

# Adequacy of reporting monitoring regimens of risk factors for cardiovascular disease in clinical guidelines: systematic review

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## ABSTRACT

**Objective** To assess the reporting of monitoring recommendations in guidelines on the prevention and treatment of cardiovascular disease.

**Data sources** Medline, Trip database, National Guideline Clearinghouse, and databases containing guidelines published from January 2002 to February 2010.

**Data selection** Three major risk factors for cardiovascular disease: cholesterol level, smoking, and hypertension. The primary outcome was the frequency with which the guidelines dealt with monitoring of risk factors. Secondary outcomes were completeness of monitoring recommendations, defined by the presence of what to monitor, when to monitor, what to do if the targets or variables were not met, and the reported level or strength of the evidence.

**Results** 117 guidelines were identified, 84 (72%) of which contained a section on lipids. Of those guidelines with a section on lipids, 53% (n=44) provided no information or specific recommendations on what to monitor, 51% (n=43) provided no information on when to monitor, and 64% (n=54) provided no guidance on what to do if the target was out of range. Guidelines for hypertension (n=79) and smoking (n=65) were little better, with 63% (n=50) and 54% (n=35), respectively, providing no recommendation for what to monitor. The number of guidelines that explicitly referenced the level of evidence for monitoring was low, with most of the recommendations based on weak levels of evidence.

**Conclusion** Many guidelines for cardiovascular disease do not report clearly what to monitor and what to do if a change is detected. If no evidence is available to support a specific monitoring schedule, this should be explicit in the guideline, with a description of the new research that would fill the gap.

## INTRODUCTION

One of the most common consultations in healthcare is for the management of cardiovascular disease and subsequent monitoring. Information derived from monitoring drives changes in therapy, clinical workload,

and sometimes prognosis. Although initiatives to improve the quality of reporting in healthcare research focus on validity, presentation of results, and treatment decisions,<sup>1</sup> less attention has been given to the description and accuracy of the monitoring processes that underpin routine clinical practice for the risk management of cardiovascular disease.

Apart from age and sex, three modifiable risk factors—smoking, blood pressure, and cholesterol level—make a substantial contribution to the risk of cardiovascular disease, with high levels accounting for 80% of all cases of premature coronary heart disease in high income countries.<sup>2,3</sup> Although guidelines often report the timing interval for screening people at low risk of coronary disease,<sup>4</sup> in our clinical practice we have difficulty delineating the actions required during follow-up of those at increased risk. For example, most lipid management guidelines clearly state the number and interpretation of initial measurements but are less specific (and in some cases discordant) about the subsequent monitoring decisions and actions to be taken in clinical practice.<sup>5</sup>

A better understanding of monitoring processes for cardiovascular disease could impact substantially on clinical decisions and overall costs to the healthcare system. For example, lipid panels were the third highest contributors to the growth in tests by Medicare between 2000 and 2004.<sup>6</sup> Clinical guidelines aim to raise the overall quality of care by standardising the decision making process; however, no systematic examination has been done of the reporting of monitoring recommendations within such guidelines. Yet they form a substantial driver of workload in healthcare. To understand if this basic need for knowledge is being met by current guidelines, we undertook a systematic review of the reporting of monitoring strategies in cardiovascular disease prevention guidelines for three major risk factors—cholesterol level, smoking, and hypertension—determining whether the guidelines reported what to monitor, how frequently to

monitor, and what to do if the variable index was out of range.

## METHODS

We included published guidelines tackling the prevention or treatment of three risk factors for cardiovascular disease: dyslipidaemia, hypertension, and tobacco consumption. We also considered guidelines including the three risk factors developed for the following specific disease areas: diabetes, chronic kidney disease, hypertension, dyslipidaemia, smoking, general practice, surgery, obesity, infertility, screening in adults, and HIV. We restricted the search to English language guidelines published or updated between January 2002 and February 2010. Where more than one version of the same guideline was found we included only the up to date version. We excluded guidelines on cardiovascular disease in pregnant or paediatric populations.

### Information source

We searched Medline using the strategy (“Cardiovascular Diseases/prevention and control” OR “Cardiovascular Diseases/therapy”) AND (“Hypertension” OR “Dyslipidemias” OR “Tobacco Use Cessation”) limiting to Practice Guideline [publication type] and English language articles. We supplemented this by searching the Trip database and the databases of the National Guideline Clearinghouse. We also searched several databases or websites that produced more than one guideline (see web extra appendix 1 for the full search strategy). Two reviewers (DB and IM) independently assessed all abstracts for potential eligibility, with discrepancies resolved by consensus.

### Types of intervention and outcomes

For the purposes of this review we defined monitoring as the periodic measurement of a chronic or recurrent condition.<sup>7</sup> We considered two forms of monitoring: before treatment, as part of recommendations regarding screening, because treatment should not start until sufficient measurements for a firm baseline have been obtained, and during treatment, because once the target is achieved the objective of monitoring is to ensure that risk factors stay within reasonable limits.

