

Questioning the Quantitative Imperative: Decision Aids, Prevention, and the Ethics of Disclosure

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2011

Hastings Center Report

Vol. 41, No. 2, March-April

[Author's version. Final published version available from:
<http://dx.doi.org/10.1353/hcr.2011.0029>]

Abstract

Patients should not always receive hard data about the risks and benefits of a medical intervention. That information should always be available to patients who expressly ask for it, but it should be part of standard disclosure only sometimes, and only for some patients. And even then, we need to think about how to offer it.

Acknowledgments

I am especially grateful to Eric Meslin and Greg Sachs for helpful discussion and encouragement. Peter Ubel and Greg Kaebnick provided critical feedback that significantly improved the manuscript, as did Meg Gaffney, Joyce Griffin, Jere Odell, and Shari Rudavsky. I presented an earlier discussion of these issues at the American Society for Bioethics and Humanities (ASBH) annual meeting in October 2008. My work was supported in part by the Predictive Health Ethics Research project (PredictER), which is funded by the Richard M. Fairbanks Foundation.

Author's version. Final version published as:

Schwartz PH. Questioning the quantitative imperative: decision aids, prevention, and the ethics of disclosure. *Hastings Cent Rep.* 2011 Mar-Apr;41(2):30-9. <http://dx.doi.org/10.1353/hcr.2011.0029>

Questioning the Quantitative Imperative: Decision Aids, Prevention, and the Ethics of Disclosure

It is easy to see why many experts recommend that patients be given *quantitative* information about the risks and benefits of a test or treatment they are considering, especially when it serves a preventive function. The value of prevention, after all, is based on its ability to reduce the risk posed by some disease or condition, and the magnitude of this risk reduction can be stated precisely only by using numbers. Many experts conclude that such data, when available, should be disclosed to patients to help them make an informed decision. Advocates of the "quantitative imperative," as I call it, often appeal to ethical principles related to informed consent or shared decision-making or, at a deeper level, to the goal of respecting patient autonomy.¹

The quantitative imperative is perhaps most prominent in discussions of "decision aids," which are pamphlets, videos, or computer programs designed to inform patients about their options and help them make better choices.² While decision aids are not yet a standard part of medical care, they are being created, tested, and recommended for a wide range of medical decisions, and they can present much more information than a health care practitioner can convey during a typical patient visit.³ The International Patient Decision Aids Standards, the most widely accepted guidelines for the design and evaluation of decision aids, recommend that all patients considering preventive interventions be given information about the baseline risk of the disease in question, the specific magnitude of risk reduction offered by the preventive service, and the probability of negative outcomes.⁴

Even though the ethical reasoning that generates the quantitative imperative appears plausible, I will argue here that there are important problems with it stemming from the way people understand and respond to numerical and graphical information. Many individuals have significant problems comprehending or applying probabilistic and mathematical concepts, reflecting widespread limitations in "numeracy."⁵ Furthermore, research in psychology and other fields has established the existence of "heuristics" and "biases" in human thought that hinder the rational processing of quantitative information, even by people who are relatively "numerate."⁶

These findings, I argue, show that health care providers should not *always* disclose the kind of data recommended by the quantitative imperative. Instead, quantitative information will be appropriate for some situations and some patients, but not for others. And while the data should always be available to patients who want it, the question is how to offer it and in what form. These issues suggest that much more empirical research and ethical analysis is required about the use of quantitative information in decision-making.

Prevention and the Use of Decision Aids

Decisions about screening tests or preventive treatments are seldom easy. Consider a forty-year old woman deciding whether to start having mammograms to screen for breast cancer. In November 2009, the United States Preventive Services Task Force issued guidelines stating that:

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The USPSTF recommends against routine screening mammography in women aged 40 to 49 years. The decision to start regular, biennial screening mammography before the age of 50 years should be an individual one and take patient context into account, including the patient's values regarding specific benefits and harms.⁷

In these guidelines, the USPSTF withdrew its previous recommendation that all women in this age group should undergo mammography, a change that led to public outcry. That controversy will not be discussed here, but it is helpful to consider the type of trade-offs that the USPSTF highlighted in making this change. Most importantly, while mammograms for women aged forty to forty-nine identify some tumors and slightly reduce mortality from breast cancer, they also result in a significant number of false positives and unnecessary biopsies.⁸ They can lead to "overtreatment" of some women, as well—that is, treatment for cancers that would otherwise never have caused a problem or perhaps even been recognized.⁹ Thus, whether one agrees with the USPSTF's guidelines or not, everyone agrees that a woman's decision to get mammograms while she is in this age range involves important trade-offs.

Decisions of this sort are "preference sensitive," since the right choice depends on the individual's beliefs and values.¹⁰ For patients facing this sort of decision, it is especially important for them to receive full information and support if they are to make a truly informed choice. Many experts believe that this makes decision aids essential.¹¹

The apparent need for decision aids stems partly from a recognition that patients talking to health care providers often do not get full information about all their options.¹² This failure is due to many factors, including a simple lack of time during busy doctor-patient visits.¹³ Decision aids aim to counteract this by providing additional information and assistance, usually outside of the visit. Decision aids have been created in many formats, ranging from printed to audiovisual or computer-based, and for decisions ranging from prostate cancer screening to treatment of atrial fibrillation and the use of estrogen by postmenopausal women.¹⁴ In fact, although decision aids are still not typically included in clinical care, more than five hundred have been created, and there have been more than fifty-five randomized controlled trials studying their impact.¹⁵ Some believe that we are nearing a "tipping point" and that decision aids will soon be much more common in clinical care.¹⁶

A recent review concludes that compared to usual care, decision aids increase patient knowledge and the feeling of being informed while decreasing indecision and passivity.¹⁷ The International Patient Decision Aids Standards—published in 2006 and based on work by an international group of more than one hundred experts and other stakeholders¹⁸—are now widely accepted and implemented.¹⁹

Although there are no decision aids focused on the question whether to get mammograms from ages forty to forty-nine, this is exactly the sort of decision for which they are supposed to be helpful. A decision aid on this topic would inform women about the benefits and risks and would encourage them to carefully consider the trade-offs involved.

