



Evidence Review Group for:

Active Surveillance/Radical Prostatectomy for Clinically Localized, Low-Risk Prostate Cancer

*Scoping Call Summary
February 23, 2009*

Present:

ICER: Steve Pearson, Dan Ollendorf, Michelle Kuba, Katy Marttila

Affiliated Researcher: Pamela McMahon

Evidence Review Group: Richard Choo, Myriam Curet, Michele DiPalo, Ted Ganiats, Scott Gazelle, Lou Hocheiser, Phil Kantoff, Terry Lindblom, David Most, Lee Newcomer, Catherine Piech, Alan Rosenberg, Martin Sanda, Ian Thompson

Absent:

Affiliated Researchers: Julia Hayes

Evidence Review Group: Peter Albertsen, John Ayanian, Peter Carroll, Marthe Gold, David Meltzer, Sean Tunis, David Veroff

Meeting Summary

- With respect to measures of clinical effectiveness, patient representatives and others agreed that survival, complications, and quality of life, particularly around long-term side effects such as erectile function and continence issues, are the key outcomes on which the ICER review should focus its literature search and decision analytic modeling. It was noted that patient anxiety, particularly the long-term impact of anxiety over the course of an active surveillance protocol, is another important quality of life consideration for which evidence should be sought.
- Caution was urged in evaluating data on outcomes from single-center studies conducted in tertiary centers; wherever feasible, evidence from multi-center and population-based studies should be given greater weight. With respect to quality-of-life data specifically, self-reported and caregiver-reported data should also be highlighted over physician-reported findings.

- Participants noted the significance of operator experience on outcomes for radical prostatectomy. As part of the systematic review, we will search for evidence related to differences in outcomes and complication rates based on operator experience. **If members of the ERG have citations or data on this topic that you would be willing to share, we would appreciate it.**
- The group discussed whether there was a need to differentiate measures of benefit or harm between open and laparoscopic/robotic radical prostatectomy. Explicit comparisons of these surgical approaches will be a target of the review, but there are no distinct categories of adverse outcomes across the various techniques. We will evaluate the evidence to determine where to appropriately distinguish data between the techniques and where to report combined results.
- There was interest in ensuring that measurement of “peri-operative” complications include post-discharge events (i.e., ER visits or readmissions to hospital), and that complications common to all major surgery, such as thrombotic events, be considered in addition to complications of interest for radical prostatectomy.
- With regard to important patient subgroups, age and/or life expectancy were cited as important for understanding the balance of potential benefits and harms for certain management options. However, the point was strongly made that age by itself is a poor marker of individual “valuation” of different potential side effects and of the trade-offs among them. The effect of age and life expectancy will be assessed in the model through the conduct of sensitivity analyses with different “prototypical” patients (e.g., younger or older patients distinguished by baseline level of sexual activity, utilities for other side effects, etc.).
- In the discussion on costs, we heard that the reimbursement structure for radical prostatectomy is often based on DRG payments; therefore, separate payment is not generally made for in-hospital complications such as need for transfusion. It was also mentioned that, as a patient remains on active surveillance, the risk of disease progression may increase over time and additional procedures such as bone scans may be added to the protocol. We will attempt to estimate changes in intensity of follow-up over time and adjust costs accordingly in the model.
- A question was posed regarding the appropriate time frame for the systematic review of the literature, given the technical evolution of the management options of interest. It was suggested that because the spectrum of incident cases has evolved since widespread adoption of PSA screening, the timeframe following the adoption of current risk criteria would be the most logical starting point for the literature review. Based on this suggestion, we will limit our search to papers published from 1996 to present.