



## A framework for re-evaluating established health screening practices

**There is increasing awareness of the complexity of screening (earlier detection), including risks of harm to participants. The authors call for a systematic and transparent approach to re-evaluation of screening practices and suggest a framework to achieve this goal.**

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*There is increasing awareness of the complexity of screening (earlier detection), including risks of harm to participants. The authors call for a systematic and transparent approach to the re-evaluation of screening practices and suggest a framework to achieve this goal.*

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### Key messages

- Changes in disease incidence and the discovery of new tests, treatments and preventive possibilities can alter the balance of benefits, harms and costs of population screening practices. Yet no clear guidelines exist on how to monitor these changes and revise practices in light of them.
- Screening the general population comes with a responsibility to ensure that screening benefits are maximised and fairly distributed, and that harms, costs and waste are minimised and justified.
- We propose a framework to guide structured, independent and transparent re-evaluations of screening practices, with input from the full range of stakeholders, and management of conflicts of interest. Our framework is a starting point rather than a finished concept and we invite comment and debate.
- The framework outlines essential steps and attributes. It can be adapted to different types of screening and healthcare systems, ideally with regulatory requirements and accountabilities.

essential: For Review Only

## 1 Introduction

From tentative beginnings over 70 years ago (1), screening (earlier detection) has become a well-established and familiar feature of modern healthcare, delivering a mix of health benefits, harms and costs (2, 3). Importantly, these benefits, harms, and costs are not constants, but differ with context and time. They change because of changes in disease incidence, new tests, treatments, and preventive possibilities.

Despite the changing circumstances, screening practices (whether organised as programmes or not) tend to be slow to react, and when change does come it is often delayed, resisted and controversial (4, 5). The reasons may be multiple: financial interests or a perception of sunk costs; lack of high-certainty evidence or proper evaluation of existing evidence; a belief that earlier detection is always better, or simple inertia. Yet screening programmes are often financed by finite collective healthcare budgets and target asymptomatic individuals. Continuation of screening in the face of changing circumstances deserves careful consideration, particularly when this potentially leads to harm and waste. Much like the principles for starting screening (1), there is an urgent need for clear, agreed methods for proactively re-evaluating existing programmes.

Over the past three years, our international group of experts from diverse disciplinary and practice backgrounds has discussed and developed a framework for regular re-evaluation of existing screening practices. The proposed framework involves a structured, transparent process, aimed at involving professionals with relevant expertise, members of the public, and patients, while managing conflicts of interest. It is intended for independent institutions that make national screening recommendations such as the U.S. Preventive Services Task Force and the UK National Screening Committee. This paper summarizes our framework and invites further comment and discussion.

### Why do screening practices need re-evaluation?

We outline four major reasons why existing screening practices need re-evaluation (Box 1). This list is not exhaustive.

#### Box 1.

Reasons to re-evaluate existing screening practices
1. Important premises may change after implementation, such as the incidence of the target condition, new test methods, or therapeutic advances.
2. Estimates of the benefits, harms, and costs which informed implementation may prove incorrect in real-world settings due to study limitations and biases. New evidence may thus necessitate re-evaluation.
3. Previously unrecognised harms may come to light, necessitating a re-evaluation of net benefit.
4. As personalised risk information becomes available, net benefit may be optimised by screening more select groups.

#### Reason 1: Change in the incidence of the target condition, new test methods, or therapeutic advances

Primary prevention may decrease disease incidence and the absolute benefit of screening, while the harms may be less affected, reducing net benefit. For instance, a 70% decline in abdominal aneurysm incidence and mortality was observed in the UK and Sweden, likely due to reduced smoking (6) and the introduction of the human papillomavirus (HPV) vaccine may reduce the disease

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3 35 burden of cervical cancer. This will change the net benefit such that screening intensity can be  
4 36 reduced, or screening even be stopped as benefits become negligible or outweighed by harms.  
5 37 Conversely, increases in incidence may improve the net benefit of screening, e.g. in obesity-related  
6 38 conditions.

8  
9 39 Improvements to outcomes at later disease stages, or across stages, tend to decrease screening  
10 40 benefits, whereas improvements to outcomes at earlier disease stages only may increase screening  
11 41 benefits. Since the introduction of systemic therapy and centralised care, there have been large  
12 42 reductions in breast cancer mortality across stages (7), with the greatest reductions (50% in many  
13 43 countries) seen in women below the typical age limit (8). Similarly, improvements in conventional  
14 44 tests or development of new tests may impact performance and change the benefit, harms or costs  
15 45 of screening.  
16 46

#### 19 47 Reason 2: Benefits, harms or cost estimates that prompted implementation may prove 20 48 incorrect

21 49 Limiting reviews of screening practices to high-quality evidence may demonstrate small or absent  
22 50 benefit. Neuroblastoma screening in children was implemented in Japan based on theoretical  
23 51 benefit and evidence from observational studies. Studies in Canada and Germany showed no  
24 52 mortality benefit but considerable overdiagnosis, resulting in de-implementation of neuroblastoma  
25 53 screening in Japan (2).