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It is easy to see why the quantitative information seems important in cases such as this. If numbers are *not* given, then a woman of this age considering whether to get mammograms might be told only that the screening will reduce her risk of dying of breast cancer "somewhat" or "by a small amount" (or some such), and that it will lead to a "significant" chance or "some" chance (or some such) of false positives and unnecessary biopsies or overtreatment. But all these terms are vague, and research has shown that such verbal descriptions—terms like "commonly," "rarely," "significantly," etc.—are interpreted in widely varying ways by patients and doctors.²⁰

In contrast, giving the numbers allows a much more precise description of the risks and benefits. Here are the relevant numbers for getting biennial mammograms from age forty to forty-nine, according to a recent model.²¹ Imagine a group of 1,300 women who are forty years old and have average risk for breast cancer. If none of them ever get a screening mammogram in their entire lives, then about forty-nine of them will die of breast cancer. If they all get biennial mammograms starting at age fifty and continuing to sixty-nine, just forty-two will die. And if they start getting mammograms at age forty instead of fifty, and continue until age sixty-nine, the number who will die drops to forty-one.²² In sum, the decision by 1,300 women to start getting mammograms at age forty rather than fifty saves one woman from dying of breast cancer. The model can also quantify the benefit as number of life-years gained: the group of 1,300 women that starts screening at forty will have twenty-seven additional life years, compared to the group that starts at fifty (which averages out to roughly 7.5 days per woman).

The prevalence of negative outcomes can also be quantified. For the 1,300 women who start screening at age forty rather than fifty, there will be a total of about six hundred more "false positives" and fifty unnecessary biopsies.²³ (These are defined in the model as a repeat mammogram or a biopsy performed when there is no cancer present). It is very hard to calculate reliable figures for the degree of "overtreatment," but according to some estimates, in this group of 1,300 women, two to four will be diagnosed with cancer who, without the extended screening, would never have known they had it.²⁴

This type of quantitative information—comparing the frequency of outcomes in two populations, one that undergoes the intervention and one that does not—is called "natural frequencies," and it can be presented with numbers, as above, or with charts or figures.²⁵ For instance, an "icon chart" might depict 1,300 faces, filled in with different colors to indicate the number of individuals in the screened and unscreened groups who will experience each possible outcome.²⁶ This would represent both the benefits and the risks of mammography.

The Quantitative Imperative

The case in favor of making these numbers a necessary part of disclosure is so transparent that commentators often offer little reason for it. Many simply assert that disclosure will help patients make better informed decisions.²⁷ Robert McNutt writes, "Numbers alone may fall short of being a language for decision making, but are a necessary place to start."²⁸ Some go a little deeper, asserting that quantitative information is necessary to respect patient autonomy.²⁹ Proponents of

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providing quantitative information must appeal to ethics, since there is little empirical support for their position. While some studies show that giving patients quantitative information improves their accuracy in describing the probability of risks and benefits, very little research has demonstrated that it has a clearly positive impact on decision-making or medical outcomes.³⁰

But the ethical arguments for the "quantitative imperative" have nonetheless carried the day in many quarters. The United Kingdom's General Medical Council, for instance, asserts that all patients considering screening should be told "the likelihood of positive/ negative findings and possibility of false positive/negative results."³¹ And as mentioned, the quantitative imperative has driven the development and implementation of decision aids. The widely accepted IPDAS guidelines, for instance, recommend that decision aids:

- disclose the specific chances of all positive and negative outcomes from a proposed medical test or treatment,
- use "event rates in a defined group of patients for a specific time," and
- describe the chance of various outcomes in the treated (or screened) group and the untreated (or unscreened) group "using the same denominator" and "over the same period of time."³²

For screening tests, the IPDAS guidelines assert, the decision aid should disclose the probability of a patient receiving a "true positive, true negative, false positive and false negative test result," as well as the "chance of disease being found with and without screening."³³

Framing Considerations

As can be seen from these recommendations, the quantitative imperative does not just recommend that decision aids should give quantitative information, but that they should frame that information in specific ways. In particular, the quantitative imperative generally mandates the use of measures that convey "absolute" probabilities or frequencies, such as in the natural frequency presentations above; that is, measures should provide information about the entire population rather than subgroups.³⁴ Also satisfying this criterion are descriptions of "absolute risk reduction" (ARR), which state the difference in risk with the intervention versus without it. For instance, the ARR of getting mammography from ages fifty to sixty-nine is calculated by subtracting the mortality rate after mammography (3.23 percent) from the rate without it (3.77 percent), resulting in an ARR of 0.54 percent (5.4 per 1,000). Choosing to start getting mammograms at age forty rather than fifty produces an additional ARR of 0.07 percent (0.7 per 1,000) (3.16 percent versus 3.23 percent). Another popular absolute measure of benefit is "number needed to screen" (NNS), reflected in the comment above that 1,300 women must choose to undergo mammography starting at age forty rather than fifty to save one woman from dying of breast cancer. NNS is identical to the concept of "number needed to treat" (NNT), used to discuss the efficacy of treatment, and mathematically both NNS and NNT are equivalent to the inverse of ARR.