The primary outcome was to identify the extent to which monitoring was tackled within the guidelines. The secondary outcome was the completeness of monitoring recommendations, defined by the presence of three components: a specific target or variable to monitor, the frequency with which the specific target should be monitored, and changes to consider if the monitored targets or variables were not met. In guidelines that reported specific time intervals for monitoring we also report the specific statement and the level or presence of evidence underpinning the recommendations (see web extra appendix 2).

### Data collection and analysis

Two reviewers (DB and IM) independently extracted data from included guidelines on the year of publication,

country or region, principal disease, whether the guideline dealt with primary or secondary prevention, the length of the guideline, the presence of a specific section dealing with risk factors, and information about monitoring (see web extra appendix 3). Information was also extracted on whether there was a definitive target or variable to monitor, when or how often it should be monitored, and what to do if the recommended target had not been met (see web extra appendix 4 for the definition used to characterise the guidelines). The inter-rater reliability (joint probability of agreement—that is, number of times each rating was assigned by each rater, divided by the total number of ratings) was 0.81. Any discrepancies were resolved by consensus and a common, single dataset was established.

After the initial analysis and results were available, two authors (DB and CH) independently identified guidelines produced by a national or international initiative, or developed by a guideline organisation or programme with high output. We then carried out a retrospective subgroup analysis of these guidelines to test whether our results differed when looking only at what might be expected to be “higher quality” guidelines.

## RESULTS

Overall, 874 abstracts were screened, including 122 guidelines published or updated between 2002 and February 2010 on the prevention and treatment of cardiovascular disease. Five were excluded because the full text could not be accessed. Data were extracted from the remaining 117 guidelines, of which 90 (77%) were either a product of a national or international initiative or developed by a guideline organisation with high output (see web extra appendix 5 for the full reference list of guidelines). All results presented were broadly similar between this subset of guidelines and those produced outside of a national or international initiative or a guideline organisation.

In total, 84 of 117 (72%) guidelines contained a section on lipids, and of these 63% (n=53) mentioned monitoring (table). Fifty three per cent (n=44) provided no information or no specific recommendations (that is, those that would be useful in clinical practice) on what to monitor, 51% (n=43) provided no information on when to monitor, and 64% (n=54) provided no guidance on what to do if the target was out of range (table).

In guidelines that report on when to monitor for lipids, the information reported differed greatly. For example, some guidelines were vague: “lipids should be checked regularly,”<sup>8</sup> or “at regular intervals,”<sup>9</sup> whereas others compounded the confusion: “risk factors assessment should be undertaken somewhere between one to three years,”<sup>10</sup> “every three to five years in all patients,”<sup>11</sup> “every five years,” or “every one or two years after middle age.”<sup>12</sup> In addition, guidelines that reported individualised advice for different categories of risk were rare.<sup>12 13</sup>

Seventy nine of 117 (68%) guidelines contained a section on hypertension, and about half of these

## Proportion of guidelines dealing with management of risk factors for cardiovascular disease, and completeness of monitoring recommendation

Risk factor	No (%) with section on risk factor	No (%) including monitoring	No (%) with section on management	Completeness of monitoring recommendation								
				What to monitor			When to monitor			What to do if target is out of range		
				Not reported	Non-specific*	Specific	Not reported	Non-specific*	Specific	Not reported	Non-specific*	Specific
Lipids	84 (72)	53 (63)	34 (40)	31†	13	40	31†	12	41	31	23	30
Hypertension	79 (68)	40 (51)	26 (32)	39	11	29	39	12	28	39	16	24
Smoking	65 (55)	37 (57)	19 (29)	35	–	30	28	17	20	28	14	23

\*Not useful in practice.

†44 guidelines provided no information or non-specific information.

(n=40) mentioned monitoring (table). Sixty three per cent (n=50) provided no information or no specific recommendations for what to monitor, 64% (n=51) for when to monitor, and 69% (n=55) for what to do if the target was out of range (table).

The monitoring of hypertension is an example of the confusion caused by discordant information in different guidelines. The duration for monitoring varied, with clinicians being able to choose among: every three years,<sup>14</sup> at least every two years,<sup>15</sup> at least annually,<sup>16</sup> every visit and at least every six months,<sup>17</sup> each healthcare encounter,<sup>18</sup> and as needed,<sup>18</sup> or simply “monitor blood pressure.”<sup>19</sup>

Sixty five of 117 (56%) contained a section on smoking, and of these 57% (n=37) mentioned monitoring (table). Fifty four per cent (n=35) provided no information or no specific (not useful in clinical practice) recommendations for what to monitor, 69% (n=45) for when to monitor, and 65% (n=42) for what to do if the target was out of range (table).

