How should we balance individual and population benefits of statins for preventing cardiovascular disease?

US and UK groups revising recommendations on primary prevention of cardiovascular disease will have to decide whether to concentrate on high risk individuals or the whole population. **Aroon Hingorani** and **Harry Hemingway** argue that the evidence favours a population approach

Guideline groups in the United Kingdom and the United States are reviewing recommendations for the primary prevention of cardiovascular disease. At their disposal will be good quality evidence on the quantitative relation between the major risk factors and the probability of a first cardiovascular event[1]; the extent of the current population exposure to risk factors[2 3]; and the safety and efficacy of drugs to lower blood pressure and cholesterol concentrations.[4 5] The decisions of these expert groups will have far reaching consequences for the millions of adults in both countries, where cardiovascular disease is the biggest cause of mortality and morbidity; around half of men and a third of women have a cardiovascular event during their life.[6]

There are new drivers to modify the existing guidance (see table 1 online at bmj.com; box), and two extreme positions could be envisaged (table 2). The first is to redouble efforts to identify high risk individuals by enhancing currently used risk prediction tools with new information from blood biomarkers or non-invasive vascular imaging; to treat those at high risk with newer more expensive statins that achieve the greatest cholesterol reduction; and to tailor treatment for each individual to achieve target cholesterol levels. The interest in C reactive protein as a new biomarker of cardiovascular risk[7] and the recent US Food and Drug Administration licence extension of the patent for rosuvastatin, with C reactive protein as a companion test, suggests that the US could follow this course. The diametric alternative is to use generic versions of the older statins in a wider population by including people whose risks fall below the current absolute risk thresholds for drug intervention and to dispense with a target cholesterol level. In the UK, eligibility criteria for statins in primary prevention have been relaxed over the years and a switch to generic statins, where possible, is already saving substantial sums.[8]

But is the first approach an unacceptably expensive strategy that fails to exploit increased opportunity for disease prevention from wider access to effective, safe, inexpensive generic statins? Is the second insufficiently refined for an era of personalised or stratified medicines where the aim is to maximise individual benefit and minimise harm?

Table 2 | Population versus high risk strategies for primary prevention of cardiovascular disease

	Population based	High risk individuals
Who to treat?	People at lower absolute risk of cardiovascular disease using established risk equations with lower treatment thresholds or people above an age threshold	People whose absolute risk of cardiovascular disease exceeds thresholds based on established risk equations with addition of new markers (eg, C reactive protein, carotid intima-media thickness, genotype)
What to treat with?	Inexpensive generic statins, perhaps in combination with generic blood pressure lowering drugs	Generic statins for those at moderate risk; newer, more potent statins for those at highest risk
What target?	None	Targets based on LDL cholesterol, blood pressure, or absolute risk, with regular monitoring and titration of drugs

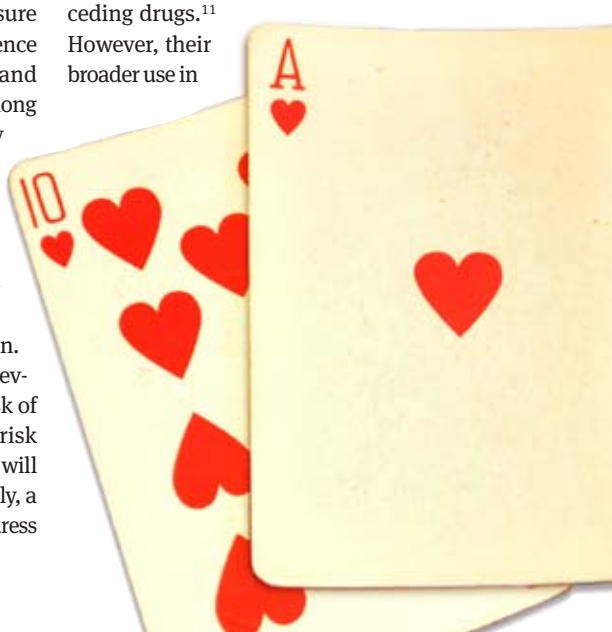
High risk individual *v* population based approaches