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Advocates of the quantitative imperative generally endorse use of natural frequencies, ARR, and NNS/T, but they reject other measures, such as "relative risk reduction" (RRR), which is calculated by dividing the ARR by the baseline risk. The RRR of getting mammograms biennially from ages fifty to sixty-nine, compared to no screening, is 15 percent (calculated by dividing 0.54 by 3.77).³⁵ Getting mammograms biennially from ages forty to sixty-nine increases the RRR to 16 percent (0.61/3.77).³⁶

The rejection of RRR is understandable, since this measure clearly leaves out crucial information. In an extreme case, for instance, patients may be very impressed when told that a treatment for some disease reduces mortality by a RRR of 50 percent, but much less impressed if told that the treatment reduces risk from two in one million to one in one million: that's an ARR of one in one million, a NNT of one million, and a RRR of 50 percent. Research has shown that people told the RRR of a hypothetical screening test or treatment are more likely to say that they would accept it than when they are told the ARR or NNS/T.³⁷ John-Arne Skolbekken argues that patients and doctors too often hear just that lowering cholesterol with statin medications can reduce cardiac mortality by 21 percent, the RRR, rather than being told that the ARR is 0.5 percent and the NNT is 200.³⁸ Hazel Thornton and coauthors argue that women considering mammography should be told the ARR or the NNS, not just the RRR.³⁹

Rejecting the RRR has widespread consequences. Much of the information available in health pamphlets or on the Internet about preventive measures such as mammography provides no quantitative measure of benefit at all, but when numbers are given, the RRR is the preferred measure.⁴⁰

One more aspect of framing as it relates to the quantitative imperative bears comment as well. While getting mammograms from age fifty to sixty-nine can be described as reducing the probability of dying of breast cancer from 3.77 percent to 3.23 percent, it can also be described as raising the chance of *not* dying of breast cancer from 96.23 percent to 96.77 percent. The first description is called "positive framing," since it is the probability of an event occurring (dying of breast cancer), and the latter is "negative framing."⁴¹ And research shows that risk reduction framed positively has a larger effect on individuals than when it is framed negatively, partly since positive framing often involves a larger relative percent change (in this case 3.23 vs. 3.77 percent, rather than 96.23 percent vs. 96.77 percent).⁴² Noting this differential effect, IPDAS recommends that decision aids should present quantitative information *both* positively and negatively, to avoid biasing individuals one way or the other.⁴³

Numeracy and the Reasonable Person Standard

But the ethical case for the quantitative imperative is deeply flawed. The first major challenge stems from evidence that many people have trouble understanding quantitative information. National surveys suggest that at least 22 percent of adults have only the most basic quantitative skills, such as counting, while another 33 percent possess only slightly more advanced skills, such as performing simple arithmetic.⁴⁴ This means that more than half of adults do not have the

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ability to comprehend and utilize the key mathematical concepts used in quantifying risk and benefit—probability, percentage, and frequency.

Further studies reveal even more widespread difficulties with mathematical concepts. On tests measuring understanding of the basic facts of probability, more than 80 percent of individuals miss at least one question.⁴⁵ These findings have been replicated in populations with relatively high levels of education, including a group in which more than 80 percent graduated from college.⁴⁶ In this highly educated group, fully 16 to 20 percent of subjects could not answer the most straightforward questions, such as whether 1 percent, 5 percent, or 10 percent represents the larger risk.⁴⁷

In another study, when patients in a general medical clinic were given information about the absolute benefit of two hypothetical preventive treatments in terms of ARR or NNT, just 42 percent and 30 percent, respectively, were able to correctly identify the more effective treatment.⁴⁸ When the benefit was described in terms of RRR, 60 percent completed the task successfully, and when patients were presented with the data framed in more than one way, the success rate dropped. (This raises questions about the IPDAS recommendation that decision aids should employ both positive and negative framing.)

Some experts have recommended the use of figures or graphs as a way to convey mathematical or probabilistic information to individuals who have limited numeracy.⁴⁹ But although such approaches may be useful, they are no cure-all. People with limited numeracy have significant problems interpreting figures and graphs, especially ones that convey information about absolute risk and benefit.⁵⁰ In a recent study, patients with low numeracy who were given relatively simple graphic representations of risk levels were unable to distinguish which was higher and which was lower.⁵¹ It appears that patients may prefer and better understand charts and figures that represent data in terms of relative risk, but this is exactly the sort of data that the quantitative imperative rejects as being inadequate for full disclosure.

One way to understand the challenge that innumeracy poses is to consider the quantitative imperative in relation to the "reasonable person standard," one of the most commonly used guides for what information should be included in minimal disclosure.⁵² This standard asserts that "the information to be disclosed should be determined by reference to a hypothetical reasonable person. Whether information is pertinent or material is to be measured by the significance a reasonable person would attach to it in deciding whether to undergo a procedure."⁵³ The quantitative imperative can be seen as claiming that a reasonable person would find data stated in terms of natural frequencies, ARR, or NNS/T as being significant for medical decisions, especially in the area of prevention.

But widespread innumeracy draws this claim into question. In particular, if the abilities of the hypothetical "reasonable person" are similar to those of a typical member of the population, it follows that he should not be assumed to understand probabilities and frequencies. And in this

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case, we might assume that the reasonable person would not find quantitative information significant.

Perhaps a defender of the quantitative imperative could claim that the reasonable person should be assumed to have higher numeracy than the average person, but this raises further problems. If the average person is not the basis for describing the "reasonable person," then what criteria should be used? And it seems odd to say that the reasonable person standard results in disclosing information that will not be understood by most people.

