

Is anxiety a suitable measure of decision aid effectiveness: a systematic review?

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Abstract

Several trials have employed anxiety measures to assess decision aid effectiveness. This study employed a systematic review method to integrate their findings. The affective impact of decision aids and the appropriateness of anxiety as a measure of decision aid effectiveness are explored. From 11,361 citations generated from searching electronic databases and journals, 26 randomised controlled trials evaluated patient decision aids; 10 included anxiety measures (HADS; STAI). The data were too heterogeneous to integrate statistically. No studies showed an increase in anxiety from exposure to decision aids versus usual care. Some patterns emerged between level of anxiety and characteristics of the decision. As raised levels of anxiety are associated with both more effective decision strategies and stressful health interventions, anxiety is an inappropriate measure to employ when evaluating decision aids. Future research needs to investigate the relationship between affect, cognition and decision aids in order to facilitate effective patient decision making.

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1. Introduction

Decision aid interventions aim to encourage patients to engage in the decision making process when making treatment or screening choices by helping them to evaluate accurate information about all the decision options and their consequences in accord with personal values [1,2]. Measures employed to evaluate the effectiveness of decision aids are varied and focus on assessments of behaviour, cognition and affect [3]. Although measures have been developed with reference to decision making theories that explicitly assess changes in health care decision processes [4–7], most trials have employed outcome measures such as quality of life, anxiety and satisfaction when assessing decision aid effectiveness [1,8]. Although these established outcome measures are suitable to assess health care interventions after patients have made a treatment choice, there is little evidence that such measures are associated with changes in patients'

effectiveness when making a choice. In consequence, their appropriateness to evaluate decision aid interventions is under debate [1,8,9].

One such established outcome measure currently employed to evaluate decision aid interventions is anxiety [1,2]. Anxiety is defined as “an unpleasant emotional state or condition that is characterized by subjective feelings of tension, apprehension, and worry, and by activation or arousal of the autonomous system” [10]. Theoretically there is still some debate as to whether anxiety responses are normal reactions to stressful events or abnormal experience like an irrational fear [11]. Despite this lack of consensus, validated measures of patient anxiety have been used in clinical practice for a considerable time [12–14]. The main reason to assess anxiety has been to evaluate whether or not these levels are reduced in patients receiving treatment for anxiety disorders [15]. However, over the last 20 years, research into the impact of receiving treatment for physical illness suggests that many procedures are stressful to patients, impairing patient recovery and adherence to treatment regimens [16,17]. Anxiety scores, then, have been used to assess the iatrogenic consequences associated with

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health care interventions and the effectiveness of information aids to ameliorate these effects. A third reason for assessing anxiety levels is in situations where patient's level of arousal or emotion state impacts on the effectiveness of making treatment choices; some increase in arousal is associated with better recall and systematic evaluation of information whereas very low or high levels are related to less optimum processing strategies, i.e. the inverted U-shaped relationship between arousal and information processing ability [18–21]. As yet, it is unclear what level of arousal is associated with effective decision making but it is possible that high anxiety levels are indicators of good decision making strategies.

It is feasible that a decision aid could be developed to facilitate the treatment of anxiety disorders; in which case, employing a measure of anxiety as the main outcome variable would be an appropriate assessment of the decision aid's effectiveness. However, it is more likely that a measure of anxiety is employed in studies to assess the iatrogenic consequences, if any, of the decision aid in a non-psychiatric healthcare setting and/or to explore the relationship between arousal and effective decision making. This systematic review aims to integrate empirical studies employing a measure of anxiety in evaluations that assess decision aid effectiveness. The systematic review's objectives are:

- To identify studies employing an anxiety measure in evaluations of decision aid effectiveness.
- To describe the measures employed and their application.
- To assess the impact of decision aids on patient anxiety.
- To explore the relationship between patient anxiety and decision making processes and outcome.
- To identify the most useful role for anxiety measures in future healthcare decision aid research.

