Technology Assessment Program

Report No. 6

Shared Decision-making® Programs

Descriptive Analysis of Experience with
Shared Decision-making® Programs in VA

A Systematic Review: Assessing the Effectiveness of
Shared Decision-making® Programs for Prostate Care

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The Health Services Research and Development Service (HSR&D) is a program within the Veterans Health Administration's Office of Research and Development. HSR&D provides expertise in health services research, a field that examines the effects of organization, financing and management on a wide range of problems in health care delivery, quality of care, access, cost and patient outcomes. Its programs span the continuum of health care research and delivery, from basic research to the dissemination of research results, and ultimately to the application of these findings to clinical, managerial and policy decisions.

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Shared Decision-making® Programs

A Descriptive Analysis of VA Experiences and A Systematic Review of the Evidence of Shared Decision-making® Programs for Prostate Care

EXECUTIVE SUMMARY

Purpose

This report was prepared in response to a request from VISN 10 to the Management Decision and Research Center (MDRC) Technology Assessment (TA) Program to provide information about Shared Decision-making® Programs[1]. The TA Program obtained information from expert opinion and published evidence to address the following questions:

1. Are Shared Decision-making® Programs in use within VA?
2. Are the programs well suited to the clients served by VA?
3. How effective are Shared Decision-making® Programs for prostate disease?

Background

Shared Decision-making® Programs (SDPs) are patient education videos designed to provide tailored, unbiased information about the benefits and risks of alternative treatments for selected disorders (Gunby 1992). They can be used with a wide range of patients. They are one of the best known technology-based tools developed to inform patients and to promote their involvement in decision making, with the goal of improving the quality and outcomes of health care.

A shared decision making model of care appears to be well suited for use with prostate diseases. Patient preference may be a particularly important component of prostate care, because there are no clear medical imperatives to guide decision making, and there are large differences in the risks, benefits, and quality of life associated with alternative treatment options.

Key Findings

VA Experiences with SDPs

- Anecdotal evidence from interviews suggests that SDPs are currently in limited use within VA, and are very well received by VA patients who have viewed them. These positive findings are based on the experiences of self-selected patients who may not be representative of all veterans served by VA.

[1] Shared Decision-making® is a registered trademark of the Foundation for Informed Medical Decision Making, Inc.

- Implementation across VA sites varied widely. SDPs are designed to help patients work with their providers to make decisions about their care; *provider buy-in and ease of patient access are essential to successful implementation.* Patient access to SDPs at Patient Education and Resource Centers, for home viewing, and during patients' clinic visits facilitated implementation. Barriers, such as initial provider resistance and the high cost of videodisc equipment and programs, were reported.

- VA has been actively involved in the creation and assessment of some SDPs. The Durham VAMC, White River Junction VAMROC, and the Northwest Center for Outcomes Research in Older Adults (HSR&D Field Program in Seattle) were members of the team of affiliated health care institutions that developed and evaluated SDPs. HSR&D-funded studies of SDPs are presently being conducted at the Milwaukee VAMC and the Pittsburgh VAMC.

Effectiveness of SDPs for Prostate Care

The definition of "effectiveness" varied among studies, but usually included some measures of patient knowledge, satisfaction, and treatment preferences. There have been no systematic overviews written about the effectiveness of SDPs for prostate screening and treatment, no long-term follow-up studies of effectiveness, and no cost-effectiveness studies. Findings from the two well-designed studies of effectiveness for the prostate SDPs are summarized below:

- *Benign Prostatic Hyperplasia (BPH)*--Compared with controls, patients who viewed the SDP (including those in VA) responded favorably, felt they had better health and physical functioning, were markedly more knowledgeable about prostate disease and the risks and benefits of treatment options, and were more satisfied with their decision making process. Limited and conflicting data preclude definitive conclusions regarding the impact of the SDP on treatment preferences for BPH (Barry et al. 1997).

- *Prostate-Specific Antigen (PSA)*--Patients who viewed the SDP about PSA screening were more knowledgeable about prostate cancer, more likely to prefer "watchful waiting" over active treatment for prostate cancer, less likely to *plan to have* PSA screening in the next 2 years, and in fact did have significantly less screening (Flood et al. 1996).

- *Prostate Cancer*--No published reports of the prostate cancer SDP were identified, although such trials are reportedly underway. Preliminary results presented in the Prostate Disease PORT Final Report (DHHS 1995) stressed the importance of patient preferences in decision making and suggested that viewers of SDPs tended to favor less screening and less surgery for prostate cancer than non-viewers.

Conclusions

Published evidence and experiences within VA suggest that SDPs support patient involvement in care, are well received by patients, and can be used with a wide range of patients. SDPs provide one element of an outcomes-focused service in health care; their methods and goals are well aligned with those of VA. Limited evidence exists to demonstrate the impact of SDPs on treatment preferences for prostate care. Further research, using large, rigorously designed studies, is needed to assess their long-term impact on the cost and quality of care.

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I. INTRODUCTION

This report was prepared in response to a request from VISN 10 to the Management Decision and Research Center (MDRC) Technology Assessment (TA) Program. The TA Program was asked to reply to the following questions:

- Are Shared Decision-making® Programs in use within VA?
- Are the programs well suited to the clients served by VA?
- How effective are Shared Decision-making® Programs for prostate disease?

Shared Decision-making® Programs (SDPs) are patient education videos. They are designed to "provide patients with tailored, unbiased information about the benefits and [possible] harms of alternative treatments" and to engage patients in the decision making process (Gunby 1992). They are one of the best known of the technology-based tools developed to enhance patient involvement in decision making, with the goal of improving the quality and outcomes of health care.

II. METHODS

The MDRC Technology Assessment Program approach to this topic consisted of obtaining information from two sources: expert opinion and published evidence. The TA Program interviewed the following content experts via telephone and email:

- representatives of the Foundation for Informed Medical Decision Making (FIMDM);
- VA providers who had experience using SDPs within VA; and
- a convenience sample of past and present researchers involved in the development and assessment of SDPs, some of whom had VA affiliations.

The TA Program conducted a broad search to obtain published evidence of effectiveness. The following bibliographic databases were searched to identify relevant primary research literature: National Library of Medicine's MEDLINE, PREMEDLINE (1966 to June 1997), and HealthSTAR (1975 to April 1997); EMBASE® (1988 to April 1997); Cinahl® (1982 to February 1997); and CancerLit® (1983 to April 1997).

Search terms included: *patient participation, decision making, shared decision making, prostate, prostatic hyperplasia*/ or *benign prostatic hyperplasia*, *BPH*, and *prostate neoplasm*. End-references from retrieved articles and listings of public domain technology assessments were also searched. Full-text copies of relevant articles were obtained for review and synthesis.