Many advocates of the quantitative imperative are aware of the problem of innumeracy, and some have conducted important research studying it.⁵⁴ These experts appear to see innumeracy mainly as a challenge to find better ways to convey and explain data to patients with limited numeracy, and some research in risk communication focuses on this goal. For instance, studies have examined whether natural frequencies, especially presented using graphics, may help overcome innumeracy.⁵⁵

It is possible, though, that there will be persistent limitations in how much quantitative information can be effectively communicated to people with limited numeracy. There might be unavoidable trade-offs between the completeness of the information presented and the degree to which patients understand it. As mentioned above, studies have shown that patients understand and apply RRR data more easily than absolute measures such as ARR or NNT, whether presented as numbers or in graphs.⁵⁶

An advocate of the quantitative imperative could respond to criticism based on the prevalence of innumeracy by arguing that innumeracy is a general social problem that should be combated, not accepted. From this perspective, if people cannot understand quantitative information that is a necessary part of informed consent, then the health care system should engage in outreach and education to overcome this problem in health literacy (as well as others). But this sort of proposal must confront questions about whether it is a feasible undertaking for a system already struggling to control costs and provide care to all. The project would have to be evaluated in comparison with other possible projects of outreach and public education, which raises questions about how to even measure the value. Any claim of benefit would have to be based, at least largely, on evidence that it helps patients with low numeracy make better decisions about health care, but such research is in its infancy: while one study has shown that a short course in quantitative reasoning can improve patients' facility with statistics, that study did not measure decision quality at all.⁵⁷

Irrational Responses to Quantitative Information

Another reason to wonder about the possible benefit of combating innumeracy is that even numerate individuals have persistently irrational responses to quantitative information about risk and benefit. In order to understand human responses to quantitative measures of risk and benefit, it is necessary to quickly review a leading theory of rationality called "expected utility theory."

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The essential idea can be summarized as follows. If an individual is choosing between action A and action B, the rationally preferable choice is the one that can be expected to lead to higher utility for him or her, where utility is understood as some measure of the goodness and badness of the resulting situations. If an action can lead to a range of possible outcomes, then the expected utility for that action is the sum of the utility of each possible outcome, weighted by the probability of its occurring.⁵⁸

This quick description of expected utility theory suggests a possible argument for the quantitative imperative that has never been explicitly stated by advocates. An individual can calculate the expected utility of some decision—such as getting mammograms starting at age forty, for instance—only if she knows the probability of the different outcomes. While a presentation of natural frequency data, as above, provides this data, neither a verbal description nor an estimate of RRR does. Therefore, providing absolute measures of benefit and risk is necessary for making rational decisions. Interestingly, unlike the argument based on the reasonable person standard, this one is not weakened by the prevalence of innumeracy. From the perspective of expected utility theory, innumerate individuals need education to allow them to make the necessary calculations, so they can make rational decisions.

But once the argument for the quantitative imperative is understood in this way, it is open to important criticisms based on research into human reasoning. Research in psychology and other fields has shown that giving individuals quantitative data about risk and benefit often leads to irrational decisions—that is, to decisions that fail to maximize expected utility. For example, in seminal experiments, Daniel Kahneman and Amos Tversky demonstrated that when individuals are told about the low probability of a certain event, especially a possible loss, they are likely to give that event excessive importance.⁵⁹ Similarly, due to "denominator neglect" people often give exaggerated importance to small risks, such as five deaths per one million cases; they are focusing on the deaths (the numerator) rather than the large population in which they occurred (the denominator).⁶⁰

Researchers have also shown the existence of an opposing tendency termed "optimism bias." For example, when told that ten out of one hundred people will develop a certain disease, many people exaggerate the chance of their being in the "lucky" group and thus downplay the risk, again leading to decisions that violate expected utility theory.⁶¹ Which of these biases come into play in a given situation—causing the individual to exaggerate or minimize a danger—depends on the individual's psychology and the way the information is presented.

In almost all cases, the setting in which a risk is described and the individual's other beliefs will affect the impact. For instance, if women are told their precise risk of developing breast cancer over the next ten years (as a percentage or a frequency, let us assume), those who previously overestimated their risk will continue to ascribe it elevated importance, compared to those who previously underestimated their risk or had no opinion.⁶² This is due to a process that psychologists call "anchoring and adjustment." In addition, if women who previously overestimated their risk for breast cancer are asked to state their estimation before being told the

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actual (lower) number, they feel more reassured by the lower figure than if they were not asked to state their estimate beforehand.⁶³

Findings such as this over the past thirty years have led psychologists to theorize that human reasoning involves two separate systems, with one carrying a representation of the specific risk (absolute probability, for example) while the other forms a "fuzzy representation," sometimes called a "gist."⁶⁴ While the first system registers the numerical facts—such as that the risk of breast cancer is 10 percent—the second constructs a general meaning of this risk, such as labeling it as "serious" or "minimal." According to such dual representation models, people's opinions of risk and decisions about how to act are based largely on the second system, which may result in the biases and heuristics that researchers have found.

If dual representation theories are correct, then any claim about the benefit of giving quantitative information must be supported by evidence that patients who receive such data actually form more effective "fuzzy representations," or make better decisions in some sense, than people who do not. But as mentioned, research of this sort is so far limited. While some studies show that individuals who are given numerical information or view graphs about risk and benefit do better on tests that measure understanding of the magnitude of risks and benefit,⁶⁵ no studies have yet shown that better performance on these tests translates into better decisions or improved outcomes.⁶⁶

Irrational Reasoning with Nonquantitative Information

At this point, however, it may appear that the line of reasoning leads to unacceptable conclusions. Psychology, after all, has found similarly irrational aspects of human reasoning concerning nonquantitative information: just as a patient may respond in ways that violate expected utility theory when told that the risk of a complication of some lifesaving surgery is one in ten thousand, he may also respond irrationally when told just that there is such a rare complication, without being given the specific probability.⁶⁷ Does this mean that patients should not be given certain types of nonquantitative information, either—such as the possibility of rare complications—unless it is established that the disclosure improves decision-making?

