

# Is population coronary heart disease risk screening justified? A discussion of the National Service Framework for coronary heart disease (Standard 4)

Andrew Rouse and Peymané Adab

## SUMMARY

*Standard 4 of the National Service Framework (NSF) for coronary heart disease (CHD) describes population cardiovascular risk screening at primary care level. General practitioners (GPs) are expected to deliver this standard and have their performance monitored as part of their clinical governance programme. Although CHD is an important preventable health problem in the United Kingdom (UK), the effectiveness of primary prevention screening programmes are minimal, even within clinical trial settings, and their cost-effectiveness is not clear. The National Screening Committee has identified clear standards for establishing a screening programme in the UK and the activities described in Standard 4 do not fulfil many of these criteria. Specifically, there are no plans for central organisation and co-ordination, no agreed quality assurance standards, and no uniform system for performance management. The clinical, social, and ethical acceptability of the interventions mandated have not been established, and GPs are left to consider how to redirect resources to achieve the standard. We argue that the benefits of population cardiovascular screening must be established through properly conducted trials and, if a programme is introduced, adequate resources and management structures must first be identified.*

**Keywords:** risk screening; coronary heart disease; risk factors.

## Introduction

THE National Service Framework (NSF) for coronary heart disease (CHD) purports to establish clear standards for the prevention and treatment of CHD that will lead to major improvements in quality and access.<sup>1</sup> These are worthy objectives, particularly as CHD is a major cause of morbidity and mortality in the United Kingdom (UK). The NSF is part of the quality framework within the government's modernisation programme and is intended to specify effective interventions and models of care. There is an expectation that standards will be delivered and monitored, and as such, the NSF is more than a mere set of guidelines.<sup>2</sup>

General practitioners (GPs) are required to lead and deliver on two standards in the NSF; namely, Standards 3 and 4. We believe that Standard 4 advocates proactive practice-based CHD risk factor screening, and argue that without considering the accepted principles of screening, it is likely to be a futile and costly exercise.

## Screening: 'benefit or bane'?

Standard 4 of the NSF for CHD states:

*'General practitioners and primary healthcare teams should identify all people at significant risk of cardiovascular disease but who have not yet developed symptoms and offer them appropriate advice and treatment to reduce their risks.'*

These activities are to be offered systematically using a risk assessment tool, and with practice-agreed plans and protocols for identifying, treating, and following up patients. There is an expectation for the development of practice registers and a system for patient recall. The aim is to reduce the risk of death, heart attack, heart failure, or other manifestation of CHD in the target population. The initial target group for this standard focuses on people who have no clinical evidence of CHD but whose risk of CHD events is greater than 30% over 10 years. Those identified are to be offered advice on smoking cessation and lifestyle modifications where necessary, advice and treatment for blood pressure over 140/85, and drug treatment if they have a serum cholesterol level over 5 mmol/l.

The UK's National Screening Committee defines screening as:

*'... the systematic application of a test or inquiry, to identify individuals at sufficient risk of a specific disorder to warrant further investigation or direct preventive action,*

A Rouse, MB BS, MPH, MFPHM, senior lecturer in public health and epidemiology; P Adab, MB CHB, MPH, MFPHM, honorary clinical lecturer in public health and epidemiology, University of Birmingham.

### Address for correspondence

Dr P Adab, Department of Public Health and Epidemiology, Medical School, University of Birmingham, Edgbaston, Birmingham B15 2TT. E-mail: p.adab@bham.ac.uk

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*amongst persons who have not sought medical attention on account of symptoms of that disorder.*<sup>3</sup>

Population screening began in the early 20th century, with the aim of improving the health of British children, and thus ensure the fitness of future army recruits. It was promoted as a means of reducing the burden of disease. Mass screening programmes were introduced; however, disappointment soon set in when it was found that these did not always lead to a reduction in mortality.<sup>4</sup>

In 1968, Wilson and Jungner published the first set of criteria for screening.<sup>5</sup> This was followed 20 years later by Holland's thorough analysis of the scientific and practical aspects of screening,<sup>6</sup> which provided convincing evidence that screening programmes were likely to be ineffective and costly liabilities unless they conformed to specified criteria. The UK's cervical screening programme is one example of a policy that failed to achieve the expected reductions in mortality in its early years, mainly because it was not set up within a nationally organised co-ordinated system.<sup>7</sup> Despite huge investment over many years, it is also an example of a screening programme that is frequently in the news because of concerns over quality and untoward incidents.<sup>8</sup>

