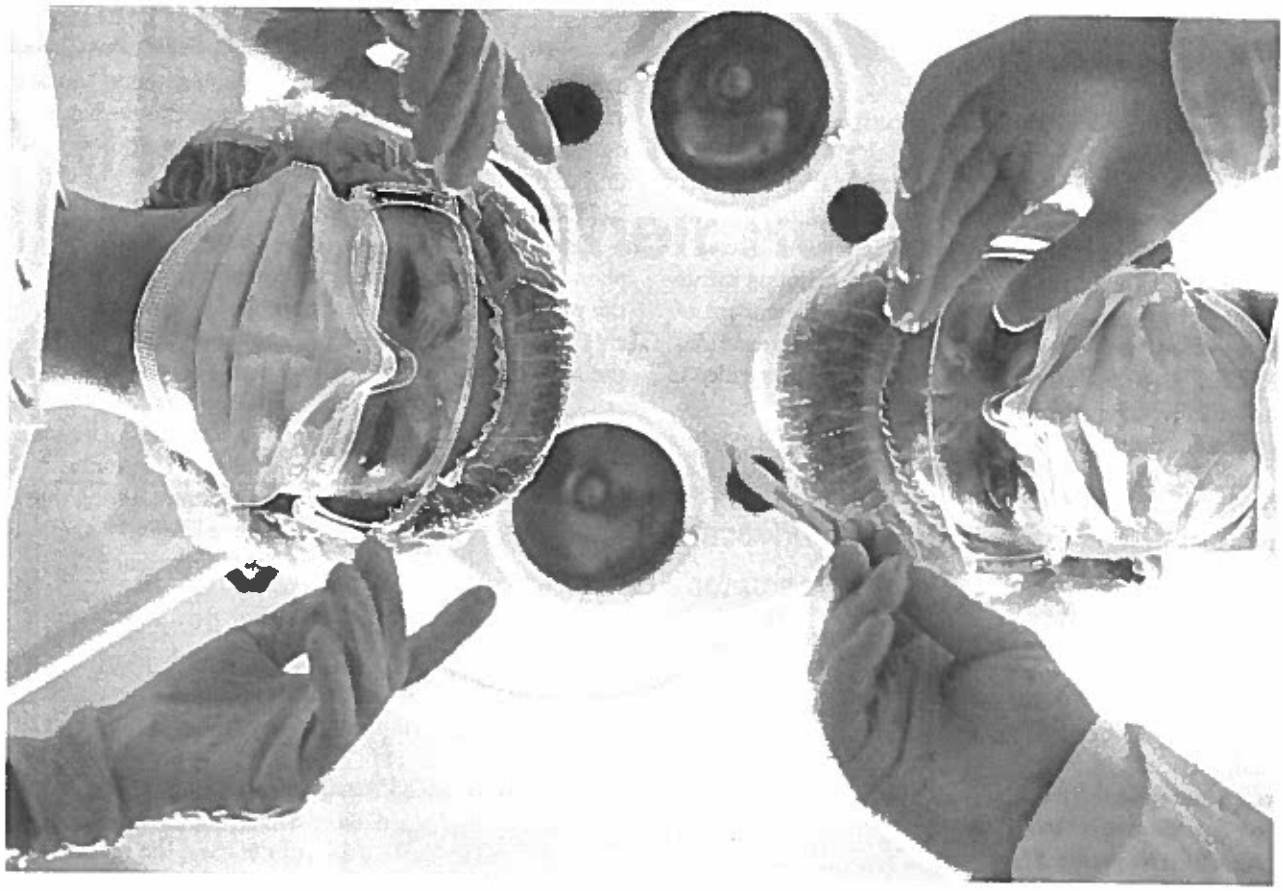

Patient Voices in Clinical Practice Guideline Development

By David E. Matz, Allen Zerkin, Amy Rebecca Gay, and Nicola Truppin

Integrating the perspectives and experiences of patients into the delivery of our health care is a key initiative of the Affordable Care Act. This article describes our experiences facilitating the development of a clinical practice guideline in a multi-stakeholder panel that included patient representatives and experts. Perhaps our greatest challenge was dealing with the ambiguity of the scientific evidence and integrating the patient representatives' values into a technical dialogue. At the end, the implications of this challenge surprised us.

