

Is patient self-report an adequate tool for monitoring cardiovascular conditions in patients with hypercholesterolemia?

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ABSTRACT

Background To determine the accuracy of patient self-reports of specific cardiovascular diagnoses and to identify individual patient characteristics that influence the accuracy.

Methods This investigation was conducted as a part of the randomized controlled ORBITAL study. Patients with hypercholesterolemia were enrolled in 1961 primary-care centers all over Germany. Self-reported questionnaire data of 7640 patients were compared with patients' case report forms (CRFs) and medical records on cardiovascular diseases, using κ statistics and binomial logit models.

Results κ values ranged from 0.89 for diabetes to 0.04 for angina. The percentage of overreporting varied from 1% for diabetes to 17% for angina, whereas the percentage of underreporting varied from 8.0% for myocardial infarction to 57% for heart failure. Individual characteristics such as choice of individual general practitioner, male gender and age were associated with the accuracy of self-report data.

Conclusion Since the agreement between patient self-report and CRFs/medical records varies with specific cardiovascular diagnoses in patients with hypercholesterolemia, the adequacy of this tool seems to be limited. However, the authors recommend additional data validation for certain patient groups and consideration of individual patient characteristics associated with over- and underreporting.

Keywords agreement, cardiovascular disease, case report forms, general practitioner information, medical records, orbital study, overreporting, patient self-report, underreporting

Introduction

A major challenge in epidemiological research is ensuring the quality of the raw data generated for analysis. Epidemiological studies and surveys often rely on self-administered questionnaires using patient self-reports to obtain information on the subject. Depending on the specific purpose of the study, the use of patient's self-reports may have several important advantages such as: lower

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costs or less organizational demands as opposed to clinical assessments or medical record extraction.¹ However, patient self-reports have potential shortfalls as well: the accuracy of self-reporters depends on the respondents' knowledge of the relevant information, the ability to recall it and the willingness to report it.²

Although there is extensive literature about agreement of self-report and medical records, several notable problems characterize the majority of these comparisons such as: lack of a nationally representative sample (most studies have been restricted geographically),³ study population (most studies relied on volunteers, persons in good health or elderly people)^{4–6} or small sample size^{6–8} (consequently, the identification of special patient characteristics associated with inaccurate reporting becomes difficult).

The authors are not aware of studies that show the validity of self-report for cardiovascular diseases in a study population with hypercholesterolemia using an appropriate and representative sample size.

Therefore, the objective of our study was to obtain more information on the accuracy of patient-provided data, on cardiovascular conditions compared with case report forms (CRFs; general practitioner information, physical examination and medical records) using the baseline data of the ORBITAL study.⁹

The following questions were addressed:

- (i) To what extent do patient self-reports accurately reflect the presence or absence of cardiovascular diseases when compared with CRFs and medical records in patients with hypercholesterolemia?
- (ii) Do certain individual patient characteristics such as age, gender, education level, body mass index (BMI), health status, frequency of consultations or choice of general practitioner influence the accuracy of self-reports on cardiovascular conditions, when compared with CRFs and medical records in patients with hypercholesterolemia?

Methods

Study design

This secondary analysis was conducted as a part of the ORBITAL project, a randomized, multicenter, open-label, parallel-group study with patients enrolled in 1961 primary-care centers all over Germany between April 2002 and November 2002 (methodology was described in detail by Willich *et al.*⁹ Briefly, male and female patients were eligible for inclusion if they were at least 18 years old and had primary hypercholesterolemia with an indication for treatment according to the Second Joint European Guidelines.¹⁰

Patients qualifying for inclusion were randomized to receive rosuvastatin therapy alone or together with a compliance-enhancing program for 12 months, followed by a 24-month observational period. After a primary-care center enrolled at the most four patients, a monitoring visit was performed at the investigator's site to ensure completeness of data. All participating physicians attended investigators meetings where they were informed of study background and received instructions regarding standardized procedures. The trial was carried out in accordance with the Declaration of Helsinki and Good Clinical Practice. The study protocol was approved by the IRB of the Charité Berlin. Written informed consent was obtained from all patients before study inclusion.

CRFs and medical record

At the time of inclusion, general practitioners at 1961 primary-care centers all over Germany compiled each patient's individual CRF, assessing medical history by a medical interview (lifetime prevalence of cardiovascular disease, history of invasive cardiac procedures in the past and cardiac risk factors over the last 3 months) followed by a physical examination (including vital signs, anthropometric data and fasting blood sample). After study inclusion, an independent monitor performed source data verification (comparison of the data in the CRF with the subject's medical record at the hospital and/or primary-care center, and other records relevant to the study).

