Education and debate

Use of decision aids to support informed choices about screening

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Decisions about screening can be more complex than those about treatment. Well designed decision aids could help patients understand the risks as well as the benefits

Patients should be able to participate in health decisions, if they so choose. Decision aids have been developed to help patients make informed decisions about treatment and have been found to improve knowledge, reduce indecision, and improve agreement between values and choice.¹ However, in screening, where informed choice is not common practice,² decision aids are controversial and their effect is currently unknown.^{3,4} Nevertheless, the complexities of decisions about screening mean that decision aids could be of immense value. In this paper we highlight eight issues that are critically important for the development and use of high quality decision aids about screening. Some of these issues arise because of fundamental differences between screening and treatment interventions; other issues flow from widespread uncritical support for screening, as illustrated by the storm over PSA (prostate specific antigen) screening for prostate cancer.^{5,6}

Problems with weighing the evidence

Weighing the evidence for and against a screening intervention is a complex task for policy makers and is likely to prove challenging for individual consumers too. In its latest edition, the US Preventive Services Taskforce has rated screening interventions on a five point scale, based on an assessment of whether benefits outweigh harms (or vice versa) and on the extent to which evidence is available to make that assessment.⁷ Unfortunately, the evidence available is often insufficient to make a recommendation.⁷ Even when evidence is available, policy makers have to judge whether the benefits outweigh the harms, and this decision is at least partly driven by the values of the people making the policy or recommendation. Their values may not accord with those of the individuals who are subsequently offered the screening test, underscoring the need for evidence based information to be presented to consumers.

To further complicate decision making, screening is implemented in various ways in different countries, on the basis of variable evidence, and with variable government regulation and protection for consumers. For example, evidence from randomised trials supports blood pressure screening,⁷ yet improved blood pressure screening and management through

People need good information on the possible benefits and harms of screening

computerised systems is variably implemented.⁸ In contrast, cervical cancer screening programmes have been established within carefully regulated systems in many countries without evidence from randomised trials.⁷ Health authorities may also hold opposing views on whether screening is worthwhile—as, for example, in regard to prostate cancer.^{7,9} Finally, some screening (for example, by total body computed tomography) is available (and heavily marketed), even though there is no evidence that benefit outweighs harm, no endorsement from any health authority, and little regulation or protection for consumers.⁶

Thus we believe decision aids for consumers are urgently needed (and will be developed) on the substantial number of screening interventions now available. Below, we use examples from a range of screening programmes to illustrate the issues relating to development and use of decision aids (box).

Developing and using decision aids for screening interventions

Detecting inconsequential disease

People making treatment decisions have a disease for which they seek treatment. Screening, however, may

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uncover inconsequential disease (pseudodisease) that will never produce symptoms.^{10–11} Detection of inconsequential disease results in unnecessary diagnosis and treatment.^{6–10–12} This problem is most clearly recognised in PSA screening for prostate cancer¹³ but applies generally. For example, screening mammography results in over-detection of both invasive breast cancer¹⁴ and ductal carcinoma in situ,¹⁵ so although screening may reduce the risk of dying from breast cancer, it increases the chance of a breast cancer diagnosis.

The problem of inconsequential disease extends to screening for risk factors. For example, people identified as having high cholesterol concentrations or high blood pressure suffer immediate “labelling” effects^{16–17} and may view these conditions as diseases. In reality, however, many people with these risk factors will not develop symptomatic cardiovascular disease for many years, if ever.¹⁸

Inconsequential disease is considered by some to be the biggest drawback of screening.^{6–12} Therefore it is of concern that the general public are poorly aware of it.⁶ Decision aids must contain clear, numerical information on the chances of having inconsequential disease found and treated.

Providing information about follow up tests and treatments

Decision aids for treatments present information about several possible options and help people weigh these

Considerations in developing decision aids for screening interventions—and suggestions to developers