Clinical practice guidelines, according to the Institute of Medicine, are "recommendations intended to optimize patient care that are informed by a systematic review of evidence and an assessment of the benefits and harms of alternative care options." These clinical practice guidelines are developed by bodies of experts over many years and are based on a review of the current evidence. The Institute of Medicine has recently raised a number of concerns, however, about the quality of the processes used to create these guidelines.

One concern is that patients have not been part of the process. Through a grant funded by the Patient-Centered Outcomes Research Institute, a federally funded program whose self-described mission is to "help people and their caregivers communicate and make informed health care decisions," the authors of this essay participated in a two-part pilot project to facilitate a multi-stakeholder group's development of clinical practice guidelines for cancer screening, the first for prostate cancer, which is the subject of this article, and the next for lung cancer.[1] The goal is to create a standard process for including patient representatives in guideline development so that the translation of medical evidence into clinical practice considers the perspective of the end user, the patient.

Background

The PSA test, which measures the amount of prostate-specific antigen in a man's blood, is used to identify men who might have prostate cancer. Until recently, doctors routinely recommended the test to their patients 50 years of age and older, and advocacy groups encouraged men to get screened. But in 2012, the United States Preventive Services Task Force[2] published a report recommending that the PSA test not be routinely used, concluding that the number of lives saved by PSA screening is small — because most men with prostate cancer will not die from it — and that the harms (e.g., incontinence, impotence, infection) stemming from unnecessary treatment outweigh the benefits.[3] Therefore, the task force recommended that primary care physicians not offer the PSA test and discuss it only if a patient asks. Not everyone agrees, however, and many argue that the task force guidelines go too far, that the benefits of PSA screening should not be lost, and that advances in diagnosis and treatment of prostate cancer make many of the harms avoidable. The debate has affected both doctors and the people they serve: already overworked primary care physicians have no clear direction on whether to offer or recommend the PSA test, and patients have no clear guidance for deciding whether to get tested.

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Concerned by this uncertainty and inspired by the goals of the Patient-Centered Outcomes Research Institute, Dr. Roger Luckmann, a clinician and Associate Professor of Medicine at the University of Massachusetts Medical Center, initiated a project to involve patient representatives in the development of guidelines for the PSA test and engage professional facilitators to assist them.[4] If the panel were successful, its guidelines would be disseminated in Massachusetts. The hope was that clearly reasoned guidelines created by such a broad-based group would be convincing to both doctors and patients.

The Process

Dr. Luckmann organized a management team to run the process. The management team comprised four groups:

- An evidence group of doctors, medical researchers, and social scientists who summarized research articles and responded to panelists' questions;
- A logistics group, which recruited panelists, scheduled meetings, and made all meeting arrangements;
- A facilitation group, which designed the process and facilitated the meetings; and
- A research group, which observed the process, interviewed panelists and the management team, and will analyze the process and help develop recommendations for including patient representatives in the creation of future clinical guidelines.

The panel had 21 members: six primary care physicians; six patient representatives; two health systems representatives; two health insurers; two public health representatives; and three urologists. Twelve panelists were men, and two of the patient representatives were African-American men. The patient representatives were selected from a group of patients and families who had worked with a health advocacy organization and ranged in age from those who were too young to have begun screening to those old enough to have stopped. Some were survivors of prostate cancer, and some were at high risk. One of the two African American patient representatives dropped out of the process because of his work schedule. The doctors on the panel were selected from physicians who had experience with patients and prostate cancer and were willing to volunteer their time.

