

Modifying Unwarranted Variations In Health Care: Shared Decision Making Using Patient Decision Aids

A review of the evidence base for shared decision making.

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ABSTRACT: Shared decision making is the process of interacting with patients in arriving at informed values-based choices when options have features that patients value differently. Patient decision aids (PtDAs) are evidence-based tools designed to facilitate that process. Numerous randomized trials indicate that PtDAs improve decision quality and prevent overuse of options that informed patients do not value. Therefore, they have a potential role in reducing unwarranted variations in the use of preference-sensitive health care options. However, barriers to their widespread use need to be addressed with coherent plans for ensuring good standards, improving access to PtDAs, training practitioners, testing practice models, and launching demonstration projects.

MANY DECISIONS IN HEALTH CARE do not have clear answers because the benefit/harm ratios are either scientifically uncertain or sensitive to the value patients place on benefits versus harms. Common examples include options for treating abnormal uterine bleeding, benign prostate enlargement, chronic back pain, and early-stage breast or prostate cancers. John Wennberg and colleagues define these decisions as “preference-sensitive” because the best choice depends on patients’ values or preferences for the benefits, harms, and scientific uncertainties of each option.¹

There can be wide regional practice variations in the use of preference-sensitive options; for example, the likelihood of having a prostatectomy or hysterectomy varies two- to fivefold from one region to another.² These variations may be “un-

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warranted” if they are not consistent with the distributions of informed patients’ preferences. To optimize the use of preference-sensitive options so that they are taken up only by informed patients who value the benefits more than the harms, a “shared decision-making” style of counseling is advocated. This involves practitioners communicating personalized information on options, outcomes, probabilities, and scientific uncertainties, and patients communicating the personal value or importance they place on benefits versus harms so that agreement on the best strategy can be reached. To streamline the process, evidence-based patient decision aids (PtDAs) have been developed as adjuncts to counseling.

In this paper we define and review the evidence base for shared decision making and PtDAs. We provide an important policy context for their widespread adoption—not only because they improve decision quality, but also because of their potential to reduce unwarranted variations in the provision of preference-sensitive health care options. Finally, we outline strategies for reducing barriers to the use of PtDAs, and we highlight policy issues, particularly in reference to current trends in consumer-directed health care.

Definitions And Evidence Review

When there is no clearly indicated “best” therapeutic option, shared decision making is the process of interacting with patients who wish to be involved in arriving at an informed, values-based choice among two or more medically reasonable alternatives (which may include “watchful waiting”). PtDAs are standardized, evidence-based tools intended to facilitate that process. They are designed to supplement rather than to replace patient-practitioner interaction. At a minimum, PtDAs provide information about the options and their relevant outcomes. They also help patients personalize this information, understand that they can participate in decision making, appreciate the scientific uncertainties inherent in their choices, clarify the personal value or desirability of potential benefits relative to potential harms, communicate their values to their practitioners, and gain skills in collaborative decision making.

PtDA development has been guided by several different decision theory and transactional frameworks from economics, psychology, and sociology.³ They have been delivered using diverse print, video, or audio media, but there is a current shift toward Internet-based delivery systems. PtDAs are self- or practitioner-administered; they are used in one-to-one or group situations. Most are designed to prepare patients for personalized counseling; however, the timing of their integration into the process of care depends on practitioners’ usual counseling practices and feasibility constraints.

Regardless of the framework, medium, or implementation strategy, there are three key elements common to their design.⁴ (1) Information provision: For a given clinical condition, decision aids include high-quality, up-to-date information about the condition or disease stimulating the need for a decision, the available

health care options, the likely outcomes for each option, the probabilities associated with those outcomes, and the level of scientific uncertainty. The information is clearly presented as a “choice situation,” in a balanced manner, so as not to persuade the viewer toward any particular option, and in sufficient detail to permit choosing among the options.

(2) Values clarification: Several methods are used to help patients sort out their “values”—that is, the personal desirability or undesirability of different features of the available options. First, patients are better able to judge the value of options that are familiar and easy to imagine. Therefore, PtDAs describe what it is like to experience the physical, emotional, and social consequences of the procedures involved and the potential benefits and harms. Second, balanced examples of how others’ values influenced their choices help patients learn how their values matter in decisions. Third, some PtDAs directly engage patients in revealing their values using balance scales, relevance charts, or trade-off techniques. For example, in balance scales, patients use the familiar one-to-five-star rating system to deliberate about the degree of personal importance associated with each possible outcome. Such visual ratings also help family members and practitioners to understand at a glance which benefits and harms are most or least salient to a particular patient.

