

**Statement of Steven D. Pearson, MD, MSc, FRCP**  
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**Hearing on “Implementing Best Patient Care Practices”**  
**Senate Committee on Health, Education, Labor, and Pensions**

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Thank you, Senator Mikulski, and Members of the Committee for the invitation to testify about the links between comparative effectiveness research and best patient care practices. My name is Steven Pearson. I am a general internist and the Founder and President of the Institute for Clinical and Economic Review, or ICER, at the Massachusetts General Hospital. ICER is an academic research group which works through a transparent process with patients, clinicians, manufacturers, and health insurers – with *all* stakeholders – to evaluate the comparative effectiveness of medical tests and treatments. ICER’s approach is distinguished by our engagement with stakeholders, and by our commitment to provide decision-makers with information on the cost-effectiveness as well as the clinical effectiveness of medical services. Perhaps most germane for today’s hearing, ICER has developed a method for translating comparative effectiveness results into a reliable rating format to enable the evidence to have traction; so that it can get off dusty academic shelves and into policy and practice in ways that will drive improvements in the value of healthcare.

The backdrop to the interest and sense of urgency surrounding comparative effectiveness research is well known to you. Although technological innovation is essential to the advancement of health care, medical tests and treatments often become widely used while significant gaps in evidence regarding their effectiveness remain. The harmful effects of this evidence deficiency grow each year, with wide, unexplained variations in care patterns and escalating costs divorced from any indication that our health care resources are being wisely spent.

I know you’ve heard this general theme before, so I’ll provide a concrete example from an ICER comparative effectiveness review on the treatment options for prostate cancer. Prostate cancer is the second leading cause of cancer deaths in men in the United States, with nearly 200,000 new cases found each year. Men with prostate cancer have many different options to consider, including several different forms of radiation therapy. Radiation can be delivered by the implantation of radioactive “seeds,” by a form of

external radiation therapy called IMRT, or by proton beam therapy. The ICER review of these options found that radioactive seed implantation and IMRT had virtually indistinguishable net health benefits for patients; for proton beam therapy, the newest option, there have been only a handful of studies, and yet what little evidence is available does not suggest that it is any better than the other options. Our review also looked at upfront costs to Medicare and we also used cost-effectiveness analysis to estimate the downstream patient outcomes and costs for patients managed with each of these three treatments. We found that Medicare pays approximately \$50,000 for proton beam therapy, \$20,000 for IMRT, and \$10,000 for radioactive seed implantation. Again, without any evidence of improved clinical outcomes, for any patients, Medicare pays doctors and hospitals as much as five times more for some treatments than for others. Not surprisingly, surveys of radiation oncologists suggest that these price differentials have led to impressive shifts in what kinds of treatments patients receive, and, as a result, it has been estimated that, without any evidence we are doing better by our patients, Medicare is now paying more than a billion dollars more per year just due to the shift to more expensive radiation therapy options for prostate cancer treatment. This is just one isolated example of how we continue to pay the highest prices in the world for many health care tests and treatments of dubious comparative value. And as we do so we put just that much further out of reach our hopes of making health care affordable for all Americans.

Comparative effectiveness research is intended to help address this challenge. In my oral testimony, I want to try to cover two specific questions:

- 1) What is the overlap between the concepts of comparative effectiveness and “best practices?”
- 2) What are the mechanisms and the requirements for effective implementation of comparative effectiveness research findings?

The term “best practice” has been around longer, and I think it’s fair to say that health policy experts recognize “best practices” as referring primarily to systems for delivering care that lead to optimum patient outcomes. Dr. Pronovost’s surgical checklist procedure for reducing hospital-acquired infections is a classic, and wonderfully effective, example. As for the concept of comparative effectiveness, the boundaries are still somewhat under construction, but in general the emphasis has been on studies that either assess existing evidence on the best treatment options for a condition, or that develop new evidence via clinical trials or registries. There is no *a priori* reason that research to evaluate alternative care delivery processes couldn’t be considered comparative effectiveness. Nonetheless, we have long had a term for that kind of

research: health services research, and comparative effectiveness as a distinct term came into being to emphasize the need for new kinds of head-to-head trials and of systematic evidence assessments to help decision-makers with decisions about specific tests or treatments. So one way to think of the relationship is to say that comparative effectiveness research helps establish what treatments are best for which kinds of patients, and “best practices” research helps us learn how to get that right care delivered as safely, effectively, and efficiently as possible.

What are the mechanisms by which the results of comparative effectiveness research can be implemented? The ideal framework is for the findings to be able to support different tools and policies that can be used by different stakeholders but that all reinforce each other. Implementation strategies include the following:

- 1) Patient information
- 2) Clinical guidelines
- 3) Physician group compensation incentives
- 4) Tiered benefit designs, in which patients would pay less out of pocket for more effective and/or higher value alternatives
- 5) Value-based coverage and reimbursement policies for emerging technologies, including the possibility of linking payment levels to an agreement to gather further evidence on clinical effectiveness

There are a couple key points I want to make about this list. First, whereas coverage determinations are included, they are not the sole, nor even the primary mechanism. Sometimes concerns are raised that comparative effectiveness can only be implemented through all-or-nothing, one-size-fits-all coverage decisions. To the contrary, comparative effectiveness evaluations are expressly framed to hunt out any evidence that specific types of patients may benefit more or less from certain treatment options, and these findings can be woven into patient materials and clinical guidelines, with any linked benefit or coverage policy made flexible enough to recognize these differences.

In order for the results of comparative effectiveness assessments to be communicated effectively to patients and clinicians, and to be “tied” in a transparent way to coverage and reimbursement, some kind of common “language” is necessary. To meet this need at ICER we have developed a rating scheme that assigns an capital letter rating of comparative clinical effectiveness on a six-part scale, and a separate lower-case letter rating of comparative value, based largely on cost-effectiveness considerations, on a three-part scale. These ratings can be looked at in isolation, or they can be put side-by-side to form an integrated evidence rating. The purpose of these ratings is to transparently communicate ICER’s overall judgment regarding the evidence on

comparative effectiveness, and to provide a template for innovative patient-clinician decision support tools as well as value-based coverage and reimbursement policies. We are now working with a coalition of employers, health plans, and provider groups in Massachusetts to implement ICER reviews of prostate cancer treatments through patient materials and policies linked to the integrated evidence ratings. The goal is to design specific patient and clinician materials to fit with coverage and reimbursement policies so that, working together, all the stakeholders can use comparative effectiveness results to increase shared decision-making and shift patterns of care to higher value alternatives.

In conclusion, I believe that comparative effectiveness research and efforts to implement “best practices” are mutually supporting and complementary efforts. Using evidence to change practice is often challenging, but it is exactly this challenge that we must address moving forward; and using evidence more effectively is exactly the right way for us to achieve a high quality, affordable health care. Thank you.