Patient self-report

Within 4 weeks after inclusion in the study, patients were required to complete a self-administered questionnaire, to collect information on the following variables: socio-demographics (age, gender, school degree and employment status), health status (lifetime prevalence of cardiovascular disease), history of invasive cardiac procedures in the past and usage of further medical resources (e.g. consultations and frequency of consultations over the last 3 months).

Data management and statistical analyses

Data management of the medical records and patient's self-report data were carried out blinded. All cardiac diseases diagnosed by the general practitioner were coded according to the internationally agreed medical dictionary for regulatory activities (MedDRA 5.0)¹¹ and converted into a yes/no format to make the records comparable with the patient data. Data extraction and coding were performed by the data management team at the Charité, Berlin (Germany). Only patients with both completed patient self-reports and

corresponding CRFs/medical records were eligible for analysis. Statistical analysis was performed using SPSS version 13.0 (SPSS Inc., USA) and STATA/SE 10.0 for Windows (StataCorp LP, USA).

Descriptive analysis was performed for baseline characteristics of the study population using the baseline information on the patient self-report. For clarity, we chose not to calculate sensitivity and specificity, but to present the proportion of underreporters (1-sensitivity) and overreporters (1-specificity). Cohen's κ coefficients were calculated to determine the agreement between self-reported questionnaire data and medical records for dichotomy variables.¹²

Because κ statistics can be strongly affected by imbalances in marginal totals (especially with regard to the high number of true-negative values) and may not provide an accurate reflection of the agreement between patient report and medical records, the Jaccard coefficient (i.e. the percentage of concordant positive results within all positive answers) was also calculated.¹³

For each variable under study, individual cases of over- and underreporting by patients when compared with physicians could be identified by comparing records. We tried to explain these 'outcomes' by using two-level random-effects binomial models with a logit link, taking into account the five fixed explanatory covariates age, gender, BMI, education and health status (number of co-morbidities), and frequency of consultation and the random effect 'individual general practitioner' with the cluster structure caused by the fact that several patients shared the same physician. We modeled over- and underreporting separately, because we assumed that different mechanisms may govern the two types of error and postulated that under certain conditions (e.g. increased age), both types of errors may increase in frequency. The covariates were studied simultaneously and kept in the model even if they were not significant, which resulted in adjusted estimates of odds ratios (ORs) of under- or overreporting that are preferable to raw ORs to avoid masking effects. However, only significant effects are reported in the tables. One of the virtues of a random-effects model is that it allows us to quantify the share of the physician's individuality on the observed under- and overreporting by calculating the variance explained by the random effect (intraclass correlation). A two-sided α level of 0.05 was considered statistically significant.

Results

A total of 8108 patients with hypercholesterolemia were enrolled into the ORBITAL study. Out of those, 7640 patients (94%) were eligible and therefore included in this secondary analysis. The average age was 60 with a standard

Table 1 Baseline characteristics of the study population

Variables ^a	Total, n = 7640 (%)	Men, n = 4271 (%)	Women, n = 3369 (%)
Socio-demographics			
Age (years, mean \pm SD)	61 \pm 10	60 \pm 10	64 \pm 10
Questionnaires were filled out (%)			
By the patient without any assistance	5546 (73)	3175 (74)	2371 (70)
With assistance of a close person	1768 (23)	936 (22)	832 (25)
Of a close person only	158 (2)	73 (2)	85 (3)
Missing	168 (2)	87 (2)	87 (2)
Education > 10 years (%)	1230 (16)	911 (21)	319 (10)
Single and living alone (%)	1493 (20)	494 (12)	999 (30)
Actively employed (%)	2432 (32)	1747 (41)	685 (20)
Type of employment ^a (%)			
Mainly physical	4276 (56)	2402 (56)	1874 (56)
Mainly sitting	3078 (40)	1795 (42)	1283 (38)
Never worked	65 (1)	1 (0)	64 (2)
Missing	221 (3)	73 (2)	148 (4)

SD, standard deviation.

^aPercentages may not add up due to rounding.

deviation (SD) of \pm 10 years for men (56%) and 64 with an SD of \pm 10 years for women (44%). Socio-demographic data of patients at baseline are given in Table 1.