(3) Guidance or coaching in deliberation and communication: PtDAs are designed to improve patients’ confidence and skills by guiding them in the steps involved in decision making and by showing them how to communicate values and personal issues to families and practitioners. Personal coaching by nurses or other professionals can also be used to guide patients through deliberation and communication. Once patients understand what is at stake in a “close call” situation and appreciate the importance of clarifying their personal values, they can meaningfully decide and communicate whether they wish to be actively involved in the health care decision.

The International Cochrane Collaboration Review Group on Decision Aids recently updated its ongoing systematic review of randomized controlled trials of PtDAs; there are thirty-four published U.S., Canadian, and U.K. trials, and another thirty or more trials are ongoing. We briefly describe the main results from this eighty-page technical document, focusing on decision quality, uptake of options, and cost-effectiveness.⁵

■ **Decision quality.** The systematic review indicated that when PtDAs are used as adjuncts to counseling, they have consistently superior effects relative to usual practices on the following indicators of decision quality: increased knowledge scores, by 19 points out of 100 (95 percent confidence interval: 13, 24); improvements in the proportion of patients with realistic perceptions of the chances of benefits and harms, by 40 percent (95 percent CI: 10 percent, 90 percent); lowered scores for decisional conflict (psychological uncertainty related to feeling uninformed), by 9 points out of 100 (95 percent CI: 6, 12); reduced proportions of patients who are passive in decision making, by 30 percent (95 percent CI: 10 percent, 50 percent); re-

duced proportions of people who remain undecided after counseling, by 57 percent (95 percent CI: 30 percent, 70 percent); and improved agreement between a patient's values and the option that is actually chosen. These improvements were accomplished without deleterious effects on patients' satisfaction or anxiety levels.

■ **Uptake rates for different options.** The systematic review reported the uptake rates in sixteen trials, of which seven focused on decision situations involving major elective surgery (Exhibit 1). Six of these seven trials demonstrated 21–44 percent reductions in uptake of the more invasive surgical options, without adverse effects on health outcomes.

In Exhibit 1 it is noteworthy that the one trial that showed a nonsignificant trend toward increasing the rates of surgery also had the lowest rate of surgery in the control group (2 percent). This was a U.K. study that had low referral rates by general practitioners (GPs) to surgeons, because of a shortage of urologists. This observation suggests that PtDAs will not always dampen uptake if the usual practice rates are too low.

EXHIBIT 1
Effect Of Patient Decision Aids (PtDAs) On Elective Surgical Decisions: Preference For More Aggressive Surgery Relative To Conservative Options

| Decision | Decision aid group | | Comparison group | | Relative risk (RR) (95% CI) ^a |
|---|--------------------|-------------------------|------------------|-------------------------|--|
| | Number | Percent choosing option | Number | Percent choosing option | |
| CAN: Coronary revascularization for angina ^b | 86 | 52.3 | 95 | 66.3 | 0.79 (0.62, 1.01)** |
| US: Coronary revascularization for angina ^c | 61 | 41.0 | 48 | 58.3 | 0.70 (0.48, 1.03) |
| UK: Hysterectomy for menorrhagia ^d | 253 | 32.4 | 244 | 41.4 | 0.78 (0.62, 0.99)** |
| US: Mastectomy for breast cancer ^e | 30 | 23.3 | 30 | 40.0 | 0.58 (0.27, 1.28) |
| US: Back surgery ^f | 171 | 25.7 | 173 | 32.9 | 0.78 (0.56, 1.09) |
| US: Prostatectomy for BPH ^g | 103 | 7.7 | 116 | 13.8 | 0.56 (0.25, 1.26) |
| UK: Prostatectomy for BPH ^h | 54 | 11.1 | 48 | 2.1 | 5.33 (0.67, 42.73) |

SOURCES: See below.

NOTES: Overall relative risk was weighted by the sample size of each trial contributing to the overall estimate. BPH is benign prostatic hypertrophy. CI is confidence interval. Pooled RR is 0.77 (0.67, 0.88).

^aRatio of decision aid group to comparison group.

^bM.W. Morgan et al., "Randomized, Controlled Trial of an Interactive Videodisc Decision Aid for Patients with Ischemic Heart Disease," *Journal of General Internal Medicine* 15, no. 10 (2000): 685–693.