In response, it is important to note that significant questions have been raised about the assumption that all available information (quantitative or nonquantitative) should be given to all patients in all situations. Carl Schneider, Onora O'Neill, and others have argued against the trend toward maximal disclosure, pointing to empirical findings suggesting that patients do not understand this information or integrate it into their decisions.⁶⁸ While bioethics has largely pushed for more disclosure, these authors argue that the desire not to know, or to ask a physician to make the decision, may be perfectly rational and reasonable.

My criticism of the quantitative imperative certainly fits with this wider attack on "mandatory autonomy."⁶⁹ Both critiques argue against the assumption that it is ethically required to ensure that all patients understand and utilize all available information, no matter how complex. And

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even though both critiques reject a picture where patients are required to consider complex data, both are compatible with the recommendation that all patients should have the opportunity to consider any information they want. While I reject the quantitative imperative, for instance, I also disapprove of the current system's failure to make that information available to those who want it.

My critique of the quantitative imperative can be seen as suggesting that disclosure of quantitative information should be tailored to individuals rather than to some abstract "reasonable person," and thus may be seen as fitting with an alternative to the reasonable person standard called the "subjective standard." According to this criterion, each individual must be given the information that will fulfill his informational needs, not those of some hypothetical reasonable person.⁷⁰ A serious challenge, of course, is determining an individual's "informational needs," both in general and in specific situations. Given widespread limitations in numeracy, the subjective standard leads to very different conclusions than the quantitative imperative's recommendation that complex quantitative data should be included in minimal disclosure to all.

Quantitative Information as Optional

This discussion leaves many questions unanswered, such as how to determine what sort of quantitative information, if any, should be included in minimal disclosure about particular tests or treatments, and how best to offer additional information to patients. The discussion highlights the need to consider such questions and to conduct additional empirical research into the desires of patients and the effect of various ways of giving data.

Seeing quantitative information as optional rather than required is consistent with other writing about the presentation of data to patients. For instance, in a review of how clinicians should describe clinical evidence, Ronald Epstein and collaborators recommend that health care providers should start the discussion by presenting relatively simple information and then offering more complicated data, including quantitative information, depending on the patient's desires.⁷¹ Similarly, the USPSTF recommends a process of shared decision-making that may or may not include disclosure of quantitative information, depending on the situation and the patient.⁷² Such approaches have not explicitly confronted the recommendations of the quantitative imperative, though, as I do here.

Also, these approaches have focused on health care practitioners, not decision aids, and they often depend on human judgment to determine how much quantitative information should be given to a particular patient. In contrast, a decision aid—such as one that is computer-based, for instance—must depend on some algorithm for making such determinations. This raises important questions about how decision aids should assess what quantitative information individual patients want.

We may reasonably conclude that the correct amount of quantitative information to provide as part of standard disclosure, and the way in which additional data is offered, depends not just on

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the patient's abilities and desires but also on the sort of intervention involved. For more invasive or risky procedures, or tests or treatments that have less clearly proven benefits or higher burdens and risks, it may be appropriate to present more extensive quantitative information and to encourage patients more strenuously to consider it. Such an approach is consistent with a model offered by Simon Whitney and collaborators where standards for decision-making vary based on the benefit and risk of the intervention, though that model does not explicitly discuss quantitative information.⁷³

Questions about how and when to disclose quantitative information will become ever more pressing as advances in epidemiology and genetics provide increasingly precise ways to characterize the risks that patients face and the possible impact of preventive treatments.⁷⁴ Simply attempting to present all information to all patients, possibly through the use of decision aids, could hurt rather than help medical decision-making. Instead, careful thought about the proper way to present such information—targeted to individuals' abilities, interests, and situations—can make an important contribution to improving prevention and medical care more generally.

