



Should patient decision aids (PtDAs) be introduced in the health care system?

November 2005

ABSTRACT

This is a Health Evidence Network (HEN) report on the use of patient decision aids (PtDAs), interventions designed to help patients discuss treatment options with their clinicians and make specific, deliberative choices. They are used as an adjunct to counselling (not a replacement).

Most evidence included in this report shows that PtDAs are superior to comparison interventions in improving indicators of decision quality such as knowledge of the facts about options, realistic perceptions of outcome probabilities, and agreement between patients' values and choice. In addition, patients who used decision aids had lower decisional conflict, participated more actively in decision-making, and were less likely to remain undecided.

PtDAs support patients in making evidence-informed choices and may be able to assist policy-makers in setting benchmarks for over-use of grey zone treatments (those treatments that rely upon the patient's judgement of associated benefits versus harms).

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Summary

The issue

“Grey zone” treatments are those that rely upon the patient’s judgement of associated benefits versus harms. When clinicians judge patients are eligible for “grey zone” treatments, their acceptance should be consistent with informed patients’ values. The question is how can one obtain informed patient values? Patient decision aids (PtDAs) are interventions designed to help patients discuss treatment options with their clinicians and make specific, deliberative choices. They are used as an adjunct to counselling (not a replacement). The aim of PtDAs is to improve decision quality and to reduce unwarranted practice variations. There are over 500 PtDAs, many of which are available on the Internet.

Findings

This synthesis summarized the results of 23 PtDAs for treatment decisions that were evaluated in 29 randomized controlled trials. Most of these trials demonstrated that PtDAs were superior to comparison interventions in improving indicators of decision quality such as knowledge of the facts about options, realistic perceptions of outcome probabilities, and agreement between patients’ values and choice. In addition, patients who used decision aids had lower decisional conflict, participated more actively in decision-making, and were less likely to remain undecided. Exposure to PtDAs reduced opting for elective invasive surgical procedures in favour of conservative options by 24%, without adverse effects on patients’ health outcomes, satisfaction, or anxiety. The effects on other treatments were more variable. There is insufficient evidence on the effects of PtDAs on continuance of chosen options, implementation of PtDAs in diverse patient populations, and cost-effectiveness.

Policy considerations

The quality of decisions for grey zone treatment options is inadequate and is likely to be leading to over-use of treatment options that informed patients don’t value. PtDAs support patients in making evidence-informed choices and may be able to assist policy-makers in setting benchmarks for over-use of grey zone treatments, so resources could be freed up to promote the choice of more effective treatments. Given the proliferation of PtDAs in recent years, universally accepted quality standards for the development and evaluation of PtDAs are needed. Furthermore, PtDA service delivery models (including practitioner training) should be developed in diverse populations, with evaluation of the effects of PtDAs on decision quality and variations in use of health services and costs.

Type of evidence used in this review

This review is based on a systematic review of randomized controlled trials evaluating the effectiveness of PtDAs.

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Introduction

Treatments decisions with adequate scientific evidence on outcomes can be classified as “black” (harmful: harms far outweigh benefits) or “white” (effective: benefits far outweigh harms) or “grey” (close call/values-sensitive: best choice depends on how patients value benefits versus harms) (1,2). The goal in evidence-based medicine is to reduce the over-use of black zone treatments and improve the under-use of white zone treatments with professional and patient education, organizational changes, and funding incentives (1,3). For grey zone decisions, it is more difficult to judge over-use and under-use of options (4-9). However, we do know that the rates of uptake of these treatments vary remarkably. In contrast to white zone surgical procedures with little regional variation (for example, surgery for hip fracture or colon cancer), the uptake of grey zone surgical options (for example, hip replacement or surgery for prostate cancer) can vary 2 to 5 fold (1,10,11). Other examples include hysterectomy for uterine bleeding, prostatectomy for benign prostate enlargement, surgery for herniated disk, mastectomy for breast cancer, or coronary bypass for stable angina. This year, the International Patient Decision Aids Standard Collaboration (www.ipdas.ohri.ca) has reached a consensus on a benchmark for grey zone decisions: when clinicians judge that patients are eligible for grey zone treatments, their uptake should be consistent with the distribution of informed patients' values.

The question is - how can one obtain informed patient values? Studies show that clinicians are poor judges of patients' values and patients often have unrealistic expectations of treatment benefits and harms. Therefore, two types of experts are needed to judge options: clinicians to provide technical information on options, outcomes and probabilities, and patients to judge the value of good and bad outcomes (for example, does potential relief of symptoms warrant the risks of complications?). Only a surgeon can judge whether a patient is a candidate for the surgical option of hysterectomy but only a patient can judge whether her uterine bleeding problems are bad enough to warrant the risks of hysterectomy. The approach taken to discuss and reach agreement on options has been labelled “shared decision making” or “evidence-informed choice” (12-15). To streamline the process, evidence-based patient decision aids (PtDAs) have been developed as adjuncts to consultation to prepare people to participate in decision-making (16,17).