Over eight months, panelists met four times for four hours each. Working groups convened via webinars between meetings. The process moved through a number of phases: grappling with the scientific studies; defining and grouping the issues and forming working groups to address them; developing and analyzing options for each issue; and reaching a full agreement.

The Challenges

Recruiting panelists

The organizers of any multi-stakeholder consensus-building process want to have a balanced and representative panel. In this case, the process of creating one took several interesting turns.

First, the twofold purpose of the process was to provide guidance to the target audience of Massachusetts primary care physicians and patients and involve patient representatives in a meaningful way. Did this mean that primary care physicians and patient representatives should have the same number of representatives as those with different kinds of stakes in the outcome, e.g., urologists, who have the greatest pecuniary interests in the use of the PSA test and the procedures that arise

from "positive" test results, and payers and health care administrators, who are affected by costs of various kinds? Should consensus mean unanimity, which would give each individual panelist veto power? After extensive discussion, the facilitation team recommended to the management team that patient representatives and primary care physicians have the largest representation on the panel (12 of the 21 members) so that the target audience would have the loudest voice in the process. Concern about vested interests also led the facilitators to recommend that "consensus" be defined as a consensus among the constituent panelist groups, so that no individual urologist or payer, for example, could block the outcome, with the proviso that any individual who disagreed with his or her group could write a dissenting opinion that would be published as part of the clinical practice guidelines. The management team accepted both recommendations.

Second, we were concerned about recruiting African American patient representatives. Prostate cancer occurs more frequently among black men, tends to manifest earlier in their lives, may be more aggressive, and more often causes death among black men than among white, Asian, or Hispanic men.[5] Although we all agreed that recruiting black men was critical, the logistics team was able to find only two African American patient representatives willing to participate, including, as it turned out, the panel member who dropped out because of scheduling. Considering the increased risks black men face, the facilitators were concerned about how the African American man would feel about being responsible (or being perceived as responsible) for representing all black men and also how being the only black man on the panel would influence his participation. We also wondered how this underrepresentation would affect the legitimacy of the panel's recommendations, a concern that grew when we found that the African American panelist was very quiet, even when we made special efforts to elicit his views.

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But the most important implication of this — discussed below — caught us completely by surprise.

Values and science

The panel was convened partly because the available science was not clear enough to settle whether the benefits of PSA screening outweigh the risks of overdiagnosis and overtreatment. Weighing benefits against risks is always problematic: How does one "compare" the worth of a life saved with the value of avoiding the various harms? The medical community faces these questions all the time, and values, rather than science, are always involved. When the risks are very small and the benefits very great, medical professionals easily conclude that the balance is clear. But when, as in this case, the potential harms are substantial but overwhelmingly nonfatal, while the benefit of lives saved is a relatively small number, the value conflict is more difficult.

To illustrate, if PSA screening is begun at age 45 instead of 50, the number of lives saved increases, but the number of men who live with the harms commonly resulting from treatment also increases. This is also true for greater frequency of screening and a higher age for stopping screening. In other words, there is a direct relationship between the number of lives saved and the amount of harm that stems from screening.

Initially, a working group struggled with this conundrum, drawing on a document that Dr. Luckmann produced. To give a sense of how the problem was focused, one portion of that document is included at the bottom of this page.

The working group was not able to come to a conclusion and left the question open for the next (third) panel session. The facilitators thus faced the question of whether to let the panelists debate it until they came to a consensus or to suggest leaving the issue unresolved, on the grounds that (a) such an effort would be futile

Excerpt from Dr. Luckmann's Decision Analyses Document:	
Decision analyses using numeric estimates of harms to evaluate quality adjusted life years (QALYs)	These assume that harms are measured on a continuum from 0 to 1, where death is 0. For some, death may not be perceived on this continuum and these patients may have a hard time associating a number with death. Without giving a numerical rating to death, decision analysis cannot be done. Available decision analyses suggest that only men who perceive incontinence and impotence as having a very minimal effect on quality of life should consider prostate cancer screening.

