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The Ethics of Information: Absolute Risk Reduction and Patient Understanding of Screening

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Some experts have argued that patients should routinely be told the specific magnitude and absolute probability of potential risks and benefits of screening tests. This position is motivated by the idea that framing risk information in ways that are less precise violates the ethical principle of *respect for autonomy* and its application in informed consent or shared decision-making. In this Perspective, we consider a number of problems with this view that have not been adequately addressed. The most important challenges stem from the danger that patients will misunderstand the information or have irrational responses to it. Any initiative in this area should take such factors into account and should consider carefully how to apply the ethical principles of *respect for autonomy* and *beneficence*.

KEY WORDS: risk and benefit data; informed consent; respect for autonomy.
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INTRODUCTION

When a patient is considering whether to undergo a preventive service such as a screening test, the relevant information to guide a decision includes the probability of risk and benefit.[1,2] Some have argued that all patients considering preventive services should be given this information in the form of *absolute probabilities*, presented numerically or graphically.[2–9] This claim is based on the worry that failing to give patients this type of risk information violates the ethical principle of *respect for autonomy*,[10] since without this information patients are unable to make a fully informed decision.

In this Perspective, we point to a number of problems with this view that have not been adequately addressed. Most important is the danger that statements of absolute risk and benefit will confuse many patients, leading to negative effects on patient autonomy and health outcomes. Although various steps could be taken to offset these problems, we argue that there is a significant chance that such steps would be inadequate. There are also important questions about how to apply *respect for autonomy* and other ethical principles in this area.

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Any initiative to provide absolute risk and benefit information to patients must take these issues into account. We limit our discussion to recommended screening tests such as mammograms, but similar issues arise when considering patient understanding of any preventive test or treatment.

PATIENT UNDERSTANDING AND FRAMING OF RISK/BENEFIT DATA

Many patients currently are not given adequate information about recommended screening tests. Research shows that primary-care providers provide very limited information when ordering a test, often doing little more than describing its purpose.[11,12] Similarly, health information about screening tests provided by brochures or on the Internet often gives incomplete information and varies widely in quality.[13,14] Moreover, the risks of false positives, false negatives, and over-treatment are rarely described.[13,14] In addition, research shows that individuals overestimate the benefits and underestimate the possible risks of screening.[15–17]

All these observations suggest that in this area the medical establishment is failing to respect patient autonomy, one of the central principles of medical ethics.[10] This principle requires, among other things, that patients guide their health care by providing informed consent to proposed interventions[18] or by participating in shared decision-making.[19–21] While the ways that patients consent for invasive procedures, such as surgery, often are subjected to more intense scrutiny than for low-risk interventions, such as mammograms, the same principle applies.[18,21] Unless the patient has an adequate understanding of the possible benefits, harms, and alternatives to the procedure, he or she cannot give adequate informed consent.[18,20]

But how much information is enough? Any quantitative data can be described in many ways, and research shows that such *framing* has significant effects on patient understanding.[22,23] Consider the various ways to frame the risks and benefits of mammograms in women over 50 years old, a test that is recommended by the US Preventive Services Task Force.[24] The most complete representation is in the form of *natural frequencies*, which present the expected probabilities of various outcomes in a population of 1,000 women undergoing screening compared to an equivalent population that is not being screened.[4] According to one model, out of 1,000 women who are screened biannually for 10 years, 178 will be called back for repeat imaging, 64 will have a biopsy, and 33 will be diagnosed as having breast cancer.[25] Over 20 years, there will be 14 deaths from breast cancer in the unscreened group, and just 9.1 in the group undergoing mammography.[25]

There are other ways to describe the risks and benefits of mammograms using absolute probabilities. For instance, the *absolute risk reduction* (ARR) is calculated by subtracting the mortality rate in the screened group from that of the unscreened group. Thus, the ARR of performing mammography regularly for 20 years is 4.9 per 1,000 (or 0.49%), i.e., 14 per 1,000 (1.4%) minus 9.1 per 1,000 (0.91%).[25] Another absolute measure of benefit is the *number needed to screen* (NNS), which describes how many people have to be screened and provided follow-up testing and treatment to save one person (a slightly modified form of the *number needed to treat* (NNT) measure).[26] According to the model above, roughly 204 women have to be screened for 20 years to save one from dying of breast cancer during that time period.[25]