Patient decision aids (PtDAs) are adjuncts to counselling (not replacements) to prepare patients to discuss treatment options with their clinicians (17). They differ from conventional education programs by presenting balanced, personalized information about options in sufficient detail for so that patients are better able to judge their value. The aim of a PtDA is to improve decision quality and to reduce unwarranted practice variations by: providing facts about the condition, options, outcomes, and probabilities; clarifying patients' values (the outcomes that matter most to them); and guiding patients in the steps of deliberation and communication so that a choice can be made that matches their informed values. As detailed in Box 1, key elements include: facts, risk communication, values clarification, structured guidance and balanced display. There are over 500 PtDAs registered in the Cochrane Collaboration inventory (www.ohri.ca/decisionaid). PtDAs are delivered as self-administered or practitioner-administered tools in one-to-one or group sessions. The media of delivery vary, and most developers are moving toward internet-based presentations.

Box 1. Patient Decision Aids: Essential Elements (17)

- **Facts** on the condition, options, and outcomes relevant to the patient's health status;
- **Risk communication** on the chances of outcomes and the level of scientific uncertainty;
- **Values clarification** to ascertain which benefits, harms and scientific uncertainties matters most to the patient;
- **Structured guidance** in the steps of deliberating and communicating with the personal health practitioner;
- **Balanced display** of positive and negative features of options.

The purpose of this synthesis is to summarize the evidence from randomized controlled trials evaluating the effectiveness of PtDAs for informing health treatment decisions.

Sources for this review

The sources of evidence included:

- Our 2003 Cochrane systematic review of randomized trials that were published between 1966 and August of 2002. In the review there were 34 randomized controlled trials of screening and treatment PtDAs, of which 22 focused on treatments (17). This current synthesis focused on trials of PtDAs focused solely on treatments.
- An update of our Cochrane systematic review with 7 additional trials published as late as August 2004.

See Annexes 1 and 2 for details of the literature search, study selection criteria, and characteristics of the PtDAs evaluated within the trials.

Outcome measures

The primary measures evaluating PtDAs were indicators of “decision quality” as defined by the International Patient Decision Aids Standard Collaboration (www.ipdas.ohri.ca), which is the extent to which a decision is informed and based on personal values. Measures included: knowledge about options and outcomes, realistic perceptions of outcome probabilities, and agreement between patients' values and choice.

Secondary measures focused on:

- quality of decision making process: decisional conflict, participation in decision making, number of patients remaining undecided, satisfaction with decision making, patient-practitioner communication;
- behaviour: choice and adherence;
- health outcomes: anxiety, health status (generic and condition-specific);
- economic measures: costs and cost-effectiveness.

It may be difficult to understand why health outcomes are not the primary outcome. As discussed earlier, PtDAs are used for grey zone close call decisions with benefit/harm ratios that patients value differently. For example, the survival rates between prostatectomy and radiation treatment for early stage prostate cancer are similar, but the harm/side effect profiles differ. Therefore, the best choice for a patient is the one which is less likely to result in harms/side effects a patient most wants to avoid. Patients wishing to avoid impotence and urinary incontinence most should avoid surgery and those wishing to avoid bowel problems most should avoid radiation therapies. Similarly, it may be reasonable for two women with

similar bothersome menopausal symptoms unrelieved by conservative measures to choose differently because of different values for benefits (symptom relief) versus harms (stroke, blood clots, breast cancer).

Findings

Twenty-nine randomized controlled trials of 21 treatment PtDAs were analysed; the origin of the studies were: 7 European, 11 Canadian and 11 American (18-49).

The main treatment decisions focused on options for abnormal uterine bleeding, benign prostatic hyperplasia, prostate cancer, breast cancer, heart disease, herniated disc, and menopause (see Annex 2). Nineteen trials compared PtDAs to standard care or usual care. Ten trials compared simpler PtDAs to more detailed PtDAs. Most PtDAs included several of the elements outlined in Box 1.

A summary of the meta-analyses of the effects of the PtDAs compared to either standard care or simpler PtDAs is presented in Table 1.

