

LES IRWIG, MBBCh, PhD,

FFPHM

*Department of Public Health and  
Community Medicine  
University of Sydney  
New South Wales, Australia*

PAUL GLASZIOU, MBBS, PhD,

FAFPHM

*Department of Social and Preventive  
Medicine  
University of Queensland Medical  
School  
Queensland, Australia*

*Effective Clinical Practice.  
2000;3:47–50.*

# Informed Consent for Screening by Community Sampling

**S**creening requires that people with no symptoms undergo testing to find out whether they have occult disease. Therefore, there is a strong ethical imperative to ensure that high-quality evidence is available from randomized trials and that screening is judged to have more benefits than harms. But how should this judgment be made, and by whom?

Delaying a death by screening is a substantial benefit that accrues to few people, but screening also has disadvantages and presents harms to many people. Benefits are often long term and include reductions in mortality or in morbidity due to the disease.<sup>1</sup> Disadvantages or harms are often immediate, arising from the screening test itself or the need for further investigation in those whose test results are positive. There may be inconvenience and discomfort for those screened. In up to 5% to 10% of screenees,<sup>1,2</sup> false-positive test results may result in anxiety and physical harm associated with further investigation. Some true-positive patients have abnormalities that would not have led to any adverse events during their lifetime and therefore have no potential for any benefit from screening.<sup>3–5</sup> As an example, consider mammographic screening in women starting at 40 years of age. To avert 1 death in the next 10 years, more than 1000 women need to be screened 5 times, and about 300 would be recalled for further investigation.<sup>6</sup> Most of these would turn out to have false-positive results. In some countries, about 35 women would have biopsies, whereas in others, the number could be three times as great.<sup>7</sup> About 15 cases of invasive cancer would be detected early, and about 3 ductal carcinomas in situ would be found, some of which might never have progressed.<sup>6</sup> Given this information, individuals may vary in their desire to be screened.

Screening for communicable disease is different. In addition to the benefits and harms for the individual, society benefits because of reduced transmission. Similarly, for some noncommunicable diseases, such as phenylketonuria, screening may save money for society and extend the benefits beyond the individual. However, most current screening is for noncommunicable disease and costs society more than it saves. Any benefit of screening accrues to—and harms or inconveniences are borne by—the individuals being screened and their families, and the total benefit to society is the sum of the net benefit to these people. In this circumstance, it seems inappropriate to frame the objective of screening as a reduction in mortality and disability from the disease being detected, when the goal of achieving this “hard” end point may be won at the cost of decreased health—broadly defined—for people being screened.<sup>8–11</sup> It seems more appropriate that people to whom screening is being offered should give informed consent to be screened.

## It Is Not Easy To Achieve Individual Informed Consent for Screening

The principle of individual informed decision making and consent is not easy to apply to screening. To start with, adequate accessible information needs to be available to enable people to assess the benefits and harms of screening. To what extent is this information available, and how much has it been used to guide decisions? In most trials and decision analyses, the only issues considered are the hard outcomes,

*This paper is available at [ecp.acponline.org](http://ecp.acponline.org).*

such as mortality and complications of the disease or the screening process, and the financial costs.<sup>12</sup> In general, studies do not adequately describe the immediate disadvantages that people experience at the time of screening, and the harms associated with false-positive results. These harms may be minor and temporary and result in only a small decrease in quality of life for each individual. However, because they occur in many people and are immediate, their total effect may outweigh the benefit of reduced mortality for a few people many years later.<sup>13</sup> Even if information is available, it is difficult to weigh probabilistic information, especially when the outcomes are rare.<sup>14,15</sup> This has been done in some cases: For example, men who are informed about the disadvantages, potential benefits, and uncertainties associated with prostate cancer screening are more likely to choose not to be screened.<sup>16</sup> Few attempts have been made to find out how women weigh the benefits and disadvantages of mammographic screening, and the studies that have been done need to be interpreted with caution because of problems with obtaining a representative sample. In a telephone survey of 40- to 49-year-old Australian women to whom the necessary information was given, 62% of women thought that the benefits of a government-funded screening program outweighed the disadvantages, 12% thought that the disadvantages outweighed the benefits, 25% thought that benefits and disadvantages were about equal, and 2% could not say. Sixty-five percent thought that women should be given all the information and make up their own minds about screening mammography.<sup>17</sup> Yet, at least in Australia, none of the many pamphlets on mammographic screening provide the information necessary to help women make that decision.<sup>18</sup>

It is a challenge to provide adequate information to each individual being offered screening. Providing this information will consume health service resources, not just in terms of preparing written material but in ensuring that the information is understood, responding to queries, and ensuring equity of access to the information.