^cS.J. Bernstein et al., "A Randomized Controlled Trial of Information-Giving to Patients Referred for Coronary Angiography: Effects on Outcomes of Care," *Health Expectations* 1, no. 1 (1998): 50–61.

^dA.D.M. Kennedy et al., "Effects of Decision Aids for Menorrhagia on Treatment Choices, Health Outcomes, and Costs: A Randomized Controlled Trial," *Journal of the American Medical Association* 288, no. 21 (2002): 2701–2708.

^eR.L.J. Street et al., "Increasing Patient Involvement in Choosing Treatment for Early Breast Cancer," *Cancer* 76, no. 11 (1995): 2275–2285.

^fR.A. Deyo et al., "Involving Patients in Clinical Decisions: Impact of an Interactive Video Program on Use of Back Surgery," *Medical Care* 38, no. 9 (2000): 959–969.

^gM.J. Barry et al., "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* 1, no. 1 (1997): 5–14.

^hE.D. Murray et al., "Randomised Controlled Trial of an Interactive Multimedia Decision Aid on Benign Prostatic Hypertrophy in Primary Care," *British Medical Journal* 323, no. 7311 (2001): 493–496.

**p < .05

Although there are no trials that directly assess the impact of PtDAs on race or sex disparities, the U.K. benign prostatic hypertrophy (BPH) trial suggests that PtDAs may promote uptake in surgery when rates are arguably “too low.” Therefore, PtDAs may address unwarranted variations stemming from both underuse and overuse of options, thereby reflecting the true underlying distribution of informed patients’ preferences.

■ **Cost-effectiveness.** Three U.K. trials have evaluated the effects of PtDAs on costs and resource use in managing menorrhagia, menopause, and BPH.⁶ In all three trials, the costs involved in achieving higher decision quality were either comparable to or less than the costs incurred in regular care. For example, in the trial involving menorrhagia, a video-based PtDA with nurse coaching generated the lowest mean cost (US\$1,566), compared with a video-based PtDA alone (US\$2,026) or usual care (US\$2,751); cost savings were largely attributable to lower hysterectomy rates and therefore to lower hospital costs.

Note, however, that each of these studies evaluated the costs of PtDAs within the context of a single condition and at a specific decision point. For a more complete picture—particularly for chronic disease management—we need cost-effectiveness analyses for “suites” of PtDAs that address the range of therapeutic decision points for a particular condition. On the one hand, some PtDAs in a suite may increase the uptake of procedures in areas or subgroups with unwarranted underuse—that is, in areas or subgroups with rates lower than would be observed if patients’ informed preferences were truly incorporated. On the other hand, these cost increments may be offset by other PtDAs that prevent subsequent unwarranted overuse of other expensive procedures. It is, therefore, important to look at the impact of costs for long-term management of a given condition.

Lowering Barriers To The Widespread Use Of PtDAs

Despite the recent evidence of the benefits of PtDAs, widespread implementation has yet to occur. Four unique barriers or facilitators to their implementation in general and in specialty medical practices have been identified: (1) awareness of the existence of an appropriate PtDA for a particular clinical decision situation; (2) accessibility to PtDAs, with practitioners recommending that access needs to be smooth, automatic, and timely; (3) acceptability issues, with practitioners recommending that PtDAs need to be compatible with their practice and personal beliefs, up-to-date, attractive, and easy to use; and not require additional cost, time, or equipment; and (4) motivations to use PtDAs such as saving time, avoiding repetition, not requiring extra calls from patients, potentially decreasing liability, and potentially reducing wait-list pressures.⁷ These barriers or facilitators may be addressed with several essential strategies: ensuring good standards, improving access to PtDAs, training practitioners in their use, testing practice delivery models, and demonstration projects.

■ **Setting quality standards.** Since 1999 the number of PtDAs in the interna-

tional Cochrane Collaboration Inventory has expanded from 17 to more than 500; most PtDAs are now developed by commercial or not-for-profit organizations. To reduce the risk of patients being exposed to low-quality PtDAs that may not have the intended effects or are designed to promote vested interests, the development and widespread acceptance of at least minimal quality standards is a timely and important enterprise. To date, the Cochrane Collaboration on Decision Aids has used six basic criteria (called “CREDIBLE”) to rate the quality of PtDAs: C = competent developers and development; R = recent; E = evidence-based; DI = disclosure of conflicts of interest; BL = balanced presentation of options, benefits, harms; and E = efficacious. A second generation of quality standards is being developed, using an international consensus process and key stakeholders such as developers, producers, users, and payers. Once criteria are developed, ensuring that PtDAs meet these criteria is an important policy question. There is no accreditation body that evaluates and approves PtDAs.

