Feasibility of a national cholesterol guideline in daily practice. A randomized controlled trial in 20 general practices

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Abstract

Objective. To evaluate the feasibility and implementation needs of a cholesterol guideline by assessing the effectiveness of simple dissemination as well as extensive implementation of this guideline on actual performance of general practitioners (GPs).

Design. Randomized controlled trial.

Setting and subjects. Thirty-two Dutch GPs in 20 general practices, 3950 patient records.

Interventions. Guideline dissemination to all 32 GPs, and a 5-month programme for improvement in the intervention group. This programme was developed after barriers to working according to the guideline had been investigated, and consisted of group education, desktop supportive materials, feedback on performance, and face-to-face instruction on location.

Main outcome measures. The outcome parameters were defined as quality of selective case finding and quality of diagnostic procedures, and were measured by chart audit.

Results. The quality of selective case finding, especially the targeting of cholesterol testing to those with positive cardiovascular risk profiles, did not improve following intervention. Performance of the procedure necessary to diagnose hypercholesterolaemia even deteriorated. The quantity of cholesterol testing increased in both groups, but this was probably explained by the increased availability of desktop cholesterol analysers.

Conclusions. Neither simple dissemination nor an intensive programme for improvement had measurable impact on actual performance on working according to the cholesterol guideline. Both the validity and the opinion about feasibility of the guideline in daily practice deserve more attention during guideline development.

Keywords: cholesterol, general practice, preventive health care, quality assurance, randomized controlled trial

Much discussion surrounds the best way, in general practice, to diagnose and treat patients with hypercholesterolaemia. The Dutch College of General Practitioners (DCGP) established a well-balanced national guideline [1] on cholesterol for screening and management of hypercholesterolaemia, which was published in November 1991 [2]. Cautiousness in screening and drug therapy characterizes the guideline. The guideline recommends selective case finding: targeting cholesterol testing to those individual patients who, for whatever reason, attend the practice office, and who are known to have an increased individual risk profile for coronary heart disease (Table 1). Targeting cholesterol testing to the persons that can benefit is important for cost-effectiveness and feasibility. Overtesting represents a waste of resources and even a potential burden to patient health, as false-positive findings can lead to unnecessary treatment or anxiety and labelling effects. Knowledge of guidelines does not necessarily lead to compliance with those guidelines [3–5]. The effectiveness of traditional education to change physicians’ behaviour is to be doubted [6]. It may affect knowledge and beliefs, but rarely results in behaviour change. Multifaceted interventions with social influence and management support seem effective in inducing change in general practice [7].

Previous studies evaluating implementation of guidelines

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The programme can be considered as a maximum effort for the trial setting reported in this study, and is far too extensive to be suitable for national implementation of the guideline. The objective was to assess the effects of simple dissemination as well as a programme for improvement on GPs’ actual performance in daily practice, taking the DCGP national cholesterol guideline as a reference, in order to test the feasibility of the guideline.

**Methods**

**Study design**

A randomized controlled trial with a 5-month intervention period was conducted in 20 practices. The guideline, together with a set of scientific background materials, were distributed to all participating GPs. Implementation took place in one-half of the general practices, the other half serving as controls. Besides willingness and motivation of the participating GPs to adhere to the cholesterol guideline, the inclusion criteria for participating practices were employment of at least one full-time GP, employment of a practice assistant, the availability of an acceptable patient registration system, and, in the case of group practices, participation of all GPs of that practice. Various strategies were applied to recruit practices (notices in the newsletters of the regional formal and informal networks of GPs, as well as personal contacts with these regional formal and informal networks). Comparability of the two groups was assured by means of stratified randomization, with the following strata: computerized medical information system (yes/no), type of practice (solo/group), and size of practice (<2500/≥2500 patients). After stratification, practices were randomized with a permuted block design to ensure exactly equal group numbers. If strata were filled with less than two practices, practices that were most alike were put together in a block. The follow-up measurement started 3 months after the intervention was completed, in order to measure maintenance of changed behaviour.

