

# Improving the Communication of Benefits and Harms of Treatment Strategies: Decision Aids for Localized Prostate Cancer Treatment Decisions

Richard M. Hoffman

**Correspondence to:** Richard M. Hoffman, MD, MPH, Medicine Service, Albuquerque Veterans Affairs Medical Center, 1501 San Pedro Dr. SE, Mailstop 111, Albuquerque, NM 87108 (e-mail: [rhoffman@unm.edu](mailto:rhoffman@unm.edu)).

Treatment decisions for localized prostate cancer are preference sensitive. The optimal treatment strategy is unknown, and active treatment is not always necessary. Choosing among the various options involves tradeoffs between cancer control and complications that affect quality of life. A shared decision-making process, particularly facilitated by a decision aid, can help a patient make an informed decision that is concordant with his values and preferences. Studies have shown that informed patients are more willing to forego aggressive treatment, but much work is needed to develop and evaluate high-quality decision aids that accurately portray active surveillance. The research agenda for decision aids includes evaluating content elements and format, timing and setting for delivery, the quality of the decision-making process, and the effects of decision support on treatment selection (which will occur repeatedly for men opting for active surveillance) and quality of life.

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Over a million additional men have been diagnosed with prostate cancer since prostate-specific antigen (PSA) testing was introduced in the late 1980s (1). Most of them underwent attempted curative therapy with surgery or radiotherapy despite a paucity of outcomes data to guide treatment selection (2). Randomized controlled trials for localized cancer have compared only surgery with watchful waiting (3,4) and external beam radiotherapy with watchful waiting (no published mortality data) (5). A Scandinavian trial, which primarily enrolled men with palpable tumors, found a significant decrease in prostate cancer mortality favoring radical prostatectomy over watchful waiting after 15 years of follow-up (3). However, the Prostate cancer Intervention Versus Observation Trial (PIVOT), most of whose subjects had screen-detected cancers, found no disease-specific survival benefit for radical prostatectomy at 12 years (6). The PIVOT results are consistent with modeling studies suggesting that a substantial proportion of PSA-detected cancers would otherwise never become clinically apparent (7). An ongoing randomized trial comparing surgery, radiotherapy, and active surveillance for men with localized cancer has yet to report results (8), though observational data indicate a very low risk for prostate cancer mortality among men selecting active surveillance (9–11). In contrast, we have extensive evidence that treatment complications occur frequently and adversely affect quality of life (12,13).

Given the uncertainty about the optimal treatment strategy for localized cancer, concerns about overtreatment, and the tradeoffs between small absolute mortality reductions and higher risks for treatment complications, the decision on how and whether to treat localized prostate cancer is considered preference sensitive care (14,15). In this context, the most important goal for physicians should be helping patients achieve a high-quality decision based on their informed values and preferences across various options, including that of no treatment (14,16).

Unfortunately, the available evidence suggests that prostate cancer treatment decisions are often not well informed. A 2006 systematic review on patient decision making for localized prostate cancer found that physician recommendations, particularly from urologists, most strongly influenced decision making (17). However, physician recommendations also overwhelmingly reflected the therapy that they deliver (18,19), and the proportion of patients who met with both urologists and radiation oncologists varied substantially (17). The influence of partners and family members on decision making was uncertain, although the experiences of friends or colleagues with prostate cancer were often important determinants of treatment selection.

Jang et al. (20) highlighted the strong association between provider visits and treatment selection using linked Surveillance, Epidemiology, and End Results (SEER)–Medicare data on 85 088 men with newly diagnosed early-stage prostate cancer. Overall, about half of these men consulted urologists only; 34% of them underwent radical prostatectomy (70% of those aged 65–69 years). Among the 44% who were seen by both urologists and radiation oncologists, 83% underwent radiation therapy. Just 22% of men visited a primary care physician between the time of diagnosis and either receipt of active treatment or within 9 months after diagnosis. However, these primary care visits were significantly associated with selecting expectant management, regardless of age or comorbidity.

The systematic review found that cancer control was a common decision issue, though patients variably defined this as either extending survival or preserving quality of life (17). However, patients did not consistently rate treatment effectiveness as a highly important decision factor. Further, their reliance on published evidence for treatment efficacy was quite variable, and misperceptions about the strength of evidence were common. Additionally, although patients placed great importance on avoiding

side effects, particularly for those selecting watchful waiting, relatively few reported weighing benefits and risks in selecting a treatment. The review authors concluded that variations in decisions seemed more indicative of the content and sources of the treatment information rather than underlying patient preferences.

Although most studies of decision making evaluated watchful waiting as the alternative to active treatment, Davison et al. (21) focused on men who chose active surveillance. Specialist recommendations were the most influential factors, and avoiding treatment side effects was the primary reason to defer treatment. Patients perceived their cancers to be indolent and were relieved that they did not require immediate treatment. A systematic review further identified lack of physician and peer support, anxiety about living with cancer, and fear of progression as factors associated with not selecting or continuing on active surveillance (22).

