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### Title

Re: Quality-of-life Effects of Prostate-specific Antigen Screening

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metastatic prostate cancer (HSM1PC) patients: results of S9346 (INT-0162), an international phase III trial [abstract 4]. *J Clin Oncol* 2012;30(Suppl).

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## Re: Quality-of-life Effects of Prostate-specific Antigen Screening

Heijnsdijk EAM, Wever EM, Auvinen A, et al.

*N Engl J Med* 2012;367:595–605

### Expert's summary:

Heijnsdijk et al. used a simulation model to adjust the mortality benefit demonstrated for prostate-specific antigen (PSA)-based screening in the European Randomized Study of Screening for Prostate Cancer (ERSPC) by accounting for the potential negative effects of screening, diagnosis, and treatment on quality of life (QOL). The analysis is based on a treatment algorithm in which men can be screened, biopsied, and diagnosed, after which they can receive treatment or active surveillance and then might progress to advanced and terminal illness. Adverse effects of irradiation and surgery both last for 12 mo, and stress incontinence and erectile dysfunction are the only QOL domains considered. Utility weights assigned to each treatment and health state are referenced from the literature, but these weights are not well validated, and varying the utility assumptions has a major effect on the model outcomes. The authors conclude that their study quantifies the extent to which the observed mortality reduction achievable by screening in ERSPC is attenuated by the QOL impact.

### Expert's comments:

Substantial challenges clearly exist in developing a quality-adjusted life-year (QALY) model calculated with a lifetime horizon from time of screening. The clinical model—the possible treatments and health states—is substantially oversimplified [1], and the authors acknowledge some of the limitations associated with their selection of utility values in the model. The broad message of the paper—that harms should be considered in evaluating the impact of screening—is clearly true, but the model is nowhere close to robust enough for the specific quantitative findings reported to be considered reliable or clinically useful.

Perhaps the most important philosophical flaw in the utility analysis is the false assumption that the “perfect” health state—the one assigned a utility of 1.0—is the naive, unscreened state. In the authors' analysis, the simple drawing of a PSA test causes an immediate decline in utility attributed to anxiety, and no utility following biopsy is ever >0.97. In reality, the majority of men screened are found to have a very low PSA [2] and, therefore, a negligible risk of prostate cancer mortality. In prior studies among men without cancer, the overwhelming majority of men prefer, and thus have a higher utility for, the state of being “normal by screening” compared with the state of unknown status without screening [3]. In other words, men perceive much value in reassurance [4], and ignoring this QOL gain in a decision analytic framework will unfairly reduce the QALY benefit associated with screening.

**Conflicts of interest:** The author has nothing to disclose.

### References

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## Re: Radical Prostatectomy Versus Observation for Localized Prostate Cancer

Wilt TJ, Brawer MK, Jones KM, et al., Prostate Cancer Intervention Versus Observation Trial (PIVOT) Study Group

*N Engl J Med* 2012;367:203–13

### Experts' summary:

This paper reports a randomized trial of radical prostatectomy (RP) versus observation for men with localized prostate cancer (PCa) in the prostate-specific antigen (PSA) era.

Men with untreated PCa were recruited over 8 yr, mostly from US Department of Veterans Affairs facilities across the United States. The men were medically fit to undergo RP and had clinical stage T2 or lower, PSA <50 ng/ml, age <75 yr, negative bone scan, any Gleason grade, and life expectancy of at least 10 yr. Subjects were randomized to RP or observation. The primary and secondary outcome measures were all-cause mortality (ACM) and PCa-specific mortality (PCSM). The study was originally designed to accrue 2000 patients, but due to recruiting difficulties, the goal was modified to 740.