Geoffrey Rose developed the important concept of the "prevention paradox": that more cases of cardiovascular disease occur among the majority at average risk than among the minority at high risk.[9] The paradox arises because risk factors such as cholesterol and blood pressure are a continuum. Each exhibits a log-linear association with risk of coronary heart disease with no safe threshold, while the population risk factor exposure follows a normal distribution.[10] A consequence is that the distribution of blood pressure and cholesterol values overlaps substantially among those who do and do not develop coronary events later in life, leading to a seemingly counterintuitive observation that risk factors such as low density lipoprotein (LDL) cholesterol are poor predictors of clinical events despite being causally related to coronary heart disease.

The prevention paradox leads to a tension. Focusing exclusively on people with high levels of one risk factor, or at high absolute risk of a clinical event calculated from multiple risk factors, overlooks the burden of events that will occur among the average majority. Conversely, a population based strategy, which seeks to address this, leads to people at low individual risk being exposed to an intervention with less personal gain. The merits of each approach are intimately linked to the efficacy, safety, cost, and convenience of the available interventions. In Rose's era, the lipid lowering drugs were poorly tolerated and only modestly effective. For this reason, dietary and lifestyle interventions became aligned with the population approach, the aim being to achieve a large overall benefit by even modest shifts in the risk factor distribution in the whole population.

Primary prevention in the early statin era

The first statins to market were better tolerated and lowered cholesterol more effectively than the preceding drugs.[11] However, their broader use in



primary prevention was constrained initially by the high costs and uncertainty about long term safety. An individualised approach to primary prevention therefore persisted in the UK based on absolute risk. Absolute risk was chosen rather than LDL cholesterol because LDL cholesterol on its own poorly differentiates those who will have events and two people with the same LDL cholesterol concentration can have widely differing risks of coronary heart disease depending on other risk factors such as age, sex, smoking habits, and blood pressure.[12] Targeting statins on the basis of absolute risk makes the justifiable assumption that the relative risk reduction from statin treatment is constant (such that the absolute benefit and number needed to treat are proportional to absolute risk) and that the particular constellation of risk factors in an individual does not modify the treatment effect.[13] Statins are as effective in people whose cardiovascular risk is mainly influenced by high blood pressure or diabetes as among people whose cholesterol concentration is the main determinant of risk.

Europe and Australasia have broadly adopted a similar absolute risk based approach to intervention, which has encouraged use of computerised, point of care risk assessment tools based on results from observational studies like the US Framingham Heart Study or routinely collected clinical data such as QRISK in the UK.[14] However, in the US, where risk assessment was initially based on LDL cholesterol alone, guidelines continue to recommend consideration of both LDL cholesterol and absolute risk when prescribing statins for primary prevention.

Why change guidance?

The absolute risk based approach has limitations. Risk assessment models assign individuals to groups with observed event rates close to those predicted. But they perform little better than their constituent variables (for example, age, blood pressure, and cholesterol) in differentiating individuals who eventually have events.[15] Just as with cholesterol, many cardiovascular events occur in people at intermediate risk, below current thresholds for statin eligibility.

Pressures for changing primary prevention strategy

Drivers for widening statin eligibility

Reduced cost through patent expiry and availability of inexpensive generic formulations with excellent long term safety profile

- Policy emphasis on disease prevention
- Development of polypill concept

Drivers for more individualised primary prevention

- Emphasis on personalised medicine
- Claimed predictive value of new biomarkers and imaging tools such as C reactive protein, carotid intima-media thickness, and coronary artery calcification

Raised concentrations of blood biomarkers such as C reactive protein and subclinical atherosclerosis in the carotid or coronary artery, detected by ultrasonography or computed tomography, have been associated with a higher risk of cardiovascular events. And at the same time, the cost of the first statins to market (simvastatin, pravastatin, etc) is dropping abruptly because their patents have expired. For example, generic simvastatin 40 mg daily now costs less than £1.40 (€1.60; $2.30) a month compared with £24.64 a month for 20 mg atorvastatin, the patent on which expires next year. Evidence of long term safety is available for established statins but not yet for the newer drugs. These developments are opening up two approaches to deal with the current limitations of absolute risk assessment based on established risk factors.