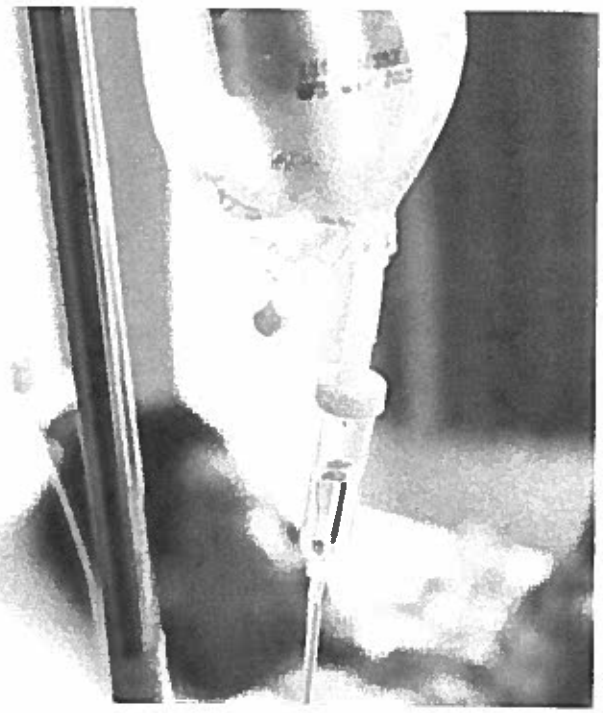
or would, at the very least, expend a vast amount of the panel's limited time; (b) any judgment reached would of necessity be arbitrary, a function of these *particular* panelists' values, and therefore might have limited persuasive power with the panel's intended audiences; and (c) the panel could fall back on the central importance of "shared decision making" — a process where patients make as informed a judgment as they can about how to weigh, with the advice of their primary care physicians, the potential benefits and risks. The patient representative voices on this issue were strong — they all felt that since the science is ambiguous and contradictory at best, the decision should be left to a patient and his doctor and not be decided by a panel.

And then we caught a break. A research team[6] previously unknown to us, working on the same problem and using mathematical modeling in addition to the existing research, was able to produce a set of harms-to-benefits ratios that converted the language of value tension into the language of quantitative choice. With this tool, the panelists, after the third panel meeting, were able to decide on what became the crucial point: should screening start at 45, 50, or 55? Going into the final panel, therefore, we had general agreement that screening for average-risk men should begin at 50 and for high-risk (e.g. black) men at 45, the conventional ages at which to begin screening. Our playing field, however, was not as stable as we had assumed.

Moving playing field

At the fourth panel meeting, two matters caught the facilitators off-guard, and the interaction of these surprises nearly derailed the process. The first surprise came at the beginning of the meeting when most of the panel members, including the facilitators, learned that the American Urological Association (AUA) had recently released a revised guideline. There was general agreement that both our guideline and the AUA's would likely be more persuasive if they were consistent, and because the AUA guideline was very close to the one our panel was considering, the panel seemed enthusiastic that we could align our guideline with the AUA's well-founded recommendations without compromising important values.

There was one element in the AUA guideline, however, that, though seemingly noncontroversial, proved very troublesome. The AUA had concluded that by raising the age at which screening should begin from the conventional age of 50 to 55, there would likely be a meaningful reduction in harms and a negligible reduction in lives saved. These relative values of harms and benefits fit those articulated by our panel, so there was no reason to anticipate any resistance to following the AUA. But increasing the starting age from 50 to 55 implied that the beginning age for screening high-risk men — a category that included all African American men and all men with a family history of prostate cancer — should also be raised by five years, from age 45 to 50.