Frequencies of over-/underreporting for different types of cardiovascular disease

The agreement between patients self-reports and CRFs/medical records for cardiovascular disease are presented in Table 2. Owing to missing values, the totals do not always equal 7640. Therefore, the response rate varied from 91% for myocardial infarction (MI) to 76% for family history of MI. The total agreement ranged from 96% for diabetes and stroke to 83% for angina pectoris. As a measure of inter-rater reliability, κ ranged from 0.89 for diabetes to 0.04 for angina pectoris. The Jaccard values ranged from 84% for diabetes to 3% for angina pectoris. The Jaccard values showed a likewise high level of agreement compared with κ values. The percentage of overreporters varied from 1% for diabetes to 17% for angina pectoris, whereas the percentage of underreporters ranged from 8% for MI to 57% for heart failure. Systematic differences between patient self-report and CRF (tested using the McNemar test) showed significant effects for all conditions and procedures ($P < 0.001$).

Table 2 Comparison between patient self-report and CRF/medical record regarding history of cardiovascular diagnoses among study participants

	N	Prevalence physician, n (%)	Prevalence patient, n (%)	Agreement, n (%)	Jaccard (%) (95% CI low/high)	κ (95% CI low/high)	κ P-value	Underreporting 1-sensitivity, n (%)	Overreporting 1-specificity, n (%)
Family history of myocardial infarction	5777	1255 (22)	1135 (20)	4967 (86)	49 (47/52)	0.57 (0.54/0.61)	<0.001	465 (37)	345 (8)
Myocardial Infarction	6922	576 (8)	1186 (17)	6216 (90)	43 (40/46)	0.55 (0.51/0.59)	<0.001	48 (8)	658 (10)
Angina pectoris	6406	65 (1)	1097 (17)	5310 (83)	3 (2/4)	0.04 (-0.01/0.09)	0.153	32 (49)	1064 (17)
Stroke	6728	189 (3)	259 (4)	6486 (96)	30 (25/35)	0.44 (0.35/0.53)	<0.001	86 (46)	156 (2)
Hypertension	6877	4248 (62)	3870 (56)	5827 (85)	77 (76/78)	0.69 (0.66/0.71)	<0.001	714 (17)	336 (13)
Diabetes	6786	1558 (23)	1368 (20)	6534 (96)	84 (82/86)	0.89 (0.86/0.92)	<0.001	221 (14)	31 (1)
Cardiac arrhythmias	6312	106 (2)	447 (7)	5935 (94)	19 (16/23)	0.3 (0.22/0.38)	<0.001	18 (17)	359 (6)
Heart failure	6337	161 (3)	277 (4)	6037 (95)	19 (15/23)	0.29 (0.20/0.38)	<0.001	92 (57)	208 (3)
History of peripheral artery disease	6275	421 (7)	615 (10)	5669 (90)	26 (23/29)	0.36 (0.31/0.42)	<0.001	206 (49)	400 (7)

Factors associated with over- and underreporting

Table 3 presents the factors associated with over- and/or underreporting. Males were more likely than females to overreport all examined conditions except for diabetes significantly: MI (OR, 2.8), stroke (OR, 1.4), hypertension (OR, 1.5) and cardiac arrhythmias (OR, 1.7). Increasing age was associated with overreporting MI (OR, 1.2), stroke (OR, 1.2), hypertension (OR, 0.9) and cardiac arrhythmia (OR, 1.4), and with underreporting hypertension (OR, 1.3). Patients with increased BMI showed less overreporting for the conditions MI and hypertension. Higher education decreased the number of underreporting in patients with hypertension (OR, 0.9). In patients with a more positive health status (less co-morbidities), the rate of overreporting decreased for all conditions (OR, 0.9) except for diabetes. The choice of physician played a major role in over- and underreporting of all diagnoses (8–43%).

Discussion

Main findings of this study

This study focuses on a high-risk cohort with hypercholesterolemia. One might suppose that this cardiac risk group exhibits a high awareness of the personal cardiovascular disease profile yielding to high accuracy in self-report data. However, the results show only partial evidence for this presumption.