Articles were included in this report if they met the following selection criteria:

- English language journal articles reporting primary data obtained in clinical settings;
- study design and methods clearly described;
- study not duplicated or superseded by subsequent publications, with the same purpose, from the same research group.

Studies reviewed for possible inclusion in this report were classified according to their study design and the strength of the evidence they provided. The strength of a study is based on the overall research design and on the quality of the implementation and analysis. The methodologic standard for judging the quality of individual studies and their causal implications is summarized in Table 1.

Table 1: Continuum of study designs and their causal implications

Study Design	Inference / Strength of Evidence
I. Anecdotes Clinical hunches Case history	Speculative
II. Time series Ecologic correlation Cross-sectional	Suggestive
III. Case-control	Moderately suggestive
IV. Before-after with controls Historical cohort	Highly suggestive
V. Prospective cohort	Moderately firm
VI. Randomized controlled trials Community randomized trials	Firm

Source: Adapted from Ibrahim, 1985.

Types I through III are observational studies, not true experiments. Observational studies are subject to many forms of bias that can diminish the accuracy of their findings. They do not provide very persuasive evidence linking interventions with the outcomes observed. They can, however, be very useful for helping to generate ideas for further research. Type IV and V studies are considered quasi-experimental designs. They are commonly used in health care (often because it is not possible to conduct true experiments with patients), and provide stronger evidence than can be obtained from observational studies. Type VI studies are true experiments, and provide the most persuasive evidence for linking interventions with the outcomes observed.

III. BACKGROUND AND SIGNIFICANCE

A. Balancing Cost and Quality

The Veterans Health Administration is undergoing rapid change, with a mission to provide efficient, cost-effective patient-centered care. To remain competitive in the present health care market, it is essential to balance cost containment efforts with increased attention to improving the quality and outcomes of care. To do this, VA must determine, on multiple levels, what truly "works best" for veterans.

There has been a growing realization about how little we know concerning the return on investments of health care dollars, and a growing appreciation of the complexity of health care decision making. The work of John Wennberg and his colleagues helped to demonstrate that treatment decisions, key drivers in determining the cost of health care, were often based on differences in physicians' knowledge and beliefs about what would work best. There was little scientific evidence to support many of these beliefs, and little patient involvement in the decision making process. There were also very high variations in practice with few differences in patient health status (Kasper and Fowler 1993). The growing appreciation for how little we know, combined with the knowledge that there are substantial differences in the risks, benefits, and costs associated with different treatment choices, helped support the development of the shared decision making model of care and the growth of outcomes research.

Congress addressed these issues on a national level by creating the Agency for Health Care Policy and Research (AHCPR). AHCPR's Medical Treatment Effectiveness (MEDTEP) Program established a group of Patient Outcomes Research Teams (PORTs). Their mandate was to assess the strength of the scientific evidence supporting conventional treatments; to promote new knowledge about the outcomes of care; and to make this information available to patients, providers, and policymakers (Wennberg et al. 1993; DHHS 1995). The PORTs addressed health care conditions of national importance, including heart disease, stroke, diabetes, back pain, and prostate disease.

B. The Prostate PORT and the SDPs

The Prostate PORT was the first to be completed. It produced pivotal studies that documented variations in practice patterns, identified and developed outcomes measures that reflect patient preferences, and established mechanisms to disseminate these findings to policy makers, providers, and patients.

As part of the Prostate PORT's dissemination efforts, team members collaborated with the non-profit Foundation for Informed Medical Decision Making (FIMDM) to develop videos to help patients work with clinicians to make decisions about their care. This

"shared decision making" approach emphasizes that the patients should be informed about their medical conditions and their choices, and should be given reasonable and reliable information about all treatment options, including the amount of uncertainty that may exist about the outcomes of care. Shared decision making is considered especially important when the optimal treatment choice is heavily dependent on the patient's values regarding both his current medical state and the outcome states possible after treatment (Barry et al. 1995).

Three of the FIMDM's patient-focused SDPs are designed to address screening and treatment of benign and malignant prostate diseases:

- Benign Prostatic Hyperplasia: Choosing Surgical or Nonsurgical Treatment
- The PSA Decision: What You Need to Know
- Treatment Choices for Prostate Cancer

C. Prostate Diseases

Prostate diseases are among the most prevalent health problems paid for by the Medicare program, and their diagnosis and treatment are of immediate significance to VA and to society. As men age, they are at increased risk of both benign prostatic hyperplasia and prostate cancer. The costs of diagnosing and treating prostate diseases are increasing rapidly, but there are substantial uncertainties about how well much of what we do actually works (DHHS 1995).

Benign prostatic hyperplasia (BPH) is a non-cancerous enlargement of the prostate gland that can interfere with urination. Symptoms, and level of concern about symptoms, vary widely among patients. By age 70, about 40% of men meet the clinical definition of BPH, and almost all would have some evidence of BPH if biopsied (DHHS 1995). Surgery for BPH remains the second most common major operation among Medicare-age men (Barry et al. 1995).

Prostate cancer is the most common non-skin cancer and the second most common cause of cancer death in American men, causing an estimated 40,400 deaths in 1995 (Salwin et al. 1995). However, the vast majority of men with microscopic evidence of prostate cancer will never develop clinically significant disease. The use of radical surgery to remove the prostate gland in men with localized cancer increased by more than 500 percent among men 65 and older between 1985 and 1990. Despite this, the death rate from prostate cancer appears to be slowly rising (Murphy 1995).

IV. DESCRIPTION OF THE TECHNOLOGY

The SDPs present general information about a medical condition and descriptions of each treatment option. The harms and benefits of each option are described, along with the probabilities of the various outcomes specific to the patient viewing the program (for the videodiscs) or specific to groups of patients (for the videotapes). Interviews with other patients who chose each of the alternative treatments, and who actually experienced the range of possible outcomes, are integrated into the programs (Kasper and Fowler 1993). Most programs are one hour long, 30 minutes of which is core material, and 30 minutes of which is an optional "Learn More" section. A few programs, including PSA, are 20 minutes in length (FIMDM, 1997). According to Dr. Joseph Kasper of the FIMDM, the programs are targeted at 100% comprehension at the 10th grade level (Millichap 1994).

Programs are accompanied by read-ahead patient materials, a list of citations for the literature on which the program is based, and recommended eligibility criteria to guide clinicians in identifying patients for whom the program is appropriate. Exclusion criteria include difficulty in understanding English, or impairments in hearing, vision, or cognition. Other criteria are disease-specific.