Table 1: Summary of PtDA effects on decision quality and the decision making process

Outcome	Comparator	Number of trials	N in PtDA group	N in comparator	Pooled weighted differences (95% CI)
Primary decision quality outcomes (informed, values-based)					
Knowledge of options and outcomes (0 to 100 scale)	Standard care only	7	667	699	WMD 17.09 (10.6, 23.6)*
	Simple PtDA	7	389	373	WMD 4.76 (2.54, 6.97)*
Realistic expectations of outcomes with and without treatment	Standard care or simple PtDA without outcome probabilities	6	644	673	RR 1.57 (1.3, 1.9)*
Match between choice and patients' values (benefits/harms that matter most) **	Simple PtDAs	3	236	229	All three trials showed PtDAs improved the match between values and choice
Secondary decision making process outcomes					
Decisional conflict-perceived uncertainty and related deficits in knowledge, values clarity and support (0 to 100 scale)	Standard care only	6	520	558	WMD -6.9 (-10.8, -3.0)*
	Simple PtDA	5	398	359	WMD -1.1 (-3.8, 1.6)
Proportion remaining undecided	Standard care only	4	440	451	RR 0.42 (0.3, 0.6)*
Participation – practitioner controlled	Standard care only	6	484	504	RR 0.68 (0.5, 0.9)*

CI=Confidence Interval

RR=Relative Risk (Relative Risk of 1 = No difference between proportion (risk) on test PtDA and comparator, >1:greater proportion on test PtDA. CI above/below 1 implies significant increase/reduction in 'risk')

WMD=Weighted mean difference (Average value on test PtDA minus average value on comparator, adjusted for variation in each group. WMD=0: no difference between test PtDA and comparator.)

*p<0.05

** unable to combine results due to different measurement approaches used

Decision quality

Those exposed to PtDAs have a consistent substantial advantage over standard care on important indicators of decision quality such as knowledge, realistic expectations of benefits and harms, and agreement between patient's values and choices (see Table 1). While simpler PtDAs are almost as good as more detailed PtDAs at improving knowledge, they are less effective for the other two indicators of decision quality (expectations and match between values and choice). The small difference in knowledge between patients who had used simple versus detailed PtDAs is likely due to the overlap in key facts provided on options, benefits, and harms. The larger differences in realistic expectations of outcomes and in agreement between values and choice may occur because detailed PtDAs provide probabilities of outcomes to re-align patients' unrealistic expectations of benefits and harms as well as ways for clarifying values such as rating exercises to clarify their personal importance.

Decision-making process

Compared to standard care, PtDAs significantly reduced decisional conflict, the proportion of patients remaining undecided, and practitioner controlled participation (see Table 1). Complex PtDAs had no significant advantage over simpler PtDAs in reducing overall decisional conflict. In general, patient satisfaction with decision making was high both for those who received standard care or used PtDAs (data not shown). One-third of trials (5 of 15) showed some improvement in satisfaction with those who used PtDAs while the other trials found no difference between groups.

Patient health outcomes

In 4 of 7 trials, PtDAs were no more effective than comparison interventions; in the other 3 trials, health status improved on some dimensions of functioning. In 9 of 9 trials, patients' anxiety did not differ between those exposed to PtDAs or comparison interventions.

Uptake of options

In 9 of 11 trials, exposure to PtDAs reduced or showed a trend in reducing the uptake of major elective surgical procedures. The meta-analysis indicated the uptake of surgery was reduced by 24% in favour of more conservative options (see Table 2). There was also a reduced uptake of medications such as hormones for menopause (in 3 of 3 trials (39,40,50)) and warfarin for atrial fibrillation (33). The effects of PtDAs on the uptake of other treatments was more variable with increased uptake of hepatitis B vaccine (22) and no effect on decisions that included chemotherapy for breast cancer (48), circumcision of male newborns (28,32), high blood pressure treatment (35) and minor dental surgery (42). Two trials evaluated the influence of PtDAs on adherence to chosen options, but neither found significant effects (33,44).

Table 2: Effect of PtDAs on major elective surgery decisions

Decision	Country (year published)	PtDA		Comparison		Weight (%)	Relative Risk (95% CI)
		n	% chose	n	% chose		
Mastectomy for breast cancer (49)	CA (2004)	94	6.0%	107	24%	3.26	0.26 (0.11, 0.61)*
Mastectomy for breast cancer (45)	US (1995)	30	23.3%	30	40.0%	3.68	0.58 (0.27, 1.28)
Coronary bypass (21)	US (1998)	61	41.0%	48	58.3 %	9.61	0.70 (0.48, 1.03)
Coronary bypass (37)	CA (2000)	86	52.3%	95	66.3%	13.72	0.79 (0.62, 1.01)*
Orchiectomy for inoperable prostate cancer (19)	Finland (2004)	77	55.8%	88	83.0%	14.65	0.67 (0.54, 0.84)*
Prostatectomy for operable cancer (19)	Finland (2004)	27	63%	18	83.0%	10.38	0.76 (0.53, 1.08)
Back surgery (24)	US (2000)	171	25.7%	173	32.9%	11.05	0.78 (0.56, 1.09)
Hysterectomy (30)	UK (2002)	253	32.4%	244	41.4%	14.23	0.78 (0.62, 0.99)*
Hysterectomy (47)	Finland (2003)	184	53.0%	179	49.0%	15.29	1.08 (0.89, 1.32)
Prostatectomy for benign prostate hyperplasia (20)	US (1997)	103	7.7%	116	13.8%	3.51	0.56 (0.25, 1.26)
Prostatectomy for benign prostate hyperplasia (38)	UK (2001)	54	11.1%	48	2.1%	0.62	5.33 (0.67, 42.73)
Pooled RR 0.76 (0.64, 0.90)*							

*p<0.05

Gaps in evidence and conflicting results

There is insufficient evidence on the effects of PtDAs on adherence to chosen option, cost-effectiveness, and patient-practitioner communication. Furthermore, more sensitive measures are required to determine the effect of PtDAs on patients' satisfaction with preparation for decision-making and emotional status (for example, distress from perceived risk or decision-making).