2. Methods

This systematic review is a sub analysis of *The Cochrane Systematic Review and An Inventory of Decision Aids for People Facing Health Treatment or Screening Decisions* [22]. Therefore, the methods for this review are only described in brief here. Experts in the field of health care decision making and information management designed the search strategy. Medical and social science electronic databases were searched, behavioural decision making journals hand-searched, reference sections of identified articles cross-checked and experts in the field contacted up to September 2001.

The study inclusion criteria were: studies employing a randomised controlled trial design; decision aid intervention compared with usual care, alternative interventions, or a combination; patients over the age of 14; 'real-world' decisions about health treatment or screening options for themselves, a child, or family member. In addition, for this sub analysis of the Cochrane review, studies needed to have employed a standardised measure of anxiety. A decision aid

was defined broadly as "interventions designed to help people make specific and deliberative choices among options (including the status quo) by providing (at the minimum) information on the options and outcomes relevant to a person's health status". Excluded from this review were: interventions focusing on decisions about lifestyle changes, clinical trial entry, advanced directives, general education programs, interventions promoting adherence, and interventions eliciting informed consent.

Two researchers reviewed all trials for this sub analysis review (FL, DS). Inconsistencies were resolved by discussion and consensus. The data extraction form was applied to each article meeting the inclusion criteria. The data extraction form elicited information on: health care decision; trial objectives; description of the intervention and control groups; sample size; power calculations; intention to treat analysis; loss to follow-up; anxiety measure particularly the scale used, timing of measurement, and scores at each time points. For trials in which there were more than two comparison groups, data were extracted from the two groups that provided the strongest contrast. For example, the most detailed decision aid group was compared with either the least detailed or the usual care control group. In addition, the two independent reviewers (DS, FL) applied the Jadad scale [23] to assess the quality of the trials.

Review Manager 4.1 was used to manage the data, summary tables were used to synthesise findings and, where appropriate, meta-analysis was planned to statistically integrate the data using weighted treatment effects with 95% confidence intervals.

3. Results

From searching the electronic databases, 11,361 unique citations were identified and a further 26 from personal files and hand-searching. Of the 600 studies exploring healthcare decision making, 10 trials met the inclusion criteria of which eight were published (study numbers (SNs) 1–5, 7–9) and two unpublished (SNs 6, 10) (Table 1). Decisions were made in the following health contexts (Table 1): prenatal screening ($n = 2$) and diagnosis ($n = 1$); benign prostatic hypertrophy ($n = 1$); hormone replacement ($n = 1$); cancer screening ($n = 1$); cancer treatment ($n = 4$); three studies were male only samples (SNs 2, 5, 9), the rest female only. The Jadad scale or trial quality ranged from two to three out of five; three was the maximum score any study could achieve as blinding is not possible in this type of applied research. Most studies reported a significant loss at follow-up ranging from 22% (SN 10) to 53% (SN 3); few reported or were able to report an intention to treat analysis.

One study employed the hospital anxiety and depression scale (HADS) [14], eight studies the state-trait anxiety inventory (STAI) [12,13] and one both measures. Both these measures assess state anxiety, a transient level of arousal associated with normal reactions to adverse situations; the

Table 1
Characteristics of patient decision aids ($n = 10$)

