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General health checks don't work

It's time to let them go

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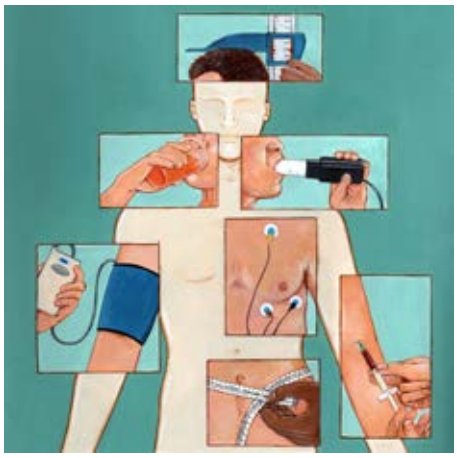
We check our cars regularly, so why shouldn't we also check our bodies so that we can find and treat abnormalities before they cause too much harm? It seems so easy, but the human body is not a car, and, in contrast to a car, it has self healing properties. Actually, the first thing we know about screening is that it will cause harm in some people. This is why we need randomised trials to find out whether screening does more good than harm before we decide whether to introduce it.

Doctors realised this early on and embarked on 16 randomised trials of general health checks between 1963 and 1999. A Cochrane review from 2012 that included 11 940 deaths did not find an effect of general health checks on total mortality (risk ratio 0.99, 95% confidence interval 0.95 to 1.03) or on mortality due to cardiovascular disease (1.03, 0.91 to 1.17) or cancer (1.01, 0.92 to 1.12).[1 2]

These trials were carried out in Europe and in the United States. The most recent one, the Danish Inter99 trial, which started in 1999, reports its results in this issue of *The BMJ*.[3] It investigated the effect of systematic screening for risk factors for ischaemic heart disease and lifestyle counselling up to four times over a five year period. People at high risk were additionally offered group based counselling. This trial also failed to find an effect on total mortality; 3163 deaths occurred, and the hazard ratio was 1.00 (0.91 to 1.09). It also failed to find an effect on its primary outcome, the incidence of ischaemic heart disease, for which the hazard ratio was 1.03 (0.94 to 1.13).

That health checks do not work is counterintuitive. We know, for example, that even brief counselling about smoking will make some people abandon their habit. A meta-analysis of 17 trials showed that the chance of quitting increased by 66% (risk ratio 1.66, 1.42 to 1.94),[4] and the Inter99 trial and several of the previous trials included counselling about smoking and other unhealthy lifestyles.

Two main likely explanations exist for the lack of effect. Firstly, many physicians already carry out testing for cardiovascular risk factors or diseases in patients whom they judge to be at risk when they see them for other reasons.[1 2] This is often considered an integral part of primary care, and adding a systematic screening approach is not beneficial.



Don't just do something, stand there

Secondly, beneficial effects of screening could be outweighed by harmful ones, and type 2 diabetes might be an example. Our drug regulators approve diabetes drugs solely on the basis of their glucose lowering effect without knowing what they do to patients. The only large trial of tolbutamide was stopped prematurely because the drug increased cardiovascular mortality,[5] but nothing material happened with its regulatory status and people continued to use it. More recently, rosiglitazone, which was the most sold diabetes drug in the world, was taken off the market in Europe, as it causes myocardial infarction and cardiovascular death,[6] and pioglitazone could also face trouble, as it has been linked to heart failure and bladder cancer.[7 8]

People who accept an invitation to a health check tend to have higher socioeconomic status, lower cardiovascular risk, less cardiovascular morbidity, and lower mortality than others.[1 2] Attendance predominantly by the worried well could contribute to the lack of effect of health checks. However, in the absence of even a trend towards benefit, this seems an unlikely explanation, as some of those who did turn up were at high risk.

Screening programmes for healthy people are justifiable only when randomised trials clearly show that benefits outweigh harms. For health checks, the trials seem to show the opposite. No discernible benefits were seen, and, although harms were inadequately reported, health checks would be expected, like other screening tests, to increase overdiagnosis and overtreatment, with their associated side effects and psychological consequences.