The contents of the programs are evidence-based, and are developed by the FIMDM in conjunction with affiliated academic and clinical centers, including VA. Programs must be updated as new evidence is published. The stated objective of the programs is to present a balanced presentation of the available evidence. Their goal is to assist patients in working with their providers to making an informed decision that is "right" for that individual patient, rather than to recommend a particular treatment option.

The SDPs were originally designed as interactive videodiscs to be used in a health care setting, and were marketed with the necessary viewing hardware. They were the first medical intervention developed using this technology (Lyon et al. 1989). The videodisc programs use a touch screen to enable patients to enter information about themselves into the program, and to select the type and amount of information that they view. The videodiscs provide patients and providers with individualized information about the risks and benefits of each treatment for the patient.

The videodiscs are still in use, but the materials are presently marketed primarily as videotapes. The videotape contents are similar to those of the videodiscs. Unlike the computer-based videodiscs, the tapes present probabilities of the risks and benefits of treatment alternatives for a range of patient groups, rather than tailoring them to the individual patient. The product line contains 9 videodiscs and 12 videotapes, and includes programs about treatment choices for low back pain, mild hypertension, ischemic heart disease, advance directives, breast cancer surgery and adjuvant therapy, hormone replacement therapy, benign uterine conditions, and the informed health care consumer.

The Foundation has recently established a relationship with a for-profit organization, and plans to create a series of services to support shared decision making and integrated health care[2]. The Foundation anticipates that the SDPs will be offered in new formats, including CD-ROM.

V. DESCRIPTIVE ANALYSIS: Experiences using SDPs within VA, and appropriateness to VA patients

VA is presently using some of the SDPs at several sites. The TA Program conducted telephone interviews and email communications with user site personnel. The qualitative data collected from the sites are summarized in Table 2 (Appendix 1). The seven identified sites may not reflect the total VA use of SDPs, and not all sites included in the table are using the prostate disease SDPs. The experiences of sites that are using SDPs, but not using prostate SDPs, have been included in the report to provide an indication of the ranges of implementation strategies and outcomes within VA.

VA was an active participant in the development and evaluation of the SDPs, as were both the Group Health Cooperative of Puget Sound and Kaiser Permanente, Inc. VA's Health Services Research & Development Service (HSR&D) funded the research that led to the development of a SDP to help patients clarify their preferences regarding life-sustaining treatments (advance directives)[3]. HSR&D is presently funding research using SDPs[4], as is the Department of Defense (DoD)[5].

The limited use of SDPs within VA is consistent with that reported for hospital systems within the United States. The programs are more commonly used by HMOs. The SDPs are presently being assessed for use within the national health care systems in Canada and England[6].

The information gathered during the interviews was generally consistent with trends reported in the literature and information provided by the vendor. When interpreting the findings, it should be noted that the interviews collected qualitative case history information, which does not yield a strong level of evidence, and may produce findings that are not generalizable to other settings.

[2] D. Eaton, Eastern Regional Sales Representative (personal communication, May 6, 1997).

[3] SDR 91-004 and Supplement: Interactive teaching videodisc to obtain advance directives from veterans. J. Wasson, Principal Investigator.

[4] Study of the effect of the ischemic heart disease SDP on patient knowledge, attitude, and decision-making. Dr. J. Conigliaro, Pittsburgh VAMC, Principal Investigator (personal communication, May 21, 1997).

[5] Study of the impact of the breast cancer SDPs. Lieutenant Colonel Ellen Lewis, USAF, Principal Investigator (personal communication, May 8, 1997).

[6] D. Eaton, Eastern Regional Sales Representative (personal communication, May 6, 1997); I. Fateman, Western Regional Sales Representative (personal communication, May 13, 1997).

A. Utilization and patient acceptance

SDPs address diagnostic and treatment options for several conditions that are highly prevalent within VA, but the programs are not used widely within the VA system. VA patients who have viewed the SDPs have generally responded positively. Of the programs used, the prostate cancer SDP is reported to be among the most frequently used, and is well received by patients.

The ischemic heart disease and mild hypertension SDPs are also in use, and are also reported to be well received by patients. Two sites reported that the low back pain SDP did not appear to address issues of interest to VA patients. The breast cancer and hormone replacement therapy SDPs are used by a Women's Health Program and by some of the VA staff, but are not seen as relevant to the patient population at some sites either because the sites reported that they had few women patients or because the women patients were not seeking care for breast disease from their VA providers.

B. Reported incentives and barriers to use

Provider buy-in for the use of SDPs is the most commonly cited factor for success of their implementation. This product is designed to be an integral part of the clinical process of care, and to be viewed prior to decision making about diagnosis and treatment. Strong support from a service chief overcame initial provider resistance at one site, and the SDP was successfully integrated into care. Support from primary care providers enabled another site to successfully perform a large study using a SDP.

The coordinator of one of the VA Patient Education and Resource Centers (PERCs) reported that providers frequently referred patients to the PERC to use their resources, which included a set of the SDPs. While this does not necessarily reflect provider acceptance of the SDPs specifically, it implies that the culture at that VA does support patient involvement in care. Because this site had located the PERC in an easily-accessible area, patients also self-referred to use available educational materials, including the SDPs.

Lack of advocacy by clinicians, either through lack of knowledge about the program or active resistance to its use, can present a major barrier to the integration of SDPs into patient care. At a site with a less-successful implementation, none of the physicians referred patients for SDP viewing. Nurses identified patients for whom the SDPs might be appropriate (either because of their primary diagnosis or because of co-morbid conditions), and offered them the option of viewing the SDPs. However, some of these patients were identified late in the treatment process, and many of the treatment decisions had already been made.

Two interviewees expressed some doubt about the appropriateness of the SDP for prostate cancer screening for use within VA. One physician reported that the patients "loved" the program, but did not necessarily fully understand its contents. Another provider reported that patients appeared to be getting more information in the programs than they were seeking.

As noted in Table 2 (Appendix 1), one VA-funded research assessment of an SDP could not be implemented due to provider resistance to the use of the prostate cancer SDP. Providers at this site were not interviewed by the MDRC, so the reasons for this resistance were not explored.

Organizational processes can act as incentives or barriers to use of SDPs. Videodisc programs are designed for use within the health care setting, so patients must come to them. At one site, appointments for viewing the videodiscs were coordinated with other clinic appointments, and were always scheduled (by mandate of the service chief) prior to physician appointments at which treatment was to be discussed. Not all sites have been so successful. Difficulty in scheduling times to view videodisc programs, and difficulty in convincing patients to take the time, have been reported within VA.

