1]. In Switzerland acute respiratory tract infections account for over 50% of antibiotic prescriptions in outpatients [2] although antibiotics are usually not needed [3, 4]. Unnecessary use of antibiotics, is associated with high costs [5], medicalising effects [6] and an increased risk of side effects [3].

Evidence from intervention studies showed that merely providing physicians with guidelines and educational material for the management of acute respiratory tract infections is not enough to

reduce the antibiotic prescription rate for these conditions [7, 8]. However, several studies indicated that components of the physician patient relationship such as the perception of and response to patients' expectations for antibiotics may influence physicians' prescribing behaviour [9, 10]. Patient-centred communication is therefore a promising approach to reduce the antibiotic prescription rate in primary care. It emphasises the provider–patient relationship, physicians' attention to patients' expectations and shared decision making [11].

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We conducted a randomised controlled trial to see if training physicians in patient-centred communication would reduce the antibiotic prescription rate. The goal of the intervention was to improve a physician's ability to convey to patients the futility of antibiotic treatment for most acute res-

piratory tract infections. We additionally investigated whether this training affected patient outcomes: days with restricted activities, days off work, re-consultation rates, patients' satisfaction with received care, and their feelings of enablement.

Methods

Design

We conducted a cluster-randomised controlled trial. General practitioners were randomised to receive only evidence-based guidelines for diagnosis and treatment of acute respiratory tract infections (limited intervention) or in addition a training programme in patient-centred communication (full intervention). A non-randomised third group of general practitioners without any intervention (control) was to blind physicians in the other two groups to the true comparison. The Ethics Committees of the University Hospital Basel and Canton Hospital Aarau, Switzerland, approved the study protocol.

Participants

We invited all general practitioners in two cantons, Basel-Stadt and Aargau (where self-dispensation of drugs is not allowed), to participate in the trial. Of 345 eligible physicians, 45 gave written informed consent by January 1, 2004. The first 30 physicians recruited were randomised into the two intervention groups; the remaining 15 physicians formed the non-randomised control group. Only one physician per practice was allowed. Allocation to either intervention was concealed and carried out using a computer-generated list created by an independent institution.

From January to May 2004 study physicians consecutively screened all eligible adults, aged 18 years or older, with symptoms (first experienced within the previous 28 days) of acute infections of the respiratory system. Inclusion criteria were a first consultation for common cold, rhinosinusitis, pharyngitis, exudative tonsillitis, laryngitis, otitis media, bronchitis, exacerbated COPD or influenza, and written informed consent. Exclusion criteria were pneumonia, not fluent in German, intravenous drug use, psychiatric disorders, not available for phone interviews or not able to give written informed consent. Study physicians completed the trial after recruiting 20 patients or on May 15, 2004 at the latest.

Intervention

Up-dated guidelines, adapted to local conditions and reviewed by local experts, were developed by HCB, MB and PT based on existing evidence-based US-guidelines for the treatment of acute respiratory infections [12–14]. The guidelines were distributed as a booklet (see <http://www.bice.ch/publications/reports>) and presented in an interactive two-hour seminar.

Physicians in the full intervention group also attended a six-hour patient-centred communication seminar in small groups and received two hours of personal feedback by phone prior to the start of the trial. The training programme focused on teaching physicians how to understand and modify patients' concepts and beliefs about the use of antibiotics for acute respiratory tract infections. Physicians were taught to practice elements of active listening, to respond to emotional clues, and to tailor information given to patients [15]. Physicians were introduced to a model by Prochaska and DiClemente for identifying patients' attitudes and readiness for behaviour change [16].

Data and outcomes

We obtained baseline data on all eligible general practitioners from the registry of the Swiss Medical Association. Study physicians collected patient baseline data on signs and symptoms, recorded their diagnostic procedures, diagnosis, co-morbidity and prescribed medication. We trained medical students, blinded to the goal of the trial, to conduct standardised follow-up interviews at 7 and 14 days by phone. Patient satisfaction and enablement were measured using validated scales [17, 18]. Due to limited resources students interviewed all patients in the two intervention groups but only a convenience sample (one third) of the patients in the control group. All pharmacists in both cantons were asked by mail to fax all prescriptions with study labels to the study centre. Fax-copies of all prescriptions were checked and entered into the database by a person blinded to the intervention group. We used Teleform®-Software (Cardwell, Cardiff, GB) for data entry.