Doctors should not offer general health checks to their patients, and governments should abstain from introducing health check programmes, as the Danish minister of health did when she learnt about the results of the Cochrane review and the Inter99 trial.

No trace of an effect on mortality

Current programmes, like the one in the United Kingdom, should be abandoned. This might be difficult. Some doctors believe strongly in the benefits of health checks, some earn a living through them, and there are many faces to be saved. We therefore have no doubt that the methods and results of the Inter99 trial will be heavily debated, but it is worth considering what this might lead to. We now have 15 103 deaths from trials that spanned 50 years and found not a trace of an effect on mortality. No amount of criticism of the trials can render this negative result positive. However, interesting factors might turn up that could be useful if anyone wished to embark on yet another trial. Additional trials of general health checks are hardly worth while; we should focus our efforts on conducting trials of those individual components that look most promising.

In clinical practice, we should use only interventions that work. Our Cochrane review did not include trials of geriatric screening, as they evaluated many other interventions in addition to screening, such as falls prevention and specialist drug review. A meta-analysis of 89 trials including 97 984 people aged 65 and above showed that community based multifactorial interventions significantly increased the chance of living at home and reduced falls and hospital admissions.[9]

Competing interests: None declared.
Provenance and peer review: Commissioned, not externally peer reviewed.
References are in the version on bmj.com.
Cite this as: *BMJ* 2014;348:g3680

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Communicating the harmful effects of medicines

Warnings may have unintended consequences

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In 2004 the US Food and Drug Administration warned that antidepressants could increase suicidality in children and adolescents.[1] Three years later it ordered that all antidepressants should carry an expanded black box warning, incorporating information about this increased risk.[2] These warnings were associated with widespread media coverage.[3-5]

Net effect: more harm?

Warnings from regulatory agencies about harms from drugs are known to reduce prescribing rates. In a linked paper Lu and colleagues show that not only did prescribing rates decrease in this age group but there was a modest but significant increase in the rate of self poisoning, an important suicidal behavior.[6] The net effect of the warning was probably counterproductive and led to more harm.

Completed suicide is such a rare event that even this large observational study lacked the power to investigate this outcome. Nevertheless, self poisoning is a major event for patients, their family, and health services. Lu and colleagues' study is a good example of the value of a quasi-experimental pharmacoepidemiological design following a timed intervention in investigating important but uncommon adverse events.[6] The findings are not only relevant to the ongoing debate about the risk of prescribing antidepressants for young people but also raise important questions about the impact of warnings about drug safety on treatment related behaviours and health outcomes.

The issue around antidepressants may be a special case, with no shortage of strong opinions that often seem driven more by ideology than by science.[7] Regardless, the negative effect of warnings about drugs should be considered in general. Scientific findings associated with harmful events probably attract more interest and therefore more media coverage than do the results of positive effects.[8] As regulatory authorities have more to lose from not providing warnings than from providing them, might they be more likely to issue warnings even if the evidence of net harm is uncertain?

The publicity around medical research needs to be managed carefully. The idea that treatments cause harms as well as benefits is well accepted. In practice, however, it sometimes seems that warnings are driven by a desire to avoid any potential harm even if this also prevents benefits—a too simplistic application of "first, do no harm." An unduly negative approach to medical treatments in the media can be harmful if doctors and patients are put off using well established drugs.

Studies of patients' beliefs about medicines show that concerns about potential harms from drugs may be more prevalent than the experience of harmful effects.[10] Moreover, concerns about specific prescribed medicines are related to more general, negative views about drugs as a class of treatment held by many people.[11-13] As well as impeding adherence, concerns about drugs may result in increased reporting of side effects. In a longitudinal follow-up study of patients with rheumatoid arthritis concerns about drug treatment at baseline predicted reports of side effects at six month follow-up, after controlling for disease and treatment variables and previous experience of side effects.[14]

From "may be" to "are"

A better understanding is needed of how warnings and reports of potential harm influence patients' concerns about their medicines, adherence, and doctors' prescribing behaviour. Negative background attitudes towards medicines may mean that statements warning that a drug "may be linked" to harm are readily interpreted as "are linked" to harm. Ironically, if such perceptions result in non-adherence to an essential drug or an increase in reported adverse effects, the warning of potential harm may cause an unintended and paradoxical increase in harm.