**The programme for improvement**

The programme started with a 3-hour educational session chaired by a local opinion leader, 1 month after the guideline had been distributed. During this session the GPs were provided with several supportive materials such as consultation registration forms, a desktop flow chart of the guideline, and a sufficient supply of patient education leaflets. Guideline topics where Dutch GPs had shown barriers to change or educational needs were discussed and thorough interactive education was provided. The rest of the programme consisted of continuous recording of ‘cholesterol consultations’ by the GPs, using standardized registration forms. The GPs were encouraged to register all of the consultations in which cholesterol was a topic (just talking about it was sufficient reason to register). These forms were constructed in such a way that the GPs got immediate feedback on their performance, so the registration of cholesterol consultations can be looked upon as general and

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**Table 1** The cholesterol guideline of the Dutch College of General Practitioners (1991)

| Case finding: | Selective case finding: men and women, 18–65 years, with one of the following risk factors: signs of familial hypercholesterolaemia (xanthoma, xanthelasma/arcus senilis before the age of 40 years), CHD in patient history, CHD in sibling or parent while younger than 60 years, hypertension, diabetes mellitus, familial hyperlipidaemia in the family |
| Diagnosis: | Diagnosis of hypercholesterolaemia: the mean of three cholesterol tests higher than 6.5 mmol/l, determined in a period of 6 weeks. First measurement <5.0 mmol/l, do not repeat; average of first and second measurement <6.5 mmol/l, do not repeat |

on cholesterol differed in their effectiveness in changing physicians’ behaviour. Several interventional strategies in several combinations have been used, e.g. group education, educational or supportive materials, feedback on performance, general or patient-specific reminders, and incentives, with varying results [8–12]. None of these studies were conducted entirely in the primary care setting. In none of these studies was an analysis of physicians’ needs performed in developing the intervention, which is an important factor for the potential for change of implementation strategies [13]. This paper presents the results of a randomized trial evaluating the feasibility of a cholesterol guideline by assessing the effects of simply disseminating the guideline as well as the effects of an extensive implementation programme, designed to enhance the adherence of general practitioners (GPs) to working according to the Dutch cholesterol guideline. We aimed at optimizing the implementation strategy by assessment of the barriers and needs perceived by GPs to working according to the guideline. These barriers were analysed in existing data sources which were based on systematic registration of performance and chart audit. An increase in the quantity of cholesterol testing by Dutch GPs in recent years was observed [14]. Current practice with respect to quality was, however, not according to the guideline in the period before [15] and during publication of the guideline [16]. Apparently, a well-designed strategy is needed to implement this guideline. Many barriers and perceived needs to working according to the guideline were mentioned by GPs in a questionnaire on this topic. These barriers and needs were translated into educational objectives and suitable learning conditions. Multifaceted implementation strategies were developed and incorporated into a programme for improvement that was designed to meet the educational objectives [17]. Our null hypothesis was that the GPs did need this programme, considering the many barriers and needs that were assessed, and that it would help them in adhering to the guidelines.

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patient-specific reminders [18]. The GPs had also registered consultations for a period of 8 weeks at baseline, in order to gain insight into their own performance before the programme for improvement started. During two outreach visits by one of the authors (TvdW) feedback on performance was given based on the registered consultations, which led to face-to-face instruction or further discussion on guideline topics and barriers to change. The only intervention in the control group was the postal distribution of the guideline with its scientific background materials.

Effect parameters and instruments

Effect parameters were defined as the quality of selective case finding and the quality of diagnostic procedures. Quality of selective case finding refers to targeting cholesterol testing to those patients with at least one of the six risk factors mentioned in the guideline, to be called ‘positive risk profile’. It was expressed as proportions: justified testing as (risk profile + and test + / all patients) × 100; unjustified testing as (risk profile− and test + / all patients) × 100; unjustified not testing as (risk profile+ and test− / all patients) × 100, and justified not testing as (risk profile− and test− / all patients) × 100. A summarizing, comprehensive measure for these proportions is the odds ratio (OR). An OR significantly greater than 1.0 [the lower limit of the 95% exact confidence interval (CI) is greater than 1.0] means that having a positive risk profile increases the chance that the patient has a cholesterol value recorded. The higher the OR, the more selective is the case finding.