■ **Improving access.** The Cochrane Collaboration Review Team is also compiling and managing a clearinghouse of PtDAs. There are two databases: an inventory of more than 200 available PtDAs that have been evaluated using the CREDIBLE criteria, and a complete database of more than 500 known PtDAs in various stages of development. The National Cancer Institute (NCI) also has a list of approved PtDAs, which requires that the specific versions have been evaluated in randomized clinical trials in oncology. Similarly, the U.S. Centers for Disease Control and Prevention (CDC) has developed and made available several PtDAs on its Web site.⁸ Although there are criteria and review processes involved in selecting the aids on these sites as well, there is no standardized set of criteria.

■ **Practitioner training.** Providing high-quality PtDAs to patients at appropriate times in their care may help offset some of the forces driving unwarranted variations in preference-sensitive care. However, simply disseminating PtDAs does not really constitute shared decision making. Ideally, there should be parallel efforts to help practitioners acquire skills in providing decision support in close-call situations, including the judicious use of good PtDAs. This requires the creation and implementation of basic curricula and continuing education programs. To this end, online “auto-tutorials” have been developed for nurses, introducing fundamental concepts and demonstrating the principles of shared decision making in selected case studies.⁹ Medical curricula and continuing medical education (CME) programs are in the early stages of development. It may be desirable to use undergoing training in shared decision making as an indication of provider quality.

■ **Models for providing patient decision support.** Decision support as a consciously planned clinical intervention is particularly needed for highly prevalent preference-sensitive situations in which poor-quality decision making is likely to generate unwarranted disparities in health care. There are several models that could be used to provide this clinically based decision support.

Clinic or hospital-based models. One model involves expanding the role of estab-

lished patient education programs. These services tend to focus on specific, recommended interventions; they could be expanded to provide systematic decision support for patients grappling with choices among two or more clinically acceptable options.

This model has the distinct advantage of fitting PtDAs into ongoing divisions and processes for providing information to patients before services are provided. The disadvantages include the potential for inappropriately providing PtDAs after the decision for an intervention has already been made and the difficulty of introducing the concept of choice into a process that is generally designed to persuade patients about the “right” choice. Finally, patient educational services are generally found only in large clinics or hospitals; even in these settings, these services are generally not billable and so are vulnerable to downsizing or elimination of those that are not mandated.

One possible route around this difficulty is to reimburse practitioners or clinics for providing decision support. For example, the Center for “Information Therapy (Ix)” (an advocacy group headed by Donald Kemper) is lobbying for reimbursement of practitioners who give “prescription strength” information tailored to individuals’ needs (that is, the right information for the right patient at the right time), as part of the regular process of care.¹⁰

Freestanding models. Patients’ and providers’ use of the Internet for health information is a growing presence in today’s health care environment. The database maintained by the Cochrane Collaboration Review on Decision Aids and the NCI’s and CDC’s PtDAs described above are examples of free, publicly available repositories of PtDAs that have met minimum review criteria and are vetted by groups without proprietary or financial interests in the decisions or decision aids. Although widespread dissemination is aided by easily accessible, free, juried PtDAs, the Internet can guarantee neither the quality of the aids nor the timeliness and appropriateness of their provision to patients. Moreover, the Internet is not equally accessible to all groups and thus is not particularly well suited to addressing disparities in unwarranted variation in preference-sensitive care.

Insurance-centered models. Implementation of PtDAs by insurance plans ranges from passive support (responding only to patients’ or providers’ requests or reimbursing for their use) to active processes that help facilitate their use in clinical settings. One model is an expansion of current nurse call centers, which are generally supported by insurance plans. Health Dialog’s nurse call centers have already added decision support for preference-sensitive options to their triage and management programs for chronic conditions. This extension to management programs is particularly efficient because the chronically ill are most likely to face preference-sensitive options, and decision points can often be anticipated, thereby permitting the provision of PtDAs in a timely sequence without requiring the patient to initiate the request.