The primary outcome was uptake of antibiotic prescriptions as reported by pharmacists within two weeks following the initial consultation. Secondary outcomes for physicians were rates of different diagnoses of respiratory infections and adherence to guidelines for antibiotic prescription. Both MB and PT assessed adherence of all prescriptions to guidelines independently and blinded to the intervention group. Secondary outcomes for patients were days with restrictions from respiratory infection, days off work, re-consultation rates, and patient satisfaction and enablement. The independent monitoring board supervising the trial reviewed any serious adverse event that occurred within 28 days of study enrolment.

Sample size

The sample size of 15 general practitioners per group, each recruiting 20 patients, was calculated assuming [19] a type I error of 5%, power of 90% to detect a 20% difference in the rate of prescribing antibiotics, a 50% prescription rate in the limited intervention group [2], and variation between practitioner clusters equivalent to an intra-cluster correlation of 4.0% and a design effect of 1.6. We assumed dropout rates of 10% for participating physicians and 20% for patients. In order to obtain equal group sizes, 15 physicians were recruited into the control group giving a total of 45 physicians.

Statistical methods

All analyses were according to the intent-to-treat principle. Analysis of the primary outcome was by calculating a 95% confidence interval (appropriate for a cluster sample [19]) for the difference between the antibiotic prescription rate in the two randomised groups. In this calculation, the intra-cluster correlation was estimated as the mean squared difference between cluster prescription rates and the average rate in each group, with this mean squared difference then divided by the variance in the overall prescription rate. Further analysis was by logistic regression, using a generalised linear mixed model with the physician as the random effect and baseline characteristics of the patient population as covariates (age, sex, ed-

ucation, number of days with restricted activities at baseline). Analysis of secondary outcomes was by generalised linear models with the same set of covariates. We checked for baseline differences between screened patients and

those enrolled into the trial. We used Stata 8.2 (Stata Corp, College Station, Texas, USA) and SAS 8.2 (SAS Institute, Cary, NC, USA) for data analysis.

Results

Of 345 eligible general practitioners contacted, 45 gave written informed consent and were recruited (figure 1). Comparison of recruited physicians with data from the Swiss Medical Association registry suggests that they were representative of all eligible general practitioners (table 1). Baseline

data recorded by recruited physicians suggest that recruited patients were representative for all screened patients (table 2), and baseline data for recruited physicians and recruited patients were similar in the two intervention groups (table 3, 4).

Figure 1

Participant flow.
 * Reasons for exclusion of physicians: 26 were not practising General/Internal Medicine, 7 were not available for training seminars, 4 saw less than 30 patients per week, 12 shared practice with physicians who had already agreed to take part;
 † Patients not fluent in German to complete telephone interviews;
 ‡ Patients not available for telephone interviews (eg vacation);
 § Patients with psychiatric disorders, active intravenous drug users, new infection of previously enrolled patients