Videotapes can be viewed at home, and so may be more convenient to use than videodiscs. One site noted that 80% of the patients in their large trial actually had VCRs available to them for home use, and that patients preferred to see the SDPs at home rather than in the hospital. Videotapes are convenient but they do have limitations. Unlike the computer-based videodiscs, videotapes cannot be customized for individual patients, and they cannot be updated by inserting new research findings into existing tape programs.

While videodiscs have some potential advantages over tapes, the videodisc technology itself can be a barrier. The initial purchase is costly, as is the software to update program contents. The equipment takes up space in patient care areas, which is also a limited resource. The equipment is supported and maintained by the vendor, and no sites reported difficulty with this process. Videodisc technology has not been particularly successful in other industries, and the vendors are presently exploring the use of other media formats for their products.

VI. SYSTEMATIC REVIEW OF THE LITERATURE:
Proof of concept, utility, and impact of SDPs for prostate disease

Thirty-one articles were retrieved for potential inclusion in this report. After review, three articles were identified which met the inclusion criteria for studies of SDPs for prostate screening or treatment. The abstracts of two additional studies were retrieved, but published findings are not yet available for review or inclusion in this report[7, 8].

[7] GM Froehlich et al., 1996. Personal communication with co-author, M.D. McDaniel, May 21, 1997.

Two further reports of primary data from studies of SDPs were retrieved. These did not address prostate care and were not included in the summary table[9]. The majority of the remaining excluded articles presented discussions of the technology or studies of medical decision making, but included no relevant primary data.

No overviews of the literature were identified. No large randomized controlled trials were identified for any prostate program, and all studies had methodologic flaws which would limit their internal validity. Patient characteristics and high variances in practice patterns across sites may limit the external validity of the studies.

The extent to which the impact of prostate SDPs is supported by published evidence is summarized in Table 3 (Appendix 2), and discussed below.

A. Benign Prostatic Hyperplasia (BPH)

A series of studies was conducted to evaluate the BPH-SDP. The most recent publication reported the findings of a randomized trial as well as an analysis of data collected from a baseline control group accrued prior to the onset of the clinical trial. The trial randomized HMO patients to one of two interventions: viewing the SDP videodisc for BPH, or receiving an informational brochure (Barry et al. 1997). Outcomes measures for the patients enrolled during the baseline control period were compared with those of the brochure group.

Compared with the brochure group, the SDP group was significantly more knowledgeable about their condition and more satisfied with the decision making process. In addition, they showed significantly less deterioration in their perceived general health and physical functioning. They did not differ significantly in measures of satisfaction with the treatment decisions themselves, perceived symptom severity, social functioning, and preference autonomy.

With two exceptions, the baseline control group did not differ significantly from the brochure group in the outcomes measured. The brochure group was more knowledgeable than the baseline control group and also had a higher preference for autonomous decision making. No direct comparisons were made between the SDP group and the baseline control group.

One year after the intervention, 7.7% of the SDP group and 13% of the brochure group had prostate surgery. While this was a 41% reduction in surgery with SDP use

[8] R. Deber, Principal Investigator (personal communication, June 3, 1997).

[9] One excluded study evaluated the SDP for ischemic heart disease. Patients from the Durham VAMC participated this study (Liao et al. 1996). The second excluded study assessed the SDP for low back pain. The Health Services Research and Development Field Program, Seattle VAMC participated in the evaluation (Spunt et al. 1995).

(consistent with findings of earlier observational studies), the confidence interval was large and the difference was not significant. Because so few participants had surgery, the study did not have the power to demonstrate the impact of the SDP on treatment selection, if such an impact in fact existed.

An earlier study of the BPH-SDP videodisc was conducted by the same group to demonstrate "proof of concept" and program utility for a broad range of patients (Barry et al. 1995). This prospective cohort study included patients at three sites: VA and two HMOs. Findings suggested that patients responded favorably to the SDP, and most reported that the program was clear, balanced, had the right amount of information, and was the right length. Patients who did not finish high school tended to give lower ratings, but the differences were not significant. The authors suggested that the SDP may be a practical method for helping to implement clinical practice guidelines.

B. Prostate-Specific Antigen (PSA) Screening

No randomized controlled trials have evaluated SDPs for PSA screening. Findings from a prospective non-randomized controlled trial suggested that patients who viewed the PSA-SDP were: more knowledgeable about prostate cancer and screening; more likely to prefer "watchful waiting" over active treatment for prostate cancer; less likely to ***plan to have*** PSA screening within the next 2 years, and did in fact have significantly less PSA screening at the next episode of care (Flood et al. 1996).

C. Prostate Cancer

No published reports of primary data from assessments of the prostate cancer treatment SDP were identified by the TA Program, although such trials are reported to be underway. The potential impact of the prostate cancer SDP has been addressed only anecdotally or in reports of preliminary observations from ongoing trials.

Preliminary results reported in the Prostate Disease PORT Final Report (DHHS 1995) suggested that patients were willing to face uncertainty regarding treatment choices for prostate cancer and were willing to actively share in the decision process. It was noted that patients with similar ages, grade of tumor, and PSA levels were reported to have chosen different treatment options, suggesting the importance of patient preference in decision making.

VII. DISCUSSION AND CONCLUSIONS

Theoretical models and limited empirical evidence have suggested that increased patient involvement in decision making could lead to more fully informed consent, shared responsibility for treatment decisions between patients and providers, improved patient compliance, increased patient satisfaction, improved outcomes, and an overall increase in the quality of care (Charles et al. 1997; Nease 1995; Terry 1994; Lantos 1993). Preliminary testing and observational studies (including Wagner et al. 1995) suggested that patients who were better informed about the true risks and benefits of some procedures, and who were more involved in decision making, chose to have fewer tests or surgical treatment than would have been prescribed by their physician.

For patients to be better informed, relevant materials need to be presented to them in a manner consistent with their cognitive style and learning skills. Both expert opinion and evidence in the published literature suggest that the SDPs are well-suited to most of the clients served by VA. In fact, VA participated in the development and evaluation of some of the SDPs. Consistent with published reports of patient reactions to the SDPs, VA patients who viewed the SDPs have generally reacted favorably to them. Based on the currently available information, it is not possible to determine whether positive reactions were in response to having been given information and included in the decision making process, or whether they were responses to the activity of viewing the program itself.

The literature suggests that, while there may be substantial variation among patients, their desire for information and involvement in decisions concerning their medical care may be higher than anticipated by many providers (Deber 1994). The weak anecdotal evidence that is available suggests that SDP viewers were not overwhelmed by the amount of information presented in the programs, and were better able to discuss their conditions and treatment options with their providers after viewing the programs. Concerns that the SDP might interfere with patient-provider interactions, or have a negative impact on the patient-provider relationship, have not been supported by either published data or by experiences in the clinical setting.