Using the classification system developed by Landis,¹² our study results showed excellent and substantial agreement for patient self-report and CRF/medical record regarding diabetes and hypertension. The κ values of 0.89 for diabetes and 0.69 for hypertension were the highest values among examined diseases. Owing to high prevalence rates of diabetes and hypertension and educational efforts in Germany, it is more likely that the public awareness is higher than in other relevant diseases such as cardiac arrhythmias or heart failure. Therefore, the patients might be more alert. Furthermore, standardized therapeutic procedures such as disease management programs or medications advised by the physician might increase the consciousness for the disease as well and may also increase the likelihood of accurate reports. Several studies have shown similar results.^{5,14–20} Colditz *et al.*²¹ found even higher agreement of almost 100% in a cohort of nurses. However, accuracy is strongly related to the study population polled (here: health professionals). In our study, we selected patients with hypercholesterolemia and speculate that the agreement is high, because being in a high-risk group for coronary heart disease (CHD) may lead to higher awareness for coronary risk factors such as diabetes and hypertension.

Since MI and stroke are often accompanied by hospitalization and physical handicaps, we expected high awareness and accuracy of self-reports as well. However, our study results showed only moderate agreement for both MI and stroke.

Table 3 Factors associated with overreporting and/or underreporting of some self-reported cardiovascular diagnoses among study participants

	Male gender versus female gender	Age per 10 years increase	BMI per 1 U increase	Education per increase in educational level (out of 6)	Health status of co-morbidities (out of 7)	Frequency of consultations per visit	Individual general practitioner (ICC in %)
MI							
Underreporting	1.16 (0.53–2.55) ^a (<i>P</i> = 0.71)	1.29 (0.87–1.92) (<i>P</i> = 0.21)	0.99 (0.91–1.08) (<i>P</i> = 0.80)	1.02 (0.72–1.45) (<i>P</i> = 0.91)	1.14 (0.80–1.61) (<i>P</i> = 0.47)	1.09 (1.05–1.14) (<i>P</i> < 0.001)	43 (<i>P</i> = 0.01)
Overreporting	2.77 (2.25–3.39) (<i>P</i> < 0.001)	1.19 (1.08–1.30) (<i>P</i> < 0.001)	0.97 (0.95–1.00) (<i>P</i> = 0.02)	0.95 (0.87–1.04) (<i>P</i> = 0.25)	0.87 (0.80–0.94) (<i>P</i> = 0.001)	1.02 (1.01–1.04) (<i>P</i> = 0.001)	29 (<i>P</i> < 0.001)
Stroke							
Underreporting	2.44 (0.80–7.44) (<i>P</i> = 0.12)	1.69 (0.96–2.97) (<i>P</i> = 0.07)	0.94 (0.82–1.08) (<i>P</i> = 0.37)	0.73 (0.40–1.33) (<i>P</i> = 0.31)	0.74 (0.47–1.15) (<i>P</i> = 0.18)	1.00 (0.93–1.08) (<i>P</i> = 0.91)	40 (<i>P</i> = 0.08)
Overreporting	1.41 (1.10–1.81) (<i>P</i> = 0.007)	1.19 (1.06–1.35) (<i>P</i> = 0.004)	1.00 (0.98–1.03) (<i>P</i> = 0.76)	0.98 (0.88–1.09) (<i>P</i> = 0.69)	0.88 (0.79–0.99) (<i>P</i> = 0.03)	1.02 (1.00–1.03) (0.09)	19 (<i>P</i> < 0.001)
Hypertension							
Underreporting	1.18 (0.99–1.40) (<i>P</i> = 0.06)	1.27 (1.17–1.39) (<i>P</i> < 0.001)	1.00 (0.98–1.02) (<i>P</i> = 0.82)	0.86 (0.79–0.93) (<i>P</i> < 0.001)	1.01 (0.94–1.09) (<i>P</i> = 0.74)	0.99 (0.97–1.00) (<i>P</i> = 0.10)	8 (<i>P</i> = 0.004)
Overreporting	1.52 (1.24–1.87) (<i>P</i> < 0.001)	0.89 (0.81–0.97) (<i>P</i> = 0.01)	0.97 (0.95–0.99) (<i>P</i> = 0.01)	1.05 (0.96–1.14) (<i>P</i> = 0.26)	0.90 (0.83–0.98) (<i>P</i> = 0.02)	1.01 (1.00–1.03) (<i>P</i> = 0.06)	16 (<i>P</i> < 0.001)
Diabetes							
Underreporting	0.95 (0.71–1.26) (<i>P</i> = 0.72)	1.11 (0.96–1.28) (<i>P</i> = 0.16)	1.06 (1.03–1.09) (<i>P</i> < 0.001)	0.95 (0.83–1.08) (<i>P</i> = 0.43)	0.99 (0.88–1.13) (<i>P</i> = 0.93)	0.98 (0.96–1.01) (<i>P</i> = 0.20)	18 (<i>P</i> = 0.001)
Overreporting	1.24 (0.93–1.66) (<i>P</i> = 0.15)	1.07 (0.93–1.22) (<i>P</i> = 0.36)	1.04 (1.01–1.07) (<i>P</i> = 0.02)	1.06 (0.94–1.20) (<i>P</i> = 0.37)	1.05 (0.92–1.19) (<i>P</i> = 0.49)	0.99 (0.97–1.02) (<i>P</i> = 0.64)	22 (<i>P</i> < 0.001)
Cardiac arrhythmias							
Underreporting	0.74 (0.39–1.40) (<i>P</i> = 0.36)	0.96 (0.71–1.30) (<i>P</i> = 0.81)	1.00 (0.93–1.07) (<i>P</i> = 0.91)	1.02 (0.77–1.36) (<i>P</i> = 0.88)	1.06 (0.80–1.42) (<i>P</i> = 0.67)	1.01 (1.00–1.06) (<i>P</i> = 0.59)	+26 (<i>P</i> = 0.18)
Overreporting	1.26 (1.09–1.47) (<i>P</i> = 0.002)	1.44 (1.33–1.55) (<i>P</i> < 0.001)	0.99 (0.97–1.01) (<i>P</i> = 0.27)	1.07 (1.01–1.15) (<i>P</i> = 0.03)	0.77 (0.72–0.82) (<i>P</i> < 0.001)	1.02 (1.01–1.04) (<i>P</i> < 0.001)	14 (<i>P</i> < 0.001)