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Footnotes

1. J. Paling, "Strategies to Help Patients Understand Risks," *British Medical Journal* 327, (2003): 745-48; G. Gigerenzer and A. Edwards, "Simple Tools for Understanding Risks: From Innumeracy to Insight," *British Medical Journal* 327 (2003): 741-44; H. Thornton, A. Edwards, and M. Baum, "Women Need Better Information about Routine Mammography," *British Medical Journal* 327 (2003): 101-3; R. Thomson, A. Edwards, and J. Grey, "Risk Communication in the Clinical Consultation," *Clinical Medicine* 5, no. 5 (2005): 465-69; A. Barratt et al., "Use of Decision Aids to Support Informed Choices about Screening," *British Medical Journal* 329 (2004): 507-510; L.J. Trevena et al., "A Systematic Review on Communicating with Patients about Evidence," *Journal of Evaluation in Clinical Practice* 12, no. 1 (2006): 13-23; J.A. Skolbekken, "Communicating the Risk Reduction Achieved by Cholesterol Reducing Drugs," *British Medical Journal* 316 (1998): 1956-58; G. Elwyn et al., "Developing a Quality Criteria Framework for Patient Decision Aids: Online International Delphi Consensus Process," *British Medical Journal* 333 (2006): 417-19; J. Austoker, "Gaining Informed Consent for Screening," *British Medical Journal* 319 (1999): 722-23; A.E. Raffle, "Information about Screening: Is It to Achieve High Uptake or to Ensure Informed Choice?" *Health Expectations* 4, no. 2 (2001): 92-98; General Medical Council, *Seeking Patients' Consent: The Ethical Considerations* (London, U.K.: General Medical Council, November 1998).
2. A.M. O'Connor et al., "Decision Aids for People Facing Health Treatment or Screening Decisions," *Cochrane Database of Systematic Reviews* no. 3 (2009); A.M. O'Connor, "Using Decision Aids to Help Patients Navigate the 'Grey Zone' of Medical Decision-Making," *Canadian Medical Association Journal* 176, no. 11 (2007): 1597-98.
3. O'Connor et al., "Decision Aids for People Facing Health Treatment or Screening Decisions."
4. Elwyn et al., "Developing a Quality Criteria Framework for Patient Decision Aids"; G. Elwyn et al., "Additional Information" (supplemental material for "Developing a Quality Criteria Framework for Patient Decision Aids"), available at <http://www.bmj.com/cgi/content/full/bmj.38926.629329.AE/DC1>.
5. National Center for Education Statistics, "National Assessment of Adult Literacy (NAAL)," subsection on overall demographics under "Key Findings" section, http://nces.ed.gov/naal/kf_demographics.asp; M. Kutner et al., "The Health Literacy of America's Adults: Results from the 2003 National Assessment of Adult Literacy," ed. U.S. Department of Education (Washington, D.C.: National Center for Education Statistics, 2006).
6. J. Baron, *Thinking and Deciding*, 3rd ed. (Cambridge, U.K.: Cambridge University Press, 2000); V.F. Reyna, "How People Make Decisions That Involve Risk: A Dual-Processes Approach," *Current Directions in Psychological Science* 13, no. 2 (2004): 60-66.

Author's version. Final version published as:

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7. United States Preventive Service Task Force, "Screening for Breast Cancer: U.S. Preventive Services Task Force Recommendation Statement," *Annals of Internal Medicine* 151, no. 10 (2009): 716-26, at 716.
8. Ibid.; H.D. Nelson et al., "Screening for Breast Cancer: An Update for the U.S. Preventive Services Task Force," *Annals of Internal Medicine* 151, no. 10 (2009): 727-37.
9. Ibid.
10. A.M. O'Connor, F. Legare, and D. Stacey, "Risk Communication in Practice: The Contribution of Decision Aids," *British Medical Journal* 327 (2003): 736-40.
11. O'Connor et al., "Decision Aids for People Facing Health Treatment or Screening Decisions"; M. Holmes-Rovner et al., "Are Patient Decision Aids the Best Way to Improve Clinical Decision Making? Report of the IPDAS Symposium," *Medical Decision Making* 27, no. 5 (2007): 599-608; Barratt et al., "Use of Decision Aids to Support Informed Choices about Screening"; Foundation for Informed Medical Decision Making, home page, <http://www.informed-medicaldecisions.org/index.html>.
12. C.H. Braddock III et al., "Informed Decision Making in Outpatient Practice: Time to Get Back to Basics," *Journal of the American Medical Association* 282 (1999): 2313-20.
13. K.S.H. Yarnall et al., "Primary Care: Is There Enough Time for Prevention?" *American Journal of Public Health* 93, no. 4 (2003): 635-41.
14. O'Connor et al., "Decision Aids for People Facing Health Treatment or Screening Decisions."
15. O'Connor, "Using Decision Aids to Help Patients Navigate the 'Grey Zone' of Medical Decision-Making."
16. A.M. O'Connor et al., "Toward the 'Tipping Point': Decision Aids and Informed Patient Choice," *Health Affairs* 26, no. 3 (2007): 716-25.
17. O'Connor et al., "Decision Aids for People Facing Health Treatment or Screening Decisions."
18. Elwyn et al., "Developing a Quality Criteria Framework for Patient Decision Aids."
19. O'Connor et al., "Decision Aids for People Facing Health Treatment or Screening Decisions"; A.M. O'Connor et al., "Do Patient Decision Aids Meet Effectiveness Criteria of the International Patient Decision Aid Standards Collaboration? A Systematic Review and Meta-Analysis," *Medical Decision Making* 27, no. 5 (2007): 554-74.

Author's version. Final version published as:

Schwartz PH. Questioning the quantitative imperative: decision aids, prevention, and the ethics of disclosure. *Hastings Cent Rep.* 2011 Mar-Apr;41(2):30-9. <http://dx.doi.org/10.1353/hcr.2011.0029>

20. D.J. Mazur and J.F. Merz, "Patients' Interpretations of Verbal Expressions of Probability: Implications for Securing Informed Consent to Medical Interventions," *Behavioral Sciences and the Law* 12, no. 4 (1994): 417-26; T.M. Marteau et al., "Numbers or Words? A Randomized Controlled Trial of Presenting Screen Negative Results to Pregnant Women," *Prenatal Diagnosis* 20, no. 9 (2000): 714-18.

21. Note that these figures are derived from one of six models presented in a paper commissioned by the USPSTF to help estimate the risks and benefits of various schedules for providing mammography (J.S. Mandelblatt et al., "Effects of Mammography Screening under Different Screening Schedules: Model Estimates of Potential Benefits and Harms," *Annals of Internal Medicine* 151, no. 10 [2009]: 738-47). Some commentators have questioned the accuracy and applicability of these models, and the model used here (the "Stanford Model") produces estimates of benefit that are lower than those of other models and some empirical research. But the question whether these numbers correctly capture the impact of mammography will not be analyzed further in this paper, since they are being used simply to demonstrate how such information could be relevant to a preference-sensitive decision. If these numbers are incorrect for mammography, they could be relevant to another preference-sensitive screening test.