Provider resistance to the implementation of SDPs has been reported. Some have expressed concern that decision support aids, including the SDPs, can bias patients against receiving what the provider believes to be necessary treatment. The intent of efforts to increase patient involvement in health care, and the intent of the developers of the SDPs has not necessarily been to decrease utilization of particular treatments, but rather, to achieve the "right" utilization (Kennedy 1995) based on our present level of knowledge and the values of the individual patient.

Relatively few published studies contain high quality evidence to demonstrate the impact of SDPs on treatment preferences. The strongest evidence available, from the recently published randomized trial of the BPH-SDP (Barry et al. 1997), failed to support earlier findings of a 40-50% reduction in prostate surgical rates in groups using SDPs. While the recent study did demonstrate a decreased prostatectomy rate in the SDP group, the numbers of patients who elected surgery in either group were small, and the reduction was not statistically significant.

The strongest evidence for the effectiveness of the PSA-SDP came from the prospective non-randomized controlled trial by Flood et al. (1996). The SDP viewers were significantly less likely to report that they planned to have PSA screening, and were less likely to have screening done at the next clinic opportunity. The PSA-SDP viewers were also significantly more likely to express a preference for watchful waiting over active treatment for prostate cancer.

The SDP for prostate cancer is newer than the BPH program, and published reports of assessments of its impact on treatment selection are not yet available. The program has been well received by VA patients who have viewed it. Reported provider reactions have been mixed, and have ranged from strongly positive to strongly negative. Lacking adequate data, it is not appropriate to speculate about how provider acceptance of the SDPs might compare to acceptance of other methods used to support increased patient participation in the process of decision making.

The available evidence on patient acceptance, usability, and impact is generally positive. The long-term effect of SDPs on quality of care and cost is unknown. Prostate diseases are medical conditions for which the best treatment truly is not known (DHHS, 1995), and the long-term cost-effectiveness of any one treatment or component of the overall process of care is therefore not measurable.

How the acceptability, effectiveness or cost of the SDPs compares with that of other education and decision-aids has not been studied.

Experience with the SDPs to date indicates that they are not simply an educational product. Rather, they provide one element of an outcomes-focused service within a health care organization. They are designed to inform patients and to promote their involvement in decision making, with the goal of improving the quality and outcomes of health care. Their long-term impact on the cost and quality of care remains to be determined.

REFERENCES

VIII. REFERENCES

Agency for Health Care Policy and Research. *Prostate disease patient outcomes research team (PORT).* 1995, DHHS. Public Health Service. Agency for Health Care Policy and Research: Rockville, MD.

Barry MJ, Fowler FJ, Jr., Mulley AG, Jr., Henderson JV, Jr., Wennberg JE. Patient reactions to a program designed to facilitate patient participation in treatment decisions for benign prostatic hyperplasia. *Medical Care* 1995; 33(8): 771-782.

Barry MJ. *Randomized trial of the shared decision-making program for benign prostatic hyperplasia.* NTIS PB97-154025. 1995, Agency for Health Care Policy Research: Rockville, MD.

Barry MJ, Cherkin DC, Chang Y, Fowler FJ, Skates S. A randomized trial of a multimedia shared decision-making program for men facing a treatment decision for benign prostatic hyperplasia. *Disease Management and Clinical Outcomes* 1997; 1(1): 5-14.

Charles C, Gafni A, Whelan T. Shared decision-making in the medical encounter: what does it mean? (Or, it takes at least two to tango). *Social Science & Medicine* 1997; 44(5): 681-692.

Deber RB. Physicians in health care management. 8. The patient-physician partnership: decision making, problem solving and the desire to participate. *Canadian Medical Association Journal* 1994; 151(4): 423-427.

Deber R, Kraetschmer N, Trachtenberg J. Shared decision making: how does one measure success? *Medical Decision Making* 1994; 14(4): 429.

Flood AB, Wennberg JE, Nease RF, Jr., Fowler FJ, Jr., Ding J, Hynes LM. The importance of patient preference in the decision to screen for prostate cancer. Prostate Patient Outcomes Research Team. *Journal of General Internal Medicine* 1996; 11(6): 342-349.

Foundation for Informed Medical Decision Making. (1997). *Shared decision making programs.* [Website]. Available: http://www.dartmouth.edu/dms/cecs/fimdm, [May 7, 1997].

Froehlich GW, Ballard EA, Flood AB, Howes PS, McDaniel MD. Moving shared decision making into practice with a videotape on prostate cancer screening. *Journal of General Internal Medicine* 1996; 11(Suppl 1): 134.

Garnick MB, Fair WR. Prostate cancer: emerging concepts, Part I. *Annals of Internal Medicine* 1996; 125: 118-125.

Greenfield S, Kaplan S, Ware JE. Expanding patient involvement in care. *Annals of Internal Medicine* 1985; 102: 520-528.

Gunby P. From cell populations to human populations, cardiovascular research examines possibiliries [Medical News & Perspectives]. *JAMA* 1992; 267(8): 1051.

Ibrahim MA. *Epidemiology and health policy*. Gaithersburg: Aspen Systems Corporation; 1985.

Kaplan S. The future of patient input into medical decision making. *Quality Review Bulletin* 1992; 18: 182.

Kaplan SH, Greenfield S, Gandek B, Rogers WH, Ware JE. Characteristics of physicians with participatory decision-making styles. *Annals of Internal Medicine* 1996; 124(5): 497-511.

Kasper JF, Fowler FJ, Jr. Responding to the challenge. A status report on shared decision-making programs. *HMO Practice* 1993; 7(4): 176-181.

Kennedy M. Making patients part of their healthcare team. *Quality Letter for Healthcare Leaders* 1995; 7(2): 2-12.

Lantos J. Informed consent: the whole truth for patients? *Cancer* 1993; 72(9 Suppl): 2811-2815.

Liao L, Jollis JG, DeLong ER, Peterson ED, Morris KG, Mark DB. Impact of an interactive video on decision making of patients with ischemic heart disease. *Journal of General Internal Medicine* 1996; 11(6): 373-376.

Lyon HC, Henderson JV, Beck JR, Mulley AG, Barry MJ, Fowler FJ, et al. A multipurpose interactive videodisc with ethical, legal, medical, educational and research implications: the informed patient decision-making procedure. *Proceedings of the 13th Annual Symposium on Computer Applications in Medical Care* 1989; 13: 1043-1045.

McPherson K. The Cochrane Lecture. The best and the enemy of the good: randomised controlled trials, uncertainty, and assessing the role of patient choice in medical decision making. *Journal of Epidemiology & Community Health* 1994; 48(1): 6-15.