The first seeks to apply new technology, whether biomarkers or imaging tools, to identify more accurately people at intermediate risk who will have events. The second seeks to circumvent the inherent difficulties in prediction altogether by simply offering statins to a wider range of adults than would currently be treated. In effect, this represents a shift towards a population based approach to prevention that includes use of cholesterol lowering drugs as well as dietary and lifestyle measures. How do the options compare?

New tools for risk assessment

The European view is that C reactive protein is little better than cholesterol at predicting risk (for similar reasons) and adds little to existing risk models.[16] However, C reactive protein is already considered an option for risk assessment in the US, based in part on a recommendation from the American Heart Association and Centers for Disease Control and Prevention[17] and is now established in Canadian guidelines.[18]

A recent meta-analysis found that thickness of the carotid intima-media and identification of plaque were insufficiently useful for screening people at intermediate risk,[19] and comparison trials have not been conducted for primary prevention. It is therefore unsurprising that neither carotid nor coronary imaging has yet been adopted by the NHS for primary prevention and that the American Heart Association, the American College of Cardiology, and the US Preventative Services Task force have been cautious about their role in predicting risk.[20 21] Despite this, the newly enacted Texas Heart Attack Prevention Bill requires health insurers to cover up to $200 towards the cost of measuring coronary calcium or carotid intima-media thickness every five years. The bill followed publication of guidelines from the Society for Heart Attack Prevention and Eradication (SHAPE) task force,[22] which were not part of the established guideline development framework of the American College of Cardiology or American Heart Association.[23]

Wider use of generic statins

The most recent guidelines from the Scottish Intercollegiate Guidelines Network (SIGN) and the National Institute for Health and Clinical Excellence (NICE) lowered the risk threshold for prescribing statins from a 10 year coronary heart disease risk of 30% (roughly equivalent to a 10 year cardiovascular disease risk of 45%) adopted in the UK soon after the introduction of statins, to a 10 year cardiovascular disease risk of 20% (roughly equivalent to a 10 year coronary heart disease risk of 15%). The proposed Department of Health vascular health checks for all 40-74 year olds would also move from opportunistic testing of cardiovascular risk factors in primary care to systematic identification of all eligible adults.[24]

But are the new risk thresholds and vascular health checks an equitable means of expanding the use of statins? Around half of men aged over 50 years in England and Wales will now be eligible for statins, but a substantial proportion of all events would be expected in men of this age group whose risk falls below the threshold of 20%, arguably leading to inequity of access to statins. Furthermore there are unresolved concerns about the extent to which risk thresholds may address, or exacerbate, social inequalities in vascular risk.[25] The number needed to screen in the vascular checks to prevent one event is also estimated to be high: 449 for men and 1638 for women.[26]

An alternative is to offer statins on the basis of age with no risk factor screening. Over 95% of cardiovascular events occur after the age of 50, and age is the overarching determinant of absolute risk.[27] Age on its own may be nearly as effective in discriminating cardiovascular events as risk equations that incorporate additional variables. Age based eligibility for statins would obviate the need for risk factor screening and reduce potential inequity of access to statins. However, it would

Should new preventive treatments of uncertain long term safety emerge from ongoing clinical trials, these would again need to be targeted at people at highest risk

result in large numbers of adults at low risk taking drugs for many years, which may make it difficult to implement.

Is there any role for newer more expensive statins?