Concern has been justified about the biased presentation of the effects of treatments, including antidepressants, as overly beneficial through publication bias and excessive marketing. We need to ensure that clinical trials are not designed to obscure harm through patient selection, drug use before randomisation, and exclusion of patients who experience adverse effects. Concealing harm through selective reporting of trial results can lead to the loss of effective treatments, which could have been retained had the harms been openly reported and clearly explained to patients (for example, rofecoxib). A lack of trust in drug manufacturers to be honest about adverse effects adds to the problem and needs to be tackled.

However, we should also be concerned about the way harms are communicated. As Lu and colleagues' show, reports of harm and warnings from regulators can cause harm as well as benefit.[6] We need a better understanding of how patients, doctors, and others respond to warnings to ensure that attempts to reduce drug related harm do not inadvertently achieve the opposite.

This sort of study has implications for premarketing regulation. Randomised trials are always going to be too small to detect important but uncommon adverse events. Excessive premarketing safety requirements inflate the cost of drug development and are one reason why many pharmaceutical companies have left the area of mental health.

Innovation is needed in regulatory approaches to new medicines. One approach would be to use the rich data in individual electronic health records to conduct extensive and powerful observational evaluations of the effects of treatments in the real world. Then, fewer and shorter randomised preregistration studies may be needed, perhaps with an initial period of marketing authorisation limited to settings participating in pharmacovigilance programmes.

Competing interests and references are in the version on bmj.com.
Provenance and peer review: Commissioned; not externally peer reviewed.
Cite this as: *BMJ* 2014;348:g4047
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While the benefits are small, the harms of screening are real and include overdiagnosis, psychological stress, and exorbitant healthcare costs

The harms and benefits of modern screening mammography

Women need more balanced information

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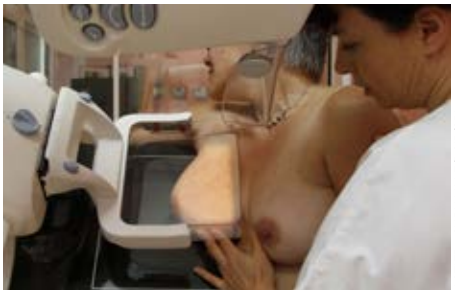
The Swiss Medical Board noted that the current debate on the benefits and harms of mammography screening is based on outdated randomised controlled trials (RCTs) and that it was "non-obvious" that the benefits outweighed the harms.[1] They recommended that no new mammography screening programmes should be introduced in Switzerland and that the existing ones should be phased out.[1]

The board relied on a review by another panel: the Independent United Kingdom Panel on Breast Cancer Screening.[2] Using data from the published RCTs, the UK panel estimated that for every 10 000 women aged 50 invited to screen for the next 20 years, about 43 would avoid a death from breast cancer and the remaining 9957 would receive no mortality benefit. About 129 women would be treated unnecessarily as a result of overdiagnosis, a ratio of three women with overdiagnosed cancers to one woman with a breast cancer death avoided.

As both panels noted, data from older RCTs are not ideal for determining the benefits and harms of modern day screening. Instead, observational studies such as in the linked paper will be increasingly relied on to monitor changes over time.[3]

Much has changed since women were first enrolled into the breast cancer screening RCTs, one of which started 50 years ago. These include factors that influence the incidence of breast cancer and the timing of diagnosis. Most importantly, breast cancer treatment has noticeably improved, and this may partially explain some of the benefit attributed to mammography.