Millichap N. (1994). *It's a wired wired wired wired world.* Available: http://griffith.dartmouth.edu/iml/WiredWorld.html, [May 5, 1997].

Murphy GP. Prostate cancer: here and now. *CA: A Cancer Journal for Clinicians* 1995; 45(3): 133.

Nease RF, Jr., Brooks WB. Patient desire for information and decision making in health care decisions: the Autonomy Preference Index and the Health Opinion Survey. *Journal of General Internal Medicine* 1995; 10(11): 593-600.

Salwin KM, Ohori M, Dillioglugil O, Scardino PT. Screening for prostate cancer: an analysis of the early experience. *CA: A Cancer Journal for Clinicians* 1995; 45(3): 134-147.

Spunt BS, Deyo RA, Taylor VM, Leek KM, Goldberg HI, Mulley AG. An interactive videodisc program for low back pain patients. *Health Education Research: Theory and Practice* 1996; 11(4): 535-541.

Terry K. Telling patients more will save you time. *Medical Economics* 1994; 71(14): 40-52.

Wagner EH, Barrett P, Barry MJ, Barlow W, Fowler FJ, Jr. The effect of a shared decisionmaking program on rates of surgery for benign prostatic hyperplasia. Pilot results. *Medical Care* 1995; 33(8): 765-770.

Wennberg JE, Barry MJ, Fowler FJ, Mulley A. Outcomes research, PORTs, and health care reform. *Annals of the New York Academy of Sciences* 1993; 703: 52-62.

Appendix 1

VA Experiences with Shared Decision-making® Programs

Table 2: Experience with Shared Decision-making Programs (SDPs) within VA: Summary of Telephone Interviews with VA Providers

Notes:

The table illustrates a range of implementation methods and outcomes related to SDP use within VA. It does not necessarily reflect the total VA experience with SDPs.

Telephone interviews were conducted using open-ended questions. The responses reflect the opinions of the providers interviewed, and are not necessarily the opinions of their organizations.

Except at research sites, there was no reported systematic data collection on the frequency of use, patient perception, or impact of the SDPs. Mechanisms for the standardized systematic collection of such data are actively being developed within VA.

Further information about the user sites is available upon request from the Technology Assessment Program.

Site	Products	Patient use and Satisfaction	Characteristics of Program Implementation
A	videotapes: complete set.	Program use • the prostate cancer, ischemic heart disease and mild hypertension SDPs are the most popular. • the breast cancer and hormone replacement therapy SDPs are also in use. • the low back pain (LBP) SDP is not used often. LBP patients primarily go to the education center to borrow the exercise videos. • PSA tape is considered "too long" by viewers, who seem to want a simple "do it" or "don't do it" message, rather than a discussion of issues. Appropriateness to VA population • the SDPs are very well-received by the patients. • viewing the SDP is never mandatory, so all viewers are self-referred. • SDPs would "probably not be appropriate for a sub-population of VA patients", but these are not patients that self-refer for education.	Reason for implementation • donated by a California consortium of private industries which negotiates its own healthcare contracts. The consortium distributed the SDPs to libraries throughout the state as part of their QA program. Site characteristics, with potential incentives or barriers to use • SDPs are available in an easily-accessible Patient Education & Resource Center. • patients are referred to the PERC by providers, or are self-referred. • SDPs are used in the Women's Program and Cardiac Rehabilitation Program. • SDPs are used by VA employees for both personal and professional reasons. Frequency of use and impact • data on utilization of SDP, utility to patients, or impact not readily available from the site. • the corporate donors had surveyed sites in the past, but that information is not available. Comments • the prostate cancer SDP "probably the best out there for discussing treatments." • educators would have purchased the more popular SDPs if they had not been donated, and if resources were available.

Site	Products	Patient use and Satisfaction	Characteristics of Program Implementation
B	videodiscs: prostate cancer, benign prostatic hyperplasia, low back pain. Several other programs tested.	Program use • mandated for all prostate cancer patients seeking treatment. • educators would like to expand their use of SDPs, but resources are not presently available. Appropriateness to VA population • SDP judged to be "probably the most effective tool" for patient education. • patients appear to be very satisfied with the SDP video, and seem to be better able to discuss issues with their providers. • since the same information is presented in several different formats, patients with a broad range of learning styles and cognitive skills are able to understand the contents. • could only remember two people for whom the SDPs appeared too long.	Reason for implementation • purchased through IRM service at request of a Service Chief. Site characteristics, with potential incentives or barriers to use • Service Chief has mandated that all patients diagnosed with prostate cancer see the SDP prior to meeting with a physician to plan treatment. • although some physicians initially expressed concern, physicians have been "very pleased" with SDPs. • appointments for viewing the SDP are scheduled to suit patients' other clinic appointments. • the high cost of purchasing and updating videodiscs was identified as a barrier to purchasing breast cancer and PSA programs. Data collection • no reported systematic data collection on SDP use or impact. • subjective impression reported to be that more patients chose watchful waiting than would have, had no video been available to them.
C	videodiscs: benign prostatic hyperplasia, low back pain, mild hypertension.	Program use • the prostate and mild hypertension SDPs are the most frequently used. Appropriateness to VA population • patient response reported to be very positive. • all patient use is voluntary, so viewers are self-selected. • breast cancer SDP no longer offered. At present, women with breast disease are typically not seeking care from providers at this site.	Reason for implementation • purchased at request of the patient educators. Site characteristics, with potential incentives or barriers to use • providers were notified of SDP availability, and it was suggested that they refer patients. • no referrals were actually obtained from physicians. • SDPs are offered to patients in the pre-bed care section. Programs offered to admitted patients "for whom they might be relevant." • with the recent consolidation of pre-bed care section space, viewing equipment has been moved to the library. Data collection • no reported systematic data collection on SDP use or impact.