A lower "on-treatment" LDL cholesterol level within trials and a larger average LDL cholesterol reduction across trials have been associated with greater reductions in cardiovascular risk. As a result, some guidelines on primary prevention have proposed treatment to target cholesterol concentrations.[28] However, the cost effectiveness of more intensive lowering of cholesterol with expensive patented statins (such as rosuvastatin) versus less intensive lowering with cheaper generic drugs has not been evaluated in primary prevention. Moreover, someone taking simvastatin but failing to reach an arbitrary cholesterol target may stand to gain a similar or greater reduction in cardiovascular risk from the addition of an inexpensive generic blood pressure lowering drug as from a switch to a different statin. The principle of targeting multiple risk factors simultaneously to maximise risk reduction at low cost is being evaluated in trials of combination tablets containing generic blood pressure lowering drugs and statins (polypills).[29]

From guidelines to health policy

Rose recognised that strategies for preventing cardiovascular disease have sociopolitical repercussions and their development could benefit from involvement not only of medical experts but also policy makers and patients. Studies are now required to evaluate the preferences of people being targeted for primary prevention, who have yet to be properly invited to the debate and to formally model the cost effectiveness of the different screening options. Prevention is now high on the health agenda. Recent guidance from NICE on prevention of cardiovascular disease at population level[30] is aimed at "government, the NHS, local authorities, industry and all those whose actions influence the population's cardiovascular health" and focuses on "legislative, regulatory, and voluntary changes" relating to salt, saturated fat and trans fat consumption, food marketing and labelling, public sector catering, and increasing physical activity.

Conclusion

In an era of safe, inexpensive generic statins where new methods for risk assessment poorly discriminate cases of cardiovascular disease, the balance of evidence appears currently to favour wider eligibility for statins, as part of a broader population based effort to reduce cardiovascular risk. However, should new preventive treatments of uncertain long term safety emerge from ongoing clinical trials, these would again need to be targeted at people at highest risk, applying the most cost effective screening tools available.

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Unanswered questions over NHS health checks

England plans to target vascular disease by offering all adults aged 40-74 a regular health check, but **Kamlesh Khunti and colleagues** point out that success is far from guaranteed

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- Cochrane review questions evidence for statins for primary prevention in low risk groups (*BMJ* 2011;342:d480)
- Unintended effects of statins in men and women in England and Wales (*BMJ* 2010;340:c2197)
- Should statins be prescribed for primary prevention of cardiovascular disease in patients with chronic kidney disease? (*BMJ* 2009;339:b294)

Vascular disease affects more than four million people in England.[1] It is responsible for 170 000 deaths a year in England (36% of all deaths) and one fifth of hospital admissions, and it is the largest single cause of long term ill health and disability. To try to reduce the high prevalence and costs, the National Health Service health checks programme for adults aged 40 to 74 years was introduced in England in April 2009, with full implementation planned for 2012-13.

The objective of the programme is to assess risk of developing vascular or metabolic disease (heart attack, angina, stroke, diabetes, and kidney disease) and manage the risk factors to prevent progression and improve outcomes (box 1). These diseases have shared risk factors including smoking, high blood pressure, obesity, physical inactivity, and impaired glucose regulation. An integrated approach to their identification and management is therefore likely to be more cost effective. The Department of Health estimates that if there is universal uptake across the country, the programme could prevent 9500 myocardial infarctions and strokes each year.[1] Advocates of these proposals hope that successful implementation may reduce health inequalities in the population by identifying people at risk of disease or with undiagnosed disease earlier. However, many unanswered questions remain.

Is there evidence of benefit?

Programmes to identify and manage vascular risk have never been implemented on this scale, and estimates of the effectiveness and cost effectiveness rely on modelling studies.[3] Economic modelling by the Department of Health suggests that the programme will cost £332m (€380m; $540m) a year when fully implemented and that the average annual benefit will be £3.8bn.[3] It also reported that the programme would cost around £3500 per quality adjusted life year (QALY) gained.