Significant results (*P* < 0.05) are in bold. The intraclass correlations indicate the percentage of total variation due to the physician (as opposed to the patient). MI, myocardial infarction; ICC, intraclass correlation coefficient. The variable 'health status' was assessed by calculating the number of co-morbidities. The lower the total numbers of conditions, the higher the health status.

^aOdds ratio (95% confidence interval low to high) = OR (95% CI low–high).

Inaccuracies might have several reasons, e.g. due to misclassification of diagnoses: Bergmann *et al.* found that patients used the term 'MI' to describe coronary artery disease, which resulted in 10% overreporting.^{21–24} Similarly, Bots *et al.*²⁵ found that patients reported 'transient ischemic attack' as 'stroke'. These misclassifications point to the need for unambiguous wording and explanations in the questionnaires to ensure validity. However, it was conspicuous in this study that only 2% of patients overreported but 46% of the patients underreported their stroke. The authors suppose that besides knowledge and lack of awareness, hiding or repressing a stroke might be a major reason for the high number of underreporting especially among male patients (odds for underreporting yielded to 2.4). Kriegsman *et al.* found an association between male gender and underreporting too. He explained the tendency of underreporting in male patients with MI with the denial of a serious chronic disease, whereas female patients admit the presence of symptoms and complaints more easily.⁵

Furthermore, we observed fair to poor agreement for history of peripheral artery disease, heart failure, cardiac arrhythmia and angina pectoris with high numbers of underreporting (49–57%) of these self-reported coronary diseases. Several reasons may affect the validity: either the patients tend to misclassify the symptoms shared with other diseases, they are not informed about the specific type of heart disease (information bias) or they simply forget to report because they are not aware of the disease (memory bias).

To be able to answer the question whether self-report is an adequate tool for monitoring cardiovascular diseases, it is important to take into account that self-report accuracy is associated with some factors and individual characteristics. The results of the binomial logit model showed that the variable 'individual general practitioner' explains 16–29% of overreporting and 8–43% of underreporting overall. This factor influenced the accuracy of almost all self-reported conditions significantly. Inaccuracies through underreporting in patients with MI and stroke are explained between 43% and 40% by 'individual general practitioner'. This can be interpreted in different ways: (i) the covariate emphasizes the importance of the relationship between patient and physician, both with regard to therapeutic effects and accuracy of data collected, (ii) some physicians are more likely to inform patients adequately about diagnoses, (iii) the findings reflect inaccuracies in the CRF. To minimize inaccuracies in the CRF, in our study, all patients had a physical examination and blood tests, and additionally data verification was done.