Site	Products	Patient use and Satisfaction	Characteristics of Program Implementation
D	videodiscs and tapes: complete set.	Program use • most of the reported experience is with the PSA videotape. • the full product line was provided to the hospital. They have not been updated, and are not "really used" at present. Appropriateness to VA population • the PSA tape was distributed to over 4000 patients, and was very well received. The researcher's impression was that patients responded positively to the increased attention and to the opportunity for involvement in the decision-making process, but that they did not necessarily understand all of the program content. • patients preferred to take tapes home than to view the videodisks or videotapes at the hospital. • 80% of patients who were offered PSA tapes to take home had VCRs available. • womens' SDPs were not well-suited to needs of the population served. • LBP patients within VA appeared more interested in education about how to live with their condition. Treatment option information in the LBP-SDP did not meet this need. • a few people have used the ischemic heart disease and the prostate cancer SDPs.	Reason for implementation • the result of a joint venture between VA and the Foundation for Informed Medical Decision Making. VA funded the construction of four viewing rooms, and the Foundation provided the SDPs and staffed a learning center. • the learning center was originally used to research, test, and showcase products. The center remains available, but is rarely used now. Site characteristics, with potential incentives or barriers to use • primary care providers gave full support for the PSA-SDP research project. • little/no support from most other clinicians, including cardiologists and urologists. • interactive videodisks seemed to be very difficult to integrate into clinical practice. • it was noted that there was little / no demand from providers for the continued use of the SDP once research and testing were completed. • patients greatly preferred to take tapes home with them, rather than view SDPs (either tape or videodisk) at the facility. Data collection • data collected for PSA research project (to be published). No reported on-going systematic data collection on SDP use or impact.
E	videodisc: ischemic heart disease.	Program use • the ischemic heart disease SDP was used in a research project. • the SDP was not integrated into clinical use at the end of the project. • note that HSR&D research project below will also use this as a test site. Appropriateness to VA population • the SDP was reported to have "worked pretty well" with VA patients. Some of the patients might have had difficulty interpreting quantitative materials that were presented in the form of a graph. • the study excluded patients with potential sensory, language, or cognitive barriers to the use of the SDP. Note that the study was a small uncontrolled trial for patients with severe cardiac disease, and findings may not be generalizable to other populations. The patients rated the program as more helpful than all other decision aids except a physician, and after viewing the SDP they expressed increased confidence in their treatment choice. The greatest effects appeared to be concentrated in those patients with less education	Reason for implementation • used as an intervention in a research project. • no attempt was made to integrate the SDP into routine clinical care at this site. • Data collection • data collected for research project only. No analysis was performed to compare VA with non-VA outcomes of the intervention.

Site	Products	Patient use and Satisfaction	Characteristics of Program Implementation
F	videodisc: ischemic heart disease.	Program use • ischemic heart disease SDP to be used in a three-site research project. • SDPs are not presently used in routine clinical care. Appropriateness to VA population • the investigator will have the opportunity to modify the SDP contents to better meet the needs of select patient populations, if that proves necessary.	Reason for implementation • to be used as an intervention in a research project. • SDP has not been integrated into the clinical care process outside a research setting.
G	videotape: prostate cancer.	Program use • the prostate cancer SDP was to be used in a multi-site research project which included VA. • the purpose of the study was to assess the impact of the SDP on treatment choice and to assess quality of life after treatment.	Reason for implementation • was to be used as an intervention in a research project. Site Experience • resistance from urologists at participating sites prevented the implementation of the study protocol.

Appendix 2

Impact of Shared Decision-making® Programs for Prostate Disease Screening and Treatment

Table 3: Impact of the Shared Decision-making Programs (SDPs) for the Screening and Treatment of Prostate Diseases

Notes:

Studies in this table were designed to evaluate Shared Decision-making Programs for prostate care. These studies meet the inclusion criteria for this report, but they vary in purpose, method, and in SDP assessed.

The Technology Assessment Program was unable to identify any published reports of primary data from studies of the Shared Decision-making Program for prostate cancer, hence none are included in the table.

Articles were excluded if they were duplicated or superseded by subsequent studies with the same purpose by the same institutions. The two studies by Barry et al. are included in the table because they address different outcomes of interest.

Abbreviations are listed at the end of the table.

Study	Type of Program Assessed / Methods	Results / Comments
Barry et al., Massachusetts General Hospital, Boston, 1997	SDP Tested • benign prostatic hyperplasia (BPH) SDP videodisc. Design and Methods • "prospective randomized trial" comparing the SDP to a "control intervention" (a brochure with information about BPH symptoms, diagnosis, and treatments). • a "baseline" control group, exposed to no intervention, was enrolled prior to the onset of the randomized trial. • patients were prospectively enrolled into the baseline group from 1991-1992; into the randomized trial from 1992-1994. • patients were recruited from three urologic practices of the Group Health Cooperative of Puget Sound (GHC). All understood English, had a clinical diagnosis of uncomplicated BPH, no history of either prostate surgery or cancer, and no unstable comorbidities. • N (SDP group) = 104; N (brochure "control" group) = 123; N (baseline "control" group) = 167. • data were collected at baseline, with one year of follow-up by mailed questionnaires (at 3, 6, and 12 months). • neither subjects nor staff were blinded. • outcome measures included: actual treatment selected (surgery, medication, or watchful waiting); knowledge about BPH; satisfaction with treatment decision; perceived BPH symptom severity; reported overall health status; desire for autonomy in decision-making • no data were reported in which the SDP group was compared with "baseline" controls.	Results • treatment preference: watchful waiting was overwhelmingly the treatment of choice in both groups. At 1 year, 7.7% of the SDP patients and 13% of the brochure "controls" had surgery. While this represents a 41% reduction in surgery with SDP use (similar to that reported in earlier observational studies), the confidence intervals around this point estimate were large, the number of patients having surgery in either group was small, and this decrease was not statistically significant. • comprehensibility: knowledge of prostate conditions, treatment options, risks and benefits, present symptoms, all significantly higher in the SDP group as compared with brochure "controls." • satisfaction: patients in the SDP group were significantly more satisfied with the decision-making process than the brochure group; this difference persisted throughout the follow-up period. However, there was no statistically significant difference between groups on satisfaction with the actual decision that was made. • autonomy preference: no significant difference in expressed preference for autonomy between the SDP and brochure groups. • symptom severity: no significant differences in reported symptoms or BHP impact between the SDP and brochure groups. • overall health status: perceived general health and physical functioning were significantly higher in the SDP group than in the brochure group. • comparison with "baseline" controls: the brochure group was significantly more knowledgeable about BPH than the baseline controls. The brochure group expressed statistically higher preference for autonomy in decision-making than the "baseline" controls. There were no statistically significant differences in other outcome measures between the "baseline" control group and the brochure group. study design did not permit comparison of the SDP group and the brochure group. Authors' Comments: • the small number of patients who elected surgery limited the power of the trial to demonstrate an impact of SDPs on treatment decisions, if that impact in fact exists. • the subjects were predominantly white, relatively well-educated HMO members. These findings may not be generalizable to other populations or other settings.