There have been no randomized controlled trials to evaluate the effect of PtDAs with patients in Eastern Europe.

Strength of the evidence

The evidence summarized in this synthesis report is based on published randomized controlled trials that have been identified using systematic review methods. Randomized controlled trials and systematic reviews can provide the strongest levels of evidence. The main limitations of these trials is that none of the patients or practitioners could be blinded to the intervention and for several trials the sample sizes were too small to detect significant differences between groups.

A challenge in this synthesis was to arrive at conclusions from diverse trials that varied in the decision contexts, design of the PtDAs (content, format, and use), characteristics of comparison interventions and evaluation procedures. Despite this limitation, the results were remarkably consistent across trials in the main indicators of decision quality (knowledge, realistic expectations, match between values and choice) and uptake of major elective surgical procedures. Although there was statistically significant heterogeneity in the pooled results for knowledge and decisional conflict (PtDAs compared to standard care), these differences were no longer significant when the Man-Son-Hing trial was removed. In this trial, the control group knowledge scores were the highest among all trials possibly because the participants were long-term aspirin users participating in another long term study.

Other Important Information

Issues of cost and cost-effectiveness

Three trials have measured the economic impact of using PtDAs. One United Kingdom trial evaluated the cost-effectiveness of PtDAs for women considering hysterectomy for treatment of menorrhagia (30,51). Based on the mean total costs and quality adjusted life years (see Table 3), the decision support intervention that included the patient decision aid and nurse coaching was the least expensive. Calculation of costs included the development and production of the interventions, duration of time by nurse coach, and woman's use of health services over 2 years (diagnostic procedures, medications, therapeutic procedures, hospital days, outpatient physician visits).

Table 3. Comparison of costs and adjusted life years for different decision support aids.

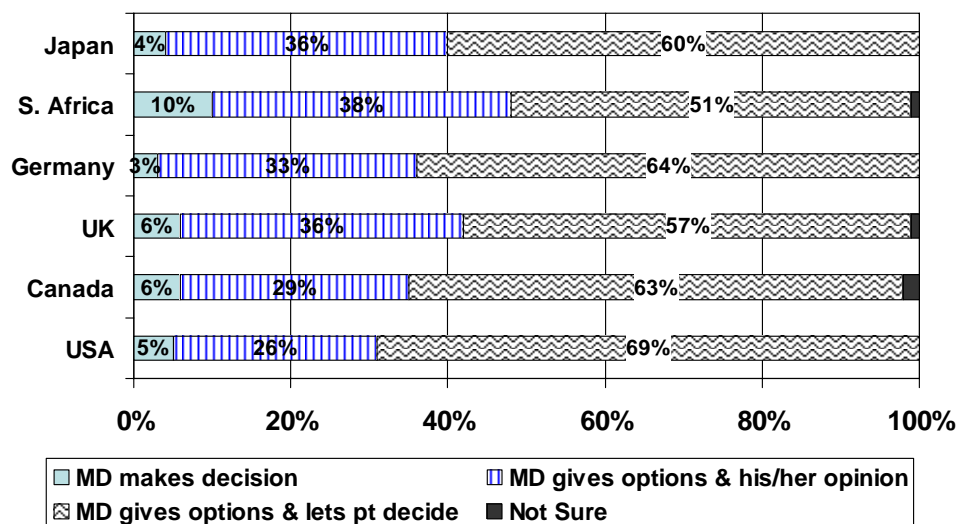
Decision Support for Menorrhagia in the United Kingdom	Average cost per patient	Average quality adjusted life year
Standard Care	£1810	1.572
PtDA video	£1333	1.567
PtDA video and nurse coaching	£1030	1.582

Two other cost minimization trials were conducted in the United Kingdom (38,39), with a focus on treatments for prostate enlargement and hormones for menopause. These trials reported that the PtDA would have been cost-neutral if less expensive delivery methods were used (such as the Internet rather than supplying equipment for interactive videodisks).

