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Informed Decision-Making and Breast Cancer Screening

In a recent Lancet publication, Hersch et al reported findings on the influence of alternative-content decision aids on knowledge, attitudes, and intentions related to breast cancer screening.[1] The alternative decision aid booklets were provided to 879 women aged 48–50 in New South Wales, Australia who were approaching the target age to begin breast cancer screening. Briefly, the authors randomized 440 women to an intervention group which received a breast screening information booklet that included quantitative information on overdiagnosis, and 439 to a control group that received the same information booklet without reference to overdiagnosis. The authors then administered a questionnaire to all randomized women, on knowledge, attitudes, and intentions relating to breast cancer screening. Based on a woman's answers, the researchers classified each woman on whether she had made an informed choice about breast cancer screening (defined as adequate knowledge and intentions consistent with attitudes). The authors concluded that women in the intervention group were more likely to make an informed choice, due to their greater knowledge about overdiagnosis. In addition, fewer women in the intervention group than in the control group intended to be screened (74% v 87%; $p < 0.001$). A companion editorial suggests that accompanying an offer of screening with information is necessary but not sufficient for informed choice, because various factors influence how that information is processed. The authors of the editorial also assert that there is a major ethical dilemma in screening, ie. while some will receive a net benefit from screening, some will receive a net harm.[2]

A number of major issues of fundamental principle exist in relation to the concept and results of the study, and the accompanying editorial. Briefly, these are:

- Detailed decision aids are particularly useful for difficult decisions and should complement counselling.[3] Hersch et al note that decision aids are provided in situations with no obviously right or wrong option. For example, a majority of organizations in the United States do not recommend for or against prostate cancer screening, and instead recommend shared decision making and the use of decision aids.[4] However, if the health service is spending millions of dollars to make screening available, typically that commitment is reflected in a recommendation for screening and invitations to screening. Such is the case of breast screening, where for decades the evidence has been judged by multiple, independent groups to be sufficiently and convincingly persuasive of net benefit. In this context, a decision aid which reduces the numbers taking up the offer of screening cannot be considered a positive development.
- The study results are to a considerable extent tautological. It is no surprise that women who are told something about overdiagnosis (or overdetection) are more likely to be able to repeat it back to the researchers than women who are not, and will thus appear "better informed." The more interesting and important question of the best way of conveying the same information is not addressed here.
- Although the authors consider their intervention aid to be unbiased, 36% of women in the intervention group considered it to be slanted against screening, as opposed to 20% who considered it to be slanted in favour. More worrisome, only 25% of women receiving the intervention decision aid strongly agreed that it was "helpful in making a decision" (compared with 38% receiving the control aid); and 10% did not find it "clear and easy to understand" (compared with 4% of controls). It is thus reasonable to conclude that the more complex booklet was confusing (to some) and resulted in fewer women making a rational choice.
- Perhaps most worrisome, for an intervention aimed at improving informed decision-making, 16% of the intervention group reported being unsure about their intention with respect to breast screening, more than twice the 7% who reported the same in the control group. Two-thirds of the decrease in those intending to be screened was due to an increase in women unsure whether to be screened. The decision aid provided to the intervention group does not seem to be helping women make a decision about screening

We also question the validity of some of the information provided in the intervention.

First, the decision aid does not mention that the health service is following the advice of independent panels of experts that screening is worthwhile. Such information is, in our opinion, essential for making an informed decision as to whether or not to accept the offer of screening. Giving the impression that the health service is neutral about the invitee's taking up the offer is misleading.

Second, the decision aid gives the impression that dying of breast cancer in the absence of screening is rare (12 per 1000), whereas the lifetime risk of developing breast cancer is an order of magnitude greater (approximately 120 per 1000), which is not consistent with current survival from breast cancer. Further, the use of icons of the same size gives the impression that a breast cancer death,

an overdiagnosis, and a false positive screening result are all of similar importance. If the icon sizes were proportional to quality adjusted life years gained or lost, a considerably different impression would be given to the reader trying to understand the tradeoffs between the benefits and harms of being screened. Far more women will have a false positive mammogram than will be prevented from dying from breast cancer, but the harm (becoming anxious and having to be investigated for breast cancer) is somewhat trivial, by any measure, compared with the benefit (avoiding chemotherapy and living an additional 25 years). Moreover, the lifetime risk of one or more false positives should be put in context as it varies by age, mammographic density and other risk factors, as well as the attendance rate, and institutional factors.[5]