At this moment, we faced our second surprise. The sole black patient representative and the representative from the state Department of Public Health shared with the group that for years a public health campaign had been in place in African American communities to promote the age of 45 as the starting point for screening African American males. The community groups the black patient representative spoke for — and the Department of Public Health — didn't want to lose ground on this campaign, and the black patient representative said that he had been encouraged by his community not to support any starting age over 45. He also shared that some health advocates in the African American community favored starting even earlier. Therefore, he couldn't support a starting age of 50 for African American men. But leaving the high-risk starting age at 45 while raising the normal starting age to 55 was problematic. Age-specific incidence rates suggested that a five-year differential roughly equalized the expected

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benefits and harms of prostate cancer screening between average and high-risk men. No known scientific rationale or evidence would support a 10-year differential, so the evidence-based character of our guideline would be undermined.

This revelation posed a serious challenge to the panel. What would it mean for the legitimacy of the guideline if the only African American patient representative did not sign the agreement? Although the panelists had agreed at the beginning that dissenters could write a minority opinion, would the guideline be perceived as legitimate if the only dissenter were African American, especially when incidence rates of prostate cancer are highest among African American men? Despite extensive debate and the exploration of various options, the issue remained unresolved as of the end of the fourth panel meeting.

Dr. Luckmann and his colleagues continued negotiating this issue via e-mail and phone calls with all the panelists. In the end, the final recommendation did not follow the American Urological Association language, staying with a starting age of 50, and also added a two-tier high-risk approach — 45 for African-American and other high-risk men and 40 for those with two risk factors — which satisfied the African American patient representative and the Massachusetts Department of Public Health and also kept the recommendation relatively straightforward, another interest held by a majority of the panel members.

Conclusion

The process produced a consensus. The recommended clinical guidelines were submitted to an organization[7] that specializes in seeking ways to implement clinical guidelines in Massachusetts that it has examined and approved, and it has now approved the recommended guidelines.

The process of involving patient representatives in the panel's decision making was a success. The patient representatives adequately mastered the scientific information and controversies, and most of them expressed their views throughout the process. Nonetheless, we have wondered if they were expressing themselves with complete candor, and we have decided that for the follow-up project we will assign one member of the facilitation team the task of reaching out early and often to the patient representatives, probing for questions or anxieties, exploring whether they have obligations to other organizations that would impact their decision making on the panel, and encouraging more involvement. The participation of African American males was the least successful aspect of the project, and our recommendation for future panels is that more effort be put into the recruitment and engagement phase. ◆

Endnotes

1 This paper focuses only on prostate cancer; the lung cancer panel is under way.

2 The USPSTF is an independent panel of primary health care providers who create clinical practice guidelines based on current scientific evidence. Their recommendations are widely used by primary health care providers.

3 The USPSTF gave the evidence a grade of "D," which means "[t]here is moderate or high certainty that the service has no net benefit or that the harms outweigh the benefits." *U.S. Preventative Services Task Force Grade Definitions*, U.S. PREVENTATIVE TASK FORCE (February 2013), http://www.uspreventiveservicestaskforce.org/uspstf/grades.htm..

4 This was the first time professional facilitators had been hired to support the development of Clinical Practice Guidelines. The facilitators selected by Dr. Luckmann were Allen Zerkin of the Wagner Graduate School of Public Service, NYU, and Amy Rebecca Gay, Nicola Truppin, and David Matz of The Mediation Group.

5 It is unknown why black men suffer more morbidity and mortality from prostate cancer. Neither genetics nor access to or quality of health care alone explains the difference.

6 Ranjay Gulati et al., *Comparative Effectiveness of Alternative Prostate-Specific Antigen–Based Prostate Cancer Screening Strategies: Model Estimates of Potential Benefits and Harms*. ANNALS OF INTERNAL MED., Feb. 2013, at 145-53.

7 The organization that agreed to examine and, if approved, implement the guideline was Massachusetts Health Quality Partners (MHQP). MHQP has agreed to implement the guideline with minor changes, and it is working with its partner organizations to have clinicians use the guideline in their treatment of patients.




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