Study	Type of Program Assessed / Methods	Results / Comments
Barry et al., Massachusetts General Hospital, Boston,1995	SDP Tested • benign prostatic hyperplasia (BPH) SDP videodisc. Design and Methods • "prospective cohort study" with 3-month follow-up. • patients were prospectively enrolled from 1989-1990. • three practice sites participated: a VA clinic, Kaiser Permanente, and GHC of Puget Sound. • all participating urologists were salaried. • 421 eligible men with uncomplicated symptomatic BPH and no history of prostate surgery were recruited; data from 373 were analyzed. • patients at three sites did not differ significantly with respect to age or symptoms. VA patients were significantly less likely to have attended college than HMO patients. • participants viewed the SDP for BPH, then responded to a computerized questionnaire. • patients were followed up at 3 months to determine if they had undergone surgery. • outcome measures included "proof of concept" and program utility measures. Patient reactions to the SDP were analyzed. • a multivariable model was developed to predict the choice of surgical treatment.	Results of Proof of Concept and Patient Utility Assessment • 93% of patients responded favorably about other patients seeing the SDP prior to making a treatment decision. Patients who did not finish high school tended to give lower ratings, but the differences were not statistically significant. • the SDP had "about right" amount of information for 87% of patients; 6% reported that it had less and 7% reported that it had more information than wanted. Patients who had not finished high school were significantly more likely than others to feel there was more information in the SDP than they wanted. • 63% reported that everything was clear in the SDP; 36% reported that most of the SDP was clear; 1% reported that some things were unclear in the presentation. • 74% reported that the presentation was completely balanced between treatment options; 8% reported that it was slanted toward surgery; 18% reported it was slanted towards watchful waiting. • the length of the SDP was "about right" for 92% of patients. Surgical rates and Associated Variable • 10.7% of patients underwent surgery within 3 months of viewing the SDP. For patients with frequent moderate and severe symptoms, bothersomeness of symptoms and patient attitudes toward the prospect of postoperative sexual dysfunction were the dominant predictors of choosing surgery. Age, education, marital status, acute urinary retention, and post-void residuals were not associated with choosing surgery. Authors' Comments • findings suggest that patients are enthusiastic about being educated about their conditions, and that they did not find the amount of information presented in the SDP to be overwhelming. • participating urologists "believed subjectively" that the patients viewing the SDP became more active partners in the decision-making process. • authors suggest that the SDP may prove to be a practical method for helping to implement practice guidelines.

<table>
<tr><th>Study</th><th>Type of Program Assessed / Methods</th><th>Results / Comments</th></tr>
<tr>
<td>Flood et al., Dartmouth Medical School, Hanover, NH, 1996

(note that two studies were reported in one article)</td>
<td>SDP Tested
• PSA screening SDP videotape.

Design and Methods: Study #1 (PSA Clinic)
• non-randomized non-controlled prospective clinical trial comparing two interventions, the SDP and a video emphasizing the importance of screening and the efficacy of early prostate cancer treatment (referred to by authors as the “control” video).
• patients recruited from clinic for men seeking free PSA testing. All ≥ 50, with no history of prostate cancer.
• N (SDP group) = 184; N (control video group) = 188.
• patients were assigned to study arms by blinded staff.
• patients were surveyed pre-and post-intervention, and occurrence of PSA testing was assessed.

Design and Methods: Study #2 (Routine GIM Clinic)
• non-randomized controlled prospective clinical trial.
• patients recruited from General Internal Medicine clinic. All ≥ 50, no history of prostate cancer.
• N=103 SDP/ 93 controls.
• assignment to arm of study based on month of appointment. Providers aware of study design, but blinded to actual onset of study or patients participation in study.
• pre-and post-intervention surveys of patients conducted, and occurrence of PSA testing assessed.</td>
<td>Results
• knowledge about prostate cancer (PrCa) natural history, treatment efficacy, and predictive value of PSA: compared with men in the control groups, men in the intervention groups of both studies, after viewing the SDP, were more likely to be knowledgeable about disease history, treatment, and outcomes.

% of subjects who responded accurately to questions:
<table>
<tr><th>Topic</th><th colspan="2">Study 1</th><th colspan="2">Study 2</th></tr>
<tr><th></th><th>Control</th><th>SDP</th><th>Control</th><th>SDP</th></tr>
<tr><td>PrCa</td><td>50.3%</td><td>71.7%</td><td>40.9%</td><td>92.9%</td></tr>
<tr><td>Treatment</td><td>11.4%</td><td>61.0%</td><td>23.7%</td><td>69.9%</td></tr>
<tr><td>PSA</td><td>30.5%</td><td>64.2%</td><td>14.5%</td><td>71.8%</td></tr>
</table>
• treatment preference: compared with men in the control groups, men in the intervention groups of both studies, after viewing the SDP, were more likely to report that they would prefer watchful waiting over active treatment.

% of subjects who reported they would prefer watchful waiting to active treatment if PSA suggested cancer:
<table>
<tr><th colspan="2">Study 1</th><th colspan="2">Study 2</th></tr>
<tr><th>Control</th><th>SDP</th><th>Control</th><th>SDP</th></tr>
<tr><td>26.4%</td><td>63.2%</td><td>39.5%</td><td>85.9%</td></tr>
</table>
• testing preference: compared with men in the control groups, men in the intervention groups of both studies, after viewing the SDP, were less likely to report that they have PSA screening within the next 2 years.

% of subjects who reported that there was a high probability of them having PSA testing within the next 2 years:
<table>
<tr><th colspan="2">Study 1</th><th colspan="2">Study 2</th></tr>
<tr><th>Control</th><th>SDP</th><th>Control</th><th>SDP</th></tr>
<tr><td>89.7%</td><td>73.9%</td><td>67%</td><td>30.4%</td></tr>
</table>
• actual use of PSA testing: compared with men in the control groups, men in the intervention groups of both studies, after viewing the SDP, were less likely to have PSA screening at the next opportunity. This difference did not reach statistical significance in Study #1 (free PSA screening group), but was highly significant in Study #2 (scheduled clinic group).

% of subjects having PSA screening at next opportunity:
<table>
<tr><th colspan="2">Study 1 (Free PSA Clinic)</th><th colspan="2">Study 2 (Internal Medicine Clinic)</th></tr>
<tr><th>Control</th><th>SDP</th><th>Control</th><th>SDP</th></tr>
<tr><td>100%</td><td>98.4%</td><td>22.6%</td><td>11.7%</td></tr>
</table>
Authors’ Comments
• differences in methods and timing between the two studies precluded interpretations comparing response levels across the studies.
• the relative merits of the SDP as compared with alternative methods of informing patients remain to be tested.</td>
</tr>
</table>

Abbreviations: BPH, benign prostatic hyperplasia; GHC, Group Health Cooperative of Puget Sound; KP, Kaiser Permanente, Inc.; PSA, prostate-specific antigen; SDP, shared decision-making program; TURP, transurethral resection of the prostate