Do Patient Decision Aids Meet Effectiveness Criteria of the International Patient Decision Aid Standards Collaboration? A Systematic Review and Meta-analysis

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Do Patient Decision Aids Meet Effectiveness Criteria of the International Patient Decision Aid Standards Collaboration? A Systematic Review and Meta-analysis

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Objective. *To describe the extent to which patient decision aids (PtDAs) meet effectiveness standards of the International Patient Decision Aids Collaboration (IPDAS).* ***Data sources.*** *Five electronic databases (to July 2006) and personal contacts (to December 2006).* ***Results.*** *Among 55 randomized controlled trials, 38 (69%) used at least 1 measure that mapped onto an IPDAS effectiveness criterion. Measures of decision quality were knowledge scores (27 trials), accurate risk perceptions (12 trials), and value congruence with the chosen option (3 trials). PtDAs improved knowledge scores relative to usual care (weighted mean difference [WMD] = 15.2%, 95% confidence interval [CI] = 11.7 to 18.7); detailed PtDAs were somewhat more effective than simpler PtDAs (WMD = 4.6%, 95% CI = 3.0 to 6.2). PtDAs with probabilities improved accurate risk perceptions relative to those without probabilities (relative risk = 1.6, 95% CI = 1.4 to 1.9). Relative to simpler PtDAs, detailed PtDAs improved value congruence with the chosen option. Only 2 of 6 IPDAS decision process criteria were measured: feeling informed (15 trials) and feeling clear about values (13 trials). PtDAs improved these process measures relative to usual care (feeling uninformed WMD = –8.4, 95% CI = –11.9 to –4.8; unclear values WMD = –6.3, 95% CI = –10.0 to –2.7). There was no difference in process measures when detailed and simple PtDAs were compared.* ***Conclusions.*** *PtDAs improve decision quality and the decision process's measures of feeling informed and clear about values; however, the size of the effect varies across studies. Several IPDAS decision process measures have not been used. Future trials need to use a minimum data set of IPDAS evaluation measures. The degree of detail PtDAs require for positive effects on IPDAS criteria should be explored.*
Key words: *decision support techniques; patient education; patient participation; randomized controlled trials.* ***(Med Decis Making 2007;27:554–574)***

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Patient decision aids (PtDAs) are adjuncts to counseling that explain options, clarify personal values for the benefits versus harms, and guide patients in deliberation and communication. With the rapid proliferation of these tools, the International Patient Decision Aids Collaboration (IPDAS) has reached agreement on criteria for judging the quality of PtDAs.[1] IPDAS is a network of more than 100 researchers, practitioners, patients, and policy makers from 14 countries. These collaborators developed a checklist of criteria that payers, patients, practitioners, developers, and researchers can use to assess PtDAs they encounter. The criteria address 3 domains of quality: clinical content, the development process, and effectiveness.

This article addresses the 3rd domain, the evaluation of PtDAs' effectiveness in fostering a high-quality decision process and a high-quality choice. Over the past decade, there has been considerable debate about the definition of a good decision when there is no single best therapeutic action and choices depend on how patients value benefits versus harms.[2–6] To select criteria for decision quality, IPDAS participants were asked to identify "the things that you would need to observe in order to say that after using a patient decision aid, the way the decision was made was good and the choice that was made was good." IPDAS endorsed the following criteria for establishing that a decision aid is effective:

- Decision quality: The PtDA improves the match between the chosen option and the features that matter most to the informed patient.
- Decision processes leading to decision quality: The PtDA helps patients to recognize that a decision needs to be made, know options and their features, understand that values affect the decision, be clear about the option features that matter most, discuss values with their practitioner, and become involved in preferred ways.

Our study objectives were 1) to describe the number and types of measures used in randomized controlled trials (RCTs) that correspond to IPDAS criteria for effectiveness and 2) to determine the extent to which RCTs of PtDAs meet these new IPDAS criteria for effectiveness.

METHODS

We have been updating the Cochrane Review of decision aids since the late 1990s.[7–9] This review differed from previous reviews by focusing on the new IPDAS criteria. Moreover, we used a new systematic review software, TrialStat SRS, to manage the search and data extraction; therefore, our search, screen, and data extraction were redone completely. Data sources included 1) electronic databases to July 2006 (MEDLINE, PsycINFO, CINAHL, and EMBASE), 2) Cochrane Controlled Trials Register (2006, issue 2), and 3) contact with known developers and evaluators to December 2006. The search strategy is described in the appendix. The search was not restricted on the basis of language.

PtDAs were defined as interventions designed to help people make specific, deliberated choices among options (including the status quo) by providing information about the options and outcomes (e.g., benefits, harms) in sufficient detail that an individual could judge their value implicitly. Patient decision aids may also include information about the clinical condition, outcome probabilities tailored to personal risk factors, an explicit values clarification exercise (e.g., a relevance chart, utility assessments of probable outcome states, a weigh scale), descriptions of others' experiences, and guidance in the steps of decision making and communicating with others. This definition excludes interventions focused solely on lifestyle changes, hypothetical situations, clinical trial entry, or general advanced directives; education programs not geared to a specific decision; and interventions designed to promote adherence to a recommended option or to elicit passive informed consent. In the current review, we also excluded studies whose PtDAs were not available for inspection to catalogue their elements according to the new IPDAS domains. As a consequence, a few studies reported in the previous reviews were not included.

We included published RCTs comparing 1) PtDAs to usual-care controls or 2) detailed PtDAs to simpler ones (which may not have the level of detail or may not contain all of the IPDAS elements). Participants were deciding about screening or treatment options for themselves, for a child, or for an incapacitated significant other.

Two reviewers independently screened each study (CB, SK, DS, AMO, VF), extracted data (CB, SK), and assessed study quality (CB, SK) using standardized forms, including the Jadad scale.[10] Inconsistencies were resolved by consensus.

Trial results were described individually. Meta-analysis was used for decision quality and for decision process measures because these effects were expected to be independent of the type of decision. Meta-analysis was performed only on those outcomes with similar types of measures.

Review Manager 4.2[11] was used to estimate a weighted treatment effect (with 95% confidence intervals [CIs]), defined as weighted mean differences (WMDs) for continuous measures and pooled relative risks (RRs) for dichotomous outcomes. The data used in each meta-analysis can be viewed in the online supplement available at http://mdm.sagepub.com/supplemental. All data were analyzed with a DerSimonian and Laird[12] random effects model because of the diverse nature of the trials. Forest plots were used to assess and display potential heterogeneity, and funnel plots were used to explore publication bias. Because of statistically significant heterogeneity for most of the outcomes, we performed post hoc subanalyses to explore the potential causes of heterogeneity. Heterogeneity was explored according to the

following factors: type of decision (treatment versus screening), type of media of decision aid (video/ computer versus audio booklet/pamphlet), and a possible ceiling effect based on good usual-care scores (removal of studies with lower knowledge and realistic risk perception scores; removal of studies with higher decisional conflict scores for subscales feeling uninformed and unclear values). We analyzed the effects of removing the biggest outlier(s) defined by visual inspection of the forest plots.

In addition, a post hoc analysis was performed to examine the effect of 1) excluding trials of low methodological quality and 2) excluding trials that were outliers and contributed to heterogeneity.

RESULTS

Of the 22,778 unique citations obtained in the review, we identified 1293 as relevant by title and then screened those abstracts (see Figure 1). Of these, 130 citations were retrieved for full-text review. Sixty-four studies were excluded for the following reasons: the study was not focused on making a choice ($n = 33$), the study was not an RCT ($n = 14$), the decision support intervention did not meet the definition of a PtDA ($n = 8$), the study involved a hypothetical situation ($n = 6$), and no outcome data were provided ($n = 3$). In all, 55 eligible trials (66 references) were found for duplicate data extraction and analysis.

The 55 published RCTs evaluating individual PtDAs[13–78] used 51 different PtDAs that focused on 23 different screening or treatment topics (see Table 1). Among the 51 different PtDAs, the elements most frequently included were information about the options and outcomes in sufficient detail to judge their value implicitly (100% by definition), information about the clinical condition (98%), outcome probabilities (84%), examples of others' experiences (59%), explicit values clarification exercises (55%), and guidance in the steps of decision making (47%). Quality ratings in the trials ranged from 0/5 to 3/5. All studies lost 2 points because patients or practitioners could not be blinded to the intervention.

As shown in Table 2, 38 of the 55 trials (69%) reported at least 1 outcome that could be mapped onto an IPDAS criterion for effectiveness; 33 (60%) measured some aspect of decision quality, and 15 (27%) measured a decision process leading to decision quality.

Decision Quality

As noted above, the definition of decision quality has 2 elements: the extent to which decisions are informed and based on personal values. Trials used 3 measures corresponding to this definition: knowledge test results, accuracy of risk perceptions, and value congruence with chosen option.

Knowledge. Twenty-seven of the 55 studies examined the effects of PtDAs on knowledge; 18 of these compared PtDAs to usual care, and 9 compared PtDAs with more or less detail. The studies' knowledge tests were based on information contained in the PtDA, thereby establishing content validity. The proportion of accurate responses was transformed to a percentage scale ranging from 0% (no correct responses) to 100% (perfectly accurate responses).

In the comparison of PtDAs to usual care[15,16,18,26,28,29,31,36,39,41,43,48,50,64,65,69,73,78] (Figure 2), PtDAs had higher average knowledge scores (WMD = 15.2%, 95% CI = 11.7, 18.7). The 9 studies comparing detailed with simpler PtDAs[22,24,30,35,54,60,61,63,66] (Figure 3) showed a smaller effect (WMD = 4.6%, 95% CI = 3.0, 6.2).

Accurate risk perceptions. Eleven of 55 studies examined the effects of including probabilities of PtDAs on the accuracy of patients' perceived probabilities of outcomes.[24,28,41,43–45,54,63,73,74,77] Eight studies measured perceived probabilities as percentages,[24,28,43–45,54,73,74] and 3 gauged probabilities in words.[41,63,77]

Perceived outcome probabilities were classified as accurate according to the percentage of individuals whose judgments corresponded to the scientific evidence about the chances of an outcome for similar people. In 4 of 5 studies that elicited perceived probabilities for multiple outcomes,[24,44,54,60] the proportion of realistic expectations was averaged; in the remaining study,[43] the most conservative result was chosen for meta-analysis.

People who received a detailed PtDA with descriptions of outcomes and probabilities were more likely to have accurate risk perceptions than those who did not receive this information; the pooled RR of having accurate risk perceptions was 1.6 (95% CI = 1.4, 1.9; Figure 4). The pooled relative risk for probabilities described in words was 1.3 (95% CI = 1.1, 1.5). The pooled relative risk for probabilities described as numbers was 1.8 (95% CI = 1.4, 2.3).

Value congruence with chosen option. Four of 55 studies measured value congruence with the chosen option; however, Lerman and others[41] did not calculate differences between interventions. The 3 trials comparing interventions were similar in that they 1) focused on the decision to take menopausal hormone replacement therapy (HRT) and 2) compared 2 active interventions. However, these trials used different measures of value

(text continued on p 565)

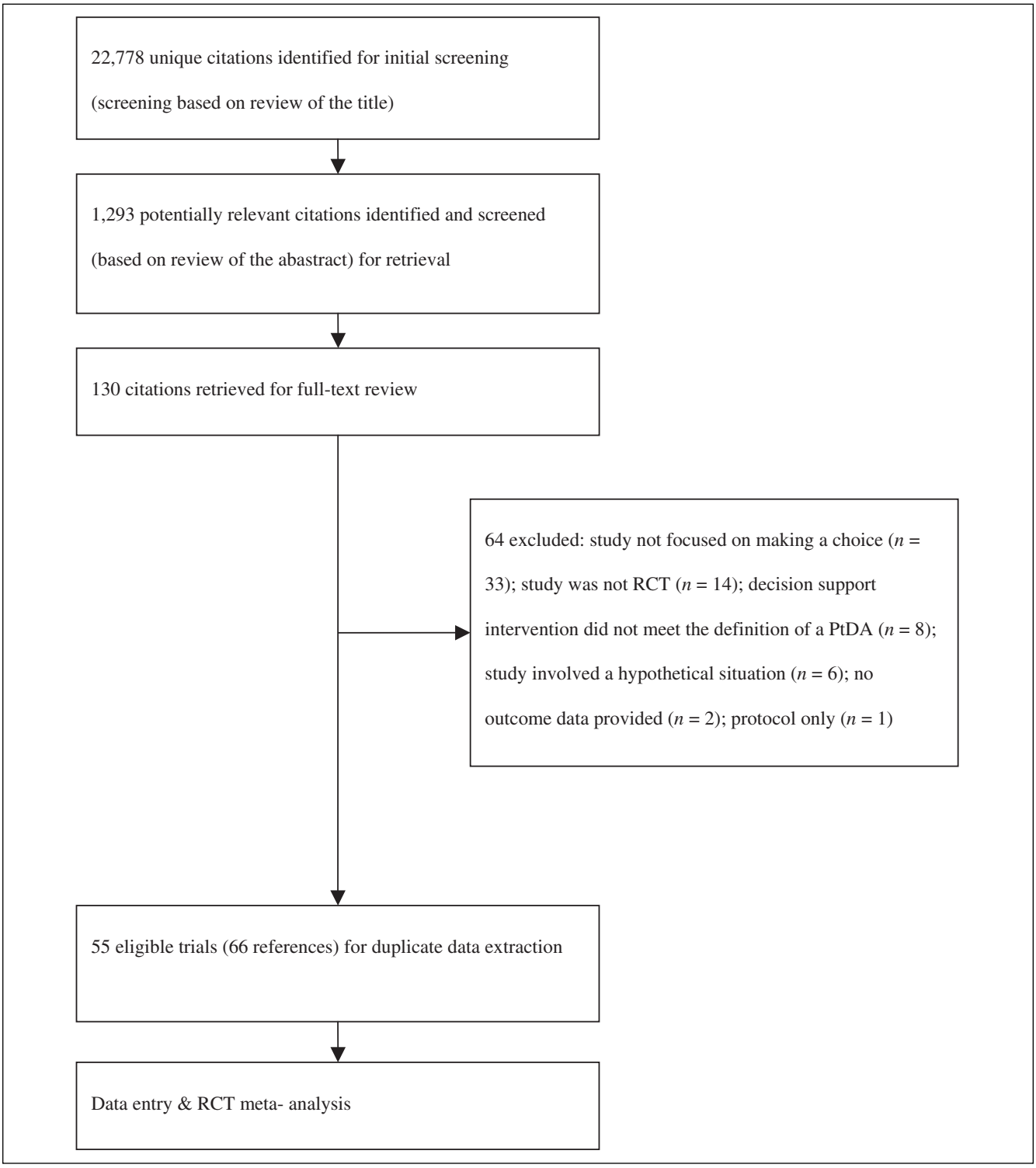

Figure 1 Flowchart of the procedural steps in the systematic review. RCT = randomized controlled trial; PtDA = patient decision aid.

Table 1 Characteristics of 55 Trials Included in the Systematic Review of Patient Decision Aids

Source, Year, Location	Number of Enrollees in Intervention + Comparison: Options Considered	Quality Rating (Jadad)	Comparison of Most and Least Intensive Intervention	Elements in DAs					
				Options and Outcomes	Clinical Problem	Outcome Probability	Explicit Values Clarification	Others' Experiences	Guidance in Steps of DM
Auvinen and others[13,14] 2004, Finland	103 + 100 men: prostate cancer treatment	3/5	Pamphlet PtDA	X	—	X	—	—	—
			Standard care by clinical guideline	—	—	—	—	—	—
Barry and others[15] 1997, United States	104 + 123 men: benign prostate hypertrophy treatment	1/5	Interactive videodisc PtDA	X	X	X	—	X	—
			Usual care	—	X	—	—	—	—
Bekker and others,[16,17] 2004, United Kingdom	59 + 58 women: prenatal diagnostic screening for Down syndrome	2/5	Decision analysis plus consultation	X	—	X	X	—	—
			Usual care	X	—	X	—	—	—
Bernstein and others[18] 1998, United States	65 + 53 patients: ischemic heart disease treatment	3/5	Video PtDA	X	X	X	—	X	—
			Usual care	—	—	—	—	—	—
Clancy and others[19] 1988, United States	753 + 263 physicians: hepatitis B vaccine	2/5	Pamphlet + decision analysis PtDA	X	X	—	X	—	X
			Usual care	—	—	—	—	—	—
Davison and Degner[20] 1997, Canada	30 + 30 men: prostate cancer treatment	2/5	Written materials, PtDA, and audiotape of consultation	X	X	X	—	X	—
			Usual care	—	X	—	—	—	—
Deschamps and others[21] 2004, Canada	67 + 61 women: HRT	1/5	Audiotape and booklet	X	X	X	X	X	X
			Pharmacist consultation	X	—	X	—	—	—
Deyo and others[22] 2000; Phelan and others[23] 2001, United States	190 + 203 patients: herniated disc or spinal stenosis treatment	3/5	Interactive videodisc PtDA	X	X	X	—	X	—
			Simple PtDA pamphlet	X	X	—	—	—	—
Dodin and others[24] 2001, Canada	52 + 49 women: HRT	2/5	Audiotape booklet PtDA	X	X	X	X	X	X
			Simple PtDA pamphlet	X	X	—	—	—	—
Dolan and Frisina[25] 2002, United States	50 + 47 adults: colon cancer screening	3/5	Computer: analytic hierarchy process and pamphlet PtDA	X	X	X	X	—	X
			Usual care	—	X	—	—	—	—
Dunn and others[26] 1998, United States	143 + 144 parents: infant polio vaccine schedules	2/5	Video and pamphlet PtDA	X	X	X	—	X	—
			Usual care	—	X	—	—	—	—
Frosch and others[27] 2003, United States	112 + 114 men: PSA testing	3/5	Video PtDA	X	X	X	—	X	—
			Internet presentation mirroring content of video	X	X	X	—	X	—

(continued)