## Informed Consent by Community Sampling

We propose that the need for information at the individual level can be minimized if we know more about the distribution of preferences among fully informed potential screenees: for example, from a random sample of the population to whom screening will be offered. To ensure that screening has a net benefit will involve collecting more information on a broader range of effects of screening—both benefits and harms—than is generally done. We also need to develop better ways of presenting this information and helping people formulate a decision on how the benefits and harms balance out.<sup>19</sup>

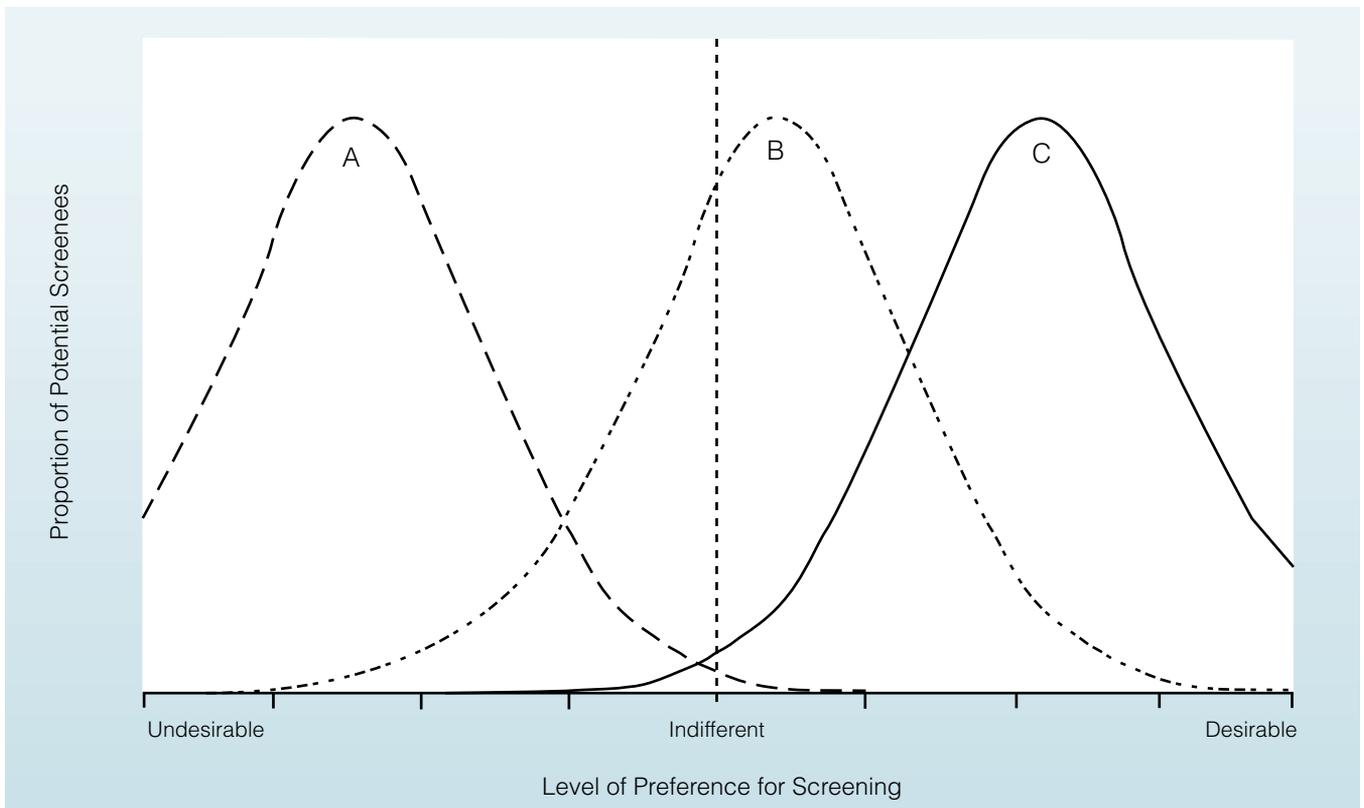
The advantages and disadvantages of attempting to obtain informed consent by community sampling are shown in **Table 1**. In general, consent procedures will require more work than current systems of advising people about screening. The provision of information and the necessary time to discuss and reflect on it require considerable effort, time, and skill.<sup>20</sup> However, particularly in the long term, this would be a less daunting task for community informed consent than for individual informed consent.

