Achievement of guideline-defined treatment goals in primary care: the German Coronary Risk Management (CoRiMa) study

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Aims The success in achieving treatment goals for cardiovascular risk factors in primary care is largely unknown. Therefore, the goals of this study were (i) to assess whether routinely collected practice data can be used to evaluate treatment in primary care, (ii) to compare current treatment with goals of published guidelines, and (iii) to calculate future risk for cardiovascular events using these real-life data.

Methods and results In 110 physician offices in Germany, data from the patient management systems of all patients seen between January 1998 and June 2005 were extracted and analysed (715 644) with current guidelines used for reference. Of those patients, 284 096 (40% of all patients analysed) had one of the following diseases: 157 101 (55% of 284 096) had hypertension, 83 005 (29%) diabetes, 64 205 (23%) coronary artery disease (CAD), 174 787 (62%) hyperlipidaemia, and 136 360 (48%) had more than one of the listed diagnoses. During the last visit, treatment goals were achieved for total and LDL cholesterol in 9 and 29%, respectively, for blood pressure in 28%, and for HbA1c in 36%. Low achievement of treatment goals was also seen in patients with CAD or diabetes. Using the Framingham risk model and the SCORE Deutschland risk charts, 20 and 22% of patients had a high 10-year risk for a primary cardiovascular event and a fatal cardiovascular event, respectively. Achieving treatment goals for all risk factors would significantly reduce the number of high-risk patients.

Conclusion (i) Routinely collected practice data can be used to evaluate quality of care; (ii) 40% of patients in primary care have cardiovascular disease or diabetes; (iii) even in high-risk patients, the majority does not achieve treatment goals; and (iv) achieving the treatment goals would reduce the proportion of high-risk patients from 20 to <5%.

KEYWORDS
Coronary artery disease; Hypertension; Diabetes; Hyperlipidaemia; Risk factors; Primary care; Risk modelling

Introduction
Cardiovascular disease is the leading cause of death worldwide, and elevated LDL-cholesterol (C) levels, hypertension, diabetes, and smoking are key modifiable risk factors.1,2 Published practice guidelines recommend aggressive treatment of individual risk factors and have defined thresholds for the initiation of and goals for treatment.3–10 However, adherence to these recommendations and the success in reaching the treatment goals in primary care are largely unknown.

Aim
Thus, the aim of this study was to evaluate treatment in primary care in Germany in a large patient cohort with cardiovascular disease and/or diabetes. Specific goals were (i) to assess whether information contained in the physician’s patient management system (‘real life’ data) could be retrieved and used to evaluate treatment in primary care, (ii) to determine the percentage of patients achieving treatment goals of current guidelines, and (iii) to calculate both the actual risk score for cardiovascular events based on these data and the hypothetical risk score if treatment goals were achieved for all risk factors.

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Methods

Patients and data extraction/analysis

The details of the technical study procedures have been described elsewhere. Briefly, 110 primary care practices, dominated by general practitioners (70%) and internal medicine (20%), well distributed all over Germany, with (i) one of approximately 20 patient management systems that could be accessed and analysed and (ii) routine electronic documentation of laboratory data and vital signs as described below, were selected for participation in this study. Prior to data transfer, all personal information was eliminated, and data were pooled and queried for patients seen between 1998 and 2005. The database contained the following information for each patient: age, gender, all visit dates, ICD 10 diagnostic codes. The values and dates of measurement for systolic and diastolic blood pressure, total cholesterol (C), LDL-C, HDL-C, triglycerides, HbA1c, respectively, and information regarding smoking were used if available in the patient management system. All patients with either coronary artery disease (CAD) and/or hypertension and/or hyperlipidaemia and/or diabetes (known as cardiovascular risk factors = CRF) and at least one pair of vital or laboratory parameter of interest at two different office visits were included in the analysis. A specific diagnosis was assigned to the patients of the pool database in two ways: patients who either had the appropriate ICD10 code (Table 1) or the following additional measurements/diagnostics were assigned the diagnosis of (i) hypertension (blood pressure values ≥140/90 mmHg or ≥135/85 mmHg in patients with diabetes at ≥2 different occasions); antihypertensive drugs were not used as criteria for the diagnosis of hypertension because they are also used for treatment of other diseases (e.g. congestive heart failure), (ii) diabetes (HbA1c levels ≥6.5% and/or use of antidiabetic medication), (iii) hyperlipidaemia (total cholesterol (C) ≥190 mg/dL and/or use of lipid lowering medication). The diagnosis of CAD was usually based on the ICD 10 coding alone. For each parameter, the first and the last values recorded were selected as the individual first and last visit record, and these were used for comparisons. For analysis, patients were stratified by diagnosis. Missing values were defined as the lack of electronically documented parameters within the patient management systems.