Gattellari and Ward[28] 2003, Australia	126 + 122 men: PSA testing	3/5	Pamphlet PtDA	X	X	X	X	—	—
			General information leaflet	—	—	—	—	—	—
Gattellari and Ward[29] 2005, Australia	140 + 140 men: PSA testing	3/5	Pamphlet PtDA	X	X	X	X	—	—
			General information leaflet	—	—	—	—	—	—
Goel and others[30] 2001, Canada	86 + 50 women: breast cancer surgery	3/5	Audiotape and booklet PtDA	X	X	X	X	X	X
			Simple PtDA pamphlet	X	X	—	—	—	—
Green and others[31] 2001, United States	29 + 14 higher risk women: breast cancer genetic testing	1/5	CD-ROM PtDA plus counseling	X	X	—	—	X	—
			Usual care	—	—	—	—	—	—
Green and others[32,33] 2004, United States	106 + 105 higher risk women: breast cancer genetic testing	3/5	CD-ROM PtDA plus counseling	X	X	—	—	X	—
			Genetic counseling	—	—	—	—	—	—
Herrera and others[34] 1983, United States	56 + 47 parent(s): circumcision of male newborns	0/5	Pamphlet PtDA	X	X	X	—	X	X
			Usual care	—	—	—	—	—	—
Hunter and others[35] 2005, Canada	116 + 126 women: prenatal diagnostic testing	2/5	Audiotape and booklet	X	X	X	X	X	X
			Individual genetic counseling	X	—	X	X	—	—
Johnson and others[36] 2006, United States	32 + 35 patients: dental surgery	3/5	Decision board PtDA	X	X	X	—	—	—
			Usual care	—	—	—	—	—	—
Kennedy and others[37] 2002, United Kingdom	300 + 298 women: menorrhagia treatment	3/5	Video plus booklet PtDA	X	X	X	X	X	X
			Usual care	—	—	—	—	—	—
Lalonde and others[38] 2006, Canada	13 + 13 patients: cardiovascular health treatment	2/5	Booklet PtDA	X	X	X	X	X	X
			Personal risk profile	—	X	X	—	—	—
Laupacis and others[39] 2006, Canada	60 + 60 patients: preoperative autologous blood donation	3/5	Audiotape and booklet PtDA	X	X	X	X	X	X
			Usual care	—	—	—	—	—	—
Legare and others[40] 2003, Canada	97 + 87 women: HRT	2/5	Audiotape booklet PtDA	X	X	X	X	X	X
			Simple pamphlet PtDA	X	X	X	—	—	—
erman and others[41] 1997, United States	122 + 164 women: breast cancer genetic testing	1/5	Discussion PtDA and counseling	X	X	X	X	X	X
			Usual care wait list control	—	—	—	—	—	—
Leung and others[42] 2004, China	100 + 101 women: prenatal diagnostic testing	2/5	Interactive multimedia PtDA	X	X	X	—	—	X
			Video and pamphlet	X	X	X	—	—	—

(continued)

Table 1 (continued)

Source, Year, Location	Number of Enrollees in Intervention + Comparison: Options Considered	Quality Rating (Jadad)	Comparison of Most and Least Intensive Intervention	Elements in DAs					
				Options and Outcomes	Clinical Problem	Outcome Probability	Explicit Values Clarification	Others' Experiences	Guidance in Steps of DM
Man-Son-Hing and others[43] 1999, Canada	139 + 148 aspirin users in atrial fibrillation trial: move to warfarin	3/5	Audiotape and booklet PtDA	X	X	X	X	X	X
			Usual care	—	—	—	—	—	—
McAlister and others[44] 2005, Canada	219 + 215 patients: antithrombotic therapy	3/5	Audiotape and booklet PtDA	X	X	X	X	X	X
			Usual care	—	—	—	—	—	—
McBride and others[45,46] 2002, United States	289 + 292 women: HRT	1/5	Pamphlet PtDA	X	X	X	X	X	X
			Usual care	—	—	—	—	—	—
Miller and others[47] 2005, United States	279 women: BRCA1 BRCA2 gene testing	2/5	Discussion PtDA and general information pamphlets	X	X	X	—	—	—
			General information pamphlets	X	X	—	—	—	—
Montgomery and others[48,49] 2003, United Kingdom	52 + 55 + 51 + 59 adults: hypertension treatment	3/5	Decision analysis PtDA	X	—	X	X	—	—
			Video and booklet PtDA	X	X	—	—	—	—
			Decision analysis, video and booklet PtDA	X	X	X	X	—	—
			Standard care	—	—	—	—	—	—
Morgan and others[50] 2000, Canada	120 + 120 patients: ischemic heart disease treatment	3/5	Interactive videodisc PtDA	X	X	X	—	X	—
			Usual care	—	—	—	—	—	—
Murray and others[51] 2001, United Kingdom	57 + 55 men: benign prostate hypertrophy treatment	3/5	Interactive videodisc PtDA	X	X	X	—	X	—
			Usual care	—	—	—	—	—	—
Murray and others[52] 2001, United Kingdom	102 + 102 women: HRT	3/5	Interactive videodisc PtDA	X	X	X	—	X	—
			Usual care	—	—	—	—	—	—
Myers and others[53] 2005, United States	121 + 121 men: PSA testing	2/5	Discussion PtDA and general information pamphlet	X	X	—	X	—	X
			General information pamphlet	X	X	—	—	—	—
O'Connor and others[54] 1998, Canada	81 + 84 women: HRT	1/5	Audiotape and booklet PtDA	X	X	X	X	X	X
			Simple PtDA pamphlet	X	X	—	—	—	—

O'Connor and others[55] 1999, Canada	101 +100 women: HRT	3/5	Audiotape and booklet PtDA	X	X	X	X	X	X
			DA without explicit values clarification	X	X	X	—	X	X
Oakley and Walley[56] 2006, United Kingdom	16 + 17 women: osteoporosis treatment	1/5	Audiotape and booklet PtDA	X	X	X	X	X	X
			Usual care	—	—	—	—	—	—
Partin and others[57] 2004, Canada	384 + 384 men: PSA testing	3/5	Video PtDA	X	X	X	—	X	—
			Usual care	—	—	—	—	—	—
Phillips and others[58] 1995, United States	37 + 37 patients: dental orthognathic surgery	0/5	Video imaging of facial reconstruction PtDA	X	X	—	—	—	X
			Usual care	—	—	—	—	—	—
Pignone and others[59] 2000, United States	125 + 124 adults: colon cancer screening	3/5	Video PtDA	X	X	—	—	X	—
			Usual care	—	—	—	—	—	—
Rostom and others[60] 2002, Canada	25 + 26 women: HRT	3/5	Computer PtDA with testing + feedback regarding knowledge	X	X	X	X	X	X
			Audiotape with booklet	X	X	X	X	X	X
Rothert and others[61] 1997; Holmes-Rovner and others[62] 1999, United States	83 + 89 women: HRT	1/5	Lecture with personal decision exercise PtDA	X	X	X	X	X	X
			Simple PtDA pamphlet	X	X	—	—	—	—
Schapira[63] 2000, United States	122 + 135 men: prostate cancer screening	1/5	Booklet PtDA	X	X	X	—	—	—
			Simple PtDA pamphlet	X	X	—	—	—	—
Schwartz and others[64] 2001, United States	191 + 190 Ashkenazi Jewish women: breast cancer genetic testing	2/5	Booklet PtDA	X	X	—	—	—	—
			Usual care	—	X	—	—	—	—
Shorten and others[65] 2005, Australia	85 + 84 pregnant women: birthing options after previous cesarean delivery	2/5	Booklet PtDA	X	X	X	X	—	X
			Usual care	—	—	—	—	—	—
Street and others[66] 1995, United States	30 + 30 women: breast cancer surgery	1/5	Interactive multimedia PtDA	X	X	—	—	X	X
			Simple PtDA	X	X	—	—	—	—

(continued)

Table 1 (continued)

Source, Year, Location	Number of Enrollees in Intervention + Comparison: Options Considered	Quality Rating (Jadad)	Comparison of Most and Least Intensive Intervention	Elements in DAs					
				Options and Outcomes	Clinical Problem	Outcome Probability	Explicit Values Clarification	Others' Experiences	Guidance in Steps of DM
VanRoosmalen and others[67,68] 2004, the Netherlands	44 + 44 women with BRCA1/2 mutation: prophylactic surgery	3/5	Video and brochure PtDA with decision analysis	X	X	X	X	—	X
			Same video and brochure PtDA pamphlet	X	X	X	—	—	X
Volk and others[69,70] 1999, United States	80 + 80 men: prostate cancer screening	3/5	Video with pamphlet PtDA	X	X	X	—	X	—
			Usual care	—	—	—	—	—	—
Vuorma and others[71,72] 2003, Finland	184 + 179 women: menorrhagia treatment	3/5	Booklet PtDA	X	X	X	—	—	—
			Usual care	—	—	—	—	—	—
Whelan and others[73] 2003, Canada	82 + 93 women: breast cancer chemotherapy	3/5	Decision board PtDA and booklet	X	X	X	—	—	—
			Usual care with booklet	—	X	—	—	—	—
Whelan and others[74] 2004, Canada	94 + 107 women: breast cancer surgery	3/5	Decision board PtDA	X	—	X	—	—	—
			Usual care	—	—	—	—	—	—
Wolf and others[75,76] 1996, United States	103 + 102 men: prostate cancer screening	2/5	Script PtDA	X	X	X	—	X	—
			Usual care	—	—	—	—	—	—
Wolf and Schorling[77] 2000, United States	266 + 133 seniors: colon cancer screening	1/5	Script PtDA	X	X	X	—	—	—
			Usual care	—	—	—	—	—	—
Wong and others[78] 2006, United States	162 + 164 women: pregnancy termination	2/5	Pamphlet PtDA	X	X	X	X	—	—
			Usual care	—	—	—	—	—	—

Note: DM = decision making; PtDA = patient decision aid; HRT = hormone replacement therapy; PSA = prostate-specific antigen.

Table 2 Trials Measuring Outcomes That Map onto the International Patient Decision Aid Standards (IPDAS) Criteria

		Cumulative Studies Still in 2007 Review Reporting Outcome in Each Cochrane Review Update			
	Outcome	**Year**	**%**	**n/N**	**Lead Author**
Decision quality	Knowledge scores	1999	54	7/13	Barry,[15] Morgan,[50] Bernstein,[18] Lerman,[41] Rothert,[61] O'Connor,[54] Street[66]
		2003	57	17/30	As above plus Schwartz,[64] Man-Son-Hing,[43] Volk,[69] Dunn,[26] Green,[31] Goel,[30] Shapira,[63] Rostom,[60] Phelan,[23] Dodin[24]
		2007	49	27/55	As above plus Bekker,[16] Gattellari,[28] Johnson,[36] Whelan,[73] Shorten,[65] Montgomery,[48] Gattellari,[29] Laupacis,[39] Wong,[78] Hunter[35]
	Realistic expectations, accurate risk perceptions	1999	15	2/13	OConnor,[54] Lerman[41]
		2003	27	8/30	As above plus Wolf,[77] McBride,[45] Man-Son-Hing,[43] Rostom,[60] Shapira,[63] Dodin[24]
		2007	22	12/55	As above plus Whelan,[74] Whelan,[73] McAlister,[44] Gattellari[28]
	Value congruence with chosen option	1999	0	0/13	
		2003	10	3/30	O'Connor,[55] Holmes-Rovner,[62] Dodin[24]
		2007	5	3/55	As above
	Decisional Conflict Scale (DCS)	1999	15	2/13	OConnor,[54] Morgan[50]
		2003	30	9/30	As above plus Murray,[51] Murray,[52] Dolan,[25] Man-Son-Hing,[43] Dodin,[24] Goel,[30] OConnor[55]
		2007	57	17/30	As above plus Montgomery,[48] Shorten,[65] Laupacis,[39] Whelan,[74] McAlister,[44] Lalonde,[38] Legare,[40] Hunter[35]
Decision process leading to decision quality	Feeling informed, subscale of the DCS	1999	15	2/13	O'Connor,[54] Morgan[50]
		2003	30	9/30	As above plus Murray,[51] Murray,[52] Dolan,[25] Man-Son-Hing,[43] Dodin,[24] Goel,[30] OConnor[55]
		2007	27	15/55	As above plus Montgomery,[48] Laupacis,[39] McAlister,[44] Wong,[78] Bekker,[16] Lalonde[38]
	Feeling clear about values, subscale of DCS	1999	15	2/13	O'Connor,[54] Morgan[50]
		2003	33	10/30	As above plus Murray,[51] Murray,[52] Dolan,[25] Man-Son-Hing,[43] Dodin,[24] Goel,[30] OConnor[55]
		2007	24	13/55	As above plus Montgomery,[48] Laupacis,[39] McAlister,[44] Lalonde[38]

Note: Trials included in 1999 and 2003 but not in 2007 are Davison and others[80] (measuring feeling informed, clear values); Maisels and others,[81] Michie and others[82] (measuring knowledge scores), and Thornton and others.[83] These authors were eliminated because we were unable to verify what was in their decision aid to meet the IPDAS definition of a decision aid.

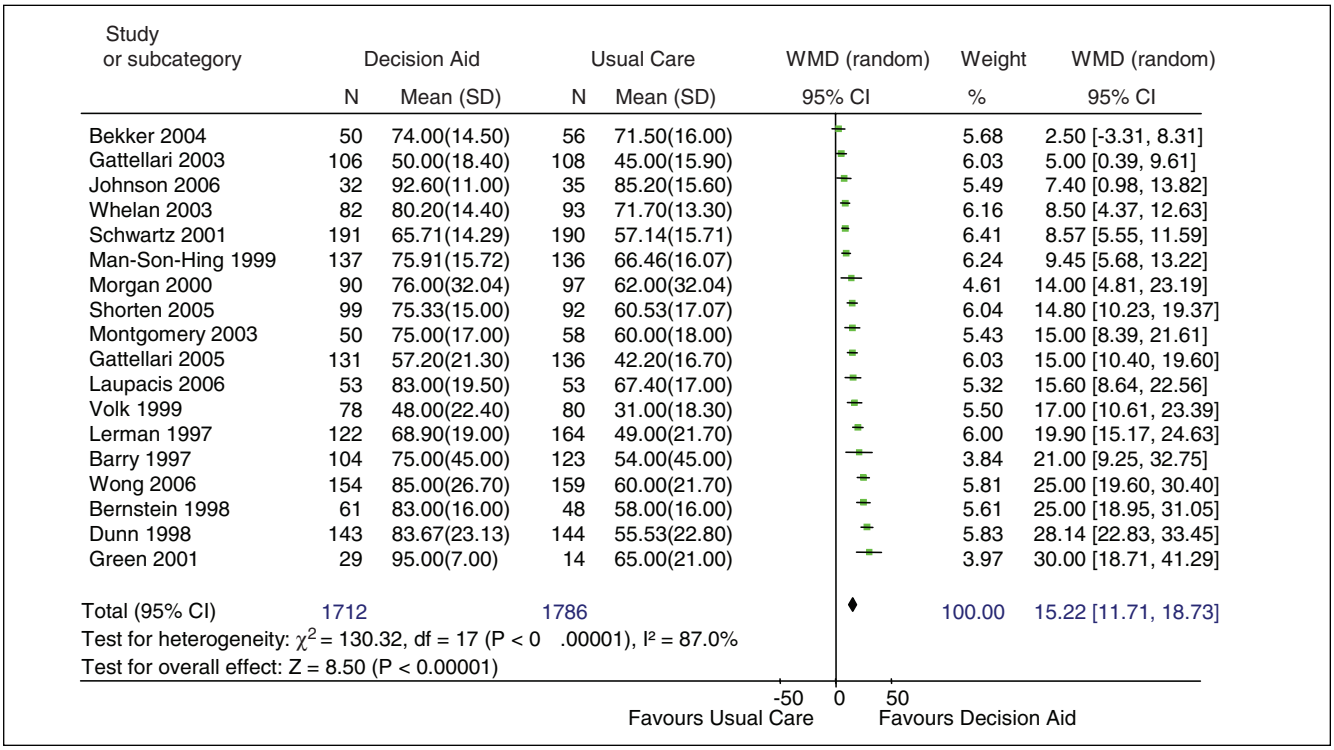

Figure 2 Effect of patient decision aids on patients' mean scores on knowledge tests: decision aid versus usual care. WMD = weighted mean difference; CI = confidence interval.

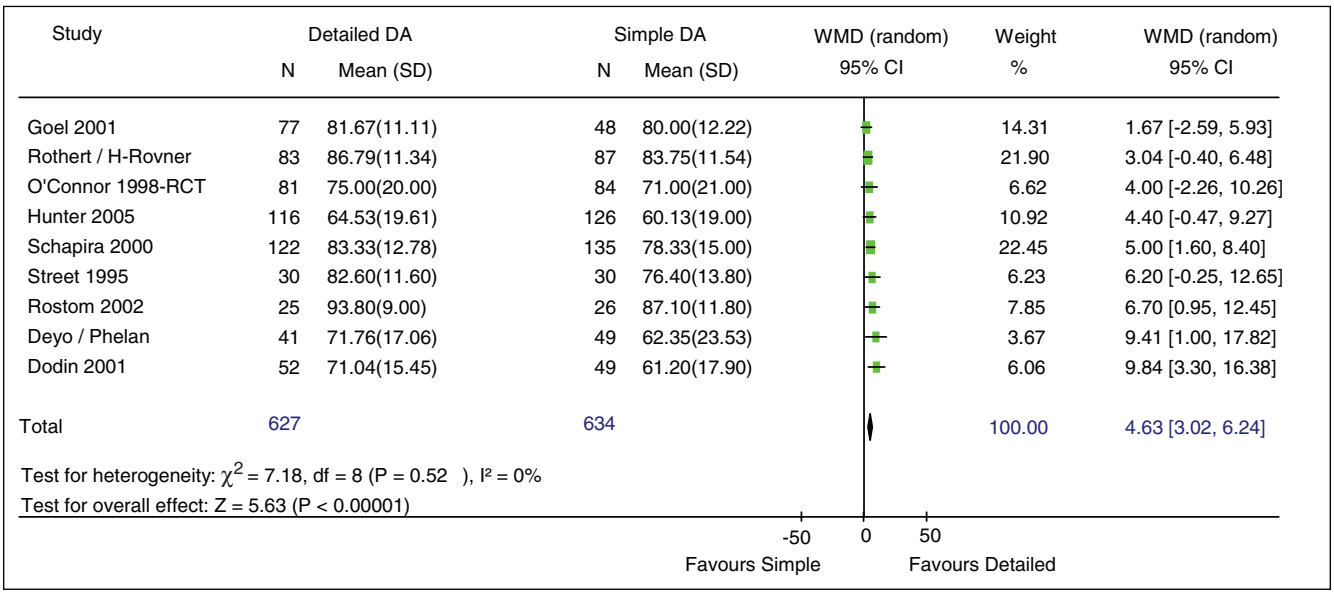

Figure 3 Effect of patient decision aids (DAs) on patients' mean scores on knowledge tests: detailed versus simple decision aids. WMD = weighted mean difference; CI = confidence interval.

