SOUNDING BOARD

Lessons from the Mammography Wars

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> People of the same trade seldom meet together . . . [without] the conversation end-[ing] in a conspiracy against the public.
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> — Adam Smith, *The Wealth of Nations*, 1776[1]

The controversy was predictable.

Since 2002, annual mammograms had been recommended for women 40 years of age or older.[2] Suddenly, an independent, government-funded panel was suggesting that this schedule might be too much — that less, in fact, might be better.

Advocates of breast-cancer screening, particularly breast radiologists, immediately took action, denouncing the panel's statements as government rationing, suggesting that the panel members had ignored the medical evidence, and even implying that the panel members were guilty of a callous disregard for the life and well-being of women. As one prominent breast radiologist put it, "Basically, [the panel] said nothing is good. Just wait until it breaks through your skin. . . ."[3] Specialty societies quickly issued countermanding guidelines.[4]

In reality, this independent panel, the Preventive Services Task Force, simply recommended that routine screening mammography begin at the age of 50 years, whereas women between the ages of 40 and 49 years should make individual decisions with their doctors as to whether their preferences and risk factors indicate screening at an earlier age. The panel also recommended that screening mammograms be performed every other year, which they suggested would reduce the harms of mammography by nearly half while maintaining most of the benefits provided by annual imaging.[5] In short, the panel concluded that we had previously overestimated the value of mammography: that mammography is good, but not that good; that it is necessary for many women, but not all; and that it should be performed at some frequency, but perhaps not every year, for every woman.

Behind the panel's conclusions regarding mammography lurks an unwelcome reality that our profession has often failed to acknowledge. Every medical intervention — no matter how beneficial for some patients — will provide continuously diminishing returns as the threshold for intervention is lowered. Mammography is just one case in point. For women between the ages of 40 and 49 years, the false positive rate is quite high, and the expected benefits are quite low: more than 1900 women would need to be invited for screening mammography in order to prevent just one death from breast cancer during 11 years of follow-up, at the direct cost of more than 20,000 visits for breast imaging and approximately 2000 false positive mammograms. Conversely, for women between the ages of 60 and 69 years, fewer than 400 women would need to be invited for screening in order to prevent one breast-cancer death during 13 years of follow-up, while accruing approximately 5000 visits and 400 false positive mammograms.[6] In short, as the risk of breast cancer increases, the benefits of mammography increase, whereas the relative harms become progressively less significant.

More generally, the net benefit of all medical treatments is a continuous function of three factors: the risk of morbidity or mortality if untreated ($\text{Risk}_{\text{NoRx}}$), the treatment's relative risk reduction (RRR_{Rx}), and the treatment's risk of harm (Harms_{Rx}):

$$\text{Net Benefit} = (\text{Risk}_{\text{NoRx}} \times \text{RRR}_{\text{Rx}}) - (\text{Harms}_{\text{Rx}}).$$

As the risk of no treatment ($\text{Risk}_{\text{NoRx}}$) decreases, the net benefit of treatment will decrease, even if the treatment's relative benefit (RRR_{Rx}) remains constant. Indeed, for many interventions, if the risk of no treatment is low enough (e.g., if we lower the threshold for treatment too far or if a patient's life expectancy is relatively limited for other reasons), then the side effects and risks of treatment will dominate, and the treatment will result

in net harm.[7-9] Since the risk of no treatment varies dramatically among patients for almost every disease or condition, even a highly effective intervention will show a gradient of net benefit in a given population.

Despite this continuous gradient of treatment benefit versus harm, medical decision making is necessarily discrete. In the case of any given patient, we must choose to treat or not treat, to screen or not screen. In an effort to help us make these choices, our profession is constantly trying to elucidate clear thresholds for intervention, such as the level of glycated hemoglobin or low-density lipoprotein cholesterol, age, or standard time intervals. What we often do not remember is that these thresholds — for example, an age of 40 versus 50 years or annual versus biennial routine mammography — are to some degree subjective and arbitrary. After all, scientific evidence can only help us describe the continuum of benefit versus harm. The assessment of whether the benefit is great enough to warrant the risk of harm — i.e., the decision of where the threshold for intervention should lie — is necessarily a value judgment. When either side in the mammography wars claims that the evidence suggests that women should or should not undergo routine mammography starting at the age of 40 years, they are deceiving themselves and the public about what the evidence can tell us. They are really just making different value judgments about where to set the threshold.

Who is right? Who should be making these judgments?

The obvious answer might seem to be "the individual patient and her doctor." But it would be folly to suggest that every medical decision ought to be made anew for each patient, with no standard of care in any case, no guidelines, and no professional norms. Instead, our profession needs to start distinguishing between choices that are clear-cut and those that require individualized decision making. To this end, for most interventions, rather than seeking a single, universal threshold for intervention (Fig. 1A), we should be arguing over a minimum of two distinct thresholds: one above which benefit clearly outweighs the risk of harm, in which case clinicians should recommend a treatment; and one below which concern about harm clearly dominates, in which case clinicians should recommend against that treatment. Between these two thresholds lies a gray area of indeterminate net benefit, in which clinicians should defer to an individual patient's preferences — including, for example, a woman's emotional response to her risk of breast cancer — in choosing whether to intervene (Fig. 1B).