All analyses were performed with SAS 8.2, and results were compared with treatment goals stated in current national and international guidelines as reference values (Table 2). Comparisons of parameters between the first and the last visit were done with the Wilcoxon matched-pairs rank test at the 5% level. For these extremely large samples, however, statistical errors are very small and probably in the magnitude of the effect of other confounding factors. Therefore, statistically significant results have to be interpreted cautiously and in relation to their clinical relevance. For the same reason, no confidence intervals for the estimated percentages are presented in the text. With the present sample sizes, the deviations of the upper and lower limits from the estimated values are less than 0.5% and thus negligible. The study protocol was reviewed and approved by local ethic committee.

**Framingham risk score**

The 10 year risk for a primary cardiovascular event was calculated using the Framingham risk score in patients without known CAD at baseline and with complete documentation of age, gender, diabetes, systolic and diastolic blood pressure, LDL-C, and HDL-C at both the first and the last visit. In patients older than the maximum scope of the Framingham score (74 years), the age for this calculation was set at that age. In addition, the hypothetical risk if treatment goals for risk factors would have been achieved was calculated.

**SCORE-risk scoring system**

For patients without known CAD at baseline and with complete documentation of age, gender, smoking status, systolic blood pressure, and total cholesterol at both the first and the last visit, the 10 year risk for a fatal cardiovascular event was calculated using the SCORE-risk scoring system and the specific risk table for the German population. In patients older than the defined scope of age (65 years), the age for this calculation was set at that age. In addition, the hypothetical risk if treatment goals for risk factors would have been achieved was calculated.

**Results**

Between January 1998 and December 2005, 284,096/715,844 patients (39.7%) with cardiovascular disease and/or diabetes were identified, and these patients with a total number of 10.5 million office visits represent the study population. The patient characteristics are shown in Table 3. 53% of patients were female, the mean age was 56 ± 17 years at the beginning and 61 ± 16 years at the end of the study. The median observation period was 1061 (quartiles 447 and 2513) days, the mean number of visits per patient was 37 (39 for women and 35 for men). There were 157,101 patients (55.3%) with hypertension, 64,205 patients with CAD (22.6%), 83,005 with diabetes (29.2%), and 174,787 patients with hyperlipidaemia (61.5%). There was significant overlap between individual risk factors (Figure 1), 48% of patients had at least one additional risk factor or comorbidity, and 3% had all 4 (Table 1).

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**Table 1** Data extracted from the physician management system

|--------------|-----------------------------------------------|----------------------------------|----------------------------------|------------------|------------|

**Table 2** Treatment goal definitions

<table>
<thead>
<tr>
<th>Parameter</th>
<th>Treatment goal</th>
</tr>
</thead>
<tbody>
<tr>
<td>Total-C</td>
<td>&lt;190 mg/dL (5.9 mmol/L) without CAD or DM</td>
</tr>
<tr>
<td></td>
<td>&lt;175 mg/dL (4.5 mmol/L) CAD or DM</td>
</tr>
<tr>
<td>LDL-C</td>
<td>&lt;160 mg/dL (4.1 mmol/L) 0–1 risk factor&lt;sup&gt;a&lt;/sup&gt;</td>
</tr>
<tr>
<td></td>
<td>&lt;130 mg/dL (3.4 mmol/L) ≥2 risk factors (10 year risk &gt;5%)</td>
</tr>
<tr>
<td></td>
<td>&lt;100 mg/dL (2.6 mmol/L) CAD or DM (10-year risk &gt;20%)</td>
</tr>
<tr>
<td>Blood pressure</td>
<td>&lt;140/90 mmHg without DM</td>
</tr>
<tr>
<td>HbA1c</td>
<td>&lt;6.5%</td>
</tr>
</tbody>
</table>

<sup>a</sup>Major risk factors (exclusive of LDL-C) that modify LDL goals: cigarette smoking, hypertension (BP ≥140/90 or antihypertensive medication), low (<40 mg/dL) HDL-C, family history of premature CAD, age (men ≥45 and women ≥55 years).
Achievement of guideline-defined treatment goals in primary care

During the first office visit, treatment goals for total-C, LDL-C, blood pressure, and HbA1c were achieved in 10, 24, 23, and 31%, respectively, and these numbers were 9, 29, 28, and 36%, respectively, at the last visit (Figure 2A). Low achievement of treatment goals was also seen in high-risk patients (i.e. those with CAD and/or diabetes), 10% and 14% (Figure 2B) of these had total-C and LDL-C levels, respectively, within the desired range at the first visit.