Providing patients with comprehensive and balanced information seems necessary for ensuring that they receive treatments consistent with their values and preferences. One strategy for supporting patient decision making is through a health decision aid, which can be written, audio, video, or web-based tools (14,16). An effective decision aid should describe alternative options, provide information on the probabilities of benefit and harm for each option, help patients clarify their values, and guide them towards achieving shared decision making.

### Quality of Educational Material and Decision Aids

In 2001, Fagerlin et al. (23) reviewed the content of patient education materials on treating early-stage prostate cancer to determine their suitability for supporting informed decision making. Only 44 of the 546 identified educational materials described all standard treatments (surgery, radiation therapy, hormone therapy, and watchful waiting), including 19 print materials, 19 Web sites, 4 videotapes, and 2 CD-ROMs. The investigators evaluated these materials for basic information on the prostate gland, prostate cancer staging and grading, the natural history of prostate cancer, and treatment. For the latter domain, materials were expected to provide detailed descriptions of treatment options, address side effects (distinguishing between temporary and permanent), describe the patient experience of undergoing treatment, and present both the pros and cons of each treatment. Investigators rated the quality of the educational materials based on the accuracy, balance, and comprehensibility (eg, reading level, design) of the information.

Only half of the education materials fully described surgery and radiation therapy, just one-third addressed risks and benefits of each treatment, and none compared outcomes of all treatments in a single summary. Overall, the authors concluded that content was accurate, balanced, and readable enough to adequately describe treatment options. However, the authors felt that the materials were biased towards active treatment and minimized the risks and consequences of side effects. Furthermore, the authors concluded that none of the materials qualified as a decision aid because they failed to provide sufficient information to actively support patients in decision making.

Recently, the International Patient Decision Aids Standards Collaboration developed an instrument to measure the quality

**Table 1.** International Patient Decision Aid Standards instrument quality dimensions (24)

Dimension	Explanation
Information	Providing information about options in sufficient detail for making a specific decision
Probabilities	Presenting outcomes probabilities
Values	Clarifying and expressing values
Decision guidance	Structured guidance in deliberation and communication
Development	Using a systematic development process
Evidence	Using evidence
Disclosure	Disclosure and transparency
Plain language	Using plain language
Decision support tool evaluation	Knowledge, match between values and chosen option
Test	For decision support tools that are directed at investigations or screening tests

of decision aids (24), based on clinical content, the development process, and effectiveness in supporting a high-quality decision-making process and choice. The International Patient Decision Aid Standards instrument (IPDASi) measures 10 dimensions of quality (Table 1). The rationale for creating IPDASi was to set a quality benchmark for existing decision aids and provide guidance for developers of decision support tools.

A Cochrane Consumers and Communication Review Group has been identifying randomized controlled trials of decision aids for people facing health treatment or screening decisions (14,25,26), including two studies of prostate cancer treatment decision aids (27,28). A systematic review evaluated whether these decision aids met IPDASi content and effectiveness standards (29). The prostate cancer treatment decision aids presented treatment options and outcome probabilities; however, only one described the clinical problem, and neither provided explicit values clarification exercises, presented examples of patient experiences, provided guidance in the steps of decision making, or sufficiently evaluated effectiveness.

### Effectiveness of Decision Aids

The Cochrane Library recently updated their meta-analysis, entitled *Decision Aids for People Facing Health Treatment or Screening Decisions*, in 2011 (14). The authors evaluated 86 studies and concluded that using decision aids compared with usual care improved knowledge of options, created more realistic expectations of possible benefits and harms, reduced decisional conflict, increased the level of participation in decision making, and helped patients make decisions more consistent with their values.

The Cochrane review included two prostate cancer treatment decision aid studies (27,28). Auvinen et al. (28) compared using oral and written decision aids to provide standardized and comprehensive information about prostate cancer treatment options against a standard treatment protocol. Investigators enrolled 203 Finnish subjects with a newly diagnosed prostate cancer. Among the 45 men with localized cancer and no contraindications to surgery, 17 (63%) of the 27 subjects who received a decision aid selected radical prostatectomy compared to 15 (83%) of 18 in the standard care group. These differences were not significant and few subjects in either group selected watchful waiting. Men with advanced stage

disease who received a decision aid were significantly less likely to select orchiectomy (42 of 65, 65%) than those in the control group (69 of 74, 93%). Receiving a decision aid significantly increased the proportion of subjects who actively participated in decision making but had no effect on anxiety or depression.