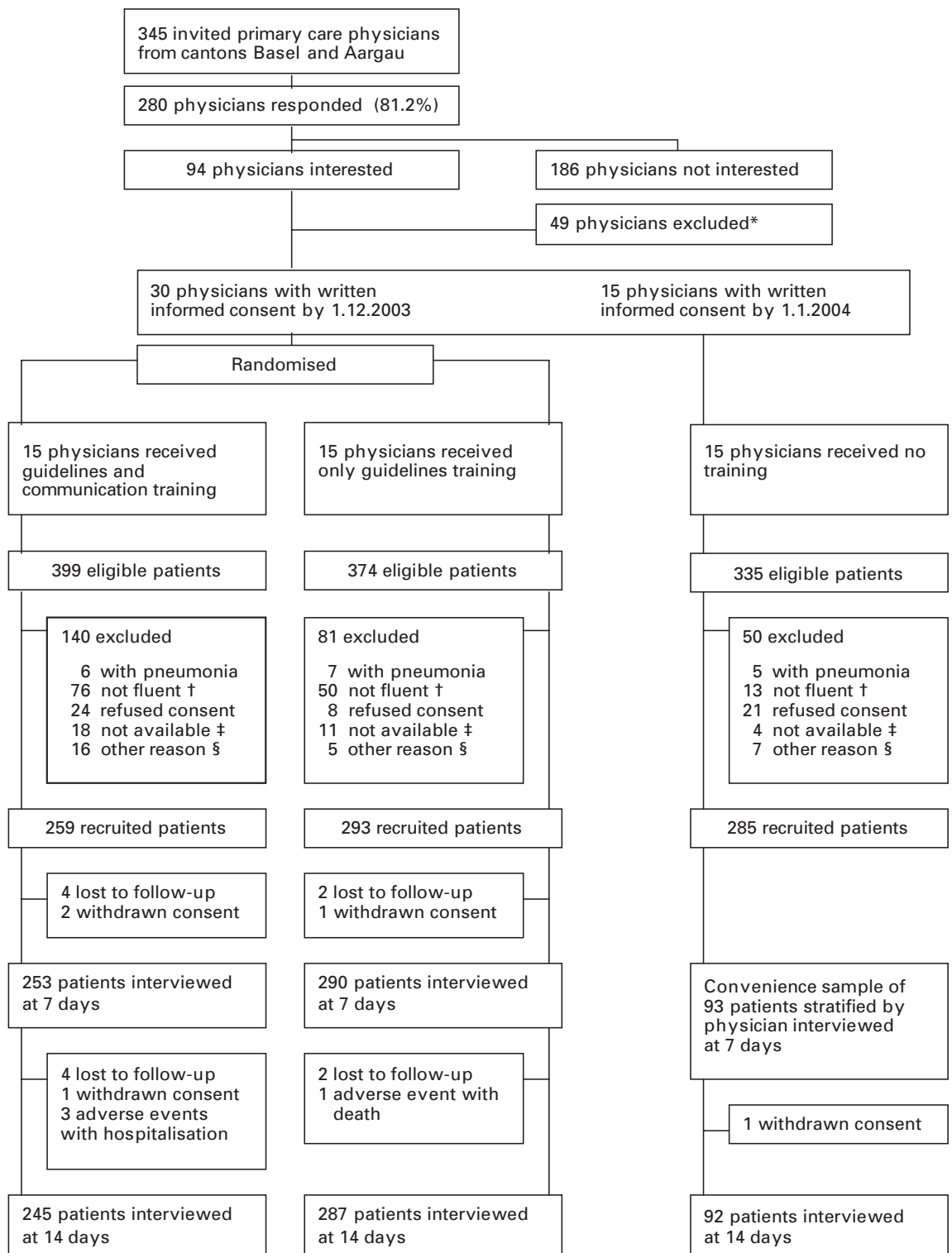


Table 1

Eligible physicians.

	Study physicians n = 45	All eligible physicians n = 345
Age – median [IQR]	51.6 [11.4]	51.1 [11.2]
Women – n (%)	8 (17.8)	67 (19.4)
Specialisation		
General medicine – n (%)	26 (57.8)	158 (45.8)
Internal medicine – n (%)	15 (33.3)	122 (35.4)
Other – n (%)	4 (8.9)	65 (18.8)
Years in private practice – median [IQR]	14.3 [15.4]	14.0 [14.4]
Years of postgraduate training – median [IQR]	9.2 [3.0]	9.2 [3.7]
Years since diploma – median [IQR]	24.0 [14.0]	24.0 [12.0]

Table 2

Study physicians.

	Randomised		Not randomised Control n = 15
	Full intervention n = 15	Limited intervention n = 15	
Age – median [IQR]	50.4 [13.5]	52.6 [11.9]	47.8 [13.1]
Women – n (%)	1 (6.7)	1 (6.7)	6 (40.0)
Specialisation			
General medicine – n (%)	10 (66.7)	9 (60.0)	7 (46.7)
Internal medicine – n (%)	3 (20.0)	5 (33.3)	7 (46.7)
Other – n (%)	2 (13.3)	1 (6.7)	1 (6.7)
Years in private practice – median [IQR]	15.0 [16.8]	17.2 [11.7]	10.3 [17.2]
Years of postgraduate training – median [IQR]	9.2 [3.2]	9.0 [1.8]	9.3 [5.4]
Previous communication-training – n (%)	1 (6.7)	1 (6.7)	4 (26.7)

Table 3

Screened patients.