26 54 Even when implementation is motivated by randomized trial evidence, it can be difficult to achieve  
27 55 similar performance with real-world roll out, e.g., due to uptake or quality of testing. This can be  
28 56 monitored with performance indicators: monitoring early cervical screening programmes revealed  
29 57 high overdiagnosis rates and moderate mortality benefit, prompting service changes (2).

30 58 Monitoring attendance rates and behaviour (e.g., regular, incidental, or structural non-participation)  
31 59 may identify differences from anticipated estimates. This affects cost-effectiveness, which may be  
32 60 different than projected (9).

33 61

#### 39 62 Reason 3: Consideration of previously unrecognised harms

40 63 Screening for cancer and (pre-) diabetes provide examples of overdiagnosis and overtreatment,  
41 64 previously unrecognised harms of screening. Note that overtreatment is not limited to the target  
42 65 disease, but may also affect its precursors and risk factors (10). Other underappreciated harms  
43 66 include psychological consequences of false positive results and labelling (11, 12). Often, important  
44 67 harms have been identified long after initial RCTs, which historically were rarely designed or  
45 68 powered to quantify them (3). Belated recognition of overdiagnosis and overtreatment in prostate  
46 69 cancer screening have reduced prostate specific antigen tests, especially in North America.

47 70

#### 51 71 Reason 4: Net benefit may be optimised by screening more select groups

52 72 Advances in risk prediction, or identification of new risk factors, may result in optimised net benefit.  
53 73 For example, in cervical screening, HPV tests are used to inform optimal screening intervals for  
54 74 subgroups of women, e.g. increasing the screening interval from five to ten years in women aged 40  
55 75 or older with a negative HPV test (13).

56 76

## 77 Three important elements in screening re-evaluation

78

### 79 1. Systematic and independent evidence aggregation and appraisal

80 Given the value judgements involved in assessments of benefits and harms, independent and  
81 systematic evaluation of evidence is necessary. People in general, but individuals with vested  
82 interests in particular, tend to overestimate the magnitude or weight of benefits and underestimate  
83 harms (14)(15). In contrast, systematic review and guideline methods such as GRADE may produce  
84 more conservative recommendations (16). Researchers on guideline panels sometimes evaluate  
85 their own work, and may not use standardised quality assessment tools or consult with end-users.  
86 This highlights the importance of systematic appraisal methods and management of financial,  
87 intellectual, and professional conflicts of interest.

### 88 2. Public involvement

89 The public should be included in decisions because screening aims to improve public health, uses  
90 resources, and generates opportunity costs (17). If public views are incorporated into  
91 recommendations on screening and how to inform future participants, this may increase  
92 acceptability, reduce negative reactions from affected communities (4), and increase legitimacy and  
93 trust in health systems. To aid involvement, data should be clearly presented, with sufficient time  
94 and expert facilitation to support public understanding and deliberation (5). Personal experience  
95 with screening has been demonstrated to increase acceptance of its harms, possibly by cognitive  
96 justification of earlier decisions to participate (18). Care is required to ensure an inclusive sample not  
97 skewed for or against screening.

### 98 3. Implementing results

99 If the re-evaluation necessitates changes, a process for implementation is required. When the  
100 benefits of screening do not justify harms and costs, there are barriers to reducing or stopping  
101 screening, including that overdiagnosis can increase enthusiasm for screening (the popularity  
102 paradox), fear of rationing, endowment effect (feeling of entitlement to goods or services), vested  
103 interests, and individual beliefs. Strong leadership and clear communication are required during re-  
104 evaluation and for changing existing practices.

105

## 106 Proposed framework

107 Many issues raised have been considered in other settings (5, 19). For example, the BMJ Rapid  
108 Recommendations demonstrate how new evidence may trigger structured re-evaluations of existing  
109 screening practices (20).

110 Our proposed process of re-evaluation (Box 2) separates the processes of supervision and advice  
111 (Steering Committee), decision-making (Health Authority), evidence aggregation (Evidence Review  
112 and Synthesis Committee, ERSC), and input from stakeholders (citizens and professionals). A  
113 precondition for any re-evaluation is political will to endorse the process and act upon  
114 recommendations.

### 115 *Step 1: Establish a Steering Committee*

116 A standing independent government-recognised Steering Committee monitors key performance  
117 indicators and new evidence, and identifies the need for re-evaluation (Box 2). A secured budget for  
118 this Steering Committee, including funding for implementation of changes to screening practices and  
119 monitoring systems, is essential. It is too resource-intensive to review all screening activities

120 regularly. However, we propose that this independent Committee assesses screening practices to  
121 identify substantial changes (see Box 1) that would necessitate a full re-evaluation.