To understand how preferences for screening obtained from community samples might be interpreted, consider the hypothetical results shown in **Figure 1** for three populations: A, B, and C. The populations may differ in the underlying risk for disease or in their attitudes about benefits and harms.

Distribution A suggests that screening need not be offered because it is seen by most people to have no net benefit. Health care funders may decide not to finance such screening, and few people are likely to be prepared to pay for it. Distribution C suggests that a community consensus about the value of screening exists. Subject to an acceptable cost-effectiveness ratio, screening can be offered. People should be informed that a representative sample of people who are similar to them and have been given detailed information about the screening process thought that the benefits outweighed the disadvantages. For many, that may be sufficient for them to decide

**TABLE 1**  
**Advantages and Disadvantages of Obtaining Informed Consent by Community Sampling**

ISSUE	STATUS QUO (NO CONSENT)	INDIVIDUAL CONSENT	COMMUNITY INFORMED CONSENT
Effort	None	High, ongoing, difficult to sustain	Small, fixed, initial
Informed decision making	Low	High	Indirect
Depth of information	Minimal	Modest	High
Attendance	Influenced by marketing	More appropriate	More appropriate



**FIGURE 1.** Possible preference distributions from community surveys. **A.** Screening clearly undesirable; do not implement. **B.** Mixed preferences; individual consent required. **C.** Screening clearly desirable; implement if acceptably cost-effective.

about screening. Some may still want more information, which should then be provided. Distribution B suggests a need for individualized decisions, as may be the case in mammographic screening in 40-year-old women. Detailed information must be available, with adequate support for people who wish to have help in making decisions, and advice that is sensitive to the needs of people who wish to delegate the decision.<sup>21</sup>

Of course, putting this principle of community informed consent into practice will be far from easy, and many questions arise. For example, how should a “representative community sample” be selected? How can one ensure that the sample understands the information? As occurs with many processes of collecting information to help address health policy decisions, answering these questions will require further debate and research. We suggest using random samples of the population to which screening will be offered. Ensuring that the sample understands the issues to which responses are being sought can be done by prior testing of instruments or developing methods that involve face-to-face discussion. In making these suggestions, we have ignored the “opportunity cost” of screening—that is, whether health care dollars could be better spent elsewhere. That is a separate stage of the process of community involvement

in health care decisions that would require an extension of the process we have described to include multiple interventions for a variety of health interventions.

We suggest that once randomized trials have shown that a screening procedure prevents deaths and disability, implementation should focus on the provision of valid, understandable information so that people can make a fully informed choice about whether the benefits outweigh the harms and disadvantages. This requires an informed consent process: either obtaining individual consent, or more feasibly, obtaining consent from a representative community sample. Only when adequate community surveys of preferences show that most potential screenees would choose to be screened does it seem ethical to actively promote screening without detailed individual consent.

#### References

1. Towler B, Irwig L, Glasziou P, Kewenter J, Weller D, Silagy C. A systematic review of the effects of screening for colorectal cancer using the faecal occult blood test, Hemoccult. *BMJ*. 1998;317:559-65.
2. Health Care Committee. Screening to prevent cervical cancer: guidelines for the management of women with screen detected abnormalities. Report by the National Health and Medical Research Council for the organised approach to preventing cancer of the cervix. Canberra, Australia: Commonwealth Department of Human Services & Health; 1994.