	Study patients n = 837	Screened patients n = 1108
Age – median [IQR]	41.5 [26.5]	42.3 [26.3]
Women – n (%)	481 (57.5)	614 (57.5)*
Days with restricted activities – median [IQR]	4 [4]	4 [4] †
Degree of discomfort (scale 1–10) – median [IQR]	5 [3]	5 [3] ‡
Diagnosis		
Common cold – n (%)	307 (36.7)	427 (38.5)
Acute rhinosinusitis – n (%)	152 (18.2)	171 (15.4)
Acute pharyngitis – n (%)	88 (10.5)	109 (9.8)
Exudative tonsillitis – n (%)	41 (4.9)	51 (4.6)
Acute laryngitis – n (%)	21 (2.5)	29 (2.6)
Acute otitis media – n (%)	17 (2.0)	23 (2.1)
Acute bronchitis – n (%)	129 (15.4)	160 (14.4)
Influenza – n (%)	69 (8.2)	100 (9.0)
Exacerbated COPD – n (%)	13 (1.6)	18 (1.6)
Community acquired pneumonia – n (%)	Exclusion criterion	20 (1.8)

* Data from 1067 patients available; † Data from 1043 patients available; ‡ Data from 1015 patients available

Use of antibiotics

The rate of uptake of antibiotic prescriptions was not significantly lower in the full intervention group than in the limited intervention group (percentage difference –2.2, 95% CI –12.2 to 7.8; odds ratio adjusted for baseline characteristics 0.86, 95% CI 0.40 to 1.93) (table 5). In the full and limited intervention groups, the rate of uptake of antibiotic prescriptions reported by pharmacists was 13.5% and 15.7% respectively. The rate of pre-

scribing antibiotics reported by physicians was 15.1% and 16.7% among recruited patients and 14.3% and 18.4% among all screened patients. When prescribing antibiotics, 53.8% and 53.1% of prescriptions for recruited patients in the full and limited intervention groups were according to guidelines. In all groups antibiotics were most frequently prescribed (in absolute terms) for acute rhinosinusitis, acute bronchitis and exudative tonsillitis (table 6).

Table 4
Study patients.

	Randomised		Not randomised Control n = 285
	Full intervention n = 259	Limited intervention n = 293	
Age – median [IQR]	41.4 [22.9]	43.6 [30.7]	40.5 [22.8]
Women – n (%)	133 (51.4)	166 (56.7)	182 (63.9)
Days with restricted activities – median [IQR]	3 [4]	4 [3]	4 [3]
Degree of discomfort (scale 1–10) – median [IQR]	5 [3]	5 [3]	6 [3]
Diagnosis			
Common cold – n (%)	106 (40.9)	110 (37.5)	91 (31.9)
Acute rhinosinusitis – n (%)	33 (12.7)	66 (22.5)	53 (18.6)
Acute pharyngitis – n (%)	19 (7.3)	26 (8.9)	43 (15.1)
Exudative tonsillitis – n (%)	17 (6.6)	9 (3.1)	15 (5.3)
Acute laryngitis – n (%)	7 (2.7)	5 (1.7)	9 (3.2)
Acute otitis media – n (%)	6 (2.3)	7 (2.4)	4 (1.4)
Acute bronchitis – n (%)	38 (14.7)	40 (13.7)	51 (17.9)
Influenza – n (%)	29 (11.2)	23 (7.9)	17 (6.0)
Exacerbated COPD – n (%)	4 (1.5)	7 (2.4)	2 (0.7)

Table 5
Outcomes.