Potential social implications

Over the last few decades, there has been a shift from a paternalistic model of decision-making to a shared or consumerist model, in which patients are active participant of care (52-55). Consistently across many countries, over 60% of patients want to take an active role in making their risk-related (“close-call”) health decisions (see Figure 1) (56). This rise in patient participation in health decisions is being driven by enhanced accessibility to health information, informed consent legislation, clinical practice guidelines identifying tradeoffs decisions that require consideration of patient values, and cultural shifts with less deference to authority figures. Although most trials in shared decision making have been conducted in North America, Western Europe, and Australia, it is likely that these findings will be relevant to Eastern European countries with increased patient access to health information and other changes in the delivery of health care services. There is, however, no widespread system in place to support the public’s involvement in health care decisions. The number of PtDAs has proliferated from 17 in 1999 (57) to over 500 in 2004. Their production is moving from academic to commercial and non-profit organizations. It is important that universally accepted quality standards for their development and evaluation be adopted. Otherwise, PtDAs may be used as marketing devices to save costs or to promote the uptake of devices, procedures, or drugs.

Figure 1: Public’s view on who should be mainly responsible for risk-related health decisions (56)



Conditions for successful implementation of PtDAs

There are three essential strategies proposed for successful implementation of PtDAs as part of the process of care (58):

1. Training practitioners to develop skills in shared decision making and using PtDAs: Most practitioners focus on fact-giving with little attention to the influence of values or others’ opinions on the process of decision making (59-62).
2. Improving access to a comprehensive library of PtDAs (see website www.ohri.ca/decisionaid for a listing of 200 available PtDAs): The Cochrane Collaboration review team are currently rating the quality of PtDAs using criteria known as CREDIBLE (C= competent developers and development; R= recent; E= evidence-based; DI= devoid of conflicts of interest; BL= balanced presentation of options, benefits, harms; E= efficacious) (63,64).
3. Developing service models for delivery of PtDAs and provision of decision coaching; current models include:

- a) patient resource libraries (on site or virtual such as NHS-Direct in the UK, Healthwise® an American-based program, BCHealthGuide program in British Columbia);
- b) nurse call centres funded by health plans (e.g. Health Dialog, Boston);
- c) shared decision-making centres linked to practices (e.g. Dartmouth Hitchcock Medical Center, Hanover NH);
- d) fully integrated practice models in which PtDAs and coaching are integrated into care pathways (e.g. UK NHS Urology Service Demonstration Project; Dartmouth Hitchcock Medical Center's Spine Center and Comprehensive Breast Cancer Center).

Ongoing projects

United Kingdom National Health Services (NHS): As part of a Urology initiative of the Modernization Agency, the UK NHS launched a multicentre implementation project to imbed PtDAs in the health service. Health teams adapted care pathways to incorporate PtDAs (for benign prostatic hypertrophy and early prostate cancer). Urology nurses, who normally provide patient education, were trained in decision support and the use of PtDAs. Audits of decision quality and the use of health services before and after implementation were conducted. The decision quality measures (specific questions on the essential information about the options and select questions around patient values) were endorsed by the participating urologists. An interim report was published in March 2005 (65), and a final report is due by the end of 2005. A roll-out beyond the pilot centres is in development.

IPDAS Collaboration: In September 2003, an international group representing several countries, including Australia, Canada, France, Norway, the United Kingdom and the United States, formed the International Patient Decision Aid Standards Collaboration (IPDAS) (www.ipdas.ohri.ca). The aim was to establish a set of international standards that will help people judge the quality of PtDAs. Standards will help people who design and test PtDAs, patients who face the decision, practitioners who counsel patients about the decision, and people who deliver or make decisions about purchasing PtDAs for the public. In June 2005, the collaboration reached agreement on the important criteria and is currently developing checklist(s) to facilitate using these criteria in developing and evaluating PtDAs (6).

Current Debate

An outstanding issue is the optimal approach to implementing PtDAs in health services. Two potential applications that dovetail with current health services priorities in some countries are waiting times and patient safety.

Waiting times for surgery and the policy of guaranteeing a maximum wait time has generally focused solely on length of wait. Alternatively the policy could also focus on decision quality guarantees. PtDAs may increase the likelihood that "right" people are on the waiting lists, namely those who have made informed values-based decisions. The impact of PtDAs on uptake of procedures may also shift the need for facilities, for example from surgical suites for prostate surgery to radiation facilities for therapy.

The second area of application is patient safety. There is a trend in PtDAs to include medical error rates (such as blood transfusion errors) and level of service needed to ensure safe care (such as staffed facilities for timely emergency caesarean section if a woman chooses vaginal birth after a previous caesarean). With emerging scientific evidence of harms related to some treatments – hormone replacement therapy, cox2 inhibitors – regulators who inform the public about risks may also find that PtDAs have a role in ensuring that patients understand the chances of harms of procedures as well as their benefits.

Discussion

Patient decision aids are designed to help patients understand health care options, potential benefits and harms, and to participate more fully in grey zone decisions. This review evaluated randomized controlled trials of patient decision aids used for a variety of treatment decisions.