Diagnostic quality refers to the recommendation that a properly diagnosed hypercholesterolaemia requires the average of three measurements to be higher than 6.5 mmol/l. As an effect parameter it was defined as at least one repetition of cholesterol testing in a period of 6 weeks in patients with a cholesterol level higher than 5.0 mmol/l (if the average of two cholesterol tests is lower than 6.5 mmol/l, no further testing is required).

The effects of the intervention were measured by chart audit; patient records of random samples of 10% of all patients aged 18 years or older were taken in the 20 general practices [19]. The data collection was deliberately not restricted to patients under the age of 65 (the upper age limit for case finding according to the guideline) or to patients with a positive risk profile, because measuring overtreatment was considered to be as important as measuring undertesting. At baseline the whole patient record was reviewed for notes on coronary heart disease (CHD) risk factors, and for notes on lipid diagnosis the audit was limited to the period of 2 years before the moment of randomization. At follow-up the patient record was reviewed for the 9 months from the moment the intervention started. The chart audit was performed by two medical students, who were blind to study group assignments.

Data analysis

The ORs per practice were pooled in an overall OR across the practices per group, using the Mantel–Haenszel method for combining data from 2 × 2 tables. The difference in selective case finding performance between groups was tested with the Mann–Whitney–Wilcoxon rank-sum test (significance level $P = 0.05$) of the log OR. In a subgroup analysis we accounted for the age range of 18–65 years (the recommended age group in which good performance can be expected). To control for the difference in time range of the baseline and follow-up period (24 and 9 months respectively), the data for the 2-year period were standardized to the data for the 9-month period by analysing with patient-years as the time denominator. This was carried out for justified testing among all the patients with a positive risk profile and for justified non-testing among all the patients with a negative risk profile. The mean pre–post differences between groups, using the simple difference between score in patient-years at baseline and follow-up for each practice, were tested with unpaired two-tailed t-tests (significance level $P = 0.05$).

The analyses at practice level, with the chart audit results clustered to each practice, is suboptimal due to variation in number of patients across practices. The alternative of an ordinary logistic regression analysis with patients as the units of analysis may suffer from type I error due to dependence between outcome of patients within the same practice. Therefore a multi-level analysis was performed, using the EGRET 1995 statistical package (version 1.02.10). A random effects logistic regression analysis was performed to control for this dependence (the intra-class correlation) by including practice as random effect and patients as unit of analysis. The dependent variable was the cholesterol test appropriately done or not done during follow-up. Independent variables in the model were the intervention, the patient’s risk profile at follow-up, age and sex of the patients, a binary quality score of the selective case finding performance at baseline (cholesterol testing± equals or not equals the patient’s risk profile±), and the interaction between risk profile and intervention.

To describe diagnostic quality, the frequency of testing was analysed in the patients in whom a cholesterol value was recorded for diagnostic purposes. (No cholesterol value or lipid-lowering therapy was recorded in the year preceding the audit to exclude testing for monitoring purposes). The proportion per practice of these patients for whom repeat testing was correctly performed was calculated. Because of skewed distribution, the difference between groups was analysed with the Mann–Whitney–Wilcoxon rank-sum test. In subgroup analyses the diagnostic quality was analysed for the group of patients aged 18–65 years and then for the group of patients aged 18–65 years with a positive risk profile, because good performance can be expected in this subgroup.