SN	Study	Decision	Decision aid intervention	Control	Outcomes	Jadad quality score (0–5)
1	Thornton et al. [24]	Prenatal screening uptake	Individual decision support counselling plus pamphlet	Pamphlet	Decision, anxiety	3
2	Davison and Degner [25]	Prostate cancer treatment	Pamphlet plus audiotape of the decision support consultation	Pamphlet	Role in decision making, anxiety and depression	2
3	Michie et al. [6]	Prenatal screening uptake	Video cassette, decision tree, and pamphlet	Pamphlet	Knowledge, anxiety, decision, systematic decision making	3
4	Maslin et al. [26]	Breast cancer treatment	Interactive videodisc with booklet and printed summary	Usual care	Anxiety, depression, quality of life, satisfaction, decision, role in decision making	Unable to assess
5	Davison et al. [27]	Prostate cancer screening uptake	Pamphlet plus individual decision support counselling	Wait list control	Decision, decisional conflict, role in decision making, anxiety	2
6	Bekker et al. [28]	Prenatal diagnosis uptake	Decision tree, utility elicitation, threshold graph within consultation	Usual care	Decision, knowledge, informed decision making, anxiety, reasons, decisional conflict	3
7	Goel et al. [29]	Breast cancer surgery	Audio-tape and booklet	Pamphlet	Knowledge, decisional conflict, decisional regret, anxiety	3
8	Murray et al. [30]	Hormone replacement therapy	Interactive videodisc with booklet and printed summary	Usual care	Anxiety, quality of Life, health utilities, costs, decisional conflict, decision, role in decision making	2.5
9	Murray et al. [31]	Benign prostatic hypertrophy treatment	Interactive videodisc with booklet and printed summary	Usual care	Anxiety, quality of life, health utilities, costs, decisional conflict, decision, role in decision making	2.5
10	Whelan [32]	Breast cancer chemotherapy	Decision board plus take-home version	Usual care	Knowledge, expectations, satisfaction, decision, anxiety, role decision making	Unable to assess

full STAI measure also includes a scale assessing trait anxiety, an individual's dispositional level of anxiety that is not reactive to external stimuli. Of all the studies that assessed state anxiety, one also assessed trait anxiety (SN 2). Four of nine studies used the short-form STAI [33] (SNs 3, 6, 8, 9). There was no consistency in the timing of measure completion; some studies assessed anxiety immediately after the intervention (SN 6), others at 12 months (SN 10). In addition, timing of measure completion varied within studies from a few hours (SN 4) to a couple of weeks (SN 5). Four studies measured anxiety on multiple occasions (SNs 1, 6, 7, 10); only one reported a repeated measures analysis (SN 6). The discrepancies in timing, the range of health contexts, different types of choices and the poor test-retest reliability of state-anxiety [11] scores meant that the data were not sufficiently homogenous to carry out a statistical integration of effect size. However, the pattern of responses from the seven studies employing the STAI in female populations indicate a mean of between 34 and 36 is a 'normal level' across different health settings, 36 and 39 the level associated with making non-invasive, risky health care decisions, and between 50 and 62 for decisions involving risky invasive and/or difficult treatment choices (Table 2). Fewer data were available for the studies with male only populations and any

response pattern was less obvious but male patients' anxiety scores were generally rated lower on the STAI than female patients (Table 2).

No interventions were designed to reduce patient's anxiety. Most studies (9/10) reported no difference in anxiety scores between patients in the decision aid versus routine groups; one reported a decrease in anxiety scores for some of the multiple follow-up scores in the decision aid group (SN 1). Only two studies evaluated aspects of the decision making processes (SNs 3, 6), five ascertained patients' role in decision making (SNs 2, 4, 5, 8, 9) and six assessed a decision outcome other than the treatment choice (SNs 5–10). However, no studies assessed the relationship between level of affect and effectiveness of patient decision making strategies (Table 2).

4. Discussion

Both the STAI and HADS have been employed to assess the iatrogenic consequences of decision aids across a number of health contexts. The review found little consistency in the methods of assessing anxiety across studies with different time-points being used to assess affect. In addition, large

