Economics, Government Intervention and Prostate Cancer Screening

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Prostate cancer (PCa) is the most common cancer in North America. It is a costly disease, representing 11% of treatment costs of all U.S. cancers. The average annual cost per patient after all diagnosis and treatment is \$81,658, adding up to \$8 billion each year.ⁱ The cost strains public and private healthcare economics.

Since 1994, FDA-approved screening of asymptomatic men resulted in increased early detection. For stage T1C the rate rose from 2.1% to 36.4%.ⁱⁱ Over the past 20 years, PCa death rates have been reduced by close to 40% without substantial changes in surgical or radiation treatment strategies, a likely result of earlier detection.ⁱⁱⁱ This would seem to underscore the value of screening—but early detection comes with a price.

The European Randomized Study of Screening for Prostate Cancer (ERSSPC) found that PSA-based screening was associated with a high risk of overdiagnosis among men who would probably not have clinical symptoms in their lifetime.^{iv} In fact, overdiagnosis, overtreatment and the side effects that can accompany it appear to be the most important adverse effects of screening, and occur more often than in screening for breast, colorectal or cervical cancer.^v

A study conducted by the Center for Public Integrity found that despite the "…enormous financial toll on the nation's health care system" doctors still "…disregard scientific guidelines out of ignorance, fear of malpractice suits or for financial gain, as patients inundated by medical advertising clamor for extra tests." Furthermore, a risk of screening is that it may set off "…a cascade of expensive tests and treatments that can waste more money and create more problems."^{vi}

Can we afford the "four overs" (over promotion, over screening, over diagnosis, and over testing)? The U.S. Preventive Services Task Force (USPSTF) was charged with finding out.

Government Panel Weighs In

The USPSTF is a panel of medical experts that was authorized by Congress in 1990 to continually assess preventive services. It is composed of 16 independent Government-appointed medical experts who volunteer their time. In October 2011, the panel drew the same conclusion as the ERSSPC and issued a draft recommendation against routine PSA screening for prostate cancer for the same reason: the disease is overdiagnosed and overtreated with most prostate cancer remaining asymptomatic (free from symptoms). In May 2012 they finalized their statement, having concluded that the potential benefit of testing did not outweigh the risk of harm, arguing against continued screening except for those with known risk factors and a life expectancy greater than 10 years. The clinical community is not fully on board with these guidelines. Experts such as Dr. Patrick Walsh and Dr. William Catalona have taken issue with the panel's decision.^{vii}

Just as there is no universal agreement on broad PSA screening, there are mixed opinions on the value of whole gland treatments. For example, the results of the PIVOT study (Prostate Intervention VS. Observation Trial) published in 2012 spoke to that issue.

Based on 731 patients randomly assigned to either radical prostatectomy or watchful waiting, the authors concluded that surgery offered no significant survival advantage over observation, while creating post-surgery adverse events for 21.4% of RP patients. Despite study flaws that have called into question its validity, ^{viii} it gained international professional and patient attention for suggesting that surgery constitutes overtreatment of early stage PCa patients. On the other hand, observation carries its own risk because

...An ever-growing volume of evidence shows that in men with low-volume cancer, progression continues for many years. For example, in a study from Sweden of men with very small cancers who were treated with observation alone, death rates from prostate cancer remained very low (15 per 100,000 persons) for the first 15 years -- but beyond that point, they skyrocketed (to 44 per 100,000 persons), and nearly all these men eventually died from prostate cancer.^{ix}

In fact, a criticism of the PIVOT trial is that very few of the enrollees lived beyond 10 years; whether they died from PCa or other causes, no long term conclusions could be drawn, especially for those assigned to observation.

<u>Dilemmas</u>

Both the public arena and individual patients face dilemmas.

Government, constitutionally chartered to promote the general welfare, strives to achieve a balance between its healthcare budget and the clinical needs of the public in an era of advanced detection, diagnosis and treatment. The recent about-face in screening policy from two decades ago is evidence of Government's dilemma.

Individual patients who are either at risk of prostate cancer, or have been newly diagnosed with localized early stage disease likewise encounter dilemmas: To biopsy or not? To treat or not? If so, how? With the Internet, they increasingly have access to the track record of conventional treatments and active surveillance. If they aren't comfortable with what they learn, they are more likely to explore alternatives to diagnostic procedures like multi-needle biopsies, and to treatments with relatively high risks of side effects.

If such patients prefer a treatment to active surveillance, they will pursue an interest in image-guided, minimally invasive treatments. Not only does this treatment category offer a potential way out of their own dilemma, many patients recognize the cost-savings such therapies may offer insurers (private companies) and Government programs (public administration).

The screening and treatment dilemmas will not be resolved quickly, but it is worthwhile to consider new and less expensive modalities in hopes of discovering a practical and logical middle ground between too much intervention and too little.

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^{iv} Schröder F, Hugosson J et al. Screening and prostate-cancer mortality in a randomized European study. N Engl J Med 2009;360:1320-1328.

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 http://abcnews.go.com/Health/CancerPreventionAndTreatment/uspstf-scuttles-recommendations-psa-screeningtest/story?id=16398686
viii For two examples of articles that identify PIVOT flaws, see http://www.bjuinternational.com/bjui-blog/the-flaws-

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^{ix} http://urology.jhu.edu/surgery saves lives.pdf