22. Mandelblatt et al., "Effects of Mammography Screening under Different Screening Schedules."

23. Ibid.

24. A. Barratt et al., "Model of Outcomes of Screening Mammography: Information to Support Informed Choices," *British Medical Journal* 330 (2005): 936-38; H.G. Welch and W.C. Black, "Overdiagnosis in Cancer," *Journal of the National Cancer Institute* 109 (2010): 605-610.

25. Paling, "Strategies to Help Patients Understand Risks"; Gigerenzer and Edwards, "Simple Tools for Understanding Risks"; Barratt, "Use of Decision Aids to Support Informed Choices about Screening."

26. Paling, "Strategies to Help Patients Understand Risks."

27. Ibid.; Gigerenzer and Edwards, "Simple Tools for Understanding Risks"; Thornton, Edwards, and Baum, "Women Need Better Information about Routine Mammography"; Raffle, "Information about Screening"; R.A. McNutt, "Shared Medical Decision Making: Problems, Process, Progress," *Journal of the American Medical Association* 292 (2004): 2516-18.

28. McNutt, "Shared Medical Decision Making," 2517.

29. Austoker, "Gaining Informed Consent for Screening," 723.

Author's version. Final version published as:

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30. O'Connor, "Decision Aids for People Facing Health Treatment or Screening Decisions"; M. Galesic, G. Gigerenzer, and N. Straubinger, "Natural Frequencies Help Older Adults and People with Low Numeracy to Evaluate Medical Screening Tests," *Medical Decision Making* 29, no. 3 (2009): 368-71.
31. General Medical Council, "Seeking Patients' Consent."
32. Elwyn et al., "Additional Information."
33. Ibid.
34. Paling, "Strategies to Help Patients Understand Risks"; Gigerenzer and Edwards, "Simple Tools for Understanding Risks"; Barratt, "Use of Decision Aids to Support Informed Choices about Screening."
35. Mandelblatt et al., "Effects of Mammography Screening under Different Screening Schedules."
36. A good deal of other research suggests a higher RRR for mammography, up to 25 percent or 30 percent. The risk reduction discussed here may be lower since it is for biennial mammograms from ages forty to sixty-nine, while other research and modeling assumes annual mammograms from ages forty to seventy-four.
37. D. Sarfati et al., "Does the Frame Affect the Picture? A Study into How Attitudes to Screening for Cancer Are Affected by the Way Benefits Are Expressed," *Journal of Medical Screening* 5, no. 3 (1998): 137-40; D. Misselbrook and D. Armstrong, "Patients' Responses to Risk Information about the Benefits of Treating Hypertension," *British Journal of General Practice* 51, no. 465 (2001): 276-79.
38. Skolbekken, "Communicating the Risk Reduction Achieved by Cholesterol Reducing Drugs."
39. Thornton, Edwards, and Baum, "Women Need Better Information about Routine Mammography."
40. E.K. Slaytor and J.E. Ward, "How Risks of Breast Cancer and Benefits of Screening Are Communicated to Women: Analysis of 58 Pamphlets," *British Medical Journal* 317 (1998): 263-64; K.J. Jorgensen, and P.C. Gotzsche, "Presentation on Websites of Possible Benefits and Harms from Screening for Breast Cancer: Cross Sectional Study," *British Medical Journal* 328 (2004): 148-151.

Author's version. Final version published as:

Schwartz PH. Questioning the quantitative imperative: decision aids, prevention, and the ethics of disclosure. *Hastings Cent Rep.* 2011 Mar-Apr;41(2):30-9. <http://dx.doi.org/10.1353/hcr.2011.0029>

41. A. Edwards et al., "Presenting Risk Information: A Review of the Effects of 'Framing' and Other Manipulations on Patient Outcomes," *Journal of Health Communication* 6, no. 1 (2001): 61-82.
42. Ibid.
43. Elwyn et al., "Additional Information."
44. National Center for Education Statistics, "National Assessment of Adult Literacy (NAAL)"; Kutner et al., "The Health Literacy of America's Adults."
45. L.M. Schwartz et al., "The Role of Numeracy in Understanding the Benefit of Screening Mammography," *Annals of Internal Medicine* 127, no. 11 (1997): 966-72.
46. I.M. Lipkus, G. Samsa, and B.K. Rimer, "General Performance on a Numeracy Scale among Highly Educated Samples," *Medical Decision Making* 21, no. 1 (2001): 37-44.
47. Ibid.
48. S.L. Sheridan, M.P. Pignone, and C.L. Lewis, "A Randomized Comparison of Patients' Understanding of Number Needed to Treat and Other Common Risk Reduction Formats," *Journal of General Internal Medicine* 18, no. 11 (2003): 884-92.
49. Paling, "Strategies to Help Patients Understand Risks"; Gigerenzer and Edwards, "Simple Tools for Understanding Risks."
50. J.S. Ancker and D. Kaufman, "Rethinking Health Numeracy: A Multidisciplinary Literature Review," *Journal of the American Medical Information Association* 14, no. 6 (2007): 713-21; J.S. Ancker et al., "Design Features of Graphs in Health Risk Communication: A Systematic Review," *Journal of the American Medical Information Association* 13, no. 6 (2006): 608-18.
51. C. Keller and M. Siegrist, "Effect of Risk Communication Formats on Risk Perception Depending on Numeracy," *Medical Decision Making* 29, no. 4 (2009): 483-90.
52. T.L. Beauchamp and J.F. Childress, *Principles of Biomedical Ethics*, 6th ed. (Oxford, U.K.: Oxford University Press, 2006); R.R. Faden and T.L. Beauchamp, *A History and Theory of Informed Consent* (New York: Oxford University Press, 1986). I will not discuss the strengths and weakness of the other two commonly recognized standards for minimal disclosure here—the professional practice standard and the subjective standard—although the subjective standard will be touched on briefly below.
53. Beauchamp and Childress, *Principles of Biomedical Ethics*, 123.