The current guidance for primary prevention of cardiovascular disease recommends multifactorial risk factor management with both drugs and lifestyle interventions. Although there is no evidence of harm from health checks,[4] trials, including the multiple risk factor intervention study (MRFIT)[5] and the UK nurse intervention OXCHECK study,[6] have not shown any benefit on hard outcomes. The National Institute for Health and Clinical Excellence (NICE) guidelines for use of statins recommend targeted case finding rather than a population approach.[7] In addition, a recent modelling study has suggested risk stratification using routinely available computer data and inviting only those at high risk is more likely to be effective for primary prevention.[8] However, the Department of Health economic modelling primarily considered universal screening.[3] Everybody identified as being at high risk by screening will be offered lifestyle intervention programmes, including advice on physical activity. Currently only 20-25% of the UK adult population adhere to the recommended guidelines. Although the evidence from epidemiological studies of the effect of physical activity on cardiovascular outcomes is compelling, intervention studies to encourage physical activity have not realised the potential benefits. Furthermore, one recent study found that people taking drugs to manage risk factors are less likely to be physically active,[9] which may imply that the drugs give false reassurance.

Intensive lifestyle interventions have been shown to prevent type 2 diabetes in those at high risk,[10] and the Department of Health's economic modelling calculated lifestyle intervention costs for people with impaired glucose regulation as the largest single cost: 42% compared with 21% for antihypertensive drugs and statins.[3] However, programmes of intensive intervention are not currently available in primary care and have not been tested in pragmatic trials. In view of these uncertainties on effectiveness, full implementation of the health checks programme should await further data from the health checks pilots.[2]

When to screen

The health checks programme recommends rescreening every five years for those found to be at low risk and does not recommend starting screening at an earlier age for people in high risk groups.[1] However, a recent modelling study has suggested that screening for type 2 diabetes is cost effective when started at age 30-45 years with rescreening every three to five years.[11]

Risk assessment

Weight, height, blood pressure, and lipid measurements are interpreted in combination with information obtained from the history and examination using risk assessment tools (figure). If the cardiovascular risk is greater than 20% over 10 years then a statin is recommended to lower cholesterol levels. The Department of Health includes both Framingham and QRISK2 in the

health checks guidelines, and primary care trusts have been left to decide which tool to use.

For chronic kidney disease, the programme recommends that people with a blood pressure ≥140/90 mm Hg have their serum creatinine measured to calculate the estimated glomerular filtration rate.[1] Evidence for this is controversial, and studies have suggested that estimated glomerular filtration rate and proteinuria are both independent predictors of future cardiovascular risk.[12] Although assessment for proteinuria is not currently recommended as an initial assessment tool, there is potential to incorporate and evaluate this in current pilots.

A key element of the programme is identifying people with type 2 diabetes and those at risk of diabetes. There is national and international debate about how best to screen and diagnose diabetes. NHS health checks guidance recommends using presence of obesity and hypertension as a pragmatic way to identify those at risk and to measure fasting serum glucose or haemoglobin A_{1c} concentration.[1] An international expert committee has called for the use of haemoglobin A_{1c} instead of an oral glucose tolerance test to diagnose diabetes,[13] and it would therefore be sensible to include haemoglobin A_{1c} as part of the health check.[14]

