Evolution and Immediate Future of US Screening Guidelines

Kirsten L. Greene, MD, MS*, Sanoj Punnen, MD, MS,
Peter R. Carroll, MD, MPH

KEYWORDS

• Prostate cancer • Screening • Guidelines • Public health • Prostate specific antigen (PSA)

KEY POINTS

- Although observational studies and simulation models have shed some interesting light on many of the uncertainties surrounding prostate cancer screening, well-done clinical trials will provide the best evidence on screening among the extremes of age, the most appropriate interval to screen, and the best complement of tests to use.
- Despite a shift away from expert opinion and favoring more objective methodology such as meta-analysis and systematic review, or perhaps because of it, guidelines can be almost deliberately vague and may be outdated soon after publication.
- Over the last 2 decades, prostate cancer screening has evolved from prioritizing sensitivity of diagnosis in an attempt to favor early detection of localized disease to specificity of detecting men at highest risk with statistically highest benefit.
- Enthusiasm for screening is temporized by acknowledgment that overdetection leads to frequent overtreatment despite evidence supporting the safety of active surveillance in many men with low-risk disease.

HISTORY AND EVOLUTION OF GUIDELINES

The evolution of practice guidelines in medicine has its origin in the early nineteenth century focusing largely on public health measures to control infectious disease epidemics, such as cholera and yellow fever.[1] In the twentieth century, diseases such as tuberculosis and syphilis expanded the role of public health and standardized practices.[2,3] After World War II, the scope of medicine in the United States and Europe expanded rapidly with the development of new drugs and technology. What started as public health mandates moved into the realm of diagnosis and treatment as new therapies for cancer and tuberculosis were developed, including radium and radiographs; these were recognized as potentially dangerous technologies that required protocols for safe use and delivery.[4]

As screening and early detection of different diseases became more ubiquitous, guidelines began to take on the role of cost containment and quality control. Hospitals were targeted as organizations that could be made more efficient by standardizing practice.[5] With so many different treatment options available, both governments and physician groups attempted to unify management as variation came under suspicion for being deviations from standard of care rather than individual judgment heretofore regarded as the "art of medicine."

Department of Urology, UCSF Helen Diller Family Comprehensive Cancer Center, University of California, San Francisco, 1600 Divisadero Street, A631, San Francisco, CA 94115, USA
* Corresponding author. Department of Urology, University of California, San Francisco, 1600 Divisadero Street, Box 1695, San Francisco, CA 94143-1695.
E-mail address: kgreene@urology.ucsf.edu

Urol Clin N Am 41 (2014) 229–235
http://dx.doi.org/10.1016/j.ucl.2014.01.005
0094-0143/14/$ – see front matter

Physician groups took on a greater role in guidelines creation in an attempt to maintain physician autonomy.[5]

The American Medical Association played a major role in standardizing medical education, state licensing, and specialty certification in collaboration with specialty societies. The American College of Surgeons began creating uniform standards in surgery by evaluating cancer therapies, standardizing terminology, and publishing results. The American College of Surgeons' first guidelines were published in 1931 addressing fracture care and organizing cancer services in hospitals.[6,7] If guidelines development was slow in the early twentieth century, with 20 guidelines in print by 1945 and 35 more by 1974,[5] publication blossomed in the 1980s and was spurred by organizations advocating cost containment and accountability.[8] In 1989 the Agency for Healthcare Research and Quality was established to produce practice guidelines and currently functions as a guidelines clearinghouse.

In the specialty of Urology, the American Urological Association (AUA) created the Practice Guidelines Committee in 1989 to develop evidence-based guidelines that aim to promote the highest standards of urologic care. The first guideline was introduced in 1994 and addressed the topic of benign prostatic hyperplasia. As evidence-based medicine emerged as a guiding force in education and standardization of medical practice, guidelines development processes changed from expert review of literature and synthesis of recommendations to systematic literature reviews and meta-analysis. Many organizations, including the AUA and European Association of Urology (EAU), have adopted grading systems for the strength of evidence and used this to characterize recommendations.

From 2000 to 2005 the AUA made a set of strategic changes in their guidelines process. This new process optimized cost efficiency of the guidelines process, used the Institute of Medicine criteria, and decreased the creation time of new guidelines from a 5-year process to a 2- to 3-year window. In 2008 the current Level of Recommendation system was implemented to link guidelines statements directly to evidence strength. In 2009, in response to rapidly changing evidence that may render existing guidelines obsolete, the AUA created a new program called the Update Literature Review. Every 15 months a methodologist and 3 panel members, 2 from the original guideline and 1 new member, evaluate new literature to determine if a guideline requires updating.[9] AUA guidelines are published on the Agency for Healthcare Research and Quality's National Guidelines Clearinghouse as well as on the AUA website at auanet.org.

Similarly, the EAU process includes systematic literature review and meta-analysis by a multidisciplinary panel, and grading of evidence based on strength of trial design. Recommendations are based on review of data and panel consensus. Newly published literature is assessed annually to guide future updates.[10]

The National Comprehensive Cancer Center Network guidelines process creates algorithms and decision pathways for management of malignancies based on critical evaluation of current evidence and consensus recommendations by a multidisciplinary panel of experts. Evidence is graded based on the extent, consistency, and quality of data as well as on the level of consensus among the panel and is expressed as categories 1, 2A, 2B, and 3. Uniform consensus requires a majority (85%) of the panel vote. Consensus requires 50% panel vote. The guidelines are continuously reviewed and updated as evidence changes (www.nccn.org).

PROSTATE CANCER SCREENING GUIDELINES

In 1990, the debate over prostate cancer screening surrounded the pros and cons of digital rectal examination (DRE). Half of the cases were detected at a locally advanced stage and still there was debate as to whether there was a survival benefit.[11] Later, the incorporation of prostate-specific antigen (PSA) testing into DRE screening was debated and found to increase overall detection dramatically as well as shift the stage of detection to clinically localized disease.[12]

The AUA released its first Best Practice Statement on prostate cancer screening in 2000. At that time, available data showed that one-third of cancers were diagnosed at a locally advanced or metastatic stage and that "a very large proportion of cancers detected through PSA testing are likely to be clinically important, but that PSA testing is unlikely to detect many of the more prevalent small-volume histologic cancers."[13] Both PSA and DRE were recommended for prostate cancer screening, using a threshold of 4.0 ng/mL, a significant increase in PSA from one test to the next, or an abnormal DRE to prompt consideration of prostate biopsy. The authors recommended a risk-and-benefit discussion with patients and individualization of early detection efforts rather than uniform application of mass screening. Furthermore, testing was recommended to all men age 50 or older with a 10-year life expectancy, and to African American men and those with a family history of prostate cancer in a first-degree relative at