Recent findings from the 25 year follow-up of the Canadian National Breast Screening Study underscore uncertainties about the applicability of the older RCTs to current screening policies. That study showed no benefit from screening, perhaps partly due to participants receiving more effective treatment than in the older RCTs.[4] Some commentators have asked for new trials, but results would take decades and it would still be questioned whether further changes in risk factors, treatment, and technology had made the RCT results obsolete.



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Party girl

The new cohort study from Norway[3] adds important information to a growing body of observational evidence estimating the benefits and harms of screening. The authors followed women for more than two decades during a time when the country's breast cancer screening programme was gradually implemented. They found that, for every 10 000 women screened, about 27 deaths from breast cancer might be avoided.

Although observational studies may provide more up to date estimates than the old RCTs, they also come with considerable uncertainty. As these studies compare groups in different periods (before and after screening programmes begin) or in different geographical areas (with and without screening programmes), they are susceptible to selection bias.[5] It is not surprising that observational studies in Norway and other Scandinavian countries have disagreed about the estimated mortality benefit of screening mammography.[6-9] The benefit reported in the present study falls near the middle of these other published estimates.

Overall, evidence from both observational studies and RCTs indicates a benefit from screening mammography. Interestingly, the estimates from the observational studies do not differ greatly from those of the older RCTs: for every 10 000 women screened over 20 years, an estimated 27 versus 43 women, respectively, would avoid a breast cancer death. The Norwegian study largely confirms what is already known: the benefits of screening mammography are modest at best. While the benefits are small, the harms of screening are real and include overdiagnosis, psychological stress, and exorbitant healthcare costs.

So how can women be helped to make informed decisions about screening? Unfortunately they are rarely presented with balanced information. While the results of complex, imperfect science do not easily translate into memorable slogans, campaigns to promote mammography do often catch women's attention. Many individuals and groups actively promote mammography screening. Doctors discussing mammography with patients are more likely to mention the potential benefits than harms of screening.[10] One US hospital promotes monthly "mingle and mammograms" parties, with women being pampered before screening to calm their nerves.[11] These parties include appetizers, foot massages, and bags emblazoned with the logo "fight like a girl." In addition to appetizers, we suggest serving women balanced information about the benefits and harms of screening to chew on.

Knowledge gap

Concern about the amount and type of information on screening mammography made available to women is increasing internationally. In the United Kingdom, concerns about women receiving inadequate information when participating in their national screening programme led to the formation of a special "citizen's jury" of women to review the issue.[12 13] After hearing evidence from experts, one participant remarked: "I can't believe how much I didn't know."[14]

Beyond its relevance to women's decision making today, the Norwegian study should make us reflect on how to monitor the changing benefits and harms of screening. Future studies will hopefully allow analyses to account for changes over time in risk factors, screening technology, and treatment. Just as quality criteria have been defined for RCTs, creative study methods and quality metrics must be developed for observational studies evaluating large screening programmes.

For future independent boards to be able to conclude that the breast cancer screening decision has finally become obvious, careful assessment of ongoing screening programmes will be required. In the meantime, make yourself comfortable—this may take a while.

Competing interests and references are on bmj.com.
Provenance and peer review: Commissioned; not externally peer reviewed.
Cite this as: *BMJ* 2014;348:g3824
NEWS, p 4; RESEARCH, p 14

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Treading a careful line between speaking up honestly for the NHS and the people it serves, while not antagonising ministers as the general election approaches, will be a key test

NHS England's chief executive sets out thinking on new models of care

He has the opportunity to make changes that in normal times would be impossible

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In a series of speeches and interviews, culminating in an address to the annual conference of the NHS Confederation earlier this month, the new chief executive of NHS England, Simon Stevens, has begun to describe his priorities for the NHS.[1] Foremost among these priorities is a desire to be radical about how services are provided. This entails further concentrating specialist services where evidence shows this will bring benefits, while continuing to provide access to local hospital services for the growing number of older people who need these services.