Davison et al. (27) compared a consultation, audiotape, and five handouts about prostate cancer treatment options with a general information pamphlet in 60 Canadian subjects newly diagnosed with prostate cancer. Six weeks after randomization, intervention subjects were significantly more likely than control subjects to have assumed an active role in decision making and had a significantly lower anxiety level. Treatment selection data were not reported, though the authors noted that most men in both groups underwent radical prostatectomy.

Another systematic review of decision aids for prostate cancer treatment identified 10 observational trials not included in the Cochrane review (30). These studies were generally quasi-experimental with pre-post design, though two used controls, one concurrent (31) and the other historical (32). Studies were conducted in various settings, including hospitals, physician offices, patient education centers, and nonclinical locations. The decision aids generally provided information in multiple formats, including written, audio, counseling, and interactive CD-ROM and computer programs. Outcome measures included knowledge, self-efficacy, decision-making involvement, treatment selection and satisfaction with the treatment decision, psychosocial function, and evaluation of the decision aid material. The study participants generally valued decision aids and were pleased with their content. Decision aids increased knowledge, encouraged more active patient involvement in decision making, and reduced psychological distress. However, decision aids did not consistently present all treatment options, sample sizes were relatively small, the feasibility of implementing decision aids was not routinely assessed, and the effects of decision aids on treatment selection and decision satisfaction were unclear.

Interestingly, a systematic review of PSA screening decision aids included four studies measuring treatment preference as an outcome (33). Subjects receiving a decision aid were significantly more likely to prefer watchful waiting compared with active treatment (relative risk ratio = 1.53, 95% confidence interval = 1.31 to 1.77).

These systematic reviews point out important limitations in the available decision support tools. Limited content, failure to provide sufficient guidance for supporting decision making, and lack of rigorous evaluation suggest that most available decision support tools have not risen to the level of being quality decision aids. Another deficiency was that these tools consistently presented watchful waiting—with the connotation of being a palliative approach—as the alternative to active treatment. Studies have shown that men are not very satisfied with watchful waiting even when active treatment is not indicated given age or comorbidity (34,35). Consequently, many older men inappropriately received primary androgen deprivation (2,36), whereas substantial proportions of men with low-risk cancers receive attempted curative therapy (37,38). However, the past decade has seen a paradigm shift in targeting conservative treatment, moving from watchful waiting in older men to active surveillance for men with low-risk disease (39).

Consequently, effective decision aids need to accurately describe active surveillance, including representing it as an appropriate strategy for men with low-risk localized prostate cancer who are concerned about complications of aggressive treatment. The message might need to become even more nuanced because recently reported surgical and radiotherapy trial results suggest that active treatment, whether radical prostatectomy or combined radiotherapy and androgen deprivation, actually offers no mortality benefit for men with low-risk cancers (6,40). Decision aids should also meet IPDASi quality standards for content, development processes, and effectiveness—demonstrating that the decision aid increases knowledge about treatment options and improves the match between patient values and the selected treatment (14). More recent publically available decision aids, including those developed by the Agency for Health Quality and Research (41) and by the University of Michigan (42), use current definitions for active surveillance. The latter decision aid is being evaluated in a study funded by the VA Health Services Research and Development Service (43).

## Research Agenda

A number of research issues are universal for all decision aids. The optimal format is uncertain. The reviewed decision aids were written, audio, or visual; now web-based decision aids are increasingly available. Little is known about how mode of delivery affects use and outcomes related to decision-making processes, treatment selection, and quality-of-life outcomes. Technical details such as how best to present evidence and whether to use patient testimonials are also being evaluated. Issues such as barriers to delivery, acceptability to patients (particularly across diverse populations) and providers, best practices for implementation, and the cost-effectiveness of decision aids also need further study.

More specific issues for prostate cancer treatment decision aids include the timing and setting of delivery. Evidence suggests that patients often fail to consider all options and make decisions that are not concordant with their preferences (17). Providing a decision aid earlier in the diagnostic process, perhaps through primary care providers at the time of biopsy referral, might improve decision making. Given that men with low-risk prostate cancer can select among several active treatments or active surveillance, researchers evaluating decision aids also need to determine the most appropriate outcomes (eg, decision process and quality, treatment selection, decision satisfaction and regret, quality of life, clinical events) and how to measure them. Study designs will need to account for the repeated nature of decisions regarding active surveillance.

## Conclusions

Current clinical practice does not consistently display high-quality decision making for treating localized prostate cancer. Providing decision aids to support shared decision making is a promising strategy for aligning treatment selection with patient values and preferences. However, effective decision aids need to provide more complete descriptions of options, particularly active surveillance, and meet recently defined quality standards. Further research is needed to evaluate the development, implementation, and acceptability of decision aids and their effects on decision making, treatment selection, and quality of life.

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**Affiliation of author:** Medicine Service, Department of Veterans Affairs Medical Center, Departments of Medicine and Family and Community Medicine, University of New Mexico School of Medicine, Albuquerque, NM.