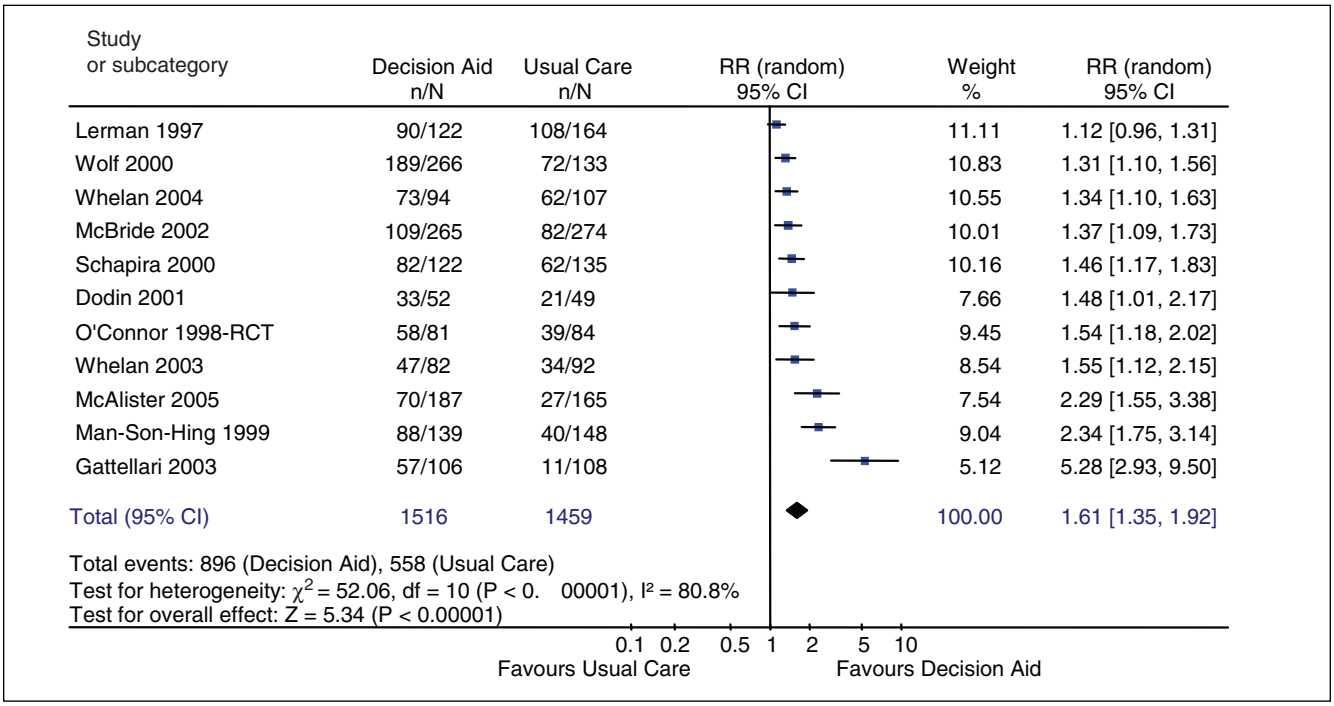

Figure 4 Effect of patient decision aids on the proportion of patients classified as having accurate risk perceptions. RR = relative risk; CI = confidence interval.

congruence. Holmes-Rovner and others[62] measured the correlation between the subjective expected value of hormones and women's likelihood of taking HRT, converted here to the percentage of variance in likelihood explained by values. Dodin and others[24] measured the percentage of variance in decisions explained by values. O'Connor and others[55] used logistic regression to estimate the percentage agreement between values and choice.

PtDAs improved value congruence with the chosen option in 2 of 3 studies. In the trial by Dodin and others,[24] 24% of the variance in HRT decisions was explained by personal values when a detailed PtDA with explicit values clarification was used; in contrast, 14% of the variance in decisions was explained when a simpler PtDA was used ($P = 0.003$). In the study by Holmes-Rovner and others,[62] the percentage of variance in the likelihood of choosing HRT that was explained by women's expected values was greater when a more detailed PtDA was used (13%–14%) than when a simpler PtDA was used (0.09%–2%). O'Connor and others[55] found that the addition of an explicit values clarification exercise in a PtDA did not improve agreement between values and the chosen option. However, in the subgroup of women who chose HRT, women who used the PtDA with explicit values clarification had a trend toward better agreement (40%) than did those who used an identical PtDA without explicit values clarification (0%, $P = 0.06$).

Decision Processes Leading to Decision Quality

There were no trials evaluating the extent to which PtDAs helped patients to recognize that a decision needs to be made, understand that values affect the decision, and discuss values with their practitioner. Although 8 trials evaluated effects on patient participation, none focused on helping patients become involved in preferred ways.

Some studies measured patients' self-reports about feeling informed and clear about personal values. The measures used to evaluate these 2 criteria were 2 subscales of the Decisional Conflict Scale (DCS). The DCS is reliable, discriminates between those who make or delay decisions, is sensitive to change, and discriminates between different decision support interventions.[54,79] The scores are standardized to range from 0 (no decisional conflict) to 100 points (extreme decisional conflict). Scores of 25 or lower are associated with follow through with decisions, whereas scores that exceed 38 are associated with delay in decision making.[54] When PtDAs are compared with usual care,

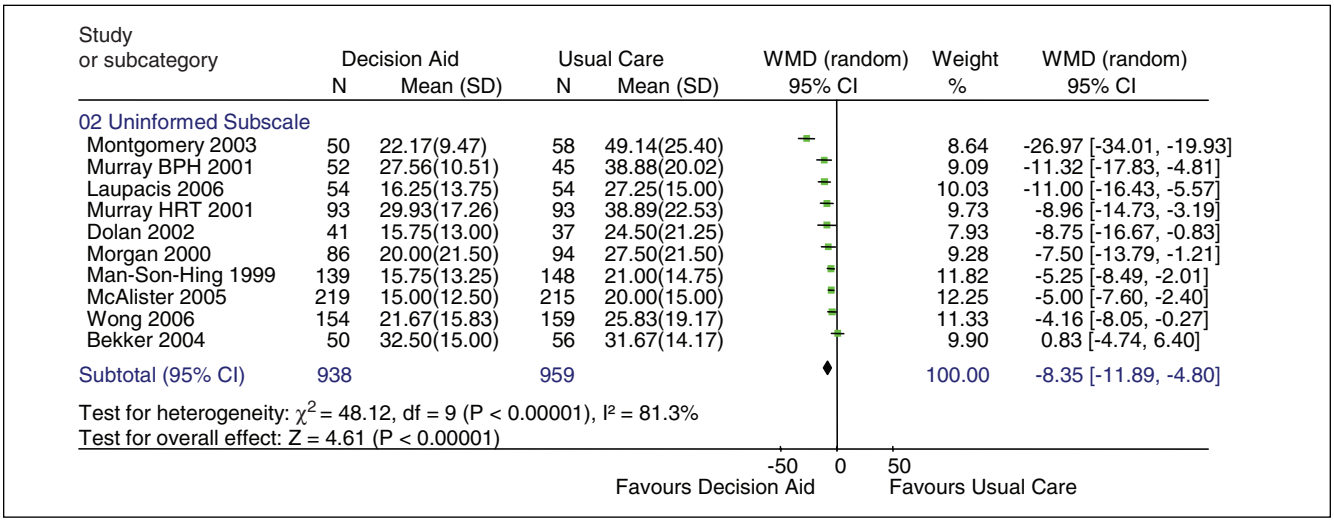

Figure 5 Effect of patient decision aids on patients' scores on the Uninformed subscale of the Decisional Conflict Scale: decision aid versus usual care. WMD = weighted mean difference; CI = confidence interval.

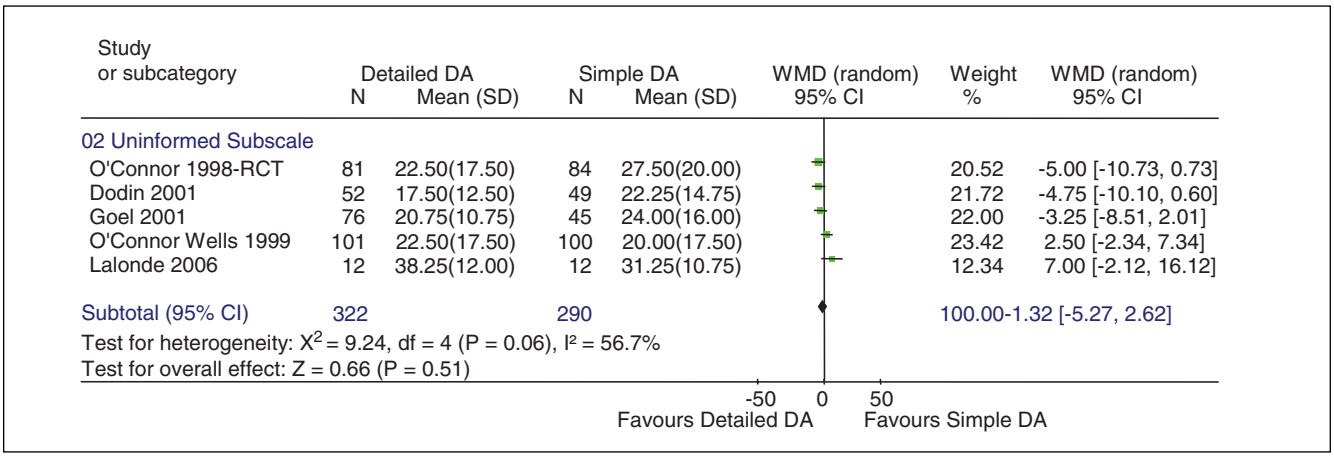

Figure 6 Effect of patient decision aids on patients' scores on the Uninformed subscale of the Decisional Conflict Scale: detailed versus simple decision aid (DA). WMD = weighted mean difference; CI = confidence interval.

a negative score indicates a reduction in decisional conflict, which is in favor of the PtDA.

In our review, 15 trials used the DCS subscale for feeling informed and 13 trials used the DCS subscale for feeling clear about values. Because this DCS subscale measures self-reported comfort with knowledge and not actual knowledge, we elected to consider it a process measure and to reserve the gold standard of objective knowledge tests in assessing decision quality.

The WMD in feeling uninformed about options, benefits, and harms was –8.4 (95% CI = –11.9 to –4.8) in the 10 trials[16,25,39,43,44,48,50–52,78] that compared the PtDAs to usual care (Figure 5). The 5 trials that compared detailed with simpler PtDAs[24,30,38,54,55] had a WMD in feeling uninformed of –1.3 (95% CI = –5.3 to 2.6; Figure 6).

Eight trials comparing PtDA to usual care[25,39,43,44,48,50–52] had a WMD of –6.3 (95% CI = –10.0, –2.7) for feeling clear about values (Figure 7). Five trials compared detailed to simpler PtDAs.[24,30,38,54,55] For these trials, the WMD in feeling clear about values was –1.1 (95% CI = –4.8 to 2.7; Figure 8).

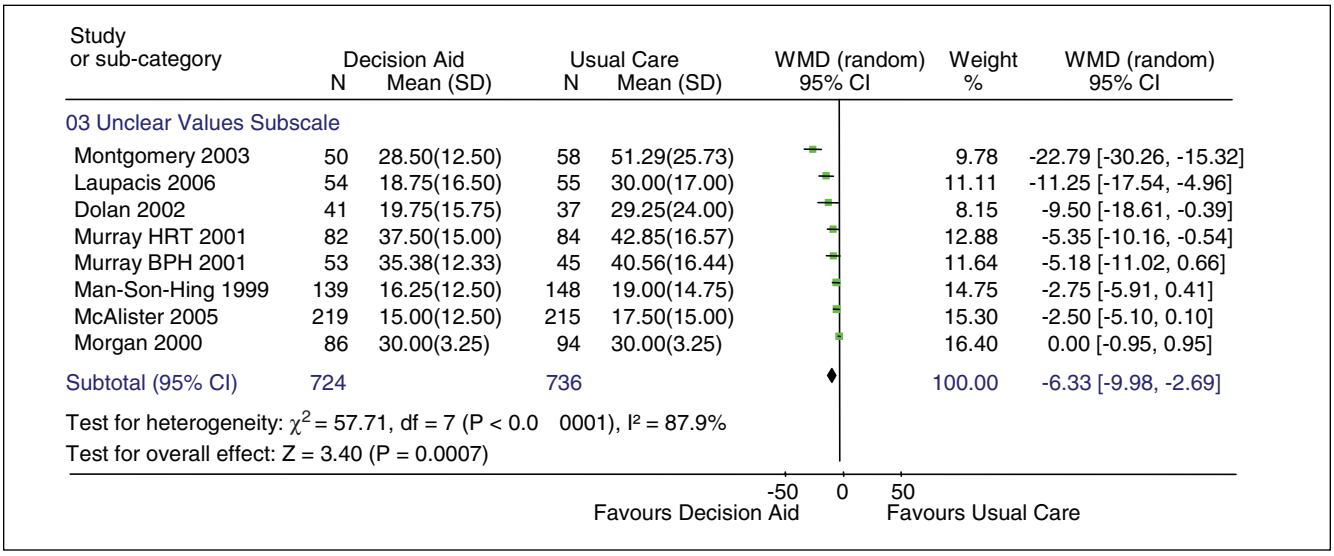

Figure 7 Effect of patient decision aids on patients' scores on the Unclear Values subscale of the Decisional Conflict Scale: decision aid versus usual care. WMD = weighted mean difference; CI = confidence interval.

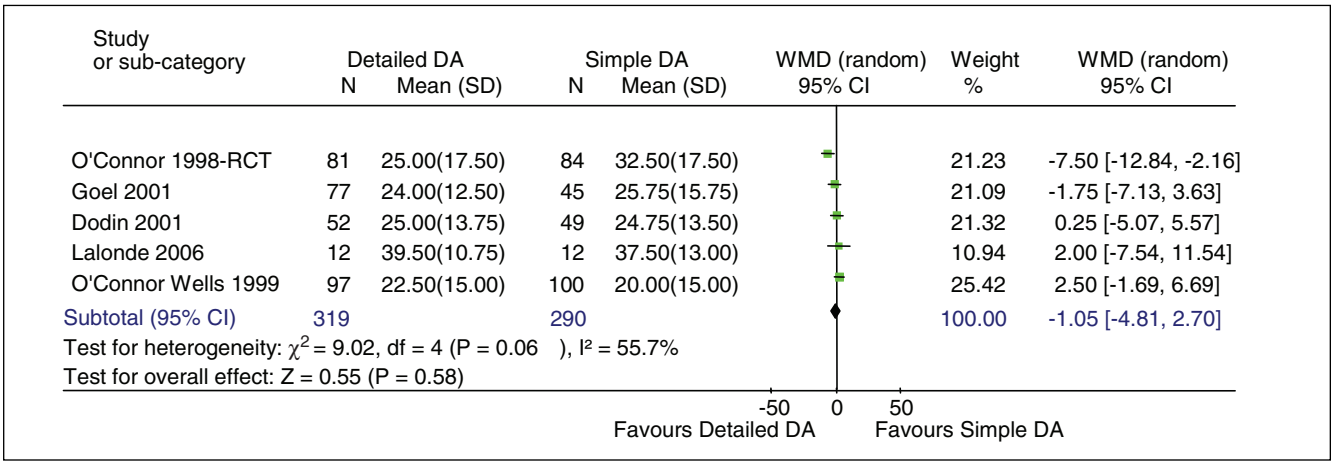

Figure 8 Effect of patient decision aids on patients' scores on the Unclear Values subscale of the Decisional Conflict Scale: detailed versus simple decision aid (DA). WMD = weighted mean difference; CI = confidence interval.

Post hoc Analysis

Effects of study quality. To examine the effect of possible bias from including trials of low methodological quality, the 13 trials[15,21,31,34.41,45,54,56,58,61,63,66,77] with Jadad scores of 0 or 1 were excluded from the analysis. Overall, the results remained the same. There was a significant improvement in knowledge scores for the comparison of PtDAs to usual-care controls (WMD = 14.0%, 95% CI = 2.4, 8.6) and for the comparison of detailed to simpler PtDAs (WMD = 5.5%, 95% CI = 2.4, 8.6). The proportion of patients having accurate risk perceptions was greater for patients receiving PtDAs with information on outcome probabilities (RR = 2.0, 95% CI = 1.4, 2.8).

Publication bias. There were too few studies to explore potential publication bias for all of the outcomes, with the exception of knowledge for the comparison of PtDAs to usual care. The funnel plot for this outcome (Figure 9) points to the absence of smaller negative studies.

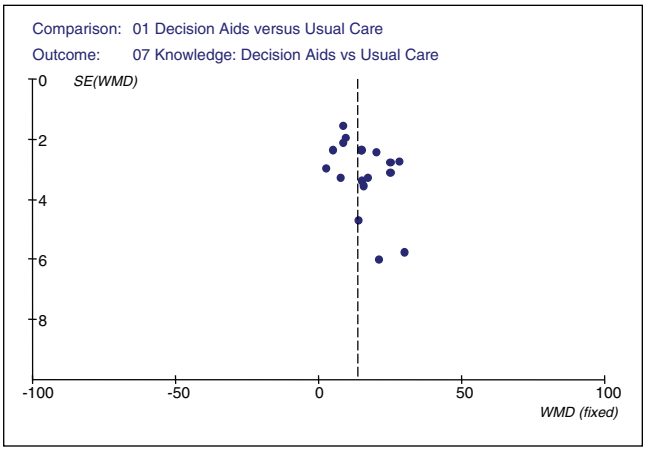

Figure 9 Funnel plot of all 18 randomized controlled trials comparing patient decision aids to usual care (knowledge). WMD = weighted mean difference.