However, health plan–supported call centers offering a decision-support ser-

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vice face a difficult challenge. Linking this service to the actual practice sites where decision making about therapy takes place is a complex undertaking. The patient’s provider may not be aware or supportive of the PtDAs and preference-based patient choice. The provider may not be the most appropriate provider for advising and referring patients to alternative choices; for example, there may be only one surgeon who does not perform both available options. Moreover, this model is generally connected to an insurance plan, and providers often care for patients insured by many different insurers. It is difficult for practitioners to have coherent, feasible strategies based on shared decision making, if their patients are insured by diverse plans that collectively offer no or different types of decision support services and may not cover all choices described.

To date, the voluntary provision of PtDAs (outside of research sites) has usually been by insurance plans closely linked to a specific set of providers, such as health maintenance organizations (HMOs) or Veterans Affairs Medical Centers (VAMCs). In such settings, it is easier to ensure that all enrollees have potential access to PtDAs in clinical settings, and there is greater provider “buy-in” to their use.¹¹ Two advantages of these models include the ability to avoid the confusion that arises when providers treat patients from a variety of insurance plans, and the ability to reach disadvantaged subgroups, such as Medicaid recipients and veterans, who are commonly covered by these insurance plans.

Nonetheless, the majority of current “managed care” plans are not closely linked to a specific network of providers. So, although integrated delivery systems have the potential incentive to incorporate and promote rational and timely use of PtDAs, such systems that restrict patients’ choice of providers are increasingly unpopular, and insurance plans are becoming less tightly coupled to integrated delivery systems.¹²

However, insurance plans have other reasons to promote the clinical use of PtDAs. James Robinson and others have observed that insurance plans are reinventing themselves to try to contain costs by rewarding cost-conscious choices, passing along negotiated price discounts, and offering a limited number of management services—particularly for chronic illnesses—but are otherwise backing out of restrictions on decisions about what consumers receive.¹³ Congress, too, is considering rewarding cost-conscious choices in government-based insurance plans such as Medicare. Employers are beginning to offer “consumer-driven health plans”—a diverse set of plans that use high deductibles and health reimbursement arrangements—to foster patient-directed, cost-conscious medical care choices by exposing patients to financial risk depending on those choices.¹⁴

Some have hailed these new manifestations as the salvation of the U.S. health

care system. Others have drawn the obvious parallel between consumer-driven health plans and the need for consumer decision aids, arguing that placing patients at greater financial risk for their use of health care makes it even more important that patients be well informed about preference-based choices, including the financial implications.¹⁵ However, analysts such as Karen Davis challenge the appropriateness of adding financial risk to choices for the poor or for people with very costly care or chronic illnesses.¹⁶ Although the arguments do not focus on PtDAs per se, these concerns imply an expanding need for their use, coupled with a responsibility to examine whether financial risk is borne fairly and whether financial risks overwhelm all other preference-based considerations, particularly for the poor or for patients facing decisions involving very-high-cost care.

In sum, the three models for implementing PtDAs in a clinical context—provider-based, freestanding, or insurance-based—all offer advantages and disadvantages regarding feasibility and effectiveness. Current trends in insurance plans increase the importance and urgency of understanding the optimal ways to integrate these models into clinical decision making and how and when they can improve the quality of the individual patient's choice and satisfaction with it.

In the specific context of evaluating PtDAs' ability to help reduce unwarranted variation in preference-based care, we also need to evaluate how their use affects the distribution of choices made and whether they improve the fairness of that distribution across groups. The body of evidence to date suggests that informed patients tend to prefer the least intensive alternative, regardless of direct links to their own financial risk. This pattern may result in less costly care in general; however, for disadvantaged groups or areas with low use of preferred treatments, PtDAs may lead to increased costs. One way to deal with this dilemma when attempting to redress underuse by the disadvantaged is to eschew the focus on patients' financial incentives in favor of using PtDAs, which help patients make preference-based choices while generally resulting in less costly care.

■ **Next steps: demonstrations.** To increase our understanding of these important policy implications, we propose demonstration projects, with three principal goals. First, we need to confirm the feasibility of building and sustaining patient decision-support systems that improve decision quality. A second objective is to confirm the cost-effectiveness of providing systematic decision support for an array of preference-sensitive choices. Resources saved by preventing unwarranted overuse of one kind of preference-sensitive intervention could be used to rectify inappropriate underuse of another. To clearly assess the overall desirability of redistributions arising from a decision support service, the financial system supporting such a demonstration project would need to be both population-based and within the context of an integrated system of incentives. Finally, demonstration projects can help establish the feasibility of widespread implementation and their potential impact on variations in care and disparities by race, sex, and socioeconomic level in particular.

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