Third, it is not clear how the claimed numbers of lives saved and overdiagnosed cases are derived. This lack of transparency is especially troubling in a scientific report, but any provider of a decision aid developed by others must scrutinize the information for both balance and accuracy, and the same holds for the developer. It would appear that the numbers relate to the increase in diagnoses and the decrease in deaths among women whilst aged 50 to 69, which is not the same as the total numbers of breast cancer deaths prevented (many of which eventually will be revealed in women over age 70) and overdiagnosed (as opposed to earlier diagnosed) cancers from screening aged 50–69. It is stated that the numbers used are from the UK Independent Review,[6] but the figure of four breast cancer deaths prevented per thousand is what the UK review estimated for the effect of being *invited* rather than for actually being screened, and it is the latter (about six per 1,000), not the former, that is relevant to the content of a decision aid. The overdiagnosis numbers also are considerably greater than the numbers estimated by the UK review for actually being screened. If, as seems likely, the elevated estimate of overdiagnosis is due to restriction of deaths and cases to those that occur within the 20-year period, some of the excess cases are not overdiagnosed, but simply diagnosed early due to lead time.[7]

Finally, the intervention aid gives considerable emphasis to treatment of overdiagnosed cancers. It describes the side-effects of surgery, hormone therapy, radiotherapy and chemotherapy, but does not make clear that chemotherapy is mostly used for advanced cancers and that it is rare for the whole breast to be removed for a small early cancer. While acknowledging that overdiagnosis is a real harm, it should be noted that overdiagnosed cancers are likely to be small and node negative, and as such, much less likely to receive mastectomy or chemotherapy. Indeed, it can be considered a benefit of screening mammography that women are *less* likely to require mastectomy or chemotherapy for breast cancer, and will have more options in their treatment choices, compared with what they would probably obtain if they opt out of screening, but eventually still are diagnosed with breast cancer.

The general tenor of the decision aid, the paper and the accompanying editorial is an emphasis on 'unnecessary' treatment. Yet it hardly needs to be pointed out that without treatment, screening would not save any lives at all. In that sense, until we can reliably identify overdiagnosed cancers, the treatment of the overdiagnosed cancers, whatever the magnitude, is necessary in order for screening to prevent (some of) those with progressive screen-detected disease from dying from breast cancer. The editorial asks: 'is it ethically acceptable to cause serious harm in some people to improve the prognosis of others?' This is a rather emotive way of framing the issue, but the answer has to be yes. Otherwise there could be no surgery for any condition, as patients sometimes die on the operating table, and no preventive health interventions because none are free of adverse outcomes associated with the therapy, test, or activity. Of fifteen women receiving multi-agent chemotherapy for breast cancer, only one has her life saved.[8] In the framework of this paper and editorial, the other fourteen are only 'harmed'.

Women invited to screening should have helpful and accurate information provided to them with their invitation. Unfortunately, what is considered helpful and accurate today with respect to mammography screening is contested terrain, and thus even the most careful pursuit of ''balance,'' rarely will satisfy everyone. In this respect the study by Hersch et al[1] is informative in a way that was unintended. The information provided to the intervention group was felt by many to be biased against screening and increased the proportion of women who were unable to make a decision regarding screening.

For us the paper by Hersch et al[1] highlights four aspects about decision aids that require further research. 1) It would seem reasonable to acknowledge that having decided that the balance of benefits and harms is such as to offer a service, the health service should not be neutral about the intervention, but should be allowed to endorse it. 2) It is important to maintain proportion about the likely positive and negative effects of what is being offered, and, in the case of breast cancer screening, not to exaggerate the risk of overdiagnosis. 3) Once agreement has been reached on the appropriate information to convey, there is room for research on how best to deliver it. 4) Finally, it is important to check whether the target population will judge a decision aid to be biased, and whether it will help them to make a decision about which they are confident, or whether it merely increases indecision. We still have a long way to go to develop a breast cancer screening decision aid that will be universally acknowledged as a good thing.

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