Stevens's radicalism extends to how hospitals will be staffed in his questioning of the assumption that almost all NHS acute hospitals need a full complement of trainee doctors to keep service afloat. With a 76% increase in the number of consultants working in the NHS since 2000, he has raised the prospect of some hospitals emulating what happens in parts of Europe, where medical care is delivered by consultants only. He has also advocated more emphasis on generalism in medicine, echoing the work of the Royal College of Physicians on the future hospital.[2]

Citing medical historian, Roy Porter, Stevens has questioned whether the founding principle of the NHS under which "consultants got the hospitals and GPs got the patients" is durable.[3] One idea is the development of multispecialty provider groups in which networks of practices work alongside specialists, community health services, and social services. These groups might take on population based budgets and join with local community or acute hospitals where there is an appetite to do so. Parallels with the United States are clear.

In putting forward this idea and others, Stevens has emphasised that he does not intend to impose a national blueprint. Instead he wants to encourage more creativity and flexibility, where each community chooses clinical and service models appropriate to its needs. This must ensure financial and clinical sustainability at a time when the NHS in England is arguably under greater pressure than ever, as more providers are in deficit and failing to achieve performance targets.[4]

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Pressure point

Stevens put down a clear marker to the Health Select Committee that he expects NHS funding to increase in real terms as economic growth returns, even though the NHS budget is currently expected to face constraints until 2021.[5] In this context he has committed to publishing a "Forward View" in the autumn on the NHS's prospects over the next five years, in conjunction with Monitor and the NHS Trust Development Authority. This will draw on the five year plans currently being prepared by clinical commissioning groups and providers. It promises to be an important statement of intent that will shape thinking on the NHS for the foreseeable future.

As well as setting out the policy and regulatory changes needed to support the development of new models of care, the Forward View will probably identify the funding needed to implement these models. At a time when politicians of all major parties are not promising major increases in the NHS budget, it will need to spell out the consequences of not providing additional resources for investment in new and different services. Treading a careful line between speaking up honestly for the NHS and the people it serves, while not antagonising ministers as the general election approaches, will be a key test for Stevens.

Changing physiology, not anatomy

Stevens's emphasis on improving services is a welcome contrast to the recent obsession with reorganising NHS structures. It indicates a preference for changing the physiology of the NHS rather than its anatomy—for example, by using financial incentives to reward providers who deliver better outcomes for populations and patients. He has also spoken of the need to improve commissioning by providing commissioners with better information and working with local authorities on joint commissioning of health and social care. A more radical option is flexibility in how the split between commissioning and provision is organised, as in the example of multispecialty groups taking on population based budgets to integrate care.

As head of the national organisation responsible for commissioning health services, and with experience in a major US based health insurer, Stevens's focus on these matters is to be expected. His observation that England is unique in entrusting so much responsibility for funding to frontline clinicians could be read as an endorsement of clinical commissioning groups or as a marker that such a bold experiment carries risks.[1] A new review cautions against believing that commissioning alone will succeed when similar attempts to deliver change have had partial success at best, and argues for more support for organisations that provide care to lead improvements.[6]

What is clear is that Stevens, his peers in other national bodies, and ministers need to develop a shared vision and strategy that is compelling and well understood and provides the direction for leaders and their teams throughout the NHS to work towards a better future. Only through sophisticated collective leadership of the NHS will it be possible to develop innovative models of care and achieve high standards of performance. His experience in helping to prepare the NHS Plan will undoubtedly come in useful in this regard, albeit in a context that is altogether more hostile than in 2000, when additional resources were about to flow into the NHS at an unprecedented rate. The opportunity this offers is to use the threat of an impending crisis to work with others in making changes that in normal times would simply be impossible.

Competing interests: I am chief executive of the King's Fund and worked with Simon Stevens in Whitehall between 2000 and 2004. The King's Fund has done contracted work for NHS England.

Provenance and peer review: Commissioned; not externally peer reviewed.

References are in the version on bmj.com.

Cite this as: *BMJ* 2014;348:g3842