Distribution of values for blood pressure, total-C, LDL-C, and HbA1c

The distribution of systolic blood pressure, total-C, LDL-C, and HbA1c values is shown in Figure 3. In patients with hypertension, there was a large group of patients with grade I hypertension. At the last visit, there was slight overall improvement in patients achieving or being close to the desired treatment goals. In contrast, the majority of patients with hyperlipidaemia had total-C and LDL-C levels significantly above recommended levels, and 46% of patients with diabetes had HbA1c levels ≥7% and 21% had levels ≥8%, and there was only slight improvement of values at the last visit.
Framingham risk score

All parameters required for the calculation of the 10 year risk for a primary cardiovascular event (Framingham risk score)\(^1\) were available in 56 152 patients. Of these, 25 235, 19 653, and 11 264 patients had a low, >10%, and >20% 10 year risk, respectively, for cardiovascular events based on the values during the last office visit (Figure 4A). This would result in a total of 7471 events over 10 years (1369 in patients with low risk, 2624 in the patients with >10% risk, and 3478 in those with >20% risk). In contrast, if the treatment goals for all risk factors had been achieved during the last office visit (Figure 4B), 34 528, 19 047, and 2577 patients would have a low, >10%, and >20% risk, respectively, over the next 10 years. In this case, there would be a total of 5753 events (2156 in patients with low risk, 3030 in the >10% risk, and 567 in the >20% risk group).

SCORE-risk scoring system

All parameters required for the calculation of the 10 year risk for a fatal cardiovascular event\(^13,14\) were available in 70 360 patients. Of these, 54 462 patients had a low and 15 898 had a high 10 year risk for a fatal cardiovascular event based on the values during the last office visit (Figure 5A). This would result in a total of 2366 fatal events over 10 years (1094 in patients with low risk and 1272 in patients with high risk). In contrast, if the treatment goals for all risk factors had been achieved during the last office visit (Figure 5B), 61 551 patients would have a low and 8809 would have a high risk for a fatal event over the next 10 years. In this case, there

Figure 3  Distribution of systolic blood pressure in patients with hypertension, LDL-C, and total-C in patients with hyperlipidaemia, and HbA\(_{1c}\) in patients with diabetes, respectively. Shown are data from the first (red) and last (blue) office visit.

Figure 4  Ten-year risk for a primary cardiovascular event using the Framingham risk score in patients without known CAD. On the left (A), the values measured at the last office visit were used. Shown on the right (B) is the hypothetical risk if treatment goals for all risk factors were achieved. This would result in a significant reduction of patients with high and moderate risk.
would be a total of 1629 fatal events (1095 in patients with low risk and 534 in the high-risk group).

Discussion

Main findings

This study shows several important results. (i) Information contained in the physician data management system can be used to evaluate treatment results in clinical practice, giving a more accurate impression of the real-life situation. (ii) Approximately 40% of patients in primary care were seen for cardiovascular disease or diabetes, and the prevalence of modifiable risk factors was high. (iii) The majority of patients did not achieve guideline-defined target values for any of the risk factors, and large subgroups of patients had substantially higher values as those stated in the guidelines. (iv) Even in high-risk patients (i.e. those with CAD and/or diabetes), treatment goals were not achieved in the majority of patients, and this did not change meaningfully over the study period. Based on the results of the last office visit, (v) 20% of patients had a high (>20%) risk for a primary cardiovascular event. This number would be <5% if guideline-defined treatment goals would have been achieved for all risk factors.

Previous studies

Use of routine data from the physician data management system

This is the first study to show that routinely collected practice data can be used to assess the quality of primary care in patients with cardiovascular disease using the German patient data management systems. At the moment, routinely collected data is still an underused resource. General practice in most countries is highly computerised but there are difficulties in obtaining data and standardising technical infrastructure, and one limitation is the use of "incomplete" datasets and interpreting data collected for one reason in another context. However, improvements in data quality and information technology now allows processing of progressively larger datasets extracted from clinical systems, and there is increasing evidence that routinely collected general practice data is useful to improve quality of care, for health service planning and reimbursement, and for research.15