Table 2
Summary of results for each study

SN	Main objective	Scale	Timing	Decision aid group			Control group			Analysis	Sample size	Comments
				<i>n</i>	Mean (S.D.)	DA change from baseline	<i>n</i>	Mean (S.D.)	DA change from baseline			
1	To compare the effect of extra information about prenatal testing with routine care information on having testing	STAI (long)	Baseline 2–4 weeks post-DA (20 weeks gestation) 4 months post-DA (34 weeks gestation) 7 months post-DA (6 weeks post-partum)	561	36 (35–38) 35 (34–37) 37 (35–38) 34 (33–35)	N/A –1.0 +1.0 –2.0	567	37 (36–38) 37 (36–38) 39 (38–41) 35 (34–36)	N/A 0.0 +2.0 –2.0	N/A Not significant $P < 0.5$ (Tukey test) $P < 0.5$ (Tukey test)	Large sample size—enough to show slight difference in anxiety. The clinical significance was not discussed	There was a loss of up to 48% post-baseline. Intention to treat analysis used. Repeated measure analysis was not used
		HAD	Baseline 2–4 weeks post (20 weeks gestation) 4 months post (34 weeks gestation) 7 months post (6 weeks post-partum)	561	6.5 (6.1–6.8) 6.1 (5.7–6.5) 6.6 (6.2–7.0) 6.1 (5.6–6.5)	N/A –0.4 +0.1 –0.4	567	6.7 6.8 7.3 6.5	N/A +0.1 +0.6 –0.2	N/A $P < 0.5$ (Tukey test) $P < 0.5$ (Tukey test) Not significant		
2	To compare empowerment information with routine information to men with prostate on their role in treatment decision making, anxiety and depression	STAI (long)	5–6 weeks post	30	35.5	–9.0	30	34.5	–2.5	Not significant	No mention of sample size calculation based on anxiety	Intervention group men had higher anxiety levels at baseline than control group men. ANCOVA employed to account for pre-test scores
3	To compare a detailed DA to a simple DA about prenatal screening on systematic decision making and outcomes including anxiety	STAI (short)	4–6 weeks post	67	35.2 (10.3)	–0.7 (8.8)	88	36.6 (10.8)	–0.6 (8.0)	Not significant	No information provided	Out of 1332 women who accepted to participate, 720 completed baseline questionnaire and 382 completed the trial. No intention to treat analysis
4	To test acceptability of a DA for breast cancer treatment: reduction in anxiety, increase satisfaction with choice	HAD	9 months post	51			49			Not significant		No results reported
5	To compare written and verbal information with routine verbal about aspects of prostate cancer screening on: decision making process, role with clinician, anxiety and decisional conflict	STAI (long)	1–2 h post	50	23.56	–1.34	50	23.86	–2.16	Not significant	Authors used Mann–Whitney procedure because results were skewed	
6	To evaluate DA with routine information about prenatal diagnosis on women's choices, process informed decision making, decisional conflict and knowledge and anxiety	STAI (short)	Pre-consultation	50	62.3		56	62.0		N/A	Sample size calculated to detect six points difference with power set at 80% and degree of significance of 5%; repeated measure analysis; intention to treat analysis on choice made only	Repeated measures analyses used. 36% sample lost at follow-up in DA group, 28% in control group. No difference in anxiety scores post-consultation by those returning or not returning at follow-up
			Post-consultation.	50	58.9		56	61.2		Not significant		
			1 month post	29	35.3		39	34.7		Not significant		

7	To compare DA with educational pamphlet (EP) in a consultation about breast cancer treatment choices on: decisional conflict, knowledge, satisfaction with decision making and anxiety	STAI	Baseline 1–3 days post 6 months post	86 74 59	51.9 (13.8) 51.2 (14.2) 36.6 (12.9)	–0.7 –15.3	50 43 39	50.8 (13.6) 50.7 (14.8) 34.3 (11.6)	–0.1 –16.5	Not significant Not significant	Accounted for cluster in final analysis. Unsure if intention to treat analysis performed. Sample size not based on anxiety	At 6 months, 31% lost at follow-up in DA group and 22% in control group
8	To compare DA with usual care by GP about HRT on: patient involvement with decision; HRT uptake; decisional conflict; health status including anxiety	STAI	Baseline 9 months post	103 93	38.87 (12.34)	0.34	102 94	38.73 (13.18)	2.49	Not significant; intention to treat analysis	Not specified. See BPH study	
9	To compare DA with usual care by GP about prostatic cancer on: involvement in decision making; choice; decisional conflict; health status including anxiety	STAI	Baseline 9 months post	57 54	33.93 (13.09)	–1.0	55 48	32.01 (10.49)	–2.0	Not significant Mann–Whitney for skewed scores; intention to treat analysis	Sample size of $n = 80$ per arm to give 90% power to detect a six-point difference in STAI-state score at the 5% level of significance; final sample size was underpowered	
10	To determine if DA with counselling improved patient comprehension about chemotherapy anxiety and satisfaction	STAI	1 week post 3 months post 6 months post 12 months post	83			93			Not significant Not significant Not significant Not significant		