Results

Characteristics of practices and GPs

Thirty-two GPs were working in the 20 participating practices. Ten of the participating GPs were working single-handed, the others were working in 10 practices with one or more
Table 2 Baseline characteristics of the study groups in absolute numbers

<table>
<thead>
<tr>
<th>Variables in stratification</th>
<th>Intervention group</th>
<th>Control group</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>$n=10$</td>
<td>$n=10$</td>
</tr>
<tr>
<td>Type of practice</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Solo</td>
<td>6</td>
<td>6</td>
</tr>
<tr>
<td>Duo</td>
<td>2</td>
<td>2</td>
</tr>
<tr>
<td>Group/health centre</td>
<td>2</td>
<td>2</td>
</tr>
<tr>
<td>Number of practices with &gt;2500 patients</td>
<td>6</td>
<td>6</td>
</tr>
<tr>
<td>Computerized</td>
<td>No</td>
<td>Yes</td>
</tr>
<tr>
<td></td>
<td>3</td>
<td>7</td>
</tr>
<tr>
<td></td>
<td>Yes, medical module</td>
<td>4</td>
</tr>
</tbody>
</table>

partners. The mean age of the GPs was 41 years (SD = 7.4). Of the 32 GPs five were female. The stratified randomization procedure ascertained comparability of groups (Table 2). Fourteen of the 20 practices were computerized, but in only seven practices (11 GPs) was patient-specific medical information recorded in the computerized medical information system. At baseline two intervention and three control practices possessed desktop cholesterol analysers. This possession of analysers had doubled at follow-up; half of the intervention as well as half of the control practices had equipped themselves with a desktop cholesterol analyser.

After sampling in the 20 practices, 3950 patient records were audited. On average 90% of the patients had actually contacted their GP at baseline [179 (SD = 39) patients per practice], and 79% of the patients at follow-up [156 (SD = 34) patients per practice]. The patient samples in the intervention and control groups were comparable for relevant demographic characteristics. The 16 GPs in the intervention group registered, on average, 15 (SD = 9) and 24 (SD = 15.4) cholesterol consultations per GP (in total 239 and 385), during the 8-week baseline and intervention periods respectively. One GP dropped out of the intervention group because of early retirement, and one GP who switched to another practice dropped out of the control group.

Quality of selective case finding

Case finding performance is presented in ORs per practice to show inter-practice variation (Table 3). No effect of the intervention was found; the likelihood for a patient with a positive risk profile to have his or her serum cholesterol tested and recorded did not increase ($P=1.00$). Instead of higher ORs, lower ORs were seen during the follow-up period. The number of significantly positive ORs decreased at follow-up, especially in the intervention group. Nevertheless, the pooled OR remains higher in the intervention group because one GP strongly improved his performance (OR = 49.5). Moreover, the quality of case finding did not improve in the subgroup of patients aged 18 to 65 years.

Adjustment for patient-years in the analyses did not result in any differences between intervention and control group in the amount of pre-post change between baseline and follow-up.

The multi-level logistic regression analysis, using 2768

Table 3 Performance scores on selective case finding (chart audit), odds ratios presented per practice, and mean score per intervention and control group