The National Screening Committee (NSC) was established in the UK in 1997 and has built on Wilson and Jungner's classic criteria to develop standards for appraising a screening programme (Box 1).<sup>3</sup> Standard 4 of the NSF does not refer to these criteria or acknowledge that it is promoting a national screening programme operated by individual general practices. Nor does it discuss the fact that cardiovascular risk screening in primary care was introduced in the 1990s<sup>9</sup> and was considered as being futile even then.<sup>10</sup>

1. There should be evidence from high quality randomised controlled trials that the screening programme is effective in reducing mortality or morbidity.
2. There should be evidence that the complete screening programme (test, diagnostic procedures, and treatment/intervention) is clinically, socially, and ethically acceptable to health professionals and the public.
3. The benefit from the screening programme should outweigh the physical and psychological harm caused by the test, diagnostic procedures, and treatment.
4. The opportunity cost of the screening programme (including testing, diagnosis, and treatment) should be economically balanced in relation to expenditure on medical care as a whole.
5. There should be a plan for managing and monitoring the screening programme and an agreed set of quality assurance standards.
6. Adequate staffing and facilities for testing, diagnosis, treatment, and programme management should be available prior to the commencement of the screening programme.
7. All other options for managing the condition should have been considered (e.g. improving treatment, providing other services).

*Box 1. The criteria for appraising the viability, effectiveness, and appropriateness, of a screening programme.*

## Primary prevention of cardiovascular disease in primary care

There is much evidence from well conducted randomised controlled trials of the effectiveness of primary care-based interventions targeted at individual risk factors. Brief advice from a GP is one of the more effective methods for achieving population smoking cessation<sup>11,12</sup> and this can be enhanced by prescribing nicotine replacement therapy.<sup>13</sup> In people with hypercholesterolaemia, use of cholesterol-lowering drugs for primary prevention can reduce the risk of major coronary events by over 30%.<sup>14</sup> Lowering blood pressure has a modest effect on reducing overall mortality in middle-aged patients, though the impact on incidence of CHD is less obvious.<sup>15</sup> Nevertheless, treatment is more beneficial in people over 60 years of age.<sup>16</sup>

The results of such studies prompted several major trials, combining such interventions into a single programme of cardiovascular risk screening and intervention. The two main primary care trials in the UK<sup>17,18</sup> have shown minimal effectiveness in reducing risk factors, despite intensive intervention. Furthermore, a cost-effectiveness analysis of these trials suggests that the benefit needs to be sustained for a minimum of 5 to 10 years for intervention to be justified.<sup>19</sup> The benefits are likely to be even less impressive outside of well resourced research studies with highly selected study populations. Nevertheless, even if we accept these nominal benefits, there is no reference in Standard 4 as to whether the mandated activities conform to the NSC criteria for a screening programme.

A review of existing screening programmes and the guidance outlined by the experts should inform us of the likelihood of success. We will now discuss the screening activities enjoined on primary care in Standard 4, in the light of a selection of these well known principles that are related to screening programmes.

### *A plan for managing the screening programme*

To be effective, screening must be comprehensive and systematic. Experience from the NHS cervical cancer screening programme demonstrated that lack of organisation, accountability, and commitment, were responsible for its initial failure.<sup>20</sup> It is therefore surprising, and unfortunate, that Standard 4 makes no mention of appointing individuals in each health district to be responsible and accountable for the screening programme.

One of the fundamental prerequisites for the success of a screening programme is the need for a computerised database holding accurate and continually updated information, to enable the correct target population to be invited for screening and follow-up.<sup>6</sup> That Standard 4 recommends the ad hoc development of practice registers is, therefore, a likely step towards failure. Development of these registers is also dependent on the level of organisation within general practices. Practices with poor organisation are less likely to identify people at risk and this process could therefore contribute to increasing health inequities.