Cardiovascular disease prevalence/achievement of treatment goals

Both the incidence of cardiovascular disease and diabetes and the lack of achieving guideline-defined treatment goals observed in this study are similar to those observed in previous studies.16–36 The EUROASPIRE II survey showed a similar high prevalence of uncontrolled hyperlipidaemia and hypertension (54 and 59%, respectively).16 Approximately 20% of patients with known CAD had a diagnosis of diabetes in this survey, and the prevalence of concurrent risk factors was high: smoking 17%, obesity 43%, hypertension 57%, and elevated total-C levels 55%. The adverse lifestyle trends observed went along with a similar lack of improvement in blood pressure management and the observation that the majority of patients with CAD did not achieve the cholesterol treatment goals. A recent survey of European primary care physicians also showed that treatment guidelines are incompletely implemented in primary care although the physicians know about the guidelines and agree with them.24 In the Minnesota Heart Survey, the mean prevalence of hypercholesterolemia in 2000–2002 was 54.9% for men and 46.5% for women although lipid lowering drug use significantly increased compared with previous years. In addition, the percentage of patients achieving cholesterol control (defined as a concentration <5.18 mmol/L) was low both for men and women.17

Even in high-risk patients, screening for treatable risk factors is rare (e.g. plasma lipid levels are frequently not determined),25,28 risk factor management is poor in patients receiving treatment, and most patients do not achieve recommended treatment goals for any of the known risk factors,31 and patients with more risk factors are less likely to achieve treatment goals.

As in our study, a high prevalence of uncontrolled hyperlipidaemia in patients with known CAD has been described previously despite widespread use of multiple lipid-lowering agents.19,37 In some of these studies, baseline levels of LDL-C were an independent predictor of achieving target lipid levels.37 In a cross-sectional study in primary care, the prevalence of hypertension was 35%, hyperlipidaemia

Figure 5  Ten-year risk for a fatal primary cardiovascular event using the SCORE Deutschland Risk Charts14 in patients without known CAD. On the left (A), the values measured at the last office visit were used. Shown on the right (B) is the hypothetical risk if treatment goals for all risk factors were achieved. This would result in a significant reduction of patients with high risk.
29%, diabetes 14%, and CHD 12%. Only 11% of all dyslipidemic patients achieved LDL-C treatment goals. In patients with diabetes, HbA1c values \( \geq 7.0\% \) were recorded in 40% and hypertension was present in 45%. \(^{38}\)

In one study in patients with primary hypercholesterolemia starting therapy in clinical practice in Germany,\(^ {19} \) 35% of men and 0.5% of women without manifest atherosclerosis had a high (\( >20\% \)) 10-year coronary heart disease risk using the PROCAM algorithm,\(^ {40} \) and only 7% of the high-risk men and 5% of the high-risk women achieved the LDL-C target goals with treatment. In addition, 65% of men and 72% of women treated for secondary prevention had LDL-C levels \( >4.2 \text{ mmol (100 mg/dL)} \), and after 9 months of statin therapy, only 21% of the men and 17% of women reached the target LDL-C levels.

Patients with only one diagnosis (hyperlipidaemia or hypertension alone) and no concomitant CAD (this were approximately 50% for each risk factor in our study) may still need aggressive treatment,\(^ {41} \) and 20% of patients in our study had high-normal blood pressure which may already be associated with higher risk for cardiovascular disease.\(^ {42,43} \)

The high prevalence of \( >1 \) risk factors in our study is particularly alarming because additive effects on outcome have been suggested.\(^ {44,45} \) Even in high-risk patients, achievement of treatment goals was poor (72% of patients with CAD/diabetes had total C levels above the guideline defined recommendations), and this did not change over the study period (50% of patients with hyperlipidaemia had LDL C levels \( >130 \text{ mg/dL at the last visit} \)).

The reason(s) for not achieving treatment goals remain to be determined and most likely include sub-optimal therapy [under-use of therapy (e.g. antihypertensive drugs, statins), inadequate dose/lack of titration], concern regarding drug side-effects, lack of time, prescribing costs, and patient non-compliance.\(^ {46-48} \)

Risk score

Despite the known limitations in using the Framingham risk score,\(^ {49,50} \) our results suggest that more aggressive risk factor management would have significant influence on outcome in this population where multiple risk factors were common. Using the SCORE Deutschland risk charts\(^ {14} \) to calculate the 10-year risk of fatal cardiovascular disease, very similar results are obtained: based on the results of the last office visit, a high number of patients were at significant risk, and if all treatment goals would have been achieved, the risk for a fatal cardiovascular event would be significantly lower.