Heterogeneity. There was statistically significant heterogeneity when PtDAs were compared with usual care for 4 outcomes: knowledge test scores, realistic risk perceptions, feeling uninformed, and feeling unclear regarding personal values (Table 3). It should be noted that the heterogeneity of the effect was not in the direction but in the size.

When we explored the potential factors contributing to heterogeneity (Table 3), we found that none of the factors eliminated heterogeneity for the outcomes of knowledge scores. When grouped into treatment and screening decisions, the WMD for knowledge scores was slightly higher for the treatment group (16.6% v. 13.1%), but there was still statistically significant heterogeneity. For the outcomes of accurate risk perceptions, heterogeneity was not significant when we removed 3 studies with lower accurate risk perception scores in the usual-care control group ($P = 0.3$).[28,43,44] For the outcome of feeling uninformed, heterogeneity was no longer significant with 1) removal of 3 studies with higher uninformed scores in the usual-care control group ($P = 0.11$), 2) inclusion of only audio booklet/pamphlet decision aids ($P = 0.06$), and 3) removal of an outlier[48] ($P = 0.06$). None of the factors eliminated heterogeneity for the outcomes of unclear values scores.

DISCUSSION

The majority of trials report on at least 1 IPDAS effectiveness measure, predominately knowledge test scores. Of those reporting IPDAS measures, we found that PtDAs were superior to usual practices in meeting the new IPDAS standards 1) for decision quality and 2) for 2 process measures (feeling informed and feeling clear about personal values). Detailed PtDAs had superior effects over simpler PtDAs on value congruence with the chosen option and on accurate risk perceptions but not on knowledge test scores or on self-reports about feeling informed and feeling clear about values. We also identified the gaps in the use of measures of effectiveness endorsed by IPDAS, notably, value congruence with the chosen option and most of the decision process measures.

There are some study limitations. Study quality ratings of all trials included in the review were low because they all lost 2 points for lack of blinding. Although not an a priori exclusion criterion for this review, in the future, we may consider using study quality ratings for the selection of included trials. The conclusions of this review are limited by 1) inadequate power to detect important differences in effectiveness in subgroups and 2) the wide variability in the decision contexts, the elements within the PtDAs, the type of comparison interventions, the targeted outcomes, and the evaluation procedures. This article focuses solely on measures of effectiveness, not harms. The small number of studies for most outcomes did not allow for analysis of publication bias because of the failure to publish negative studies. Moreover, there may have been publication bias because of failure to report all negative findings in a published study. Lastly, several of the outcomes demonstrated statistically significant heterogeneity. It reflects differences across clinically diverse studies; therefore, the pooled effect size and CI should be interpreted as a range across conditions, which may not be applicable to a specific condition.

There are several implications for future research. Studies are needed to evaluate the effects of PtDAs on congruence between values and chosen options. Moreover, the methods for quantifying value congruence should be explored.

The IPDAS decision processes criteria leading to decision quality should also be measured. It would be helpful to develop a standardized approach to measurement.

With the addition of more trials to the database, it may be possible to tease out the reason for heterogeneity of results, including variability in 1) study quality, 2) comparison intervention, 3) elements within PtDAs, 4) decision type, and 5) format of decision aid (e.g., video, Internet, booklet). The degree of detail in PtDAs that is required for positive effects on IPDAS criteria should also be explored.

Table 3 Exploration of Potential Factors Affecting Heterogeneity

Outcome	Overall Effect	Treatment Decision	Screening Decision	Video/Computer Decision Aid	Audio/Pamphlet Decision Aid	Baseline Risk in Usual-Care Group[a]	Removal of Outliers
Knowledge	15.2 (11.7, 18.7)	16.6 (12.0, 21.2)	13.1 (7.7, 18.5)	21.4 (16.5, 26.2)	11.9 (8.3, 15.6)	15.6 (11.3, 19.9)	17.3[16,28,36] (13.7, 20.9)
Accurate risk perceptions	1.6 (1.4, 1.9)	1.6 (1.4, 1.9)	1.6 (1.1, 2.3)	No data	1.6 (1.4, 1.9)	1.3 (1.2,1.5)*	1.5[28] (1.3, 1.7)
Uninformed Subscale of the Decisional Conflict Scale	–8.4 (–11.9, –4.8)	–9.4 (–13.3 –5.5)	–3.5 (–12.9, 5.8)	–12.6 (–19.5, –5.8)	–4.9 (–7.6, –2.3)***	*–5.4 (–7.7, –3.2)***	–6.2[48] (–8.4, –4.1)***
Unclear values subscale of the Decisional Conflict Scale	–6.3 (–10.0, –2.7)	–6.0 (–9.8, –2.3)	Insufficient data	–8.0 (–15.1, –1.0)	–4.5 (–8.4, –0.6)	*–3.6 (–6.8, –0.5)*	–4.0 r[48] (–6.7, –1.3)

Note: Values are presented as the weighted mean treatment effect (95% confidence interval). Chi-square heterogeneity test P value <0.00001 for all cells except $^{*}P = 0.3$, $^{**}P = 0.11$, $^{***}P = 0.06$.
a. Removal of studies with low scores (no italics) or high scores (italics) in the usual-care group.

In conclusion, compared with usual care, PtDAs meet most IPDAS effectiveness criteria that have been measured in trials. A minimum data set of validated IPDAS effectiveness measures needs to be established so that future trials report on more comparable effectiveness criteria.

ACKNOWLEDGMENTS

All authors contributed to the protocol design, interpretation of results, and revision and final approval of the article. AMO led the team, and CB coordinated the project. CB, SK, DS, AMO, and VF screened the studies and extracted data. CB and AMO analyzed the results. Dean Ferguson and George Wells provided statistical advice. The Cochrane Consumers and Communication Review Group (editors, academic and consumer referees) provided peer review and advice regarding the protocol. Jessie McGowan from the University of Ottawa assisted with literature searching. This current review was supported by a group grant from the Canadian Institutes of Health Research. AMO holds a Tier 1 Canada Research Chair in Health Care Consumer Decision Support. KBE is currently directing PtDA development for the John M. Eisenberg Clinical Decisions and Communications Science Center funded by the Agency for Healthcare Research and Quality (HHSA29020050013C), located at Oregon Health & Science University in Portland, Oregon. Several of the investigators have developed PtDAs (AMO, DS, HL-T, MH-R, MJB, NFC, KBE), but none reviewed their own studies. Three investigators (AMO, HL-T, MJB) receive support from the not-for-profit Foundation for Informed Medical Decision Making (FIMDM). FIMDM has a licensing agreement with Health Dialog (a commercial firm) that distributes and promotes PtDAs. NFC is the cofounder of Strategic Health Decisions, an organization devoted to the development and dissemination of interactive PtDAs.

APPENDIX

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003 exp decision support techniques/
004 Educational Technology/
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006 (choic$ or preference$).tw.
007 communication package.tw.
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009 exp health education/
010 Health knowledge, Attitudes, Practice/
011 informed consent.tw,hw.
012 patient.tw,hw.
013 consumer.tw,hw.
014 or/9-13
015 8 and 14
016 ((patient$ or consumer$) adj1 (decision$ or choice or preference or participation)).tw.
017 ((women or men) adj1 (decision$ or choice or preference or participation)).tw.
018 (parent$ adj1 (decision$ or choice or preferenc$ or participat$)).tw.
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021 decision aid$.tw.
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011 health knowledge/ or exp professional knowledge/
012 exp Consent/
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015 consumer.tw,sh.
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036 or/27-35
037 26 and 36

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012 or/6-11
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016 (parent$ adj1 (decision$ or choice or preferenc$ or participat$)).tw.
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020 informed choice.tw.
021 or/14-20
022 13 or 21
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038 22 and 37

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009 patient.tw,hw.

010 consumer.tw,hw.
011 exp health behavior/
012 or/6-11
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026 or/23-25
027 22 and 26

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Purchasing Over-The-Counter Medications: The Influence of Age and Familiarity

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This study examines the influence of age and type of over-the-counter (OTC) medications on decision-making processes leading to the selection of OTC medications. Manipulating type of OTC medication served as a way of examining subjects' familiarity with the decision domain. Thirty-six younger and thirty-six older adults answered questions regarding their OTC medication purchases, and completed a decision task in which they searched four computerized displays of product label information in order to select an antacid, a cold medication, a laxative, and a pain reliever. In general, older adults were slower to review information, more likely to have used OTC medications, and more organized in their searches for information. Specific to pair relievers, older and younger adults demonstrated similar information use and time to decision, and older adults specifically tailored the organization of their information searches when choosing pain relievers. Clearly, older adults selectively use product information on OTC medication packages, given adequate time to process information. Manufacturers' efforts directed at improving information availability should benefit older adults' decision processes.

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Because age-related health problems and prescription medication use increase the risk of potential harmful drug interactions, side effects, and other iatrogenic effects, there is growing concern among health care professionals regarding over-the-counter (OTC) medication usage by older adults. Empirical studies of the older adult decision-maker can illuminate cognitive processes underlying these decisions in order to allay such concerns or inform interventions. The purpose of this investigation was to empirically examine the on-line cognitive processes of older adult decision makers as they select OTC medications.

Health care professionals are increasingly concerned about the OTC medication use of older adults. Unlike prescription medications, where access is monitored by physicians and pharmacists, consumers select OTC medications. Health care professionals are concerned about these consumer decisions because they consider sources of relevant decision information, that is, product labels, advertisements, and family or friends, inaccessible, unreliable, and invalid (Sclar, Robison, & Skaer, 1996). In addition, given the number of brand names, generic, and private store labels, as well as the alternatives such as herbal or home remedies, the selection task itself can be overwhelming. For example, OTC medications for symptoms of the common cold alone number over 800 (Lowenstein & Parrino, 1987). Increasing health problems and prescription medication use related to aging increase the potential for adverse drug interactions, additive side effects, and other iatrogenic effects (Nonprescription Drug Manufacturers Association [NDMA], 1995). Sclar and colleagues (1996) documented the significance of poor decision making in the selection of OTC medications in a demonstration project where pharmacy students provided consultation to 745 customers purchasing OTC medications and prevented potentially adverse medication outcomes in 7.1% of the study population.

Selecting the appropriate OTC medication is one of the most frequent health care decisions made by older adults. Findings from a random telephone survey of 1500 households in 1992 revealed that during a two-week period, adults aged 65 and older report on average 5.1 common symptoms (e.g., headache, cold, upset stomach, etc.), for which 28% took an OTC medication (NDMA, 1995). Stoller, Forster, and Portugal (1993) reported even greater use of OTC medications for specific symptoms recorded by 669 community-dwelling older adults in a health diary kept for a three-week period. Indeed, they found that OTC medications were the most frequently used treatments for fever (45.1%), runny nose (45.8%), sore throat (62.4%), cough (49.7%), nausea (33.3%), diarrhea (44.6%), constipation (58.5), indigestion (65.9%), headache (76%), and muscle or joint pain (51.8%).

Previous studies examining age differences in decision-making processes have employed a variety of decision domains, including financial planning (e.g., Walsh & Hershey, 1993), treatment of breast cancer (e.g.,

Meyer, Russo, & Talbot, 1995), buying cars (e.g., Johnson, 1990), renting apartments (e.g., Johnson, 1993, 1997), and voting for political candidates (e.g., Riggle & Johnson, 1997). While some performance measures, such as the mean time spent viewing information, show consistent age differences reflecting more efficient viewing for younger adults and more reflective viewing for older adults (Johnson, 1990, 1993, 1997; Riggle & Johnson, 1997), other performance measures, such as information use, do not show consistent age differences (Hartley, 1989; Johnson, 1990). Findings of age differences in the organization of information searches also show that sometimes older adults prefer feature-based searches (i.e., when purchasing a car; Johnson, 1990), but also sometimes prefer choice-based searches (i.e., when voting for a political candidate; Riggle & Johnson, 1997). In these decision domains, younger adults show no particular organizational preferences for information search patterns.

The present study investigates older adults' decision-making processes leading to the selection of OTC medications. Following from earlier studies of the older adult decision maker, it was hypothesized that older adults would process information more slowly than younger adults. However, due to their previous use of OTC medications, older adults would also demonstrate greater familiarity with OTC medications and that should influence the organization of their information search patterns reflecting the application of decision rules. The task performance of older adults was compared to that of younger adults to highlight age differences reflecting improvements as well as declines. The decision task included four different types of OTC medications: antacids, cold remedies, laxatives, and pain relievers. In addition to the above hypotheses, it was expected that younger and older adults would differ on the extent of their familiarity with specific OTC medications (e.g., younger adults would be less familiar with antacids and laxatives due to less frequent use). In order to investigate the use of information from product labels and the implication of familiarity with decision-relevant information during decision processes, brand name identifiers were eliminated from study stimuli.

METHOD

Design

A 2 (age group) by 4 (type of OTC medication) by 4 (order of OTC selection) mixed experimental design addressed study goals. The experimental task employed a computerized process tracing technique in order to measure decision processing times, information use, and organization of searches of younger and older adults selecting OTC medications. This technique yielded computerized decision process tracing protocols for

each of four multichoice, multiattribute OTC drug information matrices for each subject. Younger and older adults comprised the two age groups. The four types of OTC medications were antacids (A), cold remedies (C), laxatives (L), and pain relievers (P). The four presentation orders were ACLP, CLPA, LPAC, PACL; this assured that each OTC medication appeared in each position (1st, 2nd, 3rd, and 4th). In order to describe younger and older adult samples, additional data were collected via paper/pencil on age, gender, education, vocabulary skills, health status, and health-related activities. Subjects also answered questions regarding the extent to which they typically read product labels. Further, for each of the OTC medications, subjects reported the following: the extent to which they used the product, the brand name they usually purchased, their reasons for purchasing that brand, the most important information on the label for them, and the extent to which price is important to their purchasing decisions.

Sample

Thirty-six young adults were recruited from upper level undergraduate and graduate arts and science courses on the University of Kentucky campus. Thirty-six older adults were recruited from the University of Kentucky Sanders-Brown Center on Aging volunteer subject pool. Nine younger and nine older subjects were randomly assigned to each of the four presentation conditions (ACLP, CLPA, LPAC, and PACL). The mean age of the younger adults was 23.6 years ($\pm$2.47) and the mean age of the older adults was 66.6 years ($\pm$2.78).

Procedure

Subjects participated individually using a laptop computer (previously programmed by the first author) to complete the experimental task and paper/pencil to answer all questionnaire items. After obtaining informed consent, subjects completed a brief demographic questionnaire and the Shipley Institute of Living Vocabulary test (Shipley, 1967). Demographic questions included age, gender, years of education, and self-rated health status (poor, fair, good, excellent). The vocabulary test consisted of 40 multiple-choice items with scores ranging from 0 to 40.

All participants received on oral overview and demonstration of the task to familiarize them with the computer keys. This demonstration involved selecting a sleep aid from a matrix with information on active ingredient, dosage, price, and warnings for four choices (labeled A, B, C, and D). All stimuli for the demonstration and experimental task were derived from actual brand name product labels. In the experimental task, there were four matrices presented in succession. Each matrix required subjects to choose one of seven OTC medications listed for each type of

OTC product. Information was organized into four 7 × 7 matrices with fictional names denoting the choices across the columns, and product information, (active ingredient, dosage, drug interactions [for antacids and cold remedies] or precautions [for laxatives and pain relievers], price, side effects, uses, and warnings) labeling the rows. To select a piece of information for viewing, subjects pressed cursor keys to highlight a cell of the matrix and then pressed the ⟨Enter⟩ key. When they finished reading information, subjects pressed the ⟨Backspace⟩ key; the information disappeared and the cell was marked with an asterisk. Subjects could revisit any cell already marked with an asterisk to review that information. At any time during the task, subjects could choose a medication using a DECISION option or reread the introductory description of the task and instructions regarding how to use the computer in an OVERVIEW option. After the subject made a decision about each type of OTC medication, the next matrix would appear.

After the experimental task, subjects completed a six-page questionnaire. The first page consisted of three questions regarding whether subjects typically read package labels (i) to help them decide which OTC medication to take, (ii) before taking an OTC medication for the first time, and (iii) before taking an OTC medication again (after a previous use). The next four pages focused on subjects' experience in purchasing and using each of the four types of OTC medications in the study. Questions included (i) whether they had used or purchased the medication, (ii) which brand they usually purchased and why, (iii) whether they bought generic or store labels, (iv) which information on the label was most important when buying the medication, and (v) a five-point rating of the importance of price when buying each type of OTC medication (anchored by "not at all" to "extremely"). The final page of the questionnaire listed 28 health-related activities, such as "walking for exercise" and "taking vitamins." Subjects indicated the frequency with which they engaged in the activities on a scale from 0 to 3 (never, sometimes, often, always). These items were previously used in the survey on Consumer Uses of Nonprescription Medicines commissioned by the NDMA (1992), and were included to examine the comparability of the younger and older samples.

Measures

Frequencies for response categories for gender, educational attainment, and health status, mean scores on the vocabulary test, and total scores for engaging in health-related activities were used to compare the younger and older adult samples. To determine younger and older adults' self-reported practices of reading package labels, their ratings on those three items were summed. Measures characterizing subjects' familiarity with OTC medications derived from previously purchasing and

using each of the OTC medications included: (i) percentages for previous use or purchase for each of the OTC medications and for purchase of generic products, and (ii) frequencies for the qualitative coding of brands purchased, reasons for purchasing, and important label information.

Measures from the experimental task included: time per information, information used, choice and feature ratios of repetition. *Time per information* was calculated as the mean number of seconds spent viewing each cell of information accessed. *Information used* was a proportion calculated from the number of cells accessed at least once divided by the total number of cells available. The *choice and feature ratios of repetition* reflected the organization of the information searched. A good conceptual explanation of ratio of repetition for features is simply the proportion of times that the participant views the same feature (but different choices) on two successive trials with correction for the dimensions of the matrix. These measures are similar to subjective organization measures of free recall such as Adjusted Ratio of Clustering (ARC) (see also Murphy & Puff, 1982). In these measures, features and choices are treated as two categories and the subject's information requests are "clustered" within these categories.

