Testing the Limits of Certainty and the Boundaries of Reason

by Eugene Rich, MD, FACP

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My friends on the Hill hoped important lessons had been learned since the "bad old days" of the 1990's health care debates. Back then people were afraid of gatekeepers and health plan "rationing." Paranoia about limited access to medical technology was rampant. As a result, industry advocates almost eliminated a federal agency for challenging the value of back surgery, and patient advocates successfully demanded a "right" to receive unproven (and later proved harmful) bone marrow transplantation for metastatic breast cancer. My friends felt that times were now different. They believed policy makers, pundits, and many among the US electorate better understood the value of scientific reflection untainted by special interest. Therefore the national health policy process was now ready for experts in evidence-based medicine to systematically evaluate the complex balance of risks and benefits of a health care innovation and offer patients and clinicians a clear and concise assessment. These friends thought the US Preventive Services Task Force (USPSTF), made up of scholars in health care prevention and evidence-based medicine, was a model for how this could work, with its long history of dispassionate reports, taxpayer-funded but operating behind a firewall of protection from political influence. Even the recent, bizarre charges equating comparative effectiveness research commissions with "euthanasia boards" and "death panels" had not yet blighted this hopeful perspective.

And then, in mid-November the Annals of Internal Medicine published the USPSTF relook at mammography, which concluded the evidence was unclear whether screening did more good than harm for healthy risk-factor-free women under 50. "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 into account patient context, including the patient's values regarding specific benefits and harms." (http://www.annals.org/content/151/10/716.full) Suddenly it was "Back to the Future" inside the Beltway. Dispassionate and carefully reasoned discussions of the risks of false positive screens, of NNT (the "number needed to treat"), of needless biopsies and possible erroneous treatment of pseudo-malignancies—these seemed coldly calculating. The statistics seemed to devalue the myriad anecdotes of prominent women (including politicians) who perceived they had averted a premature breast cancer death by early mammography. Obviously clinical epidemiologists still struggle with how best to summarize pages of text and clarify subtle points distinguishing breast cancer mortality from "all cause mortality," caution about the quality of otherwise productive and healthy years of life blighted by unneeded surgery and toxic drugs, acknowledge the randomness of disease and the imperfection of medical technology.

The USPSTF position seemed all the more suspicious since it reversed a 7 year old recommendation from the same group that was much more enthusiastic about the benefits of screening; "The U.S. Preventive Services Task Force (USPSTF) recommends screening mammography, with or without clinical breast examination (CBE), every 1 to 2 years for women aged 40 and older." Ann Intern Med. 2002;137:344-346. Although the 2009 review considered the results of several new large studies, these did not on balance reveal dramatically new information about the effects of screening mammography on breast cancer mortality. The authors acknowledged a 15% reduction in breast cancer mortality in favor of screening for women 40-49, corresponding to the need to invite 1904 women for screening to avoid 1 breast cancer death. Instead of embracing this seeming benefit, the evidence review highlighted new findings on such topics as "Anxiety, Distress, and Other Psychological Responses" {from Screening Mammography}; "False-Positive and False-Negative Mammography Results…"; and "Overdiagnosis."

Unfortunately, this recommendation arrived the very week the Senate Majority Leader released his office's compromise health care reform legislation (with its provisions for comparative effectiveness research and extension of benefits to services endorsed by the USPSTF). While scientists from the Task Force attempted to explain their complicated assessment of risks and benefits, these recommendations to use less technology (start later and screen less often) evoked a simpler narrative- "government-funded scientists will ration your care." Advocacy groups expressed their wrath. Spokespersons opposing health care reform jammed the political talk shows and the editorial pages, decrying these recommendations as an example of the denial of valuable services destined to occur under any "government takeover of health care." Just as quickly HHS Secretary Sebelius released an announcement distancing her office from the USPSTF and its views. The American Cancer Society was instantly and very publicly dismayed at the USPSTF suggestion that there are more harms and life goals for a 40 year old woman to consider than reducing her chance of dying from breast cancer; perhaps not surprising for an organization whose mission, after all, is "eliminating cancer as a major health problem". Even more predictable was the American College of Radiology's attack on the new USPSTF

recommendations, which threatened to cut the potential market for screening mammography, and all the related downstream testing, by over 50%.

All of this has seemed like a bad couple of weeks for the role of evidence-based medicine in health care reform. The furor seemed to challenge the feasibility of federally supported comparative effectiveness research experts advising the American people on difficult issues of clinical evidence where the individual and societal stakes are high. But perhaps the system is working as it must. The scientists undertake their analysis and release their report through the peer-reviewed scientific literature, unimpeded by thoughts of political timing or message. The stakeholders' groups posture to justify the contributions and passions of their constituents (be they radiologists or breast cancer survivors). The media outlets feed the relentless appetite for controversy created by the 24 hour news cycle. The politicians find a talking point to weave into their larger health care reform narrative.

While the political machinery may not be quite ready to appreciate the careful arguments of the USPSTF, I am hopeful that my friends', and the American peoples', greater wisdom remains intact. The US desperately needs such groups of unbiased experts able and willing to provide a clear synthesis of the complex balance of risks and benefits for a health care innovation. Tough answers can't be embraced in a day or a week. But over time I trust we will learn to consider calmly the personal significance of such cautious and nuanced scientific reflection untainted by special interest. Either that or we must prepare our children for life in a nation given entirely over to the infinitely expansile use of health care technologies and all the false certainty these provide.

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