Conclusions

Almost 40% of patients in primary care are seen for cardiovascular disease or diabetes, 20% of these have CAD and/or diabetes, and the majority does not achieve treatment goals, even if they are high-risk patients. Even with cautious interpretation of the data, the economic consequences of the observed low adherence to guidelines are most likely immense (e.g. a reduction of the 5-year incidence of major coronary events, coronary revascularization, and stroke by one-fifth is observed per mmol/L LDL-C reduction\(^ {35} \)). Our calculations using both the Framingham risk model\(^ {12} \) and the SCORE risk scoring system\(^ {14} \) suggest that therapy targeted at threshold levels of blood pressure, LDL-C, and glucose would have great impact on reducing cardiovascular disease,\(^ {45} \) and this benefit would most likely not be limited to patients with extremely high levels. Major changes will be required to achieve better implementation of guidelines and their treatment goals. Primary care physicians are in the position to screen and identify high-risk patients and to start appropriate therapy: the majority (\( >75\% \)) of patients with CAD are treated in primary care, and routine practice data can be used to assess achievement of treatment goals and may help to solve (some aspects of) the implementation problem.

Limitations

Data recorded in physician data management systems are inherently incomplete. Thus, ICD coding and additional information available from the database were used to make the diagnosis, and no additional testing was performed to substantiate the diagnosis. However, overall quality of ICD coding was good (e.g. only 10% of the CAD diagnoses were without additional information regarding coronary anatomy). Only the first and the last office visit were compared in order to maximize the time window to observe any treatment effect during the study period, and the dosage of individual drugs, laboratory values, smoking status, and body weight were frequently not completely documented. However, in contrast to controlled prospective studies, this reflects a real-life data documentation with the disadvantage of individual kinds of documentation (electronic and paper documentation of partially external services).

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Conflict of interest. The study was conceived, designed, and coordinated by an investigator-led independent steering committee, members of which represent the authors of the manuscript. The principal funding source had two non-voting members on the steering committee; both are employees of Pfizer Germany. Data analyses and the preparation of the report were done independently of the principal funding source. In addition, no specific drugs manufactured by Pfizer are discussed in the manuscript. The corresponding author had full access to all the data in the study and had final responsibility for the decision to submit for publication.

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References


Clinical vignette

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Left main coronary artery aneurysm revealed by syncopal ventricular tachycardia in a 28-year-old woman

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A 28-year-old woman was referred to our department with a syncopal sustained ventricular tachycardia with right bundle branch morphology. She was diagnosed with a pericarditis when she was 2 years old, and related an episode of palpitations five years ago. After electrical cardioversion of ventricular tachycardia, her 12-lead electrocardiogram revealed a normal sinus rhythm at 70 beats/min without any sign of myocardial ischaemia, no sign for arrhythmogenic right ventricular dysplasia or Brugada disease, or long QT interval. A chest radiograph showed an enlarged cardiac shadow without evidence of congestive heart failure. Transthoracic echocardiography showed an enlarged left ventricle with global hypokinesis, a calculated left ventricular ejection fraction of 40%, and akinesis of inferior and lateral walls. Delayed gadolinium-enhanced cardiac magnetic resonance imaging (Panels A and B) demonstrated hyperenhancement of a large subendocardial area. This area was limited to 50% of the ventricular wall thickness and located in the inferolateral wall at basal and mid-ventricular levels. The enhancement pattern was characteristic of a coronary artery distibution in the circumflex artery territory. On a subsequent coronary angiography (Panels C and D), the angiogram revealed a 12 mm fusiform aneurysm that involved the entire left main coronary artery and extended into the proximal circumflex coronary artery. She was treated with warfarin and aspirin and underwent a radiofrequency catheter ablation for the ventricular tachycardia. She was then scheduled for surgical treatment consisting of an aneurysm exclusion with bypass of both left anterior descending and circumflex arteries.

Left main coronary artery aneurysms are rare lesions, encountered in approximately 0.1% of adult patients who undergo routine coronary angiography. Over 50% of them are of atherosclerotic origin. Other aetiologies include congenital malformations, Kawasaki disease, Marfan and Ehlers-Danlos syndromes, Takayasu arteritis, syphilitic or infectious arteritis, and fibromuscular dysplasia. The aetiology of this case was not elucidated although sequelae of Kawasaki disease could be suspected because of a history of pericarditis in infancy. However, the coronary angiography was not typical of Kawasaki disease, as it showed no other associated abnormality.

The main complication of coronary aneurysms is thrombus formation within the aneurysm leading to distal embolization and myocardial infarction. Treatment still remains controversial as patients can be managed either medically with anticoagulation and antiplatelet therapy, surgically, or percutaneously using a covered stent.