There was consistent evidence that compared with standard care, PtDAs improved knowledge of the options, created realistic expectations of outcomes, reduced difficulty with decision-making and increased participation in the process. Patients were more likely to make decisions consistent with their informed values. Exposure to PtDAs significantly reduced the uptake of major elective surgery, increased uptake of Hepatitis B vaccination, and had mixed effects on the uptake of other treatments. There was no evidence that the PtDAs had an effect on patients' anxiety and few trials have evaluated costs.

Generalizability of findings

Only seven of the trials were undertaken in Europe, all in the North or West. Therefore it is unclear how this evidence relates to other countries in Europe, where patient involvement in health care decision-making may be less advanced and general communication processes and health care services may be quite different.

Policy considerations

The quality of decisions for grey zone treatment options is inadequate and is likely to be leading to over-use of treatments that informed patients do not value. PtDAs support patients in making evidence-informed choices and could be used to assist policy makers in setting benchmarks for over-use of grey zone treatments, thus freeing resources to promote more effective treatments. Moreover, in setting policies regarding waiting lists for radiation treatments, planners and policy-makers should take into account not only time-to-treatment benchmarks but also decision quality benchmarks. The potential shifting of choices could also affect facilities' planning; for example, the increasing need for surgical suites may be less compelling than the need for radiation facilities if informed patient choice is obtained through use of PtDAs.

It is important that universally accepted quality standards for the development and evaluation of PtDAs be adopted. Furthermore, there is a need to develop service models for their use, including training for practitioners to develop skills in shared decision-making.

Conclusions

Research on a selection of PtDAs shows that these evidence-based tools significantly improved the quality of patients' decision-making when the choice of treatments was difficult and depended on individual values relating to benefits and harm. As there are now over 500 PtDAs, it is essential that quality standards be adopted for their development and evaluation. Furthermore, there is a need to develop large scale implementation projects to fully evaluate service delivery models in diverse populations.

Annex 1. Synthesis methods

This synthesis report is based on the randomized controlled trials (RCT) evaluating patient decision aids (PtDAs) for treatment decisions only that were reported in a systematic review of PtDAs for treatment and screening decisions (17). The search of PtDAs for treatment decisions was updated by searching the following data sources:

- a) electronic databases from August 2001 to August 2004 (MEDLINE, PsycINFO, CIHAHL, Aidsline, and Cancer Lit);
- b) Cochrane Controlled Trials Register (2004, Issue 2);
- c) hand-searching of reference lists of included articles, tables of contents of journals frequently reporting DA studies, websites of funded research projects, and personal files;
- d) contact with known developers and evaluators through a shared decision making list-serve and e-mail contacts up to August 2004.

Search terms used combinations of the following keywords: choice behaviour, decision making, decision support techniques, choic\$, preference\$, patient\$, consumer\$, decision\$, patient compliance, consumer satisfaction, health seeking behaviour, help seeking behaviour, health education, and consumer participation. (\$indicates the use of a wildcard.)

RCTs published in any language were considered. To be included, RCTs had to evaluate PtDAs with people who were making treatment decisions about themselves, for a child or for an incapacitated significant other. PtDA was defined as interventions designed to help people make specific, deliberative treatment choices among options (including the status quo), by providing, at a minimum, information about the options and outcomes relevant to a patient's health status. We excluded interventions focused on: decisions about lifestyle changes, hypothetical situations, clinical trial entry, screening investigations, or advanced directives; education programs not geared to a specific decision and interventions designed to promote adherence to or to elicit informed consent regarding a recommended option.

Of a total of 14 366 unique citations identified, 29 involved RCTs of treatment PtDAs. The most common reasons for exclusion included: the trial did not focus on a specific decision or evaluate a hypothetical decision, the intervention did not meet the definition of a treatment PtDA, and the study design was not a RCT.

Two reviewers screened reports on the included RCT and extracted data independently using standard forms. Missing data were obtained from the authors wherever possible.

RCTs were described individually. Results were combined using meta-analysis methods for outcomes with similar measures and if the effects were expected to be independent of the type of decision (for example, PtDAs would be expected to improve knowledge and expectations about outcomes despite the clinical context). Review Manager 4.1 (2000) was used to estimate a weighted treatment effect (with 95% confidence intervals), defined as weighted mean differences for continuous measures and pooled relative risks for dichotomous outcomes. To facilitate ease of analysis, some scores, such as knowledge, were converted to percentages. All data were analyzed with a random effects model due to the diverse nature of the RCTs.

Annex 2. The characteristics of the randomized controlled trials selected for this synthesis

Note: excluded studies with reasons for exclusion are described in detail in the Cochrane Review of Patient Decision Aids (17).