For smoking, the findings were less than ideal, as less than a third reported when to monitor, and often information was missing or was general—for example, “follow up should be incorporated as needed,”<sup>20</sup> every opportunity,<sup>19</sup> “every visit,”<sup>21</sup> or “check smoking status annually.”<sup>22</sup>

Of the 41 guidelines reporting specific time intervals for lipid monitoring, 66% (n=27) did not explicitly reference the evidence or the level of evidence used for these recommendations. Two of 14 reported a B level of evidence (controlled trials or no randomisation), and 12 of 14 were based on weak levels of evidence (non-analytical study or expert opinion). Seventeen of 28 (61%) guidelines reporting specific time intervals for monitoring hypertension did not provide explicit reference for the associated evidence or the level of evidence. All 11 reporting a level of evidence were based on consensus or expert opinion, with eight based on one publication.<sup>23</sup> Sixteen of 20 (80%) guidelines reporting specific time intervals for monitoring of smoking cessation did not explicitly reference the evidence or the level of evidence for these recommendations.

## DISCUSSION

More than half of the guidelines in our sample did not deal with the monitoring of one or more of the main

risk factors for cardiovascular disease. Guidelines with a section on lipids or hypertension in which a specific paragraph on monitoring was present led to more frequent specific recommendations that would be useful in clinical practice. However, guidelines were often confusing and contradictory for monitoring recommendations.

It was rare to find a clear description of the monitoring phase in any guideline that would help clinicians to apply the recommendations clearly in clinical practice. In particular, the time intervals reported were often broad, with a wide margin of uncertainty. Time intervals for monitoring risk factors varied widely across the guidelines and even within the same guideline. Only a few guidelines offered different monitoring indications for those at low, intermediate, or high risk of cardiovascular disease.

Most of the guidelines did not explicitly reference evidence or the level of evidence underpinning the monitoring recommendations about “when to monitor.” The vast majority that did reference evidence were based on consensus, expert opinion, or weak levels of evidence. This is likely to lead to uncertainty and confusion about when to monitor. Only a few guidelines declared that there was no evidence for the best strategy of monitoring. We believe this lack of evidence leads to wide variation in monitoring in clinical practice.

## Limitations of the study

Our study has several limitations. Our main interest was on adequacy and completeness of information on monitoring so we did not carry out a formal quality evaluation of the guidelines by, for example, using the appraisal of guidelines research and evaluation (AGREE) instrument. The first reason was pragmatic: doctors rarely (if ever) apply such evaluation tools when using guidelines in their clinical practice. Furthermore, the checklist for appraisal of guidelines research and evaluation in particular considers the whole guideline and is not intended for individual recommendations.<sup>24</sup> However, we did score guidelines based on whether they were the product of a national or international initiative, or developed by a guideline organisation or programme with high output, which has previously been shown to be a marker of high quality.<sup>25</sup> A subgroup analysis of these guidelines

### WHAT IS ALREADY KNOWN ON THIS TOPIC

Monitoring regimens for cardiovascular disease (CVD) risk factors (lipid levels, hypertension, and smoking) could impact substantially on patients' outcomes, clinical decisions, and healthcare costs

Clinical guidelines aim to raise the overall quality of care by using best evidence to standardise the decision making process on diagnosis, management, and treatment

Most CVD management guidelines deal poorly with monitoring and no systematic examination has been done of monitoring recommendations in clinical practice guidelines

### WHAT THIS STUDY ADDS

Only a fifth (23/117) of English language guidelines published or updated between 2002 and February 2009 dealt with monitoring of all three risk factors, and one or more risk factors was missing from more than half the guidelines

The monitoring recommendations in different guidelines were often confusing and contradictory

It was rare to find a clear description of the monitoring phase in any guideline that would help clinicians to apply the recommendations directly in clinical practice

showed similar results to the initial analysis, therefore failing to explain the problem by variability in quality between guidelines. We selected guidelines produced in Western countries because the effect of these risk factors is consistent in men and women, across different geographical regions, and by ethnic group.<sup>2</sup> We limited our eligibility criteria to guidelines published in English, but the broad sample we found meant that the results of the review covered mainly high income countries.

#### Implications for practice and for the development of guidelines

Improving the monitoring sections in guidelines on risk factors for cardiovascular disease could greatly improve the coordination of monitoring in clinical practice. Moreover, adequately stratifying the monitoring recommendation by individual risk should also substantially aid practice. Guideline developers should describe monitoring in a separate section for risk factors that require intervention and monitoring. When a monitoring process is described, this should include clear reporting of what to monitor, when, and what to do if something changes; along with clear referencing of the evidence sources and a comment on the strength of this evidence. If insufficient evidence is available to support a specific monitoring schedule, this lack of evidence should be declared explicitly, with a description of the new research that would fill the gap.

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**Competing interests:** All authors have completed the Unified Competing Interest form at [www.icmje.org/coi\\_disclosure.pdf](http://www.icmje.org/coi_disclosure.pdf) (available on request from the corresponding author) and declare: no support from any organisation for the submitted work; no financial relationships with any organisations that might have an interest in the submitted work in the

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**Ethical approval:** Not required.

**Data sharing:** The full dataset is available from the corresponding author at [carl.heneghan@dphpc.ox.ac.uk](mailto:carl.heneghan@dphpc.ox.ac.uk).

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