However, patients are rarely given such *absolute* measures of possible benefit. In one study, just 22% of brochures concerning mammography quantified the benefit at all, and those that did only provided the *relative risk reduction* (RRR).[13] RRR is calculated by dividing the decrease in morbidity or mortality by the baseline rate. Using the same model as above, mammograms performed over 20 years provide a RRR of 36%, i.e., 4.9 per 1,000 decrease in death from breast cancer divided by the baseline rate (in the unscreened group) of 14 per 1,000.[25] In this case as in others, the RRR (36%) is a much larger number than the ARR (0.5%), and so it is not surprising that brochures that aim to encourage patients to get regular mammograms generally present RRR if numbers are given at all.[13] Research confirms that patients are more likely to accept a preventive intervention when its benefit is described in terms of RRR than ARR and are least likely to accept when NNT is given.[22]

Other screening tests offer similar levels of risk reduction, so the same framing issues arise. For example, colon cancer screening with annual fecal occult blood testing over 18 years produces an ARR of dying of colon cancer over this period of just 4.6 per 1,000 (0.46%).[27] In other words, 217 patients must undergo annual screening for 18 years to prevent one death from colon cancer. But the RRR is 31%, obtained by dividing the ARR by the baseline rate of death from colon cancer during this time period (roughly 15 per 1,000).

ARGUMENTS FOR PROVIDING ABSOLUTE RISK AND BENEFIT DATA

A number of experts argue that patients should always be given information about risks and benefits using absolute probabilities.[2–9] Some favor natural frequencies,[3–5] while others are comfortable with other absolute measures, such as ARR or NNS.[2,6,7,9] As mentioned above, this position is motivated by the worry that giving less information violates the ethical principle of *respect for autonomy*, since such patients will not have enough information to make an adequately informed decision.[18,21] For example, a patient who is told just the RRR of mammography may fail to understand the small number of patients who will benefit or the large number who must be screened to prevent one death from breast cancer. In addition, without information about absolute risk reduction, it is impossible to compare the value of different available preventive services or to fully weigh the chance of benefit against the risk of harm.[2]

Some argue that interactive computer programs—often called patient decision aids (PtDAs)—could do a good job of providing such complete information.[2,6,8] There is a growing body of literature on introducing PtDAs into preventive medicine,[6,28] and a recent set of guidelines states that they should provide data in terms of absolute probabilities.[9] According to these guidelines and other discussions, providing just RRR or failing to give numbers at all is not an acceptable level of disclosure.[3,4,6,29]

PROBLEMS WITH PROVIDING ABSOLUTE RISK AND BENEFIT DATA

While this position is motivated by important ethical principles, we believe that there are significant difficulties that have not been adequately discussed. The biggest problems stem from the danger that patients will not understand the information provided or will use the information in irrational ways. Research shows that a large percentage of adults in the USA have difficulty understanding numerical concepts in general and that they have particular difficulty with probability statements.[30–34] And although these problems with *numeracy* impact the understanding of RRR numbers as well, research shows that patients have a better understanding of this measure than ARR, NNT, or a combination of different ones.[32] Studies also have shown limitations in the ability of physicians to interpret statistics in this area.[35]

While some theorists advocate using graphs rather than numbers to convey absolute risk and benefit data,[5,36] research shows that patients also have significant problems understanding charts, tables, and other illustrations.[8,37] For example, a chart of 1,000 stick-figures printed in various colors to denote different outcomes, a popular way to graphically convey information about natural frequencies, can be difficult for patients to interpret and apply to a personal decision whether to be screened.[8,37]

Psychological research shows, further, that even well-educated, intelligent people do a poor job making decisions based on small probabilities. Irrational parts of human cognition—referred to as *heuristics* or *biases* by psychologists—may lead people to assign excessive importance to events that are quite unlikely (e.g., according to Prospect theory[38]), or to underestimate the importance of such events (e.g., because of the optimism bias[39–41] or the threshold bias[42]). In any particular case, the way that the information about absolute risks or benefits is presented may determine the patient's perception as much as the data themselves, depending on which heuristics come into play.[42] These aspects of human cognition have led some theorists to conclude that numbers do not play a key role in human decisions about how to act in the face of risk.[43,44]