Challenges to implementation

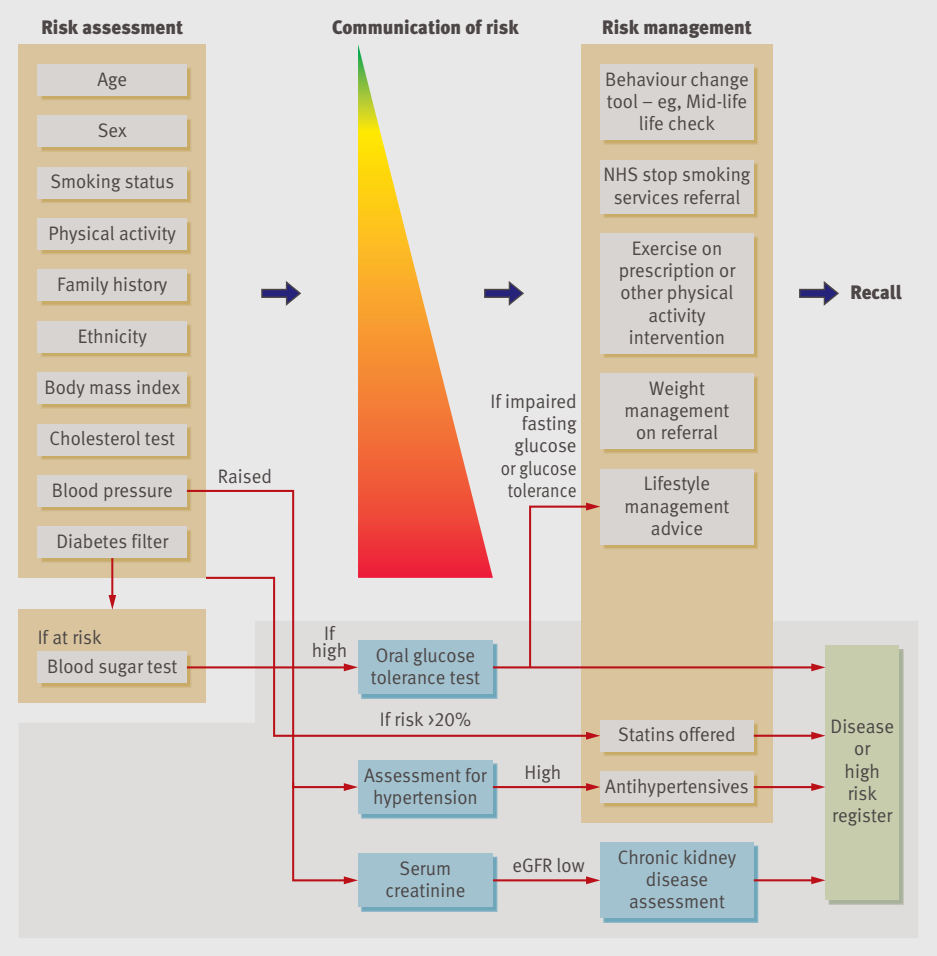
Location

Key elements of the programme include risk assessment, risk communication, management, and appropriate recall. The Department of Health has not said how to implement the programme, and primary care trusts are taking different approaches. Screening can be offered in various community settings such as pharmacies and places of worship to enhance uptake and accessibility to local populations.

The Department of Health has suggested that services could also be commissioned from the private sector.[1] However, this has potential risks, such as duplication of screening, occasional discrepancies in results, increasing inequalities by not engaging appropriate target groups, and inappropriate use of scarce healthcare resources. If these problems can be overcome, delivery by different organisations is to be welcomed because it is more likely to be appropriate for the needs of the local population. However, a key challenge will be quality assurance, details of which are currently lacking. Additionally, the challenges of data communication between providers and primary care need to be overcome.

Box 1 | NHS health checks programme

- Adults aged 40 to 74 years without a diagnosis of vascular disease will be contacted by their primary care trust and offered a health check
- Risk assessment includes collection of demographic data, family history, smoking status, cholesterol and blood pressure measurement, and a diabetes filter (figure)
- An individualised management plan is then developed according to the risk assessment
- Currently 19 "test bed sites" are piloting the health checks
- In most pilots the checks are being done by nurses or pharmacists in various community locations
- Piloted programmes are being evaluated, with data available on the learning network website[2]
- Phased roll-out of the programme will follow evaluation of these pilots with full implementation by 2012-13



NHS programme for assessing and managing risk of vascular disease[1]

Uptake

The Department of Health cost effectiveness modelling assumes a 75% uptake.[3] A recent pilot in one region reported response rates of 29%, with even fewer attending for follow-up.[15] Furthermore, response rates for screening programmes are low in areas of socioeconomic deprivation and multiethnic communities,[16] which could widen disparities in these groups. Reasons for low response in these groups are complex and include variations in health beliefs and help seeking behaviour.