- Screening leads to over-detection and over-treatment—Present the chances of having pseudodisease as well as clinically important disease detected by screening
- Screening may include invasive follow up investigations and treatments—Give information about the whole of the early detection and treatment process
- Benefits of screening are delayed, whereas harms are immediate—Present balanced information about the cumulative chance of benefits and harms over equivalent time frames
- Few people experience benefits from screening compared with the number who would be expected to benefit from most treatments—Present very small numbers by using large and consistent denominators, for example, outcomes per 1000 or per 10 000 people screened
- Individual values and preferences are critical to screening decision making—Screening decision aids need to accommodate flexibility in labelling the outcomes of screening as benefits or harms
- Evidence base for screening decision aids is often limited—Explicitly declare where high quality evidence is lacking; use ranges or some other method to convey uncertainty in numerical estimates
- Public attitude is that early detection and or prevention must be good—Explain that there is a choice and the reasons why people might decide to decline screening
- Little regulation is in place to protect consumers from aggressive marketing, and there may be strong financial incentives to get people to participate in screening—Information about financial gains to the organisation offering the screening test may need to be included in decision aids

up. Screening, on the other hand, involves a longer, more complex process, including the initial test plus the follow up investigations and treatment. Informed decision making requires a consumer to understand the whole process before making a decision, yet few people realise the consequences of a positive screening result until they face that abnormal result. For example, few women who participate in cervical screening know much about the follow up tests and examinations for an abnormal smear test result, and knowledge levels are low, even in those who undergo colposcopy and biopsy.^{19–20} Thus developers of screening decision aids must include information about the whole screening process (including follow up tests and treatments).

Presenting cumulative benefits and harms over an appropriate time

In the treatment context, people are sick and treatment may result in improvement in the near future. Thus an immediate treatment benefit may need to be traded off against immediate (or perhaps delayed) side effects. In screening, the benefits are usually to be experienced in the future, possibly quite far into the future, but the harms can be immediate. Thus immediate harms must be traded against an uncertain future benefit. For example, screening can reduce the risk of death from bowel cancer by about 23% if people attend screening regularly every two years, for 10 years.²¹ This possible benefit over the next 10 years has to be traded against the risk of a perforated bowel as a result of a colonoscopy, which could occur after the first or any subsequent screening test.²¹ To present balanced information about benefits and harms, therefore, decision aids need to present information about the cumulative risk of benefits and harms (such as the cumulative risk of a false positive result, or requiring a biopsy²²) over an appropriate time frame (most likely 10 years or more).

Communicating outcomes with a low probability

The numbers needed to treat associated with most treatments for symptomatic conditions are relatively small.²³ In contrast, the benefits of screening are relatively rare, and the numbers needed to screen are large. For example, the number of men who need to be screened for raised cholesterol concentration to prevent one death from heart disease within five years range from 21 067 for men aged 25–34 to 231 for men aged 55–64, and the numbers are greater for women.¹⁸ For cervical screening, an estimated 1000 women need to be screened for 35 years to prevent one death from cervical cancer.²⁴

Conveying very low event rates is technically difficult. The cumulative deaths over 10 years from bowel cancer for Australian men in their 60s are about 98/10 000 without screening and about 75/10 000 with screening.²¹ Thus the diagrams used to aid screening decisions may need to use 1000 faces or even 10 000 faces to show event rates as whole figures instead of the 100 faces used in diagrams for treatments.²⁵ Furthermore, it is important to provide a context within which to consider the impact of screening.²⁶ For example, the decision aid might include the risk of death from other causes or all causes over a similar time.

Valuing outcomes

Research indicates that people vary in the way they value screening outcomes such as false positive results.^{6 27 28} This is consistent with qualitative reports we have received from participants in bowel, breast, and cervical screening programmes: some people consider a false positive a good result because they feel reassured that they have been thoroughly checked and found not to have the target disorder, while others regard a false positive as inconvenient, anxiety provoking, unpleasant, or dangerous. Thus the information presented by and values clarification exercises used in screening decision aids need to be flexible about classifying outcomes as pros and cons. The aid might allow people to assign positive (pro) or negative (con) status to different outcomes themselves, rather than use a fixed scheme for everyone.

Quality of evidence

For treatments, decision aids use evidence from randomised trials about outcomes of different options. Such high quality data are often not available for screening, partly because trials of screening need to be very large and may require follow up over many years, making them expensive and time consuming. Worse, by the time the trial reports, the screening test may have been substantially updated, so the applicability of the results of the trial is unclear. Thus developers may have to rely on observational data with all its inherent biases (including lead time bias, length time bias, and the healthy volunteer effect^{10 11}), which should be explicitly stated.

Even when trials are available, there are usually only a few, and so estimates are subject to substantial uncertainty. For example, meta-analysis of trials of screening for bowel cancer using faecal occult blood tests shows a 23% relative risk reduction for death from bowel cancer for people who screen regularly, with a 95% confidence interval of 11% to 43%.²¹ There may be even greater uncertainty about estimates from randomised trials in other contexts—for example, mammography screening.²⁹ It is challenging to adequately convey the uncertainty in the data about screening. Ranges may be better than point estimates, but their use may compromise the simplicity and clarity of communication.