Prescription outcomes	Randomised		Not randomised Control n = 285
	Full intervention n = 259	Limited intervention n = 293	
Prescribed antibiotics reported by pharmacists – n (%)	35 (13.5)	46 (15.7)	61 (21.4)
Percentage difference (95% CI)	–2.2 (–12.2 to 7.8)		
Adjusted odds ratio (95% CI) *	0.86 (0.40 to 1.93)		
Prescribed antibiotics reported by physicians – n (%)	39 (15.1)	49 (16.7)	73 (25.6)
Adjusted odds ratio (95% CI) *	0.90 (0.44 to 1.98)		
Antibiotics prescribed according to guidelines – n (% of prescribed antibiotics)	21 (53.8)	26 (53.1)	30 (41.1)
Adjusted odds ratio (95% CI) *	1.03 (0.30 to 3.09)		
Patient outcomes			
Days with restricted activities – mean [SD]	6.18 [3.94]	6.81 [3.94]	7.28 [4.09]
Adjusted coefficient (95% CI) †	–0.40 (–1.07 to 0.27)		
Re-consultations within 14 days – n (%)	113 (44.7)	143 (49.3)	39 (41.9)
Adjusted rate ratio (95% CI) ‡	0.97 (0.78 to 1.21)		
Patients off work within 14 days – n (%)	135 (53.4)	137 (47.2)	54 (58.1)
Adjusted odds ratio (95% CI) *	1.00 (0.63 to 1.57)		
Patients with satisfaction score of 70 out of 70 – n (%) §	121 (47.8)	142 (49.0)	42 (45.2)
Adjusted odds ratio (95% CI) *	1.00 (0.64 to 1.31)		
Patient enablement score (0–12) – mean [SD]	8.49 [1.98]	8.15 [2.03]	8.19 [1.90]
Adjusted coefficient (95% CI) †	0.35 (–0.05 to 0.75)		

* Logistic regression with random effect for each cluster and patient covariates (age, sex, education, days with restrictions at baseline)
 † Linear regression with random effect for each cluster and patient covariates (as above)
 ‡ Poisson regression with random effect for each cluster and patient covariates (as above)
 § We used the proportion of patients with a maximum score of 70 as an outcome because satisfaction scores (scale 14 to 70) were highly skewed.

Table 6
Prescribed antibiotics per diagnosis.

	Randomised						Not randomised Control, n = 285		
	Full intervention, n = 259			Limited intervention, n = 293			Total n	Antibiotics n	According to guidelines (n)
	Total n	Antibiotics n	According to guidelines (n)	Total n	Antibiotics n	According to guidelines (n)			
Common cold	106	4	1	110	0	–	91	1	0
Acute rhinosinusitis	33	7	4	66	25	16	53	26	17
Acute pharyngitis	19	2	0	26	1	1	43	6	2
Acute exudative tonsillitis	17	11	9	9	6	4	15	13	7
Acute laryngitis	7	0	–	5	1	0	9	1	0
Acute otitis media	6	3	2	7	2	0	4	3	0
Acute bronchitis	38	9	2	40	8	2	51	20	2
Influenza	29	0	–	23	1	0	17	1	0
Exacerbated COPD	4	3	3	7	5	3	2	2	2

Patient outcomes

On average, patients in both the full and limited intervention groups experienced between 6 and 7 days with restricted activities (table 5). The difference in mean days with restricted activities between groups was -0.40 (95% CI -1.07 to 0.27). Re-consultation rates in the full and limited intervention group were 44.7% and 49.3% respectively. The adjusted rate ratio for re-consultation in the full relative to the limited intervention group was 0.97 (95% CI 0.78 to 1.21).

Scores for patient satisfaction (median 68 out of 70) and patient enablement (median 8 out of 12)

were high compared to scores in validation studies [17, 18]. There was no difference in patient satisfaction between groups. We found weak evidence of higher patient enablement in the full intervention group (difference in means score between groups 0.35, 95% CI -0.05 to 0.75).

Three patients had serious adverse events, all requiring hospitalisation: in the full intervention group, a man with pericoxitis and endoprosthesis removal and a woman with a severe depressive episode; in the limited intervention group, a 91-year-old man with pneumonia followed by a fatal myocardial infarction.

Discussion

In this trial, patient-centred communication training did not reduce the rate of prescribing antibiotics among general practitioners receiving evidence-based guidelines for the treatment of acute respiratory tract infections. There were no significant differences in patient related outcomes between the two intervention groups. We found some evidence suggesting that communication training might increase patient enablement. Patient satisfaction remained high, although antibiotic prescription rates were low in both groups.

In our trial prescription rates for antibiotics were lower than in a similar Dutch primary care trial (where rates were 23–37%) [20] and lower than we anticipated [2]. It may be difficult to find any intervention that can further reduce the low antibiotic prescription rate seen in our trial. In theory it is possible, because half of all the antibiotics prescribed in our trial were not prescribed according to guidelines. But in practice the low rate in our trial may reflect a “floor effect”, where physicians have reduced their prescription rates down as low as they dared.