Source, Year, Location	Number of Enrolees in Intervention + Comparison; Options Considered	Outcomes Measured	Comparison of Most and Least Intensive Intervention	Elements in PtDAs				
				Options & outcomes	Clinical problem	Outcome probability	Values clarification	Guidance in steps of DM
Auvinen 2001; 2004 Finland	103 + 100 men; prostate cancer treatment	- uptake of options - participation in decision making	Pamphlet PtDA created for the trial	X	--	X	--	--
			Standard care by clinical guideline	--	--	--	--	--
Barry 1997; US	104 + 123 men: benign prostate hypertrophy treatment	- uptake of options - knowledge -satisfaction -health outcomes	Interactive videodisc PtDA from Foundation for Informed Medical Decision Making (US)	X	X	X	--	--
			Standard care	--	X	--	--	--
Bernstein 1998; US	65+53 patients: ischemic heart disease treatment	-uptake of options -knowledge -satisfaction -health outcomes	Video-cassette PtDA from Foundation for Informed Medical Decision Making (US)	X	X	X	--	--
			Standard care	--	--	--	--	--
Clancy 1988; US	753+263 physicians: Hepatitis B vaccine	-uptake of options	Pamphlet + decision analysis PtDA	X	X	--	X	X
			Standard care	--	--	--	--	--
Davison 1997; CA	30 + 30 men: prostate cancer treatment	-participation in decision making -anxiety	Written materials PtDA and audiotape of consultation	X	X	X	--	--
			Standard care	--	X	--	--	--

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Source, Year, Location	Number of Enrolees in Intervention + Comparison; Options Considered	Outcomes Measured	Comparison of Most and Least Intensive Intervention	Elements in PtDAs				
				Options & outcomes	Clinical problem	Outcome probability	Values clarification	Guidance in steps of DM
Deyo 2000; Phelan 2001; US	190+203 patients: herniated disc or spinal stenosis treatment	-uptake of options -knowledge -satisfaction -health outcomes	Interactive videodisc PtDA from Foundation for Informed Medical Decision Making (US)	X	X	X	--	--
			Simple PtDA pamphlet	X	X	--	--	--
Dodin 2001; CA	52+49 women: hormone replacement therapy	-preferred option -knowledge -decisional conflict -realistic expectations -match values & choice	Audiotape booklet PtDA from Ottawa Health Decision Centre	X	X	X	X	X
			Simple PtDA pamphlet from professional society	X	X	--	--	--
Dunn 1998; US	143+144 parents: infant polio vaccine schedules	- knowledge	Video and pamphlet PtDA created for the trial	X	X	X	--	--
			Standard care	--	X	--	--	--
Goel 2001; CA	86+50 women: breast cancer surgery	-knowledge -decisional conflict -decisional regret -anxiety	Audiotape and booklet PtDA created for the trial	X	X	X	X	X
			Simple PtDA pamphlet from professional society	X	X	--	--	--
Herrera 1983; US	56+47 parent(s): circumcision male newborns	-uptake of option	Pamphlet PtDA created for the trial	X	X	X	--	X
			Standard care	--	--	--	--	--
Kennedy 2002; UK	300 + 298 women: menorrhagia treatment	-uptake of option -satisfaction -health outcomes -cost-effectiveness	Video plus booklet PtDA created for the trial	X	X	X	X	X
			Standard care	--	--	--	--	--

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Source, Year, Location	Number of Enrolees in Intervention + Comparison; Options Considered	Outcomes Measured	Comparison of Most and Least Intensive Intervention	Elements in PtDAs				
				Options & outcomes	Clinical problem	Outcome probability	Values clarification	Guidance in steps of DM
Legare 2003; CA	97 +87 women; hormone replacement therapy	-decisional conflict -satisfaction	Audiotape with booklet PtDA from the Ottawa Health Decision Centre	X	X	X	X	X
			Simple PtDA Pamphlet from professional society	X	X	X	--	--
Maisels 1983; US	23+28 parent(s): circumcision male newborns	-uptake of option -proportion remaining undecided	Pamphlet PtDA created for the trial	X	X	--	--	X
			Standard care	--	--	--	--	--
Man-Son-Hing 1999; CA	139+148 aspirin users in atrial fibrillation trial: move to warfarin	-uptake of option -proportion remaining undecided -knowledge -realistic expectations -decisional conflict -satisfaction -participation in decision making -adherence	Audiotape with booklet PtDA from Ottawa Health Decision Centre	X	X	X	X	X
			Standard care	--	--	--	--	--
McBride 2002; US	289+292 women: hormone replacement therapy	-realistic expectations -satisfaction	Pamphlet PtDA created for the trial	X	X	X	X	X
			Standard care	--	--	--	--	--
Montgomery 2003; UK	51+52+55+59 adults; hypertension treatment	-uptake of option -knowledge -decisional conflict -anxiety	Decision analysis PtDA created for the trial	X	--	X	X	--
			Video and booklet PtDA	X	X	--	--	--
			Decision analysis, video booklet PtDA	X	X	X	X	--
			Standard care	--	--	--	--	--