### *Agreed quality assurance standards*

The importance of national standards, mechanisms for qual-

ity assurance (QA), and a designated local programme co-ordinator were all emphasised during the recent enquiry into untoward events within the cervical screening programme at Kent and Canterbury Hospitals NHS Trust.<sup>21</sup> Quality assurance requires consistency, standardisation, and accountability. The key criteria for QA includes explicit quality standards, monitoring systems (to allow performance to be compared with those standards), and clear lines of managerial authority.<sup>3</sup> The NSF suggests that there should be local protocols for the investigation, recording, and treatment offered to the target population, which should be agreed at primary care or district-wide level. There are approximately 10 000 general practices and 500 primary care groups in the UK, which makes this recommendation managerially difficult to monitor.

### *A plan for monitoring the programme*

If a government agency advises asymptomatic people to enter a screening programme then there is a clear responsibility for that agency to monitor and ensure the effectiveness of that programme. Yet Standard 4 makes no provision for a uniform system of performance management, information collection, record linkage, or for the QA of the many other aspects of screening. In fact, Standard 4 admits that there will be differences in the quality of information available for audit.

### *Evidence of clinical, social, and ethical acceptability of the programme*

Screening stands apart from traditional medicine in that it offers a procedure, with the possibility of subsequent investigation and treatment, to apparently healthy people who have not been seeking medical attention. In contrast with most services in the NHS, which are patient-initiated, screening is provider-initiated and therefore there is additional social and ethical responsibility to ensure that the potential benefits outweigh the risks. No screening programme is free of harm. People identified as being at risk will be labelled as such, and this may result in social and psychological harm.<sup>22</sup>

The benefits of all the recommended interventions in Standard 4 are not clear. A systematic review of interventions for the primary prevention of CHD concluded that information and advice offered to healthy people is not particularly effective in changing behaviour and reducing the risk of clinical events.<sup>23</sup> Treatment with antihypertensive and cholesterol-lowering drugs, although effective in a clearly defined target group, also has disadvantages. There has been no assessment of whether these potential 'treatment harms' will outweigh the potential benefits gained, particularly for those at a lower initial level of risk.

Unlike many other screening programmes, Standard 4 seeks to identify persons as 'at risk' or 'not at risk', using a relatively arbitrary 10-year event risk cut-off of 30%. Currently available risk assessment methods have not been validated by comparing risk prediction based on their algorithm with the occurrence of coronary events. Consequently, there is much discrepancy in the people identified using the various risk assessment tools.<sup>24,25</sup> Our current understanding of the aetiology of CHD does not allow accurate prediction of coro-

nary events based on risk factors and using any threshold will inevitably misclassify certain individuals, resulting in both under- and over-treatment. Furthermore, there is increasing evidence of patients' interest to be involved in decision-making about their treatment.<sup>26</sup> Patients' preferences often disagree with recommendations based on guidelines. While any individual may regard a given threshold as either too high or too low, using patient preferences generally results in more conservative decisions regarding treatment.<sup>27,28</sup> There is some suggestion that the 30% threshold used in Standard 4 would be unacceptable to the public, and to health professionals.<sup>29,30</sup>

### *Adequate staffing and facilities*

All authorities on screening agree that screening programmes should not be established unless adequate resources are committed and that they do not increase the workload of existing medical services.<sup>6</sup> Arrangements suggested in Standard 4 that GPs re-direct resources from lower priority activities are therefore in conflict with this principle.

## **Discussion**

The objectives set out in the NSF are laudable. The relatively high prevalence of the major risk factors for CHD mean there is likely to be a significant number of people at high risk. However, there is no clear evidence that population cardiovascular risk screening for primary prevention as proposed in Standard 4 would be beneficial or cost-effective. Furthermore, when we consider the important criteria for any screening programme, the NSF standard does not fulfil these. The likely effectiveness of the programme is therefore, at best, doubtful. This does not mean that GPs should not be offering opportunistic health promotion interventions, such as giving advice on smoking cessation, weight control, or measuring blood pressure in older individuals who arrive for consultation. Nor does it detract from the important role of primary care in the secondary prevention of CHD.

We believe that the primary care screening activities recommended by Standard 4 of the NSF will not be effective. They do not meet the well established criteria for a screening programme, including the need for ensuring adequate structure, co-ordination, management, and appropriate resources. The government should heed the lessons of history and review Standard 4 with consideration of the well known principles of screening. Ideally, before establishing a screening programme, a randomised controlled trial should be performed to determine whether such screening is likely to reduce morbidity and mortality associated with CHD and, if so, at what cost. Only then can this activity be convincingly accepted as a 'high priority' and of 'high value.'

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