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Review

Executive summary

False-negative results in screening programmes: systematic review of impact and implications

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Background

When assessing whether a screening programme is appropriate, there is a particular obligation to ensure that the harms as well as the benefits are considered. Among these harms is the likelihood that false-negative results will occur. In some cases, the consequences of these can be difficult to assess, although false reassurance leading to diagnostic delay and subsequent treatment has been suggested. However, no test is totally accurate (with 100% sensitivity and specificity), and false-negative results are inherent in any screening programme that does not have 100% sensitivity.

This review was carried out to assess the medical, psychological, economic and legal consequences of false-negative results that occur in national screening programmes.

Objectives

- to determine the consequences of false-negative findings
- to investigate how their adverse effects can be minimised
- to assess their implications for the NHS, including the impact of false-negatives on public confidence in screening programmes
- to identify relevant theoretical perspectives that may be potentially useful when considering the implications of false-negative results.

Methods

A systematic literature review was carried out. This included a search of 18 electronic databases, various bibliographies and contact with experts to identify relevant literature and perspectives. Outcomes included in the review fell into four categories:

- medical outcomes (morbidity and mortality)
- psychological outcomes (distress, false reassurance, loss of confidence in services)
- economic outcomes (such as costs to the NHS)
- legal outcomes (such as litigation).

Other outcomes, such as the impact of false-negatives on public confidence in screening programmes, were also included.

The participants included individuals taking part in screening programmes, healthcare professionals and organisations responsible for screening programmes.

Methodological details of the review are provided in the full report.

Results

A total of 6660 abstracts were screened, and 420 potentially relevant papers were identified. Most of the studies that were identified presented only anecdotal evidence.

- Medical outcomes: In all, 13 papers presented quantitative information relevant to the medical consequences of false-negative results; seven of these were primary studies, and the remaining studies were literature reviews or models examining the likely impact of false-negative results.
- Psychological outcomes: A total of eight published studies presented information on the psychological consequences of negative results in general; only one study, on antenatal screening, provided direct evidence of the psychological consequences of false-negative results, where they were associated with lower parental acceptance of the affected child and with blaming others for this outcome.
- Economic outcomes: Only two studies presented information on the economic consequences.

The strength of evidence from most of the primary studies was low. There is some evidence that false-negative results may have a large legal impact. For example, in cervical screening they have led to legal action and its associated costs, including payment of compensation; this is based on reports of events in both the UK and US health systems. There also seems to be a consensus in the literature that false-negatives may have a negative impact on public confidence in screening; evidence is again limited however.

Conclusions

False-negatives are evident in all screening programmes, even when the quality of the service provided is high. They may have the potential to delay the detection of breast and cervical cancer, but there is little evidence to help assess their psychological consequences in these or other screening programmes. False-negatives are likely to lead to legal action being taken by those individuals affected, and potentially may reduce public confidence in screening. Their impact may be reduced by the provision of full information to participants about the benefits and harms of screening programmes, and by increasing public education on these issues.

Implications for policy

New screening programmes need to 'start starting correctly'. In the context of false-negative results, this means that it is desirable that participants in screening programmes are provided with full information on the meaning of negative results. Screening programmes might also include evaluation of the impact of false-negatives. Greater public and professional education on the meaning and limitations of screening is also needed. The wider provision of public education materials that include clear information about the limitations and benefits of screening, and the meaning of all types of test result, may be particularly helpful in this regard. This will help participants to make informed decisions about whether to participate or not in screening programmes.

Recommendations for research

Research is now required that prospectively investigates the long-term medical, psychological and other consequences of false-negative results in a range of screening programmes. Research on the most effective means of presenting information on residual risks to those individuals undergoing screening is also needed. The development of sensitive economic models, which include a full evaluation of the benefits and harms of screening, will also be helpful. These will aid in assessing the appropriateness of screening programmes before their introduction.

Publication

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NHS R&D HTA Programme

The overall aim of the NHS R&D Health Technology Assessment (HTA) Programme is to ensure that high-quality research information on the costs, effectiveness and broader impact of health technologies is produced in the most efficient way for those who use, manage and work in the NHS. Research is undertaken in those areas where the evidence will lead to the greatest benefits to patients, either through improved patient outcomes or the most efficient use of NHS resources.

The Standing Group on Health Technology advises on national priorities for health technology assessment. Six advisory panels assist the Standing Group in identifying and prioritising projects. These priorities are then considered by the HTA Commissioning Board supported by the National Coordinating Centre for HTA (NCCHTA).

This report is one of a series covering acute care, diagnostics and imaging, methodology, pharmaceuticals, population screening, and primary and community care. It was identified as a priority by the Population Screening Panel and funded as project number 95/40/01.

The views expressed in this publication are those of the authors and not necessarily those of the Standing Group, the Commissioning Board, the Panel members or the Department of Health. The editors wish to emphasise that funding and publication of this research by the NHS should not be taken as implicit support for the recommendations for policy contained herein. In particular, policy options in the area of screening will be considered by the National Screening Committee. This Committee, chaired by the Chief Medical Officer, will take into account the views expressed here, further available evidence and other relevant considerations.

Reviews in *Health Technology Assessment* are termed 'systematic' when the account of the search, appraisal and synthesis methods (to minimise biases and random errors) would, in theory, permit the replication of the review by others.

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Reports are published in the HTA monograph series if (1) they have resulted from work either prioritised by the Standing Group on Health Technology, or otherwise commissioned for the HTA Programme, and (2) they are of a sufficiently high scientific quality as assessed by the referees and editors.

The editors have tried to ensure the accuracy of this report but cannot accept responsibility for any errors or omissions. They would like to thank the referees for their constructive comments on the draft document.

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