Population diversity

Decisions about when and who to screen are particularly important because the UK population is so diverse and the incidence of vascular disease variable. South Asians, for example, have a 50% higher mortality from coronary heart disease than white Europeans.[17] The health check is being offered to people over 40 years of age, but the age of onset of diabetes or cardiovascular disease in South Asians is around a decade earlier,[18] partly because a higher proportion have risk factors at a younger age.[18] Furthermore, a body mass index of 27.5 has been suggested as a threshold for intervention for people of South Asian and Chinese ethnicity, with recent data suggesting even lower thresholds.[19] However, at the moment there is no plan to adjust the programme's criteria according to ethnicity.

Workload

Implementation will be challenging in an already overstretched primary care. Around 20% of people screened are expected to be at high risk,[1] and this figure is likely to be higher in some areas. NHS Nottingham found 66% of patients recruited in their pilot NHS health check, who were mainly

By focusing on prevention rather than cure, the programme is an important attempt to allow people who may otherwise not access healthcare services, an opportunity to do so

from areas of high deprivation, had a cardiovascular risk of greater than 20% over 10 years.[20]

General practices will need to provide a substantial number of additional appointments for risk assessments and follow-up. A typical surgery list size of 5600 people would have to provide 330 vascular checks a year, or five to six a week.[1] However, most of the check, including support to help people manage their risk, does not need to be carried out by general practitioners. Existing services such as community dietitians, smoking resolution clinics, and active lifestyle schemes are also likely to experience an increased workload.

Box 2 | Key challenges and uncertainties of the NHS health check programme

- Evidence of effectiveness and cost effectiveness is lacking except from modelling studies
- Recent modelling studies suggest the programme is likely to be cost effective if targeted at high risk groups
- Uptake of screening programmes is low in areas of socioeconomic and multiethnic communities
- Recommended intensive lifestyle interventions for prevention are not currently available in primary care
- Interventions to increase physical activity have had limited success
- Implementation is likely to be challenging in an already overstretched primary care
- Information technology to capture and transfer data between organisations providing health checks is not yet available

NHS health checks are expected to be done in primary care, and primary care trusts are negotiating with general practitioners to provide this programme as a locally enhanced service with remuneration provided for each patient assessed. Some primary care trusts have also developed a new structured initiative scheme that includes financial rewards for general practitioners reaching locally agreed targets for the NHS health checks programme.[21]

Information technology

Although primary care computer systems capture data on risk factors and prescriptions, they contain little information on lifestyle factors such as physical activity and diet. Computer templates to allow this information to be captured will be essential to evaluate improvements in lifestyle factors. Furthermore, the Department of Health funded diabetes screening pilot identified several practical obstacles including screening occurring ad hoc outside the eligibility criteria, poor follow-up of individuals who were found to be at risk, and poor data capture in general practice computer systems.[16] These deficiencies must not be repeated in the current programme.

Conclusions

The NHS Health checks programme is one of the most ambitious attempts to universally detect and reduce vascular and metabolic risk and should be welcomed. By focusing on prevention rather than cure, the programme is an important attempt to allow people who may otherwise not access healthcare services, an opportunity to do so.

In order for the programme to succeed, primary care trusts (and, in future, commissioners) and practices will need to work in close partnership and negotiate how the programme can be feasibly provided. Several challenges will need to be overcome (box 2), and learning from the pilots before full implementation will be essential. Finally, robust evaluation of cardiovascular outcomes and cost effectiveness will be required to determine the benefits of the programme and to ensure inequalities are not being widened.

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