122 To minimize influence of vested interests while maintaining relevant input, we suggest that Steering  
123 Committee members have relevant expertise, but should not be involved in screening interventions  
124 under review through practice or research. Similarly, the public representatives on this Committee  
125 should not come from disease-specific patient organisations.

126 Instead, the Steering Committee may consult with professionals involved in the screening practice  
127 under review and people with the target condition to inform how screening works in practice, how  
128 aspects of service delivery may affect the interpretation of evidence, to what extent international  
129 findings are applicable to local context, and the experience of participating. In addition to overseeing  
130 the systematic re-evaluation process, the Steering Committee should define thresholds for  
131 acceptable levels of benefits, harms, and their balance, as well as for acceptable costs, *before* the  
132 evidence is aggregated.

133

## 134 **Box 2**

<b>Proposed framework for re-evaluation of screening practices</b>	
<b>Step 1: Steering Committee</b>	
<i>Who</i>	Leaders in their field with diverse expertise in healthcare, e.g. in public health, methodology, social sciences, medicine, health economics, ethics, and public representatives with some knowledge of health systems and health decision making processes. Members are without financial or professional ties to the screening practice under review.
<i>What</i>	Identify need for reassessment: either after periodic evidence review or triggered by advances in knowledge. Establish an Evidence Review and Synthesis Committee consisting of methods experts. Formulate the research questions and assignments to the Evidence Review and Synthesis Committee, ensure delivery of outputs, provide recommendations for optimised screening.
<i>How</i>	Define core outcomes, net benefit and cost thresholds for decision making. Provide support, guidance, and oversight of the re-evaluation process. Is informed by various stakeholders including the wider public (see step 3), experts involved in the screening intervention under review, and people with the target condition.
<i>Why</i>	To ensure independent, successful delivery of the re-evaluation process to maximise benefits, minimise harms and bias, and ensure the framework for re-evaluation is correctly applied.
<b>Step 2: Evidence Review and Synthesis Committee</b>	
<i>Who</i>	Committee of technical staff competent in knowledge synthesis methods
<i>What</i>	Construct a Summary of Findings Table and write a report on screening options under the five domains: benefits, harms, costs, the distribution, and community understanding of those (Box 3). Determine the magnitude and certainty of benefits, harms, and costs.
<i>How</i>	Conduct systematic reviews, analyse monitoring data (if available) and synthesise other evidence that completes the Summary of Findings Table.
<i>Why</i>	Produce the evidence to be presented during the deliberative engagement with the public and to guide the decisions made by the Steering Committee.
<b>Step 3: Deliberative engagement the public</b>	
<i>Who</i>	An inclusive sample of members of the general public ensuring no relevant group is systematically excluded.
<i>What</i>	Consider information from the Evidence Review and Synthesis Committee, including the benefit, harm, and cost trade-off for each screening option and community understanding thereof. Provide recommendations or consensus answers to the Steering Committee.

<i>How</i>	Hear quantification and assessment of certainty of benefits, harms, and costs based on the Evidence Review and Synthesis Committee's findings and use a deliberative process to reach consensus on questions about screening practices posed by the Steering Committee. Rank available screening options and provide detailed reasons for ranking.
<i>Why</i>	To involve members of the public in the process of value judgement to improve legitimacy and trust in the decision and provide a recommendation to the Steering Committee.
<b>Step 4: Final Recommendations</b>	
<i>Who</i>	The Steering Committee with input from stakeholders.
<i>What</i>	Make recommendations to the relevant Health Authority for or against changing screening practices based on steps 2 and 3.
<i>How</i>	Write a final report for the relevant Health Authority and present findings to the community.
<i>Why</i>	Synthesise and interpret evidence regarding screening practices to improve the benefit, harm, and cost trade-off at a societal level (opportunity costs), being explicit about the values involved.
<b>Health Authority</b>	
<i>Who</i>	"Health authority" is used as a generic term for the relevant decision-making body in a jurisdiction
<i>What</i>	Makes final decision or makes recommendation to politicians. Oversees implementation of existing or changed screening practices. Ensures monitoring data are collected and available for regular analysis.

135

136 *Step 2: Evidence Review and Synthesis Committee produce the evidence synthesis*

137 The ERSC systematically assesses the evidence across five domains (Box 2 and 3) and applicability to  
 138 local conditions. It will provide estimates of effects in absolute numbers and the uncertainty around  
 139 these. Ideally, prospectively collected monitoring data will be available for each domain to  
 140 supplement evidence from randomised trials. If not, monitoring and registries should be established  
 141 as soon as possible to collect data and allow long-term follow-up. Ideally, countries work together to  
 142 harmonise data collection to enable comparisons.