Informed choice in the context of screening

Consumers are reasonably familiar with having different treatment options to choose between, as there have been different drugs or management options available for many conditions for a long time. The concept of having options with regard to screening is less familiar.⁶ Developers of decision aids for screening should be prepared for users to respond with “But why wouldn’t I be screened for X? That’s the responsible thing to do.” We have found it necessary to explain the down sides of screening and reasons why you might choose not to be screened at the start of decision aids.

Furthermore, some healthcare providers may feel uncomfortable with the information provided in evidence based decision aids about screening and may disagree with consumers about the amount and balance of information. When pilot testing a mammography decision aid we found that healthcare providers thought it contained too much information and was slanted against screening, while women said the information was about the right length and slanted

Summary points

The effects of decision aids about screening on decision quality and participation in screening are largely unknown

Public (and professional) understanding of the drawbacks of screening is limited

As well as information on benefits, decision aids need to include information on detection of inconsequential disease and about the risks of the full range of investigations and treatments which may be entailed if results are abnormal

Information on benefits and risks should be given over similar time frames

People may vary in viewing outcomes of screening as pros or as cons

towards screening (D Stacey et al. Reasons for Hope, Ottawa, 25-27 Oct 2003). Our experience is consistent with previous research showing ultrasonographers felt they couldn’t give women information contained in an evidence based leaflet about antenatal screening.³⁰ Developers should probably expect some discomfort among healthcare providers, who may feel that the decision aid is unbalanced, that it runs counter to their view of screening, or that information about harms will cause anxiety among patients.

Incentives to participate in screening

Financial incentives or performance targets are rarely related to acceptance of treatment. In the screening context, companies directly market “off the shelf” screening kits such as faecal occult blood test and genetic screening kits. Unlike treatments, screening tests are not well regulated by government, and the public is not well protected against the commercial promotion of screening tests.⁶ Even within authorised and accredited government funded screening programmes, there is a perceived need to meet participation targets in order to maximise population benefits.² Healthcare funders and those delivering services may be reluctant to support the use of screening decision aids by consumers if they think it will reduce participation. The impact of screening decision aids on participation rates is unclear,^{3 4} but is likely to vary between different screening interventions. Developers may need to work closely with providers of the screening service to develop and evaluate screening decision aids. Any vested interest should be declared.

Conclusions

Screening decisions are complex, and relevant information, such as information about the increased risk of diagnosis with screening, is often counterintuitive. Benefits are relatively rare and often delayed, and the screening process can involve a whole series of interventions. The harms of screening are poorly understood by the public, and screening tests are often viewed uncritically. As such, screening decisions gener-

ate unique issues for consideration in the development and implementation of decision aids. Developers of screening decision aids need to ensure these issues are adequately addressed.

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Experiences of the *BMJ* ethics committee

Elizabeth Wager on behalf of the *BMJ* ethics committee

The *BMJ* established its ethics committee nearly four years ago. What has it achieved and has it changed the journal's practice?

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The *BMJ* ethics committee was established to help editors with difficult cases, to review policies that have ethical implications, and to expand the journal's coverage of ethics.¹ Unlike the Committee on Publication Ethics (which considers anonymised cases submitted by journal editors), the *BMJ*'s committee discusses possible future policies as well as responding to specific issues and sees full details of all cases (although they are anonymised for the minutes, which are available on the *BMJ*'s website (http://bmj.bmjournals.com/advice/bmj_ethics.shtml)).

Since our inception in November 2000 we have met 13 times and discussed 70 cases from the editorial team. Three broad themes have emerged from our discussions. These are:

- Patient confidentiality
- The journal's responsibilities to people outside the publishing process, and
- Research misconduct.

Patient confidentiality

Like many ethical issues, the confidentiality of the doctor-patient relationship sounds straightforward until you are confronted with difficult cases. As part of our review of journal policies with ethical implications, we considered the *BMJ*'s guidelines on publishing information on individual patients. These stated that information should not be published without the patient's consent. That sounds fine, until Minerva wants to publish a picture of an Egyptian mummy^{2,3} or someone submits a piece with an important message describing a patient who died decades ago in a remote part of the world. The committee has therefore revised the guidelines to describe the situations in which publication of individual information without consent might be appropriate.⁴

We also considered whether rules about consent to publish individual data still applied after a patient had