<table>
<thead>
<tr>
<th>Sample size baseline, follow-up (number of GPs)</th>
<th>Odds ratio baseline</th>
<th>Odds ratio follow-up</th>
<th>Sample size baseline, follow-up (number of GPs)</th>
<th>Odds ratio baseline</th>
<th>Odds ratio follow-up</th>
</tr>
</thead>
<tbody>
<tr>
<td>218, 190 (3)$^1$</td>
<td>6.9$^1$</td>
<td>22.9$^1$</td>
<td>205, 171 (3)</td>
<td>5.8$^1$</td>
<td>5.3$^1$</td>
</tr>
<tr>
<td>231, 217 (3)</td>
<td>5.0$^1$</td>
<td>5.4$^1$</td>
<td>209, 169 (2)$^2$</td>
<td>4.9$^1$</td>
<td>3.4$^1$</td>
</tr>
<tr>
<td>209, 180 (2)</td>
<td>3.3</td>
<td>3.3</td>
<td>212, 190 (3)$^1$</td>
<td>6.6$^1$</td>
<td>2.9$^1$</td>
</tr>
<tr>
<td>223, 185 (2)$^1$</td>
<td>3.1$^1$</td>
<td>3.0$^1$</td>
<td>216, 187 (1)$^1$</td>
<td>3.8$^1$</td>
<td>18.4$^1$</td>
</tr>
<tr>
<td>215, 194 (1)$^1, 2$</td>
<td>5.3$^1$</td>
<td>3.1</td>
<td>167, 160 (1)$^1$</td>
<td>5.9$^1$</td>
<td>3.5$^1$</td>
</tr>
<tr>
<td>186, 124 (1)$^1$</td>
<td>2.5</td>
<td>2.9</td>
<td>185, 152 (1)</td>
<td>1.3</td>
<td>1.8</td>
</tr>
<tr>
<td>117, 98 (1)$^1$</td>
<td>25.4$^1$</td>
<td>5.3</td>
<td>179, 163 (1)$^1$</td>
<td>3.1$^1$</td>
<td>1.8</td>
</tr>
<tr>
<td>116, 122 (1)$^1, 2$</td>
<td>12.2$^1$</td>
<td>3.0</td>
<td>152, 151 (1)$^1$</td>
<td>19.7$^1$</td>
<td>11.2$^1$</td>
</tr>
<tr>
<td>135, 119 (1)</td>
<td>2.4</td>
<td>2.5</td>
<td>134, 111 (1)$^1$</td>
<td>2.0</td>
<td>21.1$^1$</td>
</tr>
<tr>
<td>134, 118 (1)$^1$</td>
<td>9.2$^1$</td>
<td>49.5$^1$</td>
<td>134, 115 (2)</td>
<td>3.4$^1$</td>
<td>4.3</td>
</tr>
<tr>
<td>Pooled odds ratio</td>
<td>5.1</td>
<td>4.9</td>
<td>Pooled odds ratio</td>
<td>4.2</td>
<td>3.8</td>
</tr>
<tr>
<td>95% CI</td>
<td>3.7–7.4</td>
<td>3.1–8.4</td>
<td>95% CI</td>
<td>3.1–5.8</td>
<td>2.6–5.9</td>
</tr>
</tbody>
</table>

$^1$Practices with a computerized medical information system, including the medical module.

$^2$Desktop cholesterol analyser available in the practice (at follow-up).

$^3$Significant odds ratios, the lower limit of the 95% exact confidence interval (CI) is greater than 1.0.
observations, did not show any effect of the intervention. The interaction variable was left out because it was far from significant. The odds ratio was 0.76 (95% CI = 0.44–1.30). Although there appears to be an inhibitory effect of the intervention with regard to testing, no statistically significant and clinically relevant effect of the intervention was seen.

**Diagnostic quality**

There were 415 patients during the baseline and 193 patients during the follow-up period with a diagnostic cholesterol value recorded on their record. At baseline 53 (SD = 22) cholesterol tests per 1000 patient-years were audited per practice in the intervention group, and 63 (SD = 22) in the control group. At follow-up the number of cholesterol tests per 1000 patient-years increased in both groups: 72 (SD = 39) in the intervention practices and 96 (SD = 38) in the control practices. The increase in cholesterol testing was significantly higher (P = 0.033) in the practices that were equipped with a desktop cholesterol analyser.

The median proportion of patients for whom the GP performed repeat testing to diagnose hypercholesterolaemia was low in both groups during the baseline period: intervention group, 11.8 (interquartile [IQ] range = 4.4–28.8) and control group, 13.4 (IQ range 8.2–18.8). This proportion should ideally be 100% but decreased to zero in both groups at follow-up: intervention group, 0.0 (IQ range 0.0–24.5) and control group, 0.0 (IQ range 0.0–13.3). The subgroup of patients aged 18 to 65 years with a positive risk profile for whom good performance might be expected did not show better results.