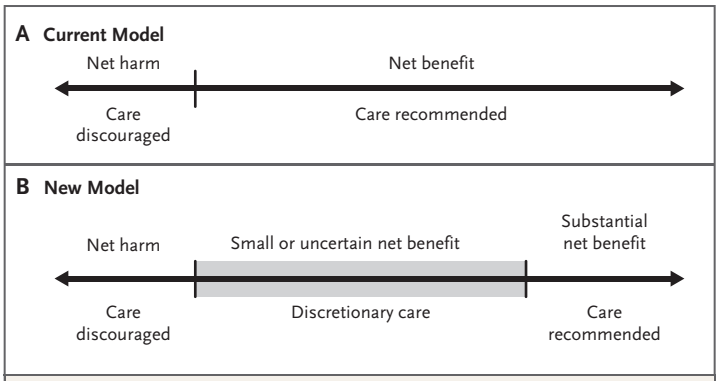

Figure 1. Creating a New Risk–Benefit Model that Allows for Individualized Decision Making.

For most interventions, the current practice of seeking a single, universal threshold for intervention (Panel A) might be replaced by a model that allows for individualized decisions about whether to intervene on the basis of personal risk factors and preferences (Panel B).

It is just such a gray area into which women in their 40s are assigned by the new mammography guidelines. Of note, there are quantitative methods available that can assist clinicians in guiding individual decision making even in these gray areas.[6-10] In our profession's apt pursuit of more systematized care, however, we have generally preferred to ignore these gray areas altogether. It is easier, after all, to simply lower the threshold for intervention — to recommend mammography for all women 40 years of age or older — than to rely on individual judgments about which of these women actually warrant screening.

However, our current approach is more than just a quest for uniformity. When a given service is successfully extended to more people with more intensity, the profession providing that service tends to grow in importance and profitability. In the United States, where medical specialists often enjoy an exalted status in the minds of the public, if experts shout loudly that every woman 40 years of age or older must be screened annually for breast cancer, then breast cancer must be important, screening must be a basic human right, and doctors who provide this service must have great value and authority.

But what if those experts are basing their recommendations on more than the interest of patients alone? In any other industry, we accept the idea as natural that those providing a service or

product hold their own and their shareholders' interests as a primary objective. Why have we failed to acknowledge that the same phenomenon occurs in health care? Although it is true that individual medical providers care deeply about their patients, the guild of health care professionals — including their specialty societies — has a primary responsibility to promote its members' interests. Now, self-interest is not in itself a bad thing; indeed, it is a force for productivity and efficiency in a well-functioning market. But it is a fool's dream to expect the guild of any service industry to harness its self-interest and to act according to beneficence alone — to compete on true value when the opportunity to inflate perceived value is readily available.

It is for this reason that some degree of market regulation is necessary, such as truth-in-advertising and antitrust laws. It is only in health care that we have failed to recognize the need for analogous protections. It is only in health care, after all, that the same group that provides a service also tells us how valuable that service is and how much of it we need, as when the Society of Breast Imaging sets the recommendations for mammography.[4] If there is overutilization in health care, we can be sure that it will continue unabated as long as those with a vested interest are allowed to win the public-relations wars by shouting about "rationing" or "death panels" whenever anyone suggests that more health care, in fact, may not be better.

It is time for a change. We must acknowledge that just as in any other profession or industry, self-interest is unavoidably at work in health care. Rather than even acknowledging practice guidelines offered by vested experts, we ought to borrow from the wisdom of sound governance and implement a system of checks and balances when it comes to the interpretation and application of medical evidence. At the same time, we need to recognize that these two tasks are distinct. Although the interpretation of medical evidence is (or ought to be) a scientific exercise, the application of that evidence, as in guideline formation, is ultimately a social exercise.

Decisions regarding practice guidelines can, and certainly should, be informed by evidence. But they will always require value judgments regarding how much evidence is sufficient to dictate care, for example, or whether and to what degree costs should be considered. By separating the processes of evidence review and guideline formation, fair disagreements about the quality or substance of the evidence can occur separately from, and before, disagreements about the implications for clinical care.

Ideally, we ought to have a system in which independent panels of generalists, with expertise in the methods of evidence review and synthesis, are responsible for objectively synthesizing the medical evidence around a given question or process of care. These independent panels could then seek input from the relevant clinician groups regarding their views concerning the evidence and where they feel the thresholds for recommended care versus individualized decision making should reside. To facilitate impartiality and political viability, a public–private alliance might be best, with funding and representation for the independent panels coming from government, private foundations, and provider and payer groups.

Furthermore, unlike one-time or occasional panels, this process of evidence review and guideline formation ought to be adequately funded to allow for regular updates as new evidence becomes available. Recent proposals to increase spending on comparative-effectiveness research are certainly laudable, but it is unrealistic to think that an investment in research alone will have a sizable effect on the practice of medicine without a concomitant investment in a credible process for vetting medical evidence and clinical care guidelines.

The Preventive Services Task Force approaches the format that we propose here, since the panel is composed of expert generalists. This panel, however, tends to interpret the evidence and write the recommendations as a single process, creating the appearance, and perhaps the reality, of allowing too little input from vested interests and often conflating disagreements about the evidence with disagreements about the recommendations. Furthermore, as seen in the mammography wars, the panel's perceived failure to seek sufficient input from specialty groups was a prominent, and seemingly effective, argument against the guidelines.[11] Even the perception that the process of guideline formation is closed or does not consider specialists' opinions can make it easy for those arguing that more care is better to prey on the public's legitimate concern that government and insurers are out to deny them lifesaving care.

As a profession, we have the potential to play

a very real role in improving our health care system. We can choose to acknowledge the gray areas of medicine and insist that they be reflected in clinical-practice guidelines and in performance measures. And we can work to prevent vested interests from being granted the loudest voices in health care — even when those voices blazon from our own specialty — by granting credence to groups such as the Preventive Services Task Force that seek to formulate evidence-based guidelines in an objective way.

Or we can, instead, conduct our own version of the mammography wars when a prudent application of the evidence threatens the profitability and stature of our own specialty.

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