RESULTS

Sample Characteristics

Measures describing younger and older adult samples are shown in Table 1. Chi-square analyses revealed no differences in gender, education, or health status associated with age. The lack of differences in health status was not surprising given that older adult subjects were a relatively "young" group, and were obtained from a highly educated and healthy pool of research volunteers. Further, regarding their self-reported health status, older adults often report better self-assessed health than objective indicators of health would suggest (Idler, 1993). Although older adults subjectively report similar health status compared to younger adults, in this study the similarity may not be objectively true. Later results, showing somewhat higher OTC medication usage by older adults, imply poorer objective health status in the older group. Regardless, for purposes of this study, comparable self-reported health status is acceptable because findings involving OTC medication decisions should generalize to persons who perceive themselves to be healthy enough to engage in self-care rather than requiring formal care for poorer health status. Older adults had higher vocabulary scores than younger adults ($t(70) = .3.65$, $p < .0005$), and were also more likely to report engaging more frequently in health-related activities in comparison to younger adults ($t(70) = .3.73$, $p < .0005$).

TABLE 1 Percentages and Means (With Standard Deviations) for Measures Describing Characteristics of Younger and Older Adult Samples

Measure	Younger adults ($n = 36$)	Older adults ($n = 36$)
Gender (% male)	52.7%	50%
Education		
8th grade	—	3%
High school	3%	8%
College	67%	42%
Professional	31%	47%
Health status		
Poor	—	—
Fair	8%	8%
Good	44%	44%
Excellent	47%	47%
Vocabulary (of 40)	32.5 (3.96)	35.6 (3.37)
Health-related activities (of 84)	59.9 (9.64)	68.6 (10.31)

Familiarity with OTC Medications

Younger and older adults responded similarly to three items regarding the extent on a 4-point scale to which they read product labels (summed means: $M_Y = 9.2$ [± 1.56], $M_O = 9.7$ [± 1.77]; $t(70) = 1.34$, *NS*). These findings relate to differences in familiarity with information relevant to the decision domain. For three of the four OTC medications, younger and older adults were just as likely to have previously purchased or used the medication. As shown in Figure 1, most younger and older adults had previously purchased or used cold remedies and pain relievers, although there were fewer from both age groups who had previously purchased or used antacids. There were no age differences in these distributions. However, younger adults were less likely than older adults to have purchased or used laxatives ($X^2(1, n = 72) = 16.0$, $p < .001$). Of note, these percentages suggest that all subjects were familiar with antacids, cold remedies, and pain relievers and less familiar with laxatives; even though more older adults had purchased or used laxatives, almost half of the older adult sample had not.

In contrast, older adults were more likely than young adults to respond that they bought generic equivalents rather than brand name OTC medications. This requires more familiarity with active ingredient information. Forty-two percent of older adults compared to 4% of younger adults bought generic antacids ($X^2(1) = 9.51$, $p < .01$), 42% of older adults compared to 9% of younger adults bought generic cold

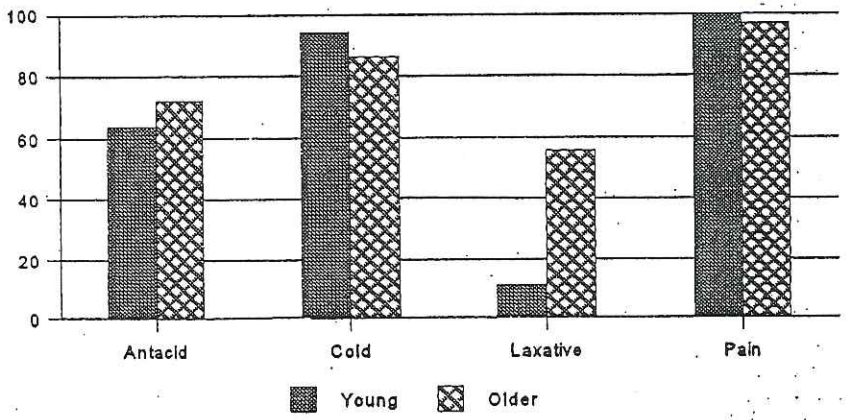

FIGURE 1 Percent of young and older adults previously using or purchasing OTC medications.

remedies ($X^2(1) = 9.58$, $p < .01$), and 60% of older adults compared to 25% of younger adults bought generic pain relievers ($X^2(1) = 8.91$, $p < .01$). Although the comparison did not reach significance due to small numbers of observations, 45% of older adults compared to 0% of younger adults who brought laxatives chose generic products. Purchasing generic products requires greater familiarity with OTC medications in order to determine which generics are equivalent to brand name products. Consequently, this finding implied that even though younger adults were as likely to have purchased or ever used antacids, cold remedies, and pain relievers as older adults, younger adults did not appear to be as familiar with equivalent to brand name OTC medications.

Finally, despite the economic incentives for purchasing generic OTC medications instead of their brand name counterparts, older adults did not consider price to be more important to their purchasing decisions than younger adults. Younger and older adults ratings of the importance of price to the purchase of antacids, cold remedies, laxatives, and pain relievers showed no statistical differences (mean price ratings for antacids: $M_Y = 2.81$ (± 0.98), $M_O = 2.83$ (± 1.21); mean price ratings for cold medications: $M_Y = 2.56$ (± 1.16), $M_O = 2.63$ (± 1.29); mean price ratings for laxatives: $M_Y = 2.69$ (± 1.06), $M_O = 2.54$ (± 1.27); mean price ratings for pain relievers: $M_Y = 3.08$ (± 1.05), $M_O = 2.94$ (± 1.15); all p values were nonsignificant).

Decision Task Performance

Means (and standard deviations) for each of the performance measures are displayed in Table 2. Two (age) by four (OTC medication) by four (order of selection) mixed analyses of variance (ANOVAs) were con-

TABLE 2 Means for Decision Task Performance Measures

	Younger adults ($n = 36$)				Older adults ($n = 36$)			
Measure	Antacid	Cold	Laxative	Pain	Antacid	Cold	Laxative	Pain
Time/Information	2.6	2.5	2.9	2.8	4.8	5.4	5.0	4.9
	(1.02)	(.93)	(1.40)	(1.23)	(1.87)	(2.78)	(2.25)	(2.23)
Information Used	.53	.57	.56	.48	.58	.60	.63	.49
	(.188)	(.160)	(.172)	(.192)	(.258)	(.254)	(.219)	(.245)
Feature organization	.65	.70	.70	.63	.73	.71	.72	.62
	(.194)	(.168)	(.173)	(.200)	(.211)	(.205)	(.221)	(.236)
Choice organization	.23	.19	.20	.26	.23	.24	.21	.29
	(.160)	(.144)	(.176)	(.192)	(.249)	(.217)	(.228)	(.247)

Note. Values in parentheses are standard deviations.

ducted on the mean time per information and the proportion of information used. These analyses revealed a main effect for age on mean time per information cell, an indicator of whether older adults process information more slowly than younger adults ($F(1,64) = 40.24$, $p < .0001$, $MSE = 394.00$). The main effect of age on mean time per information was accompanied by two interactions, an OTC medication by order of selection interaction ($F(9,192) = 7.87$, $p < .0001$, $MSE = 7.41$) and an age by OTC medication by order of selection interaction ($F(9,192) = 2.04$, $p < .05$, $MSE = 1.92$). The main effect indicated that older adults were slower to view information cells than younger adults, the prediction and finding consistent with previous research. The interaction of OTC medication by order showed that viewing information was also dependent on type of OTC medication and order of presentation, suggesting that familiarity with specific OTC products and having made previous decisions within the experimental task also influenced viewing time. This finding was particularly evident for all subjects when pain relievers were last in order of presentation (mean time per information = 3.0 s), compared to when they were first in order of presentation (mean time per information = 4.5 s). The second interaction of OTC medication by order by age showed that older adults took longer to view information about OTC medications. For example, when older adults made decisions about cold remedies, mean time per information was 6.7 s when cold remedies were first in order of presentation, compared to 5.2 s when they were last in order of presentation. Similarly, for antacid decisions made by older adults, mean time per information was 5.0 s when antacids were first in order of presentation, versus 2.2 s when they were presented last. (Younger adults, in general, took less time to view information but showed similar variation across medications.) A main effect for type of OTC medication on proportion of information used ($F(3, 192) = 11.13$, $p < .0001$, $MSE = .180$), a measure reflecting the influence of familiarity with OTC medications, confirmed that younger and older adults used less information when selecting pain relievers in comparison to other OTC medications.

A two (age) by four (OTC medication) by four (order of selection) by two (feature- and choice-based ratios of repetition) mixed ANOVA was conducted on the organizational measures, to examine whether younger and older adults organized their information searches differently depending on their familiarity with specific OTC medications. This analysis revealed a main effect for age ($F(1,64) = 14.65$, $p < .001$, $MSE = .094$) and a main effect for ratio of repetition ($F(1,64) = 126.13$, $p < .0001$, $MSE = 29.76$). The main effects of age and ratio of repetition indicated that older adults showed more organization in their search patterns and that both younger and older adults favored feature-based organization (i.e., they looked at rows of information rather than columns). The analysis also revealed an interaction of OTC medication and ratio of

repetition ($F(3,192) = 7.61$, $p < .0001$, $MSE = .181$). This interaction indicated that the search pattern varied according to type of OTC, confirming that familiarity with OTCs also influenced decision rules.

Linking Self-Reported Purchasing to Decision Task Performance

In order to further establish that differences in familiarity with OTC medications influenced decision performance, we linked self-reported purchasing experiences to decision task performance measures. Linkages between the two sources of data focused on (i) the information cited as most important to purchasing decisions and the information most often used in the experimental task, and (ii) the brand names listed as usually purchased and the OTC medication selected in the experimental task (albeit the labels of the alternatives included in the experimental decision task did not use brand names although the information from labels was identical to the original brands).

Content analysis of younger and older adults' responses to the most important information from product labels when purchasing OTC medications showed that they considered different types of information to be most important. Most younger adults listed side effects and product uses to be the most important information when purchasing antacids, cold remedies, and laxatives. They listed active ingredients and side effects to be the most important information when purchasing pain relievers. In contrast, older adults listed active ingredients and side effects to be most important in purchasing cold remedies, laxatives, and pain relievers; and active ingredients and warnings to be most important when purchasing antacids. Data from the experimental task confirmed the importance of active ingredient information to older adults (possibly linked to their purchasing generic brands). That is, older adults consistently requested active ingredient information significantly more often than younger adults (antacids: 4.4 ($\pm$3.14) vs. 2.5 ($\pm$2.84), $t(70) = 2.60$, $p < .05$; cold remedies: 3.4 ($\pm$3.18) vs. 2. 0 ($\pm$2.56), $t(70) = 2.12$, $p < .05$; laxatives: 4.2 ($\pm$3.08) vs. 2.3 ($\pm$2.66), $t(70) = 2.75$, $p < .05$; pain relieves: 4.3 ($\pm$3.25) vs. 2.7 ($\pm$3.02), $t(70) = 2.25$, $p < .05$). The only other significant difference in requests for information involved the price of pain relievers. Younger adults viewed price information for pain relievers more often than older adults (3.9 ($\pm$2.72) vs. 2.7 ($\pm$2.60), $t(70) = 2.03$, $p < .05$).

To test whether subjects' self-reported purchasing preferences translated into their selections in the decision task, brand name preferences from the questionnaire were linked to final choices from the decision task. The frequencies of subjects' listings brand names were conditionalized on the number of subjects reporting that they had previously purchased or used the OTC medications. For antacids, 21 of 23 of younger adults and 19 of 26 of older adults listed a brand name. Of those listing a brand name, 16 younger adults and 18 older adults listed one of the seven brand name antacids that were used in the experimental task. Despite the lack of identifying brand names in the decision matrices, only 4 younger adults and 5 older adults chose the brand they usually bought from the decision matrix. For cold remedies, 28 of 34 of younger adults and 19 of 31 of older adults listed a brand name. Of those listing a brand name, 7 younger adults and 3 older adults listed one of the seven brand name cold remedies that were used in the experimental task. Only one of these subjects (a younger subject) actually chose the brand she or he usually bought. This was similar to the pattern observed for laxatives: 3 of 4 of younger adults and 13 of 20 of older adults previously purchasing or using laxatives listed a brand name that they usually bought. Three younger adults and 9 older adults listed brand names used in the experimental task, but only one of these (an older subject) actually chose the brand she or he usually bought. Although the above findings for antacids, cold remedies, and laxatives were not conclusive of a link between previous familiarity and decision performance, the pattern for OTC pain relievers revealed a sharp contrast. Thirty-three of 36 of younger adults and 23 of 35 of older adults who had previously purchased or used relievers listed a brand name that they usually bought. Thirty-three younger adults and 21 older adults listed brand names used in the experimental task. Nine younger adults and 10 older adults chose the alternative in the experimental task that was the same as the brand they usually bought. Although these numbers were suggestive of age differences, they were not statistically significant due to cell frequencies. Thus, greater familiarity with OTC pain relievers may have led both younger and older adults to choose their regularly preferred brand even in the absence of the actual name in the experimental task.

DISCUSSION

Analysis of the mean time spent viewing information revealed a main effect for age, a two-way interaction for type of OTC medication and order of selection, and a three way interaction of age, type of OTC medication, and order of selection. Consistent with predictions made from previous research, older adults took almost twice as much time as younger adults to view information. Viewing time, however, was also affected by interactions involving the type of OTC medication and the order of selection of OTC medications and age. Specifically, younger and older subjects took less time to review information about pain relievers (especially when presented last) than any other OTC medications. Older subjects took longer to view information about cold remedies and laxatives, especially when they were the first decisions made. This would suggest that familiarity with pain relievers moderated the impact of age-

related slowing. Further, the order effect indicated that repeatedly selecting OTC medications accelerated subjects' application of decision rules, suggesting implications for training or practice. Analysis of the proportion of information used revealed only a main effect of type of OTC medication. Younger and older adults used less information when selecting pain relievers—the OTC medication almost all subjects had previously used or purchased. It is quite likely that possessing prior familiarity with the pain relievers in a decision-making task reduced the information needed to make a selection. Linkages between subjects' self-reported purchasing practices and decision task performance also suggested that knowledge about specific OTC medications guided selections made in the experimental task. These findings fit with those of Meyer and her colleagues (1995) who also found that older adults took longer to view information and, in some instances, used less information. Indeed, these findings may suggest that there are particular conditions or decision domains requiring less information before making decisions.

Study findings also revealed age-related differences in the organization of information searches that have implications for the application of decision rules. Older adults were more organized than younger adults. For the most part, both younger and older adults preferred to search matrices by row (features) rather than columns (choices). However, the pattern of means and a significant two-way interaction between type of OTC medication and feature- versus choice-based measure indicated that the predominance of feature-based searches was attenuated when selecting pain relievers—the most commonly used OTC medication. Feature-based searches using smaller proportions of the available information are indicative of Elimination By Aspects (EBA) decision rules. That is, decision makers prioritize features and evaluate all alternatives on the most critical feature. If no single alternative meets their criteria, decision makers evaluate only those alternatives meeting the most important criteria on the second most important feature (i.e., eliminating some of the alternatives). Decision makers continue eliminating alternatives until only one remains—their final choice. In contrast, choice-based searches also using smaller proportions of the available information are indicative of Satisficing decision rules. As in the EBA strategy, decision makers use only the featural information most important to them. However, when using this rule, decision makers look at all the featural information deemed important for one alternative, and, if it satisfies their criteria, they select that alternative. If the first alternative fails to satisfy their criteria, decision makers continue evaluating each alternative and select the first one to meet their criteria. Thus, the significant interaction on the measures of organization of information searches could indicate that subjects used decision rules similar to EBA for most OTC medication selections, but that some used decision rules similar to satisficing for the selection of pain relievers with which they were more familiar—

linking familiarity with the application of decision rules.

In this study, we experimentally manipulated type of OTC medication in order to examine the influence of familiarity. It would have been better to directly manipulate familiarity with OTC medications, but this was not feasible. In lieu of direct manipulation, we indirectly manipulated familiarity via type of medication. Although medications within each type were highly similar on salient features (e.g., package size, medication delivered in pill form, and price), it could still be argued that OTC medication types varied on other features in addition to familiarity. Findings from the decision task performance and self-report questionnaires, however, support our interpretation and choice of manipulations. Thus, we conclude that examining the influence of familiarity through the indirect manipulation was plausible as well as feasible.

Conceptually, however, familiarity is not necessarily factual information about OTC medications, but may reflect awareness of brand name products. For example, subjects reviewing active ingredients may have associated that information with well-advertised brand names; and, because there was only one pain reliever whose active ingredient was acetaminophen, many of these subjects selected their usual brand of choice (i.e., Tylenol). Older adults' comments supported this, as several suggested that although it was important information, knowing the active ingredient wasn't always helpful because they didn't know much about drugs. Despite their inability to readily use information, older adults realized the importance of reviewing such information, because it enables them to purchase the generic equivalents of brand name products.

Several other indicators also suggested that age-related differences in familiarity with OTC medications had an effect on decision-making processes. First, linkages between self-report and task performance data suggested that not only did older adults consider information about an OTC medication's active ingredients to be important, they also reviewed that information when selecting OTC medications, despite doubting their comprehension of the information. Second, almost one third of the younger and older adults matched the brand name pain relievers listed as usually purchased with their selections of pain relievers in the experimental task, despite the missing brand name. This finding suggests that even though brand names were excluded in the decision task, subjects had sufficient knowledge of their brand preferences to choose them from among the alternatives. In contrast, neither older nor younger subjects were very familiar with laxatives. Even the minority who had previously used or purchased laxatives were not able to match the brand they typically bought to those in the decision task.

Understanding the decision processes and OTC medication knowledge of older adults is important because it can inform the development of interventions aimed at aiding older adults in their use of OTC medica-

tions. Comprising approximately a 10th of the population, older adults are responsible for consuming over a quarter of OTC medications used in this country (NDMA, 1995). Given that drug interactions present a potential danger to older adults, interventions should be directed at persuading and informing older adults of the importance of this information on product labels and enabling them to use information more effectively. For example, in the intervention Sclar et al. (1996) report, they directed their pharmacy students to encourage older adults to purchase generic products. Data from the present study suggest that older adults were more likely to purchase generic products than younger adults, and in searching information about alternatives, were more likely to examine information about active ingredients. It would seem that older adults have not only realized the value of purchasing generic products but also understand how to evaluate potential replacements for their brand preferences. However, they may need additional information to fully comprehend information about active ingredients.