**Discussion**

No effect of simply disseminating nor an intensive strategy to implement a national guideline on hypercholesterolaemia could be demonstrated. There was, first of all, no difference (in pre–post change) between the groups for the quality of selective case finding. Although cholesterol testing did not improve qualitatively, it did increase quantitatively. The positive association that was found between cholesterol testing and the availability of a desktop testing device was also reported by others [20–22]. The large number of patients actively requesting cholesterol testing (about 40% of the patients tested at follow-up) might be another factor associated with this increase in testing. This kind of external influence, such as the demanding patient or marketing activities of drug companies who provide desktop test devices, might play a major role in the cholesterol screening activities of GPs, and may be more decisive than the cholesterol guideline and the programme for improvement that was used in this trial. The low and even deteriorating performance on the diagnosis of hypercholesterolaemia, the stepwise repeat testing of serum cholesterol, is alarming. Apparently, this is a major problem in daily practice, also reported by American physicians [23].

Could a real difference between the intervention and control group exist without being detected (type 2 error)? It is highly unlikely, considering the lack of improvement – deterioration is even seen after application of the solid intervention – that the direction of the results would have changed if a larger group of general practices had been involved. The most appropriate analysis, the multi-level analysis based on a sample size n = 2768, did not show any effect of the intervention. The other outcomes of this trial, concerning the effect of the intervention on the GPs’ knowledge and attitude [24], indicate the same trend.

Why did the intervention not work? Although there may be methodological restrictions to this study, we believe it is very unlikely that a strong effect was hidden. We had tried to maximize the contrast between the groups by not allowing the control group GPs to register cholesterol contacts during baseline (measuring behaviour may have an intervening effect, the Hawthorne effect). According to the educational and behaviour change theories, this implementation programme ought to be a solid intervention. Features of the guideline itself may have impeded its implementation. For instance, there is the preventive character of the cholesterol topic. Nearly all or at least a majority of the GPs see cholesterol reduction as an important task [25–28]. Despite this belief in preventive care, actual performance is low. The participating GPs were asked in semi-structured interviews which barriers to adherence to the guideline they had experienced [24]. Many barriers were brought up such as limitations or lack of time, reimbursement, motivation, practice organization, and patient compliance. Also, the complexity of the guideline algorithm was often mentioned. The role and responsibilities of the GP in the field of prevention are disputed by others. Doctors are educated and prepared for investigating symptomatic patients and for caring for and curing the sick, rather than for keeping the healthy ones healthy. Preventive medicine may disturb this function [29]. A systematic and supportive public health approach to professional, patient and organization-related barriers to the delivery of preventive services [30–32] seems needed to make the cholesterol guideline feasible. Especially in preventive care, it seems important to ensure that efforts to change doctors’ clinical behaviour match prevailing reimbursement and administrative policies [33]. The lack of motivation for prevention mentioned by many GPs and their hesitation to interfere in patients’ lifestyles is a sign that primary prevention of CHD cannot be the task of GPs alone. A supportive public health approach is needed, with strategies like educating youngsters about the relationship between lifestyle and the risk of CHD, and a proper reimbursement policy. The preventive approach of the general practitioner should be integrated into a broad strategy of preventive activities.

Furthermore, the guideline might just not be good enough [34]. The method of developing the guideline determines its scientific validity [35,36]. Whereas many GPs believe that good practice is not always necessarily based on scientific evidence [37], the scientific validity of the guideline has not gone unquestioned. In addition, the publications on various cholesterol guidelines have been contradictory and controversial throughout the years. The ongoing debate about
which high-risk groups benefit most from cholesterol screening seems to need clarification by the GP. A higher level of evidence might be needed, accompanied by descriptions of the strength of the evidence, as well as information on cost-effectiveness in the primary health care setting [38], to convince GPs of the importance of certain guidelines [39]. At least guidelines should be clear and user-friendly, which, according to the GPs, is not the case with the cholesterol guideline.

Overall it can be concluded that neither disseminating the guidelines nor the extensive implementation programme had any relevant impact on working according to the guideline. It may have been too early for promoting implementation of recommendations on cholesterol screening in general practice, due to the controversial and preventive character of the guideline. During the process of development or updating such guidelines, much attention should be given both to the scientific validity of the guideline, including cost-effectiveness of cholesterol lowering in general practice, and to its feasibility and applicability in daily practice.

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