In our study cohort, overall overreporting was less frequent (1–17%) than underreporting (8–57%). The covariates 'male gender' and 'age' significantly influenced the odds

of underreporting stroke by 2.4 and 1.7. Goldman *et al.*² attributed this finding not only to memory problems among older respondents, but also to increased exposure to screening procedures without receiving accurate information about the results leading to misclassification. In contrast, St Sauver *et al.*²⁶ postulated that older patients may be more aware of their health status because of their longer period of contact with medical care. However, further research is needed to judge the real influence of age on accuracy in patients with hypercholesterolemia.

What is already known on this topic?

The reported accuracy of self-reported diagnoses is inconsistent in the literature and raises some questions, for example, on: representativeness (only few validation studies have been based on nationally representative studies),³ appropriate study sample size (many validation studies have been based on small samples only),^{6–8} different study cohorts asked (volunteers,^{14,26,27} persons in good health,⁸ health professionals²³ and elderly population).^{5,19}

Furthermore, a literature review revealed a substantial variability from one study to another in the reporting rates for disorders depending on three types of factors: the choice of reference data for the analysis, the methods used for self-reported collection, and some individual and disorder-related characteristics.^{4,5,22,28–31}

What this study adds

Although large numbers of literatures about the accuracy of self-reported health information exist, the results are inconsistent and fragmentary.

High-risk patients with hypercholesterolemia often have an already complex medical history with many co-morbid diseases. The authors are not aware of studies that show the validity of self-report in these patients. Therefore, the objectives of this study were to obtain more information on the accuracy of patient-provided data in this population using representative data with an appropriate sample size of patients from the ORBITAL study.⁹ The high agreement for diabetes and hypertension supports the conclusion that certain self-reported diagnoses are highly accurate, whereas the low agreement for cardiac arrhythmia, heart failure and peripheral artery disease suggests that patient self-reports are unreliable.

Our study underscores the potential limitations of patient self-reports, particularly for diseases with less individual and public awareness, less monitoring and/or no standardized therapeutic procedure required. Identification of patients who are not in agreement with CRFs and/or medical

record may represent patients who are not aware of their clinical diagnosis and may be targets for educational interventions.

The binomial model with a logit link revealed several factors, such as ‘choice of individual general practitioner’, ‘male gender’ and ‘age’, associated with over-/underreporting. These individual characteristics might improve the validity of data when included in the analysis and should be particularly taken into consideration when epidemiological studies are interpreted.

Limitations of this study

This study was conducted in 1,961 primary-care centers all over Germany; therefore, the study can be considered as broadly representative for Germany. However, since the study was restricted to patients with hypercholesterolemia, the results cannot be generalized to the whole population.

Patients with hypercholesterolemia may have a broad spectrum of risk profile and complex medical history (e.g. elevated low-density lipoprotein cholesterol with or without diagnosis of CHD and with or without presence of diabetes). In this analysis, we did not adjust for risk strata.

The data obtained were asking for the lifetime prevalence. Unfortunately, we did not ask for the point in time when an event or diagnosis occurred; therefore, we were not able to analyze some kind of ‘memory bias’.

Another limitation of our study is the assessment of validity. In this study, we compared the patient self-reports with data from the CRFs. Although the CRFs included different medical sources and additional source data verification was performed, it cannot be considered gold standard.³² There is evidence that medical records are often incomplete, particularly for persons who are under the care of several doctors.³³

The differences in wording between patients’ questionnaires and CRFs might have affected the accuracy of the self-report. Although the patient questionnaire relied primarily on closed questions, the survey employed to collect data from the CRFs relied on open questions (see Appendix).

Conclusion

Since the agreement between patient self-report and CRFs/medical records varies with specific cardiovascular diagnoses and procedures in patients with hypercholesterolemia, the adequacy of this tool seems to be limited. The authors recommend using different data sources in addition to patient self-reports, such as medical records or physical examination, to ensure validity for research. Furthermore, educational support for certain patient groups (e.g. elderly, men) might be helpful if self-report was being used.

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Appendix

Case report form	Patient self report
Are there present or past relevant diseases or diseases requiring medical treatment (not hypercholesterolemia) (free text)	Has a doctor ever diagnosed you with...? <ul style="list-style-type: none"> • Myocardial infarction (yes/no/don't know) • Angina pectoris (yes/no/don't know) • Stroke (yes/no/don't know) • Hypertension (yes/no/don't know) • Diabetes (yes/no/don't know) • Cardiac arrhythmias (yes/no/don't know) • Heart failure (yes/no/don't know) • Peripheral artery disease (yes/no/don't know)

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