3. Hirst GH, Ward JE, Del Mar CB. Screening for prostate cancer: the case against. *Med J Aust.* 1996;164:285-8.
4. Ernster VL, Barclay J, Kerlikowske K, Grady D, Henderson C. Incidence of and treatment for ductal carcinoma in situ of the breast. *JAMA.* 1996;275:913-8.
5. Forrow L, Wartman SA, Brock DW. Science, ethics, and the making of clinical decisions. Implications for risk factor intervention. *JAMA.* 1988;259:3161-7.
6. Irwig L, Glasziou P, Barratt A, Salkeld G. Review of the evidence about the value of mammographic screening in 40-49 year old women. National Health and Medical Research Council National Breast Cancer Centre; 1997. Available at: <http://www.nbcc.org.au/pages/info/resource/nbccpubs/scr4049/contents.htm>.
7. Elmore JG, Barton MB, Mocerri VM, Polk S, Arena PJ, Fletcher SW. Ten-year risk of false positive screening mammograms and clinical breast examinations. *N Engl J Med.* 1998;338:1089-96.
8. Stewart-Brown S, Farmer A. Screening could seriously damage your health. *BMJ.* 1997;314:533-4.
9. Rembold CM. Number needed to screen: development of a statistic for disease screening. *BMJ.* 1998;317:307-12.
10. Woolf SH, Lawrence RS. Preserving scientific debate and patient choice: lessons from the Consensus Panel on Mammography Screening. *JAMA.* 1997;278:2105-8.
11. Sox HC. Benefit and harm associated with screening for breast cancer. *N Engl J Med.* 1998;338:1145-6.
12. The cost-effectiveness of screening for type 2 diabetes. CDC Diabetes Cost-Effectiveness Study Group, Centers for Disease Control and Prevention. *JAMA.* 1998;280:1757-63.
13. Krahn MD, Mahoney JE, Eckman MH, Trachtenberg J, Pauker SG, Detsky AS. Screening for prostate cancer. A decision analytic view. *JAMA.* 1994;272:773-80.
14. Tversky A, Kahneman D. The framing of decisions and the psychology of choice. *Science.* 1981;211:453-8.
15. Redelmeier DA, Rozin P, Kahneman D. Understanding patients' decisions. Cognitive and emotional perspectives. *JAMA.* 1993;270:72-6.
16. Wolf AM, Nasser JF, Wolf AM, Schorling JB. The impact of informed consent on patient interest in prostate-specific antigen screening. *Arch Intern Med.* 1996;156:1333-6.
17. Cockburn J, Pit S. Perceptions of screening mammography amongst women aged 40-49. National Health and Medical Research Council National Breast Cancer Centre, Australia; 1998. Available at: <http://www.nbcc.org.au/pages/info/resource/nbccpubs/perc4049/contents.htm>.
18. Slaytor EK, Ward JE. How risks of breast cancer and benefits of screening are communicated to women: analysis of 58 pamphlets. *BMJ.* 1998;317:263-4.
19. O'Connor AM, Tugwell P, Wells GA, et al. Randomized trial of a portable, self-administered decision aid for postmenopausal women considering long-term preventive hormone therapy. *Med Decis Making.* 1998;18:295-303.
20. Dolan P, Cookson R, Ferguson B. Effect of discussion and deliberation on the public's views of priority setting in health care: focus group study. *BMJ.* 1999;318:916-9.
21. Degner LF, Kristjanson LJ, Bowman D, et al. Information needs and decisional preferences in women with breast cancer. *JAMA.* 1997;277:1485-92.

#### Correspondence

Les Irwig, MBBCh, PhD, Department of Public Health and Community Medicine, Building A27, University of Sydney, New South Wales, 2006, Australia; telephone: 61-2-9351-4370; fax: 61-2-9351-7420; e-mail: [lesi@pub.health.usyd.edu.au](mailto:lesi@pub.health.usyd.edu.au).