143 **Box 3.**

**The Evidence Review and Synthesis Committee synthesises and appraises evidence across five domains**

1. Magnitude, uncertainty, and timing of benefits to the population of participants;
2. Magnitude, uncertainty, and timing of harms to the population of participants;
3. Financial costs of the entire screening cascade and cost-effectiveness;
4. Distribution of benefits, harms, and costs in the population; and
5. Community understanding of the benefits, harms, and costs

144

145 Finally, the ERSC develops a Summary of Findings (SoF) table and prepares a report. SoF tables  
 146 should be constructed for the current screening strategy and, if appropriate, present alternatives  
 147 such as different screening frequencies, screening tests, and target populations. The ERSC then  
 148 presents them to the Steering Committee.

149

150 *Step 3: Deliberative engagement with the public*

151 Citizens will hear presentations based on the ERSCs findings. They will consider the trade-off of  
 152 benefits, harms, and costs, distribution of outcomes, and people's understanding, to reach collective  
 153 judgements. They will rank the available screening options from most to least desirable, and



154 transparently describe their reasoning. Secondary outputs may include recommendations for  
 155 monitoring, implementation, and how potential screening participants should be informed.

156 *Step 4: Final recommendations*

157 Results from the ERSC and citizen deliberations (Steps 2 and 3) will be considered by the Steering  
 158 Committee, which will gather feedback from experts involved in screening and other stakeholders  
 159 (Box 2). The Steering Committee will use their pre-defined benefit-harm thresholds to make  
 160 recommendations to the relevant Health Authority. These will depend on the quality of evidence  
 161 and value judgments of the stakeholders and Steering Committee. Possible recommendations  
 162 include no change, generate more evidence, or change current practice (Box 4). The feasibility and  
 163 acceptability of implementing changes would be discussed with the Health Authority to understand  
 164 the effects on the broader health care system, including key organisational, political, social, and  
 165 resource considerations.

**Box 4. Options for final recommendations of the Steering Committee**

- Sufficient certainty of evidence and agreement on net benefit to recommend continuing current screening practices;
- Sufficient certainty of evidence and agreement of net benefit or net harm to change existing screening practices, which include:
  - a) Changes to screening pathway, e.g. change communication with potential participants, replace test or treatment strategy;
  - b) Changes to eligibility, e.g. expand or contract target population age range;
  - c) Expand or contract screening interval;
  - d) Stop screening.
- Insufficient certainty of evidence to recommend changing screening practices, which may lead to a recommendation to:
  - a) gather and analyse observational data; or
  - b) randomise invitees to different screening strategies (existing versus new).

167  
 168 Additional recommendations could focus on monitoring to facilitate future re-evaluations or  
 169 research, or randomisation to different screening strategies when there is important uncertainty  
 170 (21). Recommendations regarding information for potential participants should focus on improved  
 171 understanding rather than increased participation.

172 **Challenges**

173 Strong governance and leadership by national health authorities are necessary to ensure that the  
 174 outlined framework will be followed and recommendations implemented; these may not always be  
 175 readily accepted by stakeholders.

176 Though our proposal requires resources, we believe this is justified considering the harms and costs  
 177 of screening, and the potential for cost-saving and increased net-benefit with optimised practice.  
 178 Screening healthy individuals comes with the responsibility to continually monitor and evaluate the  
 179 outcomes systematically, transparently, and independently.

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2  
3 180 There may be no 'one-size-fits-all' approach to re-evaluation, and our framework is a starting point  
4 181 rather than a finished concept. It can be adapted to individual types of screening and healthcare  
5 182 systems, ideally with a regulatory requirement for both the re-evaluation framework and monitoring  
6 183 to ensure the feasibility and integrity of the process. The framework itself should be evaluated and  
7 184 refined.  
8  
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10 185

## 11 186 Conclusion

12 187 Monitoring and re-evaluation are essential to generate and incorporate new knowledge that informs  
13 188 the balance of benefits and harms, and should be a requirement for any screening practice. This will  
14 189 ensure that screening maximises benefits, and minimises the harms, cost, and waste of health  
15 190 resources.

16 191 This four-step framework is intended for health authorities to ensure systematic, consistent and  
17 192 independent processes that strengthen decisions and recommendations around change. By bringing  
18 193 together experts and public values in a process led by a standing committee that operates  
19 194 independently, society will benefit from transparent and evidence-based screening practices that  
20 195 ensure benefits outweigh harms at a reasonable cost and are acceptable to the majority.  
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## 30 215 **Conflicts of Interest**

32 216 We have read and understood BMJ policy on declaration of interests and have no relevant interests  
33 217 to declare. The authors alone are responsible for the views expressed in this article and they do not  
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