The study findings raise additional questions regarding the nature of the empirical relationship among experience, familiarity, domain-specific knowledge, and potentially, the development of expertise. Other cognitive aging researchers have also tried to disentangle the effects of age from familiarity or prior experience. In doing so, some researchers have focused on differences between younger and older adults with specific expertise such as airline pilots (e.g., Morrow, Leirer, Altieri, & Fitzsimmons, 1994). Others have examined the effects of training novices to perform complex cognitive tasks such as financial planning (e.g., Hershey, Walsh, Read & Chulef, 1990). Sampling young and older adults augments the influence of familiarity due to the known differences in utilization rates of various OTC medications—that is, older adults are more likely to self-medicate with OTC medications and are therefore more familiar with them. Charness and Bieman-Copland (1992) explain the linkages between familiarity, learning, and knowledge (particularly domain-specific) that can mitigate the normal cognitive declines of aging. They suggest that experience provides knowledge in the form of increased "access to normatively poorly known" information. Although it is clear that expertise moderates the effects of age-related declines in basic cognitive processes, the extent to which familiarity ameliorates those same declines remains to be established. Clearly, more research is needed to determine the influence of familiarity on OTC medication decision processes.

Implications

Theoretically and practically, older adults did not appear to be at a disadvantage when selecting OTC medications. However, the source of

their knowledge about OTC medications, as well as the quality of information and their ability to use the information are not clearly understood. Further, the role of brand names in decision processes and the impact of advertising are poorly understood. The importance of these influences on the selection of OTC medications was illustrated by the recent Food and Drug Administration announcement that the active ingredient in many OTC laxatives may pose a carcinogenic risk for humans. In response, one of the major nonprescription drug manufacturers recalled their product and began an advertising campaign so that their customers would remain loyal to the brand name that was retained on the re-formulated product. A month after the original announcement and campaign, a media survey reported that only 6% of laxative users were aware of the news and only about 20% realized there were major differences in the active ingredients of laxatives (Travis, 1997). Clearly, the information processing of older adults as they make decisions about the purchase and use of OTC medications warrants additional research.

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CHAPTER SIX

EXPECTED VALUE DECISION MAKING

With this chapter, our emphasis shifts from *diagnosis* to *making choices.* A clinician makes many choices every working day: a test is ordered, a treatment is chosen, or a patient is hospitalized. The experienced clinician makes many decisions easily because there is little at stake or because the problem is familiar. The experienced clinician has standard operating procedures for many such situations. These heuristics, or *clinical policies,* are among the distinguishing features of the master clinician.

Unfamiliar problems are important sources of intellectual stimulation for clinicians. These situations often require careful thought before a choice is made. When perplexed, the physician seeks help from a colleague or goes to the library. These responses are important but are not always sufficient, because the solutions obtained from the medical literature or a colleague's personal experience may not apply to an individual patient. Required resources may be unavailable. Clinicians need a general approach to decision making when the situation is unique, the outcome is uncertain, and the stakes are high or when trying to formulate a clinical policy that will be applied many times in the future.

There are several quantitative methods that use the ideas developed in the preceding chapters to solve difficult clinical decision problems. These methods include:

- *The decision tree:* A method for representing and comparing the expected outcomes of each of the management alternatives
- *Threshold probability:* A method for deciding if new information can change a management decision

These methods enable the decision maker to understand the decision problem and choose the management alternative that is most likely to help the patient.

The purpose of this chapter is to show how decision analysis is applied to an easy clinical problem. In learning about decision analysis, the reader will understand the importance of measuring clinical outcome, which will be described in the following two chapters. Decision trees and decision thresholds are the subjects of subsequent chapters. At that point, the reader will have learned a general approach to making difficult clinical decisions.

This chapter is divided into two parts:

A. Basic concepts of expected value decision making
B. Decision analysis: An introductory example

A. BASIC CONCEPTS OF EXPECTED VALUE DECISION MAKING

A.1 Comparing Uncertain Prospects

Most biological events occur randomly. Consequently, the outcome of an individual's illness is unpredictable. Even something as stereotyped as a common cold may last 2 days, 1 week, or even 2 weeks. Choosing among treatments with unpredictable effects is a challenging problem. Consider two hypothetical treatments for a fatal illness. Survival after undergoing either treatment is unpredictable, as illustrated by a frequency distribution of length of life (see Figure 6–1). These distributions may also be summarized in tabular form, as in Table 6.1.

Giving treatment A is a gamble. There is no way to know which year will be the patient's last. The time of death is also uncertain with treatment B. Although survival until the fourth year is more likely with treatment B, the patient might die in the first year with treatment B and survive to the fifth year with treatment A. Thus, the choice between these treatments is a choice between gambles.

How should one choose between these two gambles? One approach is to characterize each gamble by one number and use that number as the basis for choice. The ideal criterion for choosing a gamble should be a number that reflects preferences for the outcomes of the gamble. *Utility* is the name given to a measure of preference that has a desirable property for decision making: the gamble with the highest utility *should* be preferred. Utility will be described in Chapter 7.

FIGURE 6–1
Time of death after two hypothetical treatments for a fatal disease.

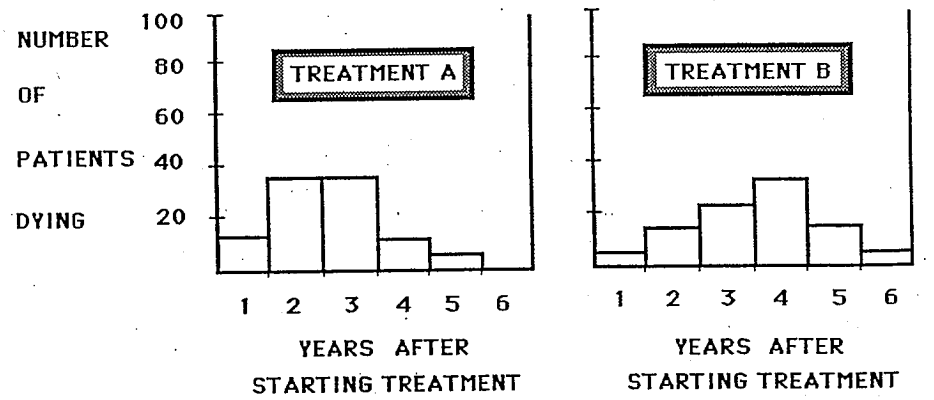


TABLE 6.1
Mortality Probabilities of Two Treatments

	Probability of Death	
Years after Treatment	*Treatment A*	*Treatment B*
1	.15	.05
2	.35	.15
3	.35	.25
4	.10	.35
5	.05	.15
6	0	.05

For this introductory chapter, we will use the average duration of life to summarize gambles involving length of life. The mean duration of survival is obtained by weighting the length of a period of survival by the probability that death will occur at the end of that period and summing these over all possible lengths of life. (Death during an interval is assumed to occur at the midpoint of the interval.)

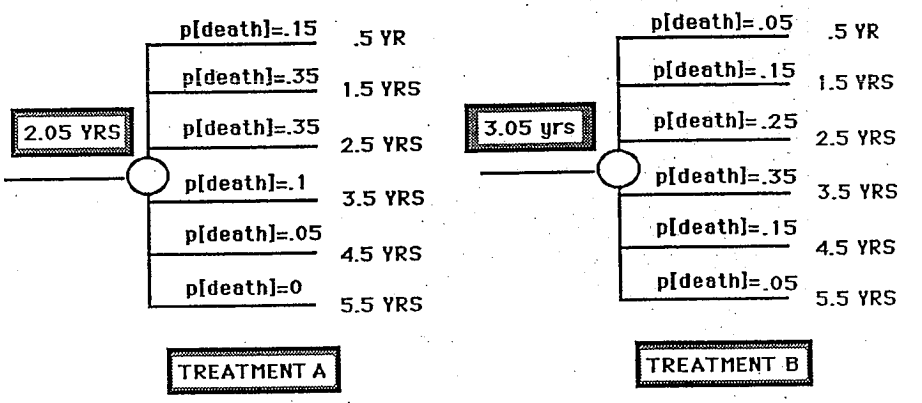
$$\begin{aligned}\text{Mean survival for treatment A} &= (.15 \times .5 \text{ yrs}) + (.35 \times 1.5 \text{ yrs}) + (.35 \times 2.5 \text{ yrs}) \\ &\quad + (.1 \times 3.5 \text{ yrs}) + (.05 \times 4.5 \text{ yrs}) \\ &= 2.05 \text{ years}\end{aligned}$$

$$\begin{aligned}\text{Mean survival for teatment B} &= (.05 \times .5 \text{ yrs}) + (.15 \times 1.5 \text{ yrs}) + (.25 \times 2.5 \text{ yrs}) \\ &\quad + (.35 \times 3.5 \text{ yrs}) + (.15 \times 4.5 \text{ yrs}) \\ &\quad + (.05 \times 5.5 \text{ yrs}) \\ &= 3.05 \text{ years}\end{aligned}$$

Thus, treatment A is a gamble characterized by an average length of life equal to 2.05 years. Treatment B is a gamble characterized by an average survival of 3.05 years. If length of life is the criterion for choosing, treatment B is a better gamble.

The uncertainty of the length of life after the two treatments may also be represented as shown in Figure 6–2. The circle is a *chance node,* which is a symbol that is used in a decision tree. A chance node is a representation of an event that is under the control of chance. Each line emanating from the chance node corresponds to one of the events that might occur. The expected value at these chance nodes is calculated by the process just described: Each chance node outcome is multiplied by the probability that it will occur, and

FIGURE 6–2
A chance node representation of survival after two treatments.



the products are summed over all outcomes. The place of chance nodes in a decision tree will be discussed in the latter half of this chapter.

A.2 Expected Value Decision Making

The terminology for characterizing gambles is expected value. *Expected value is the result that is expected on the average.* Death could occur earlier with treatment B than with treatment A, although the opposite is more likely. We do not know when any one patient will die, but we do know what to expect on the average: The expected length of life with treatment A is 2.05 years and 3.05 years with treatment B.

We will use *expected value* as our terminology for characterizing choices with uncertain outcomes. In this example, the outcome measure was length of life. The outcome measure could have been dollars spent for care, number of days confined to bed, or a measure of how the patient felt about the quality of his life. These gambles would then have been characterized by their expected cost, expected bed days, or expected utility, respectively.

Consider the following strategy when there are treatment choices with uncertain outcomes: Calculate the expected value of each decision alternative, and then pick the alternative with the highest expected value. This approach is called *expected value decision making.* In this chapter, the value that we will use to characterize treatment decisions is *length of life.* Maximizing expected length of life is a reasonable criterion for choice but is not necessarily the best criterion. Nevertheless, we shall use length of life as a means of helping the reader to achieve the goals of this chapter: *learning how to create a decision tree and compute expected value.*

B DECISION ANALYSIS: AN INTRODUCTORY EXAMPLE

The expected value decision maker must become proficient in representing decision problems as decision trees. To introduce the steps involved in creating and analyzing a decision tree, we will use a hypothetical problem: Should surgery be performed on a patient with a potentially fatal illness? This decision occurs often in clinical practice. Often, there is little reason to hesitate before operating. However, the decision may be quite difficult when the disease may resolve without surgery, when the operation does not guarantee a cure, and when the operation itself is sometimes fatal.

There are four steps in decision analysis:

1. Create a decision tree: This step is the most difficult because it includes formulating the decision problem, assigning probabilities, and measuring outcomes.
2. Calculate the expected value of each decision alternative.
3. Choose the decision alternative with the highest expected value.
4. Use sensitivity analysis to test the conclusions of the analysis.

B.1 Create the Decision Tree

A decision tree is a method for representing in schematic form all the clinically important outcomes of a decision. Creating a decision tree is an opportunity to clarify one's understanding of the decision problem. The decision tree is a means of communication that may resolve conflict between several decision makers.

The following sequence of steps is used to create a decision tree:

1. Define the decision problem.
2. Identify the decision alternatives.
3. List the possible clinical outcomes of each of the decision alternatives.
4. Represent the sequence of events leading to the clinical outcomes by a series of chance nodes and decision nodes.
5. Choose a time horizon for the problem.
6. Determine the probability of each chance outcome.
7. Assign a value to each clinical outcome.

B.1.1 Define the Decision Problem

The first step in solving any problem is to define the problem clearly. To do so may require writing out a statement of the problem and reviewing each word to be certain that the problem definition is free from ambiguity.

B.1.2 Identify the Decision Alternatives

The second step in creating a decision tree is to understand the decision maker's range of options. The term *decision alternative* denotes one of the choices. The

clinician should list each decision alternative. The decision itself is represented by a *decision node.*

> **DEFINITION Decision node:** A point in the decision tree at which several choices are possible.

The symbol for a decision node is a *box.* Each decision alternative is represented by a line attached to the box (see Figure 6–3). In this case, there are two decision alternatives: surgery and medical management. Therefore, there are two lines attached to the box that represents the decision node. The decision node that represents the basic decision problem is usually placed at the left side of the decision tree.

B.1.3 List the Possible Clinical Outcomes of Each of the Decision Alternatives

Having listed the decision alternatives, the next step is to list the final outcomes of each alternative. In this case, the outcomes are given in Table 6.2.

B.1.4 Represent the Sequence of Events Leading to the Outcomes by a Series of Chance Nodes and Decision Nodes

The next step in creating a decision tree is to write down the tree. Regardless of which decision alternative is chosen, the patient's final outcome is determined by a series of chance events. An event whose outcomes are under the control of chance is denoted by a *chance node.*

> **DEFINITION Chance node:** A point in a decision tree at which chance determines which outcome will occur.

FIGURE 6–3
A decision node with two decision alternatives.

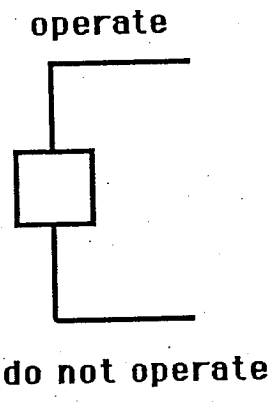


TABLE 6.2
elineating Clinical Outcomes

Decision Alternative	*Outcome*
Do not operate	Die of disease
	Survive
Operate	Die of operation
	Survive operation but die of disease
	Survive operation and remain alive

The symbol for a chance node is a circle (see Figure 6–4). Each outcome of a chance event is denoted by a line attached to the circle. Each line is labeled with the name of the outcome. Events under the control of chance include the outcome of treatment, the results of a test, or the diagnosis. The decision tree is usually written from left to right, starting with the initial decision node on the extreme left and the final outcomes on the extreme right. The sequence of chance nodes from left to right in the decision tree usually follows the temporal sequence of events. For the decision to "operate," the first event is the findings at the operation. The surgeon may find the disease to be *present* or *absent.*

- *Disease absent:* The patient may die during surgery. If the patient survives the operation, he is cured;
- *Disease present:* If disease is discovered at the time of operation, the surgeon then has a choice: carry out a risky curative operation or do a less risky but noncurative operation. This choice is represented by a decision node on the "disease present" branch of the first chance node (Figure 6–5).

FIGURE 6–4
A chance node at which two outcomes are possible.

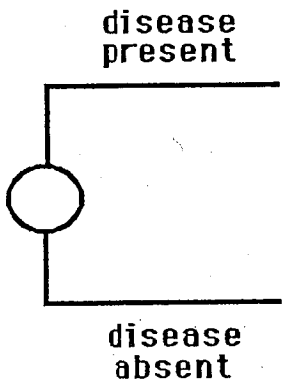
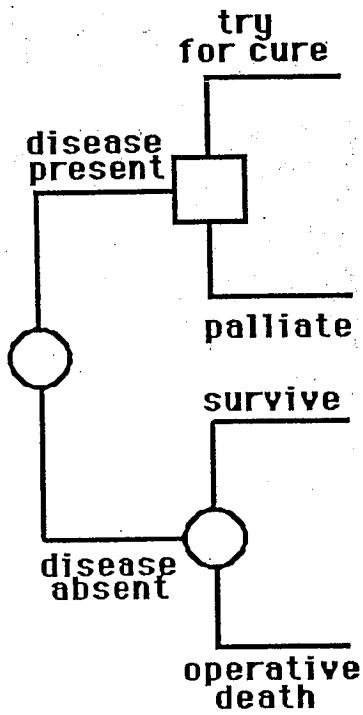


FIGURE 6–5
Outcome of the decision to operate on a patient with a hypothetical disease.



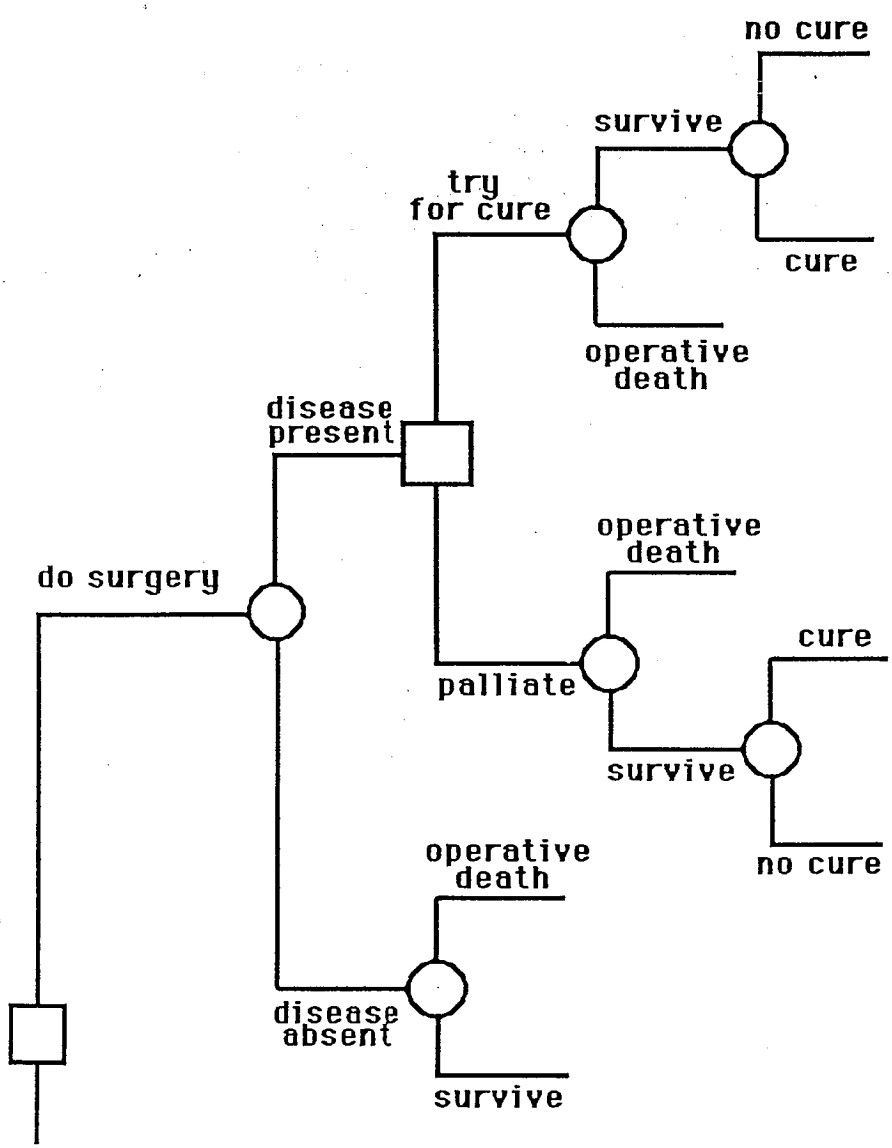
The remaining events are represented as follows: Either surgical procedure could be fatal; if the patient survives the operation, the patient may be cured. These events are represented by a series of chance nodes (Figure 6–6). The completed tree is shown in Figure 6–7.