Author's version. Final version published as:

Schwartz PH. Questioning the quantitative imperative: decision aids, prevention, and the ethics of disclosure. *Hastings Cent Rep.* 2011 Mar-Apr;41(2):30-9. <http://dx.doi.org/10.1353/hcr.2011.0029>

54. Schwartz et al., "The Role of Numeracy in Understanding the Benefit of Screening Mammography"; U. Hoffrage and G. Gigerenzer, "Using Natural Frequencies to Improve Diagnostic Inferences," *Academic Medicine* 73, no. 5 (1998): 538-40.
55. Gigerenzer and Edwards, "Simple Tools for Understanding Risks."
56. Sheridan, Pignone, and Lewis, "A Randomized Comparison of Patients' Understanding of Number Needed to Treat and Other Common Risk Reduction Formats."
57. S. Woloshin, L.M. Schwartz, and H.G. Welch, "The Effectiveness of a Primer to Help People Understand Risk: Two Randomized Trials in Distinct Populations," *Annals of Internal Medicine* 146, no. 4 (2007): 256-65.
58. M.D. Resnik, *Choices: An Introduction to Decision Theory* (Minneapolis: University of Minnesota Press, 1987); Baron, *Thinking and Deciding*.
59. D. Kahneman and A. Tversky, "Prospect Theory: An Analysis of Decision under Risk," *Econometrica: Journal of the Econometric Society* 47, no. 2 (1979): 263-92.
60. Baron, *Thinking and Deciding*; Reyna, "How People Make Decisions that Involve Risk."
61. N.D. Weinstein, "Unrealistic Optimism about Future Life Events," *Journal of Personality and Social Psychology* 39, no. 5 (1980): 806-20; N.D. Weinstein, "Unrealistic Optimism about Susceptibility to Health Problems: Conclusions from a Community-Wide Sample," *Journal of Behavioral Medicine* 10, no. 5 (1987): 481-500.
62. A. Cull et al., "The Impact of Genetic Counseling about Breast Cancer Risk on Women's Risk Perceptions and Levels of Distress," *British Journal of Cancer* 79, no. 3-4 (1999): 501-8; I. Senay and K.A. Kaphingst, "Anchoring-and-Adjustment Bias in Communication of Disease Risk," *Medical Decision Making* 29, no. 2 (2009): 193-201.
63. A. Fagerlin, B.J. Zikmund-Fisher, and P.A. Ubel, "How Making a Risk Estimate Can Change the Feel of That Risk: Shifting Attitudes Toward Breast Cancer Risk in a General Public Survey," *Patient Education and Counseling* 57, no. 3 (2005): 294-99.
64. V.F. Reyna, "A Theory of Medical Decision Making and Health: Fuzzy Trace Theory," *Medical Decision Making* 28, no. 6 (2008): 850-65; Reyna, "How People Make Decisions That Involve Risk."
65. Galesic, Gigerenzer, and Straubinger, "Natural Frequencies Help Older Adults and People with Low Numeracy to Evaluate Medical Screening Tests"; Woloshin, Schwartz, and Welch, "The Effectiveness of a Primer to Help People Understand Risk."

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66. O'Connor et al., "Decision Aids for People Facing Health Treatment or Screening Decisions."
67. Baron, *Thinking and Deciding*.
68. C.E. Schneider, *The Practice of Autonomy: Patients, Doctors, and Medical Decisions* (New York: Oxford University Press, 1998); N.C. Manson and O. O'Neill, *Rethinking Informed Consent in Bioethics* (Cambridge, U.K.: Cambridge University Press, 2007); C.E. Schneider, "After Autonomy," *Wake Forest Law Review* 41, no. 2 (2006): 411-44; A.I. Tauber, *Patient Autonomy and the Ethics of Responsibility* (Cambridge, Mass.: MIT Press, 2005); O. O'Neill, *Autonomy and Trust in Bioethics* (Cambridge, U.K.: Cambridge University Press, 2002).
69. Schneider, *The Practice of Autonomy*.
70. J. Katz, *The Silent World of Doctor and Patient*, rev. ed. (1984; repr., Baltimore, Md.: Johns Hopkins University Press, 2002).
71. R.M. Epstein, B.S. Alper, and T.E. Quill, "Communicating Evidence for Participatory Decision Making," *Journal of the American Medical Association* 291 (2004): 2359-66.
72. S.L. Sheridan, R.P. Harris, and S.H. Woolf, "Shared Decision Making about Screening and Chemoprevention: A Suggested Approach from the U.S. Preventive Services Task Force," *American Journal of Preventive Medicine* 26, no. 1 (2004): 56-66.
73. S.N. Whitney, A.L. McGuire, and L.B. McCullough, "A Typology of Shared Decision Making, Informed Consent, and Simple Consent," *Annals of Internal Medicine* 140, no. 1 (2004): 54-59; S.N. Whitney, "A New Model of Medical Decisions: Exploring the Limits of Shared Decision Making," *Medical Decision Making* 23, no. 4 (2003): 275-80.
74. W. Burke and B.M. Psaty, "Personalized Medicine in the Era of Genomics," *Journal of the American Medical Association* 298 (2007): 1682-84; M.J. Khoury, L.L. McCabe, and E.R.B. McCabe, "Population Screening in the Age of Genomic Medicine," *New England Journal of Medicine* 348 (2003): 50-58.

Author's version. Final version published as:

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