

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

*Clinical Subcommittee Call Summary
May 5, 2009*

Present:

ICER: Steve Pearson, Dan Ollendorf, Katy Marttila

Affiliated Researcher: Julia Hayes

Clinical Subcommittee: Catherine Piech, David Veroff, Ian Thompson, Michele DiPalo, Phil Kantoff, Richard Choo, Terry Lindblom

Absent:

Affiliated Researcher: Pamela McMahon

Clinical Subcommittee: Ingolf Tuerk

Meeting Summary

- Clinical Effectiveness
 - There was considerable discussion regarding whether or not to consider watchful waiting studies such as the Swedish RCT (Bill-Axelsson 2005, 2008) as one end of the spectrum of active surveillance. Some felt that, because there was monitoring for local progression in this trial, it should be considered; others felt that, because the decision to treat was not explicitly tied to progression, it did not constitute active surveillance. *ICER Note: we have further examined the trial reports, and while the risk of progression in the WW cohort approaches 40% at 10 years of follow-up, only 14% of WW patients received curative treatment. We will develop an algorithm for considering studies that represented some form of surveillance vs. those that simply involved no definitive treatment, and share it with the ERG.*
 - There was no disagreement expressed with our early judgment that the current evidence cannot identify any differences in survival or biochemical recurrence by surgical approach.

- While there was also general agreement that the data on “learning curve” for radical prostatectomy was highly variable and arbitrary when examined by surgical approach, it was suggested that the general concept for all prostate surgery be considered (in particular, the work of Peter Scardino at Sloan-Kettering).
- Symptoms on Active Surveillance
 - Questions were raised regarding the ability to examine differences in the effects of incontinence and ED, given their high baseline prevalence as reported in the older WW literature and the dearth of data in the AS literature. *ICER Note: we plan to examine this issue in further detail, including obtaining age-specific estimates for both baseline prevalence and progression from the literature on the general male population.*
 - It was noted that anxiety on active surveillance would be expected to be relatively low, as this is a self-selected group with low anxiety regarding their cancer to begin with.
- Harms
 - A suggestion was made to depict the wide range of estimates on surgical complications as well as short- and long-term post-operative ED and incontinence using histograms, with a possible adjustment for study sample size.
 - There was confirmation from the clinicians that the rate of anastomotic stricture quoted in recent decision-making aids (17%) was far too high, and that the rates in our early review (2-3%) were more in line with modern surgical series.
 - It was suggested that, where feasible, rates of ED be quantified among prostatectomy patients undergoing bilateral nerve-sparing, unilateral nerve-sparing, and neither technique.
 - There was general agreement with our early judgment that there were no material differences by surgical approach in the rates of complications or side effects. The differences that were observed

(e.g., blood loss, LOS, cath-in time) do not appear to correlate with meaningful clinical differences. It was noted that low hemoglobin might have an affect on short-term function, but it was agreed that this finding is difficult to quantify.

- Nominal differences in the rate of positive surgical margins (lower for robotic vs. open) were felt to be driven primarily by differences in pathology by surgical approach. *ICER Note: we will examine the distribution of pathological tumor stage by surgical approach as part of the systematic review.*
- General Comments
 - There was agreement with our decision to generate pooled estimates of effectiveness and harms without providing any additional weight to comparative series over single-arm studies.
 - ICER will provide a bibliography of abstracted studies for review by the ERG; suggestions regarding additional studies to consider are welcome.