All these observations raise important questions about the value of providing absolute risk and benefit data to patients considering recommended screening tests such as mammography. If a given type of data will not help patients do a better job of making decisions reflecting their values and desires, then it will not further their autonomy.[45]

DISCUSSION

Advocates of disclosure of absolute risks and benefits may respond to evidence about possible misunderstanding or

misuse of the information by arguing that health-care providers simply need to do better a better job educating patients. Initiatives could aim at improving numeracy and counteracting irrational heuristics and could seek to present information that integrates risk and benefit data about multiple screening tests.

But this proposal must be evaluated in light of the challenges of educating patients sufficiently and the resources that would be required to do so. Doctor visits are already overcrowded with managing acute problems and chronic diseases and instituting an ever-growing list of preventive steps.[46] While some of the education could be done by other health-care providers, such as nurses or other staff, limitations in availability and expertise would have to be addressed.[47] Also, although PtDAs could play a key role in informing patients, there would most likely still need to be dedicated efforts by doctors or others to answer questions and provide follow up discussion.[47] Finally, all these activities would incur expense for an uncompensated activity in a health-care system whose costs are already growing beyond all bounds.

Balancing these issues—the possible advantages of disclosing absolute risk and benefit against the resources required to do it right—requires careful examination of the relevant ethical principles. And while *respect for autonomy* is central to health-care ethics, it can be difficult to clarify what level of disclosure or understanding is necessary for a specific patient in a specific situation. Different patients, with varying interests, goals, and levels of education, may well need different levels of information to adequately consent to a medical intervention.[18,45,48,49] This variability supports an approach where patients are given a standard body of information and are then given an opportunity to ask questions or request more information. Research confirms that people want varying amounts of information concerning their medical care.[49–51]

Ethical principles provide little guidance on whether data about absolute risks and benefits should be part of the standard disclosure or should be seen as additional information that some may want. One precept requires that each patient be given any information that a *reasonable person* would want to know.[18] And although absolute risk and benefit data are certainly relevant to a complete consideration, it seems possible that this sort of data—which is confusing to many and may not play a central role in human cognition—may be something that would be desired by some reasonable patients but not by others. In addition, some have argued that low-risk, well-supported interventions may require significantly less disclosure and discussion than other interventions.[52,53]

These issues emphasize the challenge of articulating the ideal of patient autonomy and balancing it against other medical goals, such as beneficence (doing what is best for the patient).[10] While there has been a long tradition in western medical ethics of focusing on autonomy, that prioritization has now been critiqued.[49,54] And there is clearly an issue of beneficence involved when health-care providers give information that may lead their patients to reject preventive services that have been proven to reduce morbidity or mortality. For many interventions, patient uptake drops when additional information concerning risk and benefit is provided, even when those data generally support the intervention.[23,55,56] Admittedly, if a certain sort of information is central to decision-making, then its disclosure is mandatory despite any effect on well-being. For example, it would be unethical (and illegal) to withhold information about the risks of operative complications from heart surgery. But this is not the case for data about absolute probabilities of risk and benefit in screening tests. Benefit and harm of such tests must be discussed, for instance, but it is much less clear what level of precision is necessary.

Hearing this, some will sense paternalism and reject such considerations out of hand. And while this concern is important—nobody wants a return to *doctor-knows-best*—it should not lead us to disregard the concerns raised above. The simple fact is that medicine has multiple goals, not just providing any and all information that might be relevant.[49,54] In almost all of our daily decisions, and even in most medical contexts, absolute risk and benefit data are not available or supplied.

In the end, numerous considerations should come into play when deciding whether absolute risk and benefit data will be presented to patients, and in what form, when discussing recommended screening tests. Similar issues will come up in other settings of preventive care, such as when patients are considering long-term preventive treatments such as taking medication for high blood pressure or choosing to have less well-supported tests. In all these areas, decisions about how much information should be disclosed to all patients must be made in light of careful consideration of patient understanding and possible impacts on uptake and well-being, using all applicable ethical principles.

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