When designing our trial, we assumed a 50% prescription rate in the limited intervention group, a lower rate than reported in other studies [2, 21]. We considered a difference of at least 20% necessary to provide sufficient public health and clinical benefit to warrant implementing our intervention. By assuming a prescription rate of 50% for the limited intervention group the variance in the estimate of that rate is at a maximum. Thus, irrespective of the prescription rate in the limited intervention group, we would have at least 90% power to detect a 20% difference. The main difficulty in designing cluster-randomised trials is choosing a suitable value for the intra-cluster correlation [22]. In calculating the confidence interval for the difference between the prescription rates in the two randomised groups, the intra-cluster correlation was estimated as 9.7% giving a design effect of 2.9. These figures were higher than anticipated (4.0% and 1.6 respectively), but the width of the resulting confidence interval (-12.2 to 7.8) was still the required 20%.

We had difficulties in recruiting physicians for our trial (informed consent from 13% of eligible

physicians). Recruitment began just as a new nation-wide computer based reimbursement system was introduced for Swiss physicians, and many general practitioners were reluctant to participate in the trial fearing a further increase in their workload. By participating at all, trial physicians demonstrated a high degree of motivation, an interest in improving the management of acute respiratory tract infections, and a willingness to commit additional time for patient recruitment and data collection. Additionally, physicians behave differently when monitored, a phenomenon known as the “Hawthorne effect” [23]. Together with the selection of motivated physicians this could explain at least in part the low antibiotic prescription rates in our trial compared to survey data [2, 21].

The slightly higher antibiotic prescription rate in the third non-randomised group could be due to lower motivation. Physicians who knew they were in a control group were perhaps less motivated to reduce their prescription rate than those who felt part of a treatment group [23]. By blinding the intervention groups to the true comparison we tried to balance these motivation effects among randomised physicians. Probably Hawthorne and motivation effects operate in any intervention trial of this sort. There is some evidence from similar trials that the Hawthorne effect and any intervention related reductions in the antibiotic prescription rate tend to diminish over time [20, 24]. Therefore, long-term follow-up is essential to see if effects are real and lasting. In our initial proposal we had planned for an extended follow-up period, but the funding we received did not allow this.

The strengths of our trial are a cluster-randomised design appropriate for an intervention at the practice level, a high follow-up rate, the blinding of general practitioners and trial staff, and a focus on the primary care setting outside the context of physicians’ peer review groups [20] or managed care organisations [7]. Our design allowed us to compare prescription rates among recruited patients with rates among all screened patients. In addition we measured patient satisfaction [17] and

enablement [18] using validated instruments and collected data on other patient outcomes. Most other studies evaluating interventions designed to reduce the antibiotic prescription rate for respiratory tract infections either do not measure patient satisfaction [7, 8, 24] or use non-validated scales [20], and do not look at such a wide range of patient outcomes.

Reductions in antibiotic prescriptions in other studies were in the range of 3% to 26%, but most of these studies used designs without randomisation or without randomising each physician to an intervention [7, 20, 24]. The trial with the most rigorous design found a reduction of 3% in the antibiotic prescription rate for pharyngitis using multiple tailored interventions [8]. There is empirical evidence that effects are lower in trials with more rigorous designs [25]. These findings suggest that it is difficult to change practice with intervention programmes, and that large changes over a short period are not typical.

In conclusion, this trial suggests that in motivated physicians with already low rates of antibiotic prescription for acute respiratory tract infections, patient-centred communication training

does not further reduce these rates in the short-term. Future research should evaluate patient-centred communication training in physician populations with higher rates of antibiotic prescription and investigate long-term effects. Results from this trial suggest that low antibiotic prescription rates are feasible for motivated Swiss primary care physicians and are not associated with adverse patient outcomes but with high patient satisfaction. Other well designed studies are needed to confirm this finding.

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Correspondence:

Dr. Matthias Briel

Basel Institute for Clinical Epidemiology

University Hospital Basel

CH-4031 Basel

Switzerland

E-Mail: brielm@ubbs.ch

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