Although this decision tree shows just two immediate outcomes at each chance node, *the number of immediate outcomes at a chance node is unlimited.* For example, if there were three outcomes of a treatment (cure, palliation, and immediate death from drug toxicity), the chance node would have three lines emanating from it. One rule must be remembered: *The events at a chance node must be mutually exclusive and exhaustive.* Thus, all events must be listed, and there must be no overlap in the definition of these events.

B.1.5 Represent the Time Horizon for the Problem

An essential step in creating a decision tree is to decide how far in the future to describe the outcomes of the decision. Ideally, the tree should represent all events until the patient dies, but such a tree is often unnecessarily complex. The decision maker has several choices:

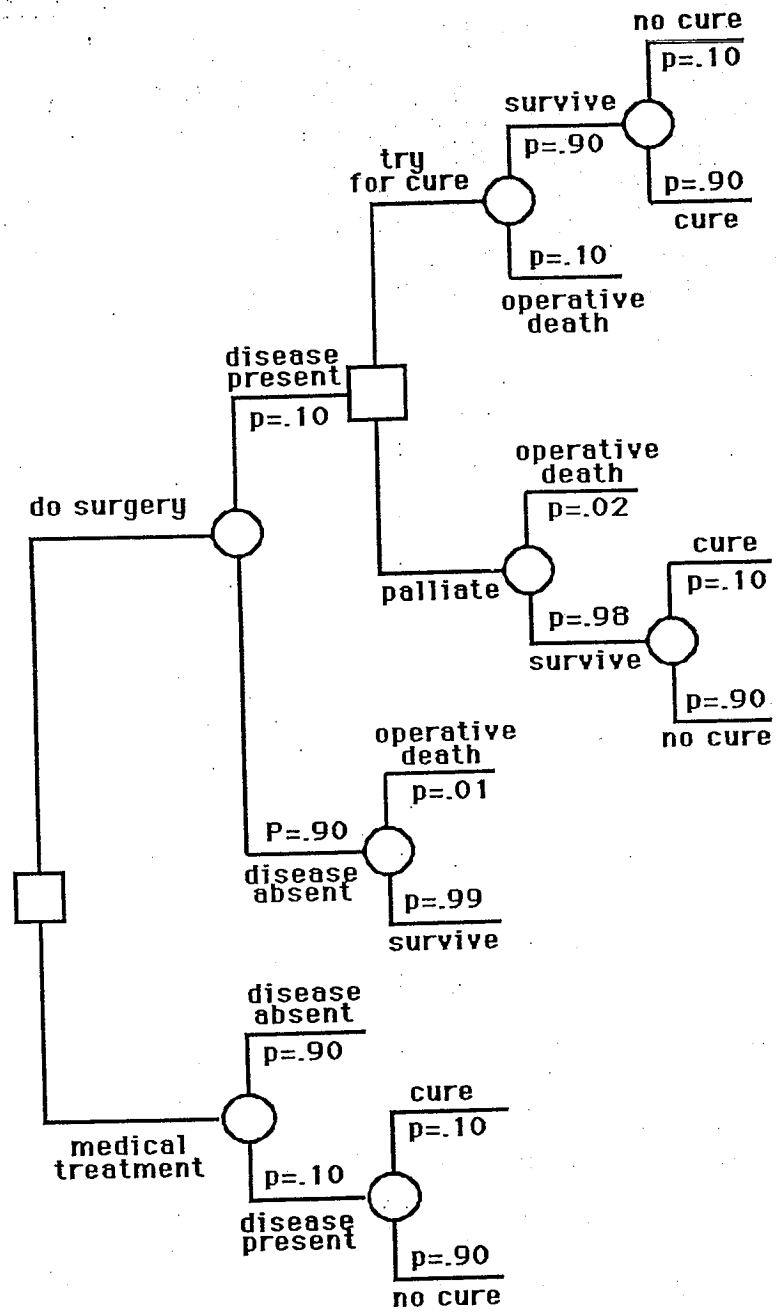
FIGURE 6–6
Outcomes of surgery for a hypothetical disease.



1. Choose a time horizon that is sufficiently short that the tree can include all possible events without becoming overly complicated.

   EXAMPLE: In an acute illness, such as sore throat or suspected appendicitis, the illness has usually resolved within a few weeks.

FIGURE 6–7
The complete decision tree for comparing medical and surgical treatment of a hypothetical disease.



2. Use a long time horizon but remove branches if possible to avoid needless complexity ("pruning the tree").

   EXAMPLE: The patient's lifetime is often the appropriate time horizon, particularly for chronic diseases or acute illnesses with chronic sequellae.

3. Use a decision model that is suited to representing the events in the course of a chronic disease. We will briefly review one such method (the Markov model) in Chapter 7.

In this hypothetical decision problem, we will choose the patient's lifetime as the time horizon.

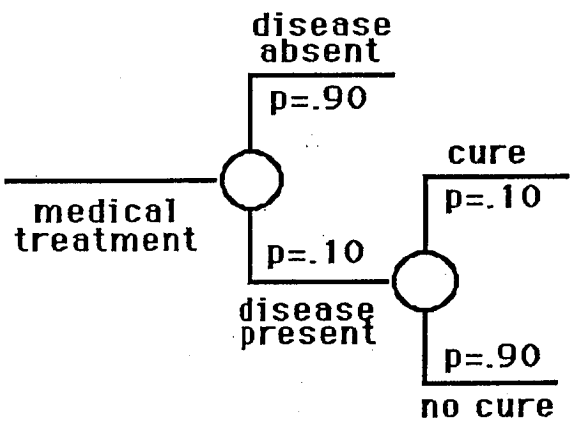
B.1.6 Determine the Probability of Each Chance Outcome

The next step in creating a decision tree is to assign a probability to each event that is controlled by chance. To estimate the probability of the outcomes faced by the patient, we may use published prior experience with similar patients, or we may make a guess based on an intuitive processing of personal experience.

If we do not operate, the only uncertainty is whether the patient has the disease. This information is often found in the medical literature. In this hypothetical example, we shall say that the probability of disease is .10. If the patient has disease, there is a 10% chance of spontaneous cure. The decision tree should be labeled with these two probabilities (Figure 6–8).

If we operate, there is a 10% chance that disease will be discovered. If disease is present, the surgeon may choose a radical procedure that has a 10% operative mortality and a 90% chance of cure. If the surgeon chooses a l ıtive procedure, the operative mortality is only 2%, and there is a 10%

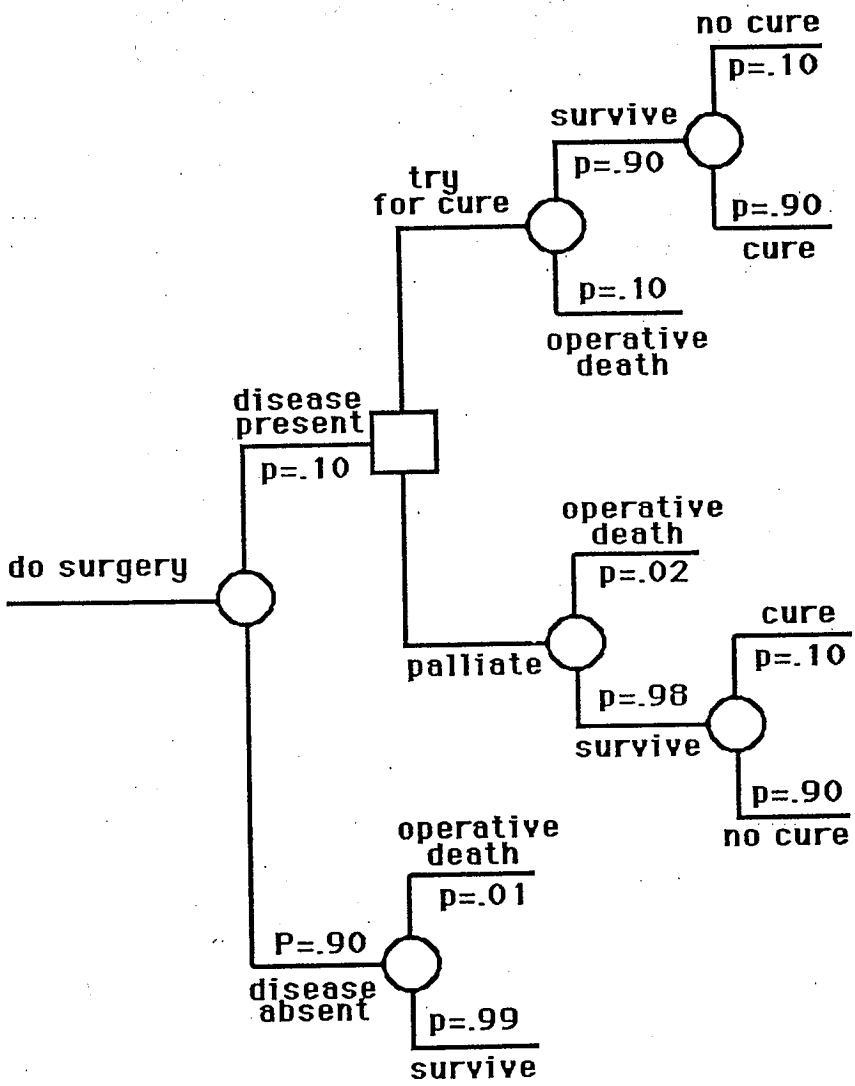
FIGURE 6–8
Probabilities of the outcomes of medical treatment.



chance of spontaneous cure. These probabilities are represented on the tree depicted in Figure 6–9.

In assigning the probabilities to the immediate outcomes at a chance node, the following rule must apply: *The sum of the probabilities at a chance node must be 1.* Thus, checking to be sure that the probabilities at each chance node add up to 1 is an essential part of this step.

FIGURE 6–9
Probabilities of the outcomes of surgical treatment.



Often, the clinician is quite uncertain about the probability of an event but knows the lowest and highest probability that could apply. In addition to a best estimate of the probability, the clinician should list the range of probabilities.

B.1.7 Assign a Value to Each Final Outcome

Assigning a value to each outcome is often the most difficult step in creating a decision tree. This topic will be discussed in the next two chapters. For this example, we shall use average length of life as the measure of the outcome states (see Table 6.3).

B.2 Calculate the Expected Value of Each Decision Alternative

The next step in the analysis is to calculate the expected value of each decision alternative. The analysis done with the best estimates of the probabilities and outcome values is called the *base case analysis.* The expected value of each decision alternative is calculated by a process known as *averaging out and folding back.* This process is easily understood by following an example. The process starts at the "tips of the branches of the tree" and works back to the "root" of the tree.

Start by calculating the expected length of life with medical treatment. Begin at the tips of the tree following the chance node that describes what can happen to a patient who has the disease. The expected length of life with disease is calculated by multiplying the length of life associated with each outcome of the disease by the probability of the outcome (Figure 6–10).

$$\begin{aligned}\text{Expected length of life} &= p[\text{medical cure}] \times \text{normal length of life} \\ &\quad + p[\text{no medical cure}] \times \text{shortened length of life} \\ &= 0.1 \times 20 \text{ years} + 0.9 \times 2 \text{ years} \\ &= 2.0 + 1.8 = 3.8 \text{ years}\end{aligned}$$

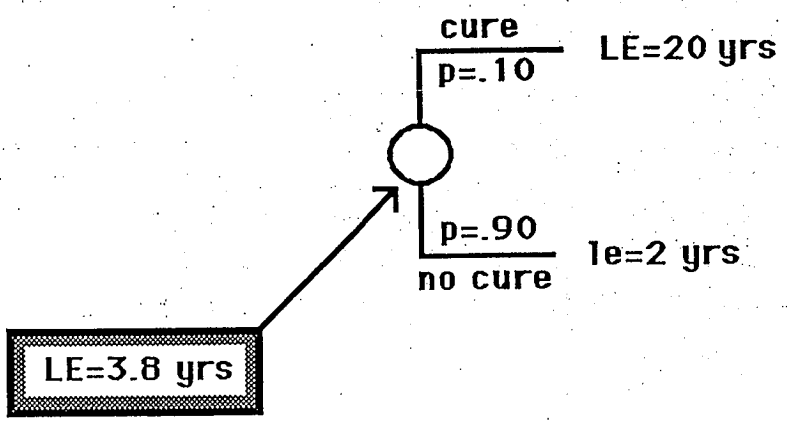
Now examine the chance node that represents the occurrence of disease in medically treated patients (Figure 6–11). The outcomes at this node are "disease absent" and "disease present." The outcome of the "disease absent"

TABLE 6.3
Allotting Values to Outcomes of Illness

Outcome	*Value of Outcome**
Operative death	0 year
Death from progression of the disease	2 years
Cure	20 years†

*Average length of life.
†Normal life expectancy.

FIGURE 6–10
Calculating the expected length of life for medically treated diseased patients.



branch is a life of normal length. The outcome of the "disease present" branch is either cure or no cure. The expected length of life for people who are diseased was just calculated to be 3.8 years.

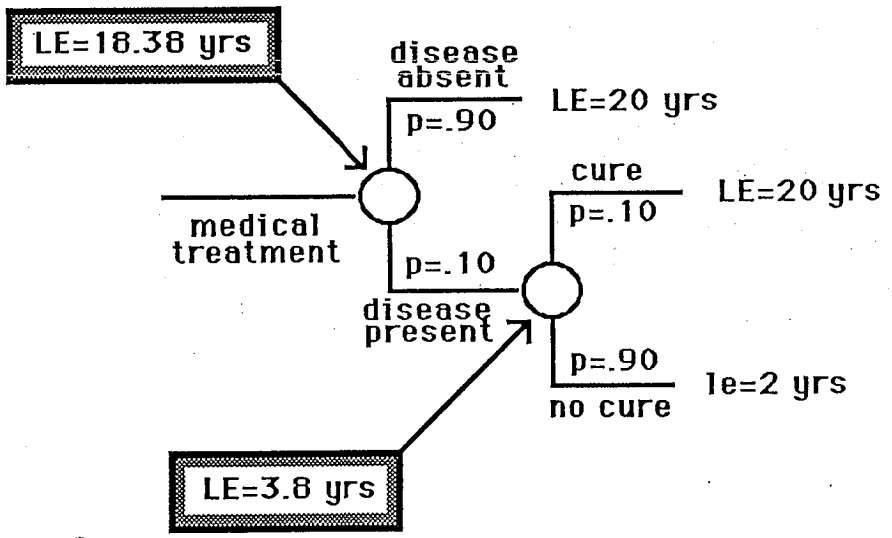
$$\begin{aligned}\text{Expected length of life} &= p[\text{disease}] \times \text{expected length of life with disease} \\ &\quad + p[\text{no disease}] \times \text{normal length of life} \\ &= 0.1 \times 3.8 \text{ years} + 0.9 \times 20 \text{ years} \\ &= .38 + 18.0 = 18.38 \text{ years}\end{aligned}$$

A similar process is followed for the "surgery" branch of the decision tree. This branch of the tree has a decision node within it: When the surgeon discovers that the patient has disease, there is a choice between a radical procedure with a high cure rate but a high operative mortality and a palliative procedure that has a low cure rate and low operative mortality. At each decision node, the surgeon chooses the procedure that offers the highest expected length of life. The process of choosing the branch with the highest expected value and ignoring the other branches is called *folding back* (Figure 6–12).

B.3 Choose the Decision Alternative with the Highest Expected Value

After calculating the expected length of life with each decision alternative, the tree may be represented in simplified form by Figure 6–13. The expected value decision maker will choose the decision alternative with the highest expected value. In this case, the expected length of life with surgery (19.46 years) is higher than with medical treatment (18.38 years). Surgery is the option with the highest expected length of life.

FIGURE 6–11
Calculating the expected length of life with medical treatment.