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Source, Year, Location	Number of Enrolees in Intervention + Comparison; Options Considered	Outcomes Measured	Comparison of Most and Least Intensive Intervention	Elements in PtDAs				
				Options & outcomes	Clinical problem	Outcome probability	Values clarification	Guidance in steps of DM
Morgan 1997-2000; CA	90+97 adults: ischemic heart disease treatment	-uptake of option -knowledge -decisional conflict -participation in decision making -satisfaction -health outcomes	Interactive videodisc PtDA from Foundation for Informed Medical Decision Making (US)	X	X	X	--	--
			Standard care	--	--	--	--	--
Murray 2001; UK	57+55 men: benign prostate hypertrophy treatment	-uptake of option -decisional conflict -participation in decision making -health outcomes -costs / health utilities -anxiety	Interactive videodisc PtDA from Foundation for Informed Medical Decision Making (US)	X	X	X	--	--
			Standard care	--	--	--	--	--
Murray 2001; UK	102+102 women: hormone replacement therapy	-preferred option -proportion remaining undecided -decisional conflict -participation in decision making -health outcomes -costs / health utilities -anxiety	Interactive videodisc PtDA from Foundation for Informed Medical Decision Making (US)	X	X	X	--	--
			Standard care	--	--	--	--	--
O'Connor 1998; CA	81+84 women: hormone replacement therapy	-preferred option -knowledge -decisional conflict -realistic expectations	Audiotape with booklet PtDA from Ottawa Health Decision Centre	X	X	X	X	X

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Source, Year, Location	Number of Enrolees in Intervention + Comparison; Options Considered	Outcomes Measured	Comparison of Most and Least Intensive Intervention	Elements in PtDAs				
				Options & outcomes	Clinical problem	Outcome probability	Values clarification	Guidance in steps of DM
			Simple PtDA pamphlet from professional society	X	X	--	--	--
O'Connor 1999; CA	101 +100 women: hormone replacement therapy	-decisional conflict -match values & choice	Audiotape with booklet PtDA from Ottawa Health Decision Centre	X	X	X	X	X
			Same PtDA without explicit values clarification	X	X	X	--	X
Phillips 1995; US	37+37 patients: dental orthognathic surgery	-preferred option -realistic expectations	Video imaging of facial reconstruction PtDA created for the trial	X	X	--	--	X
			Standard care	--	--	--	--	--
Rostom 2002; CA	25+26 women: hormone replacement therapy	-knowledge -realistic expectations -satisfaction	Computer PtDA from Ottawa Health Decision Centre with testing + feedback re knowledge	X	X	X	X	X
			Audiotape with booklet from Ottawa Health Decision Centre	X	X	X	X	X
Rothert 1997; Holmes-Rovner 1999; US	83+89 women: hormone replacement therapy	-knowledge -decisional conflict -satisfaction -adherence	Lecture with personal decision exercise PtDA created for the trial	X	X	X	X	X
			Simple PtDA pamphlet	X	X	--	--	--
Street 1995; US	30+30 women: breast cancer surgery	-uptake of option -knowledge	Interactive multimedia PtDA created for the trial	X	X	--	--	X
			Simple PtDA	X	X	--	--	--

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Source, Year, Location	Number of Enrolees in Intervention + Comparison; Options Considered	Outcomes Measured	Comparison of Most and Least Intensive Intervention	Elements in PtDAs				
				Options & outcomes	Clinical problem	Outcome probability	Values clarification	Guidance in steps of DM
Van Roosmalen 2004; Netherlands	44 +44 women with BRCA1; prophylactic surgery	-decision uncertainty -perceived weighing pros/cons -perceived participation -anxiety -health outcomes	Video and brochure PtDA with decision analysis created by for the trial	X	X	X	X	X
			Same video and brochure PtDA	X	X	X	--	X
Vuorma 2003; Finland	184 +179 women; menorrhagia treatment	-uptake of option -perceived knowledge -proportion remaining undecided -anxiety -satisfaction	Booklet PtDA created by for the trial	X	X	X	--	--
			Standard care	--	--	--	--	--
Whelan 2003; CA	82 + 93 women; breast cancer chemotherapy	-preferred option -knowledge -anxiety -realistic expectations -satisfaction of patient -participation in decision making	Decision board PtDA and booklet created by for the trial	X	X	X	--	--
			Standard care with booklet	--	X	--	--	--
Whelan 2004; CA	94 + 107 women; breast cancer surgery	-preferred option -knowledge -realistic expectations -decisional conflict -anxiety -satisfaction	Decision board PtDA created by for the trial	X	--	X	--	--
			Standard care	--	--	--	--	--

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