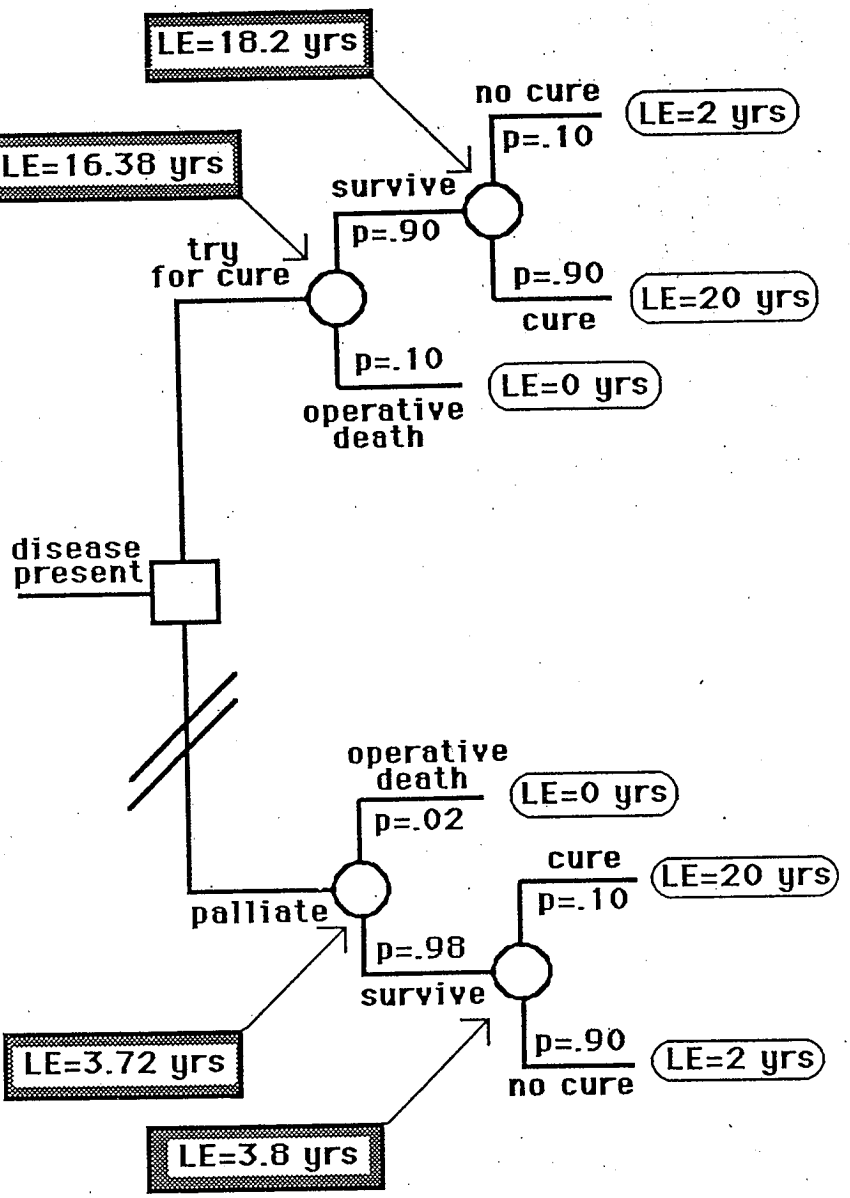
The clinician can identify the most probable outcomes by calculating *path probabilities.* There is one sequence of branches at chance nodes that leads from the root of the tree to the tip of each branch. One obtains the path probability by taking the product of all the probabilities along the path from the root of the tree to the tip of one branch. The expected value of an outcome is the product of the path probability and the value of the outcome. The expected value of the path indicates the contribution of an outcome to the expected value of a decision alternative. The clinician can use the expected value of a path to analyze the importance of the outcome for decision making. These concepts are illustrated in Figure 6–14.

The alert reader may note that the surgical option may lead to radical surgery, which has a 10% operative mortality. Some patients might favor a treatment that offers a larger chance of survival for at least 1 year. Thus, preferences for length of life might be a better outcome measure than length of life itself. The decision alternative that maximizes a measure of the patient's preference for illness outcomes may be the best choice for the patient.

B.4 Perform Sensitivity Analysis

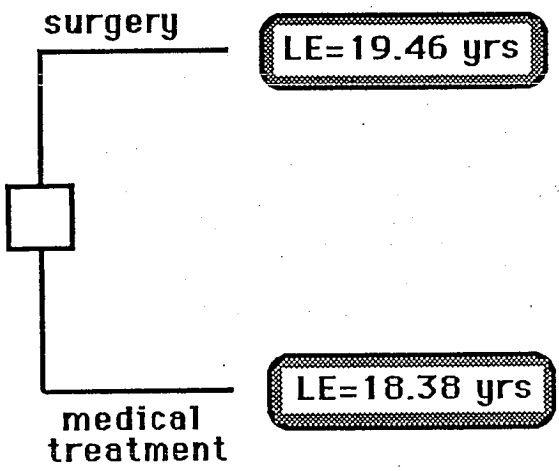
The last step in analyzing a decision tree is *sensitivity analysis.* Sensitivity analysis is a method for testing the validity of the conclusion of a decision analysis. Although the probability at a chance node may be the best estimate

FIGURE 6–12
Calculating the expected length of life in diseased patients treated with surgery.



that is available, there is often a wide range of "reasonable" probabilities that could be used with nearly equal confidence. Sensitivity analysis asks this question: "Do my conclusions change when the probability and outcome estimates are assigned values that lie within a reasonable range?"

FIGURE 6–13
Expected value of the decision alternatives.



DEFINITION **Sensitivity analysis:** A test of the stability of the conclusions of an analysis over a range of probability estimates, value judgments, and structural assumptions.

For this example, we have done several sensitivity analyses to see how the expected values of the decision alternatives are affected by assigning a range of reasonable values to:

- The probability of death during radical surgery—which takes account of the patients whose medical condition makes them a relatively poor operative risk.
- The probability of disease—which indicates how the preferred treatment may change in patients who have relatively few of the typical clinical findings of the disease.

The process in each sensitivity analysis is the same. The expected value of each treatment is calculated several times. Each time, the probability or outcome is assigned a different value within the "reasonable" range. If one treatment has the highest expected value throughout the range of a probability or outcome estimate, the decision is not sensitive to that factor.

B.4.1 Effect of the Operative Mortality from Radical Surgery

The sensitivity analysis for the probability of death during radical surgery indicates that this factor is not an important determinant of the expected outcome (see Table 6.4). Life expectancy with surgery is higher than with medical treatment even for a patient who is a very poor operative risk.

FIGURE 6–14
A path probability.

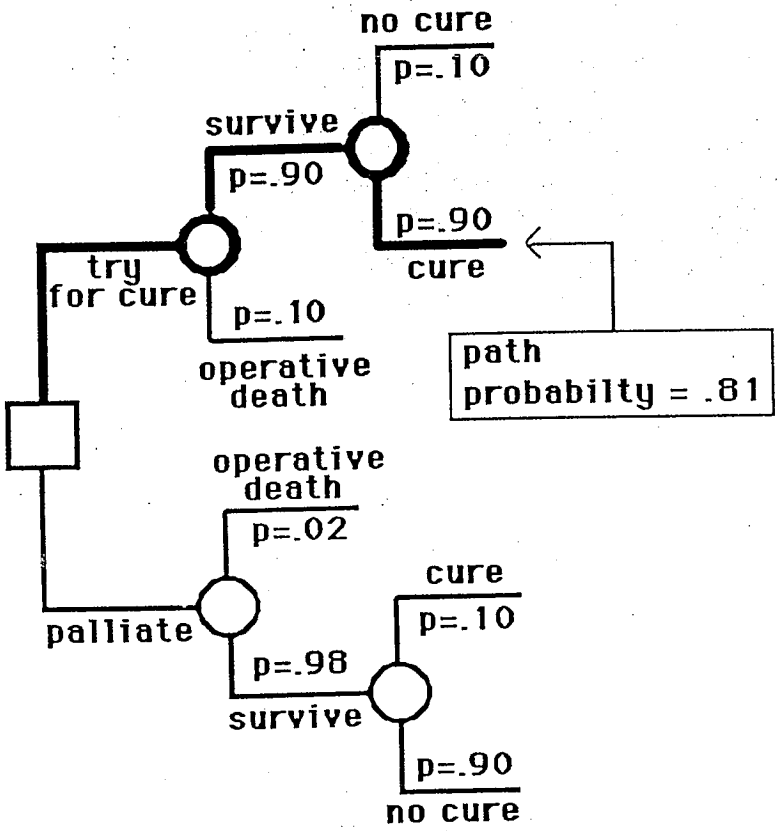


TABLE 6.4
Sensitivity Analysis of the Effect of Operative Mortality

	Life Expectancy	
p (Operative Death)	*Surgery (years)*	*Medical (years)*
0	19.64	18.38
.05	19.55	18.38
.10	19.46	18.38
.15	19.37	18.38
.20	19.28	18.38
.25	19.19	18.38

TABLE 6.5
Sensitivity Analysis of the Effect of the Probability of Disease

	Life Expectancy	
p[Disease]	*Surgery (years)*	*Medical (years)*
0	19.80	20.00
.10	19.46	18.38
.20	19.11	16.76
.30	18.77	15.14
.40	18.43	13.52
.50	18.09	11.90

6.4.2 Effect of the Probability that the Patient has the Disease

Recall that this operation is performed when there is still uncertainty about the true state of the patient. When the probability of disease increases, the advantage of surgery increases (Table 6.5). As the disease becomes more likely, life expectancy for both treatments decreases. However, a medically treated patient's life expectancy decreases much faster than that of a surgery patient.

This analysis shows that surgery is preferred even when the probability of disease is less than .10. In fact, surgery is preferred when the probability of disease is .016 or greater. The probability of disease at which the expected length of life is the same for medical and surgical treatment is called the *treatment threshold probability*. The treatment threshold probability is discussed in Chapter 9.

These sensitivity analyses provide considerable reassurance about the validity of the conclusions of this decision analysis. The base case analysis favored surgery. We tested this conclusion by making several assumptions that were prejudicial against surgery.

SUMMARY

This chapter introduced several important ideas that will dominate our detailed consideration of decision making:

- Representing a decision alternative by its expected value
- Expected value decision making
- The decision tree
- Averaging out and folding back
- Sensitivity analysis

Even a hypothetical example shows how a decision problem that seems difficult at first can be understood once it has been represented by a decision tree. When one decision alternative consistently has the highest expected value after sensitivity analysis has been performed for all variables, the clinician may proceed with confidence. *Even when the decision alternative with the highest expected value has been chosen, an individual patient may suffer a bad outcome. However, each patient will have the best chance at a good outcome if the physician is an expected value decision maker.*

PROBLEM

1. Your patient may have acute Tarkism. If not treated, acute Tarkism is fatal in 20% of patients. An operation always cures acute Tarkism if the patient survives the operation. However, the operation is fatal in 10% of patients.

   There is a test (the AT-test) that is always positive in patients who have acute Tarkism. However, the test is sometimes positive in patients who have symptoms of Tarkism but do not have Tarkism. Therefore, not everyone with a positive test has Tarkism.

   Suppose you have done the AT-test and it is positive. To decide whether to operate, you look up the performance characteristics of the AT-test. At what probability of acute Tarkism in patients with a positive AT-test should you be indifferent between operating and not operating?

NEW WORDS IN THIS CHAPTER

Chance node: A point in a decision tree at which chance determines which outcome will occur.
Decision node: A point in the decision tree at which several choices are possible.
Sensitivity analysis: A test of the stability of the conclusions of an analysis over a range of probability estimates, value judgments, and structural assumptions.

From: Sox, H.C. jr., Blatt, M.A., Higgins, M.C. & Marton, K.I. (1988). Medical Decision Making, Stoneham, MA: Butterworth & Heinemann.

All patients who get the gold standard test will have a positive index test. Since no test-negative patients get referred for the gold standard procedure, there cannot be any false-negative or true-negative patients. Therefore, the true-positive rate of the test will be 1.0 as will the false-positive rate. This study is an extreme example of test-referral bias.

a. The study population consists of two groups: healthy laboratory technicians and patients dying of advanced cancer.

- Healthy persons do not have any diseases; neither the disease that the test is supposed to detect nor other diseases that may cause abnormal test results, which would be counted as false-positive results. Therefore, the false-positive rate of the test will be much lower in this group than in sick patients who do not have the disease the test is supposed to detect.
- When cancer has spread all over the body, it is easy to detect, and the true-positive rate of a test will appear much higher than it would in a representative population of cancer patients.

b. The study population consists of persons who have undergone the index test as part of patient care. The index test result was not the sole determinant of referral for the gold standard test, but it definitely influenced this decision.

- When the index test influences the decision to refer for the gold standard procedure, patients with negative index test results are less likely to be referred. A population depleted of test-negative patients is a population depleted of persons who could have false-negative results or true-negative results. Therefore, the true-positive rate of the test and the false-positive rates will appear higher than they really are.

c. The gold standard procedure is a surgical operation that is only performed on relatively sick patients. Not everyone in the index population is sick enough to warrant doing this operation.

- The true-positive rate will be higher than in the index population because sicker patients will have more advanced, more easily detectable disease. The false-positive rate will also be too high because patients who do not have the disease that the test is designed to detect may have other diseases that give positive results. These positive tests would be counted as false-positives.

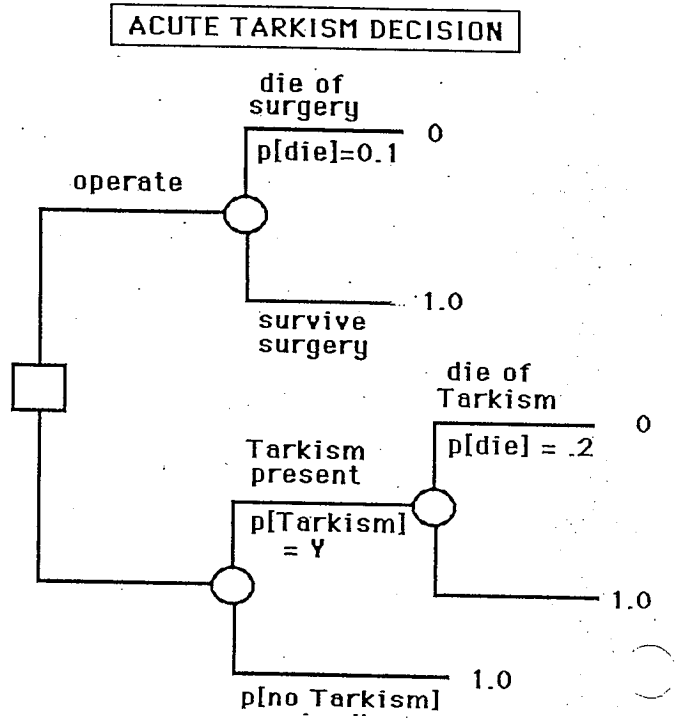
d. The index test is a noninvasive procedure for imaging the blood vessels of the kidney. The gold standard procedure is a renal arteriogram (an invasive imaging procedure). The radiologist who decides whether the index test is normal or abnormal attended a conference in which the patient. The radiologist has a very good memory, and is able to remember the results of the gold standard test on each of these patients.

- Some index test findings are difficult to classify as normal or abnormal. Deciding whether to call these borderline results "positive" or "negative" may be influenced by knowledge of the results of the gold standard test, which indicates the patient's true state. Thus, there will be a tendency for the results of the index test to agree with the results of the gold standard test, leading to too many true-positive and true-negative results.

CHAPTER 6

1. You want to find the probability of acute Tarkism at which the expected value of operating equals the expected value of not operating. Set up the decision tree, as shown in Figure P–1, and solve for *p*[acute Tarkism given positive test].

FIGURE P–1
Decision tree for choosing between surgery or no treatment for the hypothetical disease "acute Tarkism."



There are only two outcomes to this problem: death or normal life expectancy. Let 1.0 equal the value of a normal life expectancy and 0 equal the value of dying (assume that the value of dying of the operation is the same as dying of rapidly fatal Tarkism. Let Y equal the probability of acute Tarkism at which the expected value of operation and no operation are the same.

Expected value [operate] = Expected value [do not operate]

$$p[\text{surgical death}] \times 0 + p[\text{survive}] \times 1.0 = Y \times (p[\text{die of Tarkism}] \times 0 + p[\text{survive Tarkism}] \times 1.0) + (1 - Y) \times 1.0$$

$$0 + .9 \times 1.0 = Y \times (.20 \times 0 + .80 \times 1.0) + (1 - Y)$$

$$.9 = .8Y + 1 - Y$$

$$Y = .50$$

Therefore, the probability of Tarkism given a positive test need only be .50 for you to prefer surgery.

CHAPTER 7

1. Treatment A maximizes the patient's survival. Under the assumptions of the problem, the annual mortality rates associated with the three treatments can be used as a basis for this comparison. First, the mortality rate for treatment A is stated to be .10/year. Second, since the 5-year survival rate for treatment B is 50%, the annual mortality rate for this second alternative is given by the expression:

$$\text{Mortality rate} = -\frac{\ln(.5)}{5 \text{ years}} = .14/\text{year}$$

Third, the life expectancy of 5 years for treatment C implies that the mortality rate for the third alternative is given by the expression:

$$\text{Mortality rate} = \frac{1}{5 \text{ years}} = .2/\text{year}$$

Therefore, treatment A maximizes survival since it is associated with the smallest annual mortality rate.

2. First, we will compute the life expectancy for the untreated patients. If the 5-year survival for this group was 30%, the average annual mortality is given by the following:

$$\text{Total annual mortality rate} = -\ln(.30)/5 = .241$$

Therefore, the average annual mortality due to colon cancer without surgery is computed by subtracting the average annual mortality rate f 55-year-old white men:

$$\text{Average annual mortality due to colon cancer} = .241 - .009 = .232$$

This implies an average annual mortality for our 65-year-old patient c .232 plus .020 (the average annual mortality for 65-year-old men), whic equals .252. Therefore, the life expectancy for our patient if he foregoe surgery is 1 over this last number or

$$\text{Life expectancy} = 1/.252 = 3.97 \text{ years}$$

Now we will compute the life expectancy for our patient if he survive surgery. Ninety-five percent of the study subjects survived the operation implying that the 5-year survival for the surgery survivors in the stud was

$$\text{Five-year survival if surgery is successful} = .4/.95 = .421$$

Therefore, the average annual mortality in the surgery survivors is

$$\text{Average annual mortality} = -\ln(.421)/5 = .173$$

The average annual mortality due to colon cancer with surgery is computed by subtracting the average annual mortality rate for 55-year-old men:

$$\text{Average annual mortality due to colon cancer} = .173 - .009 = .164$$

This implies an average annual mortality for our 65-year-old patient of .164 plus .020 which equals .184. Therefore, the life expectancy for our patient if he survives surgery is 1 over this last number or

$$\text{Life expectancy} = 1/.184 = 5.43 \text{ years}$$

Therefore, if p denotes the probability of an operative death for our 65-year-old patient, his life expectancy with surgery is

$$\text{Life expectancy with surgery} = p \times 0 \text{ years} + (1 - p) \times 5.43 \text{ years} = (1 - p) \times 5.43 \text{ years}$$

Setting this last term equal to our patient's life expectancy without surgery and solving for p, we find that surgery will increase his life expectancy if $p < .26$.

That is, as long as the operative mortality rate is below 26%, our patient's life expectancy will be increased if he has the operation.