attrition rates were observed at follow-up and appropriate analyses were not always employed. These methodological issues and varied decisions across several health contexts meant the data were too heterogeneous to integrate statistically. However, the findings did support prior research that indicates anxiety scores vary by patient's sex, men consistently provided lower ratings than women [12,13]. In addition, as none of the studies reported higher anxiety scores in patients exposed to the decision aid interventions, the pattern of findings suggests it is unlikely that decision aids have associated iatrogenic consequences when assessed by anxiety. Only three studies assessed aspects of the decision making process, none of which reported analyses to investigate the association between decision strategies and level of arousal. It is unclear, therefore, what the relationship is between level of arousal and strategies employed to make decisions across different types of health care decisions.

These studies employed standardised anxiety instruments to assess the iatrogenic consequences of decision aids across several healthcare settings. Both the STAI [12,13,33] and HADS [14] were developed to assess mood changes in non-psychiatric patient populations in order to screen for anxiety related disorders. The STAI manual listings of mean norm scores for different populations are 35 for non-psychiatric, 48 for psychiatric and 50–61 for non-psychiatric populations in stressful situations, variations are observed by age, sex and occupation [13]. As mentioned, research over the last 20 years has identified that there are many health care settings and procedures that patients find stressful. In these situations, anxiety scores have been lowered by the provision of good information that prepare patients for the procedures they are having, i.e. treatments for which decisions have already been made [16,17]. This systematic review has illustrated that patients making health screening or treatment decisions about invasive procedures have raised levels of anxiety. However, as no studies have assessed whether or not these levels of arousal were associated with more or less effective decisions, there is no evidence to indicate that these levels are an adverse response to decision aid interventions. On the contrary, decision theorists argue that increased arousal is normal and associated with more effective evaluation of decision relevant information [16,18,21]. In consequence, anxiety measures are an unsuitable assessment of the iatrogenic consequences associated with decision aids because increased arousal is a necessary and desirable aspect of engaging actively with the decision making process, i.e. the aim of decision aid interventions [1,2].

Although anxiety scores are not useful in assessing the iatrogenic consequences of decision aids, anxiety scores are necessary to further understand the relationship between affect and cognition. As mentioned, an individual's level of arousal is associated with the employment of decision making strategies; if arousal is too low or too high, ineffective strategies are more likely to be employed [19,21]. What has not been identified within the health care decision research is a set of scores that indicate which levels of

anxiety are associated with the employment of optimum decision strategies and/or how these 'norms' might vary according to the characteristics of the decision being made. All the studies included in this review recorded levels of anxiety rising in response to difficult decisions about risky healthcare procedures but then returning to normal levels. By crudely grouping the findings, it was possible to see the beginnings of a response pattern suggesting an anxiety score by decision difficulty. However, as so few studies assessed aspects of the decision process, and none reported any associated analyses in these publications, we are unable to comment on how anxiety, decision characteristics and employment of decision strategies are related in these health contexts. Further research should aim to identify these 'decision-affect norms' and investigate the degree to which decision aids can impact on these cognitive and emotional factors in order to facilitate effective decision making.

The advantage of this systematic review was that as a subsidiary analysis of studies included in the Cochrane review of decision aids [22], it followed a rigorous methodology. In consequence, it is likely that the studies included in the review are exhaustive of decision aid research, the data were extracted systematically from articles and the findings reported are valid. It is clear from the review that there is no consensus when it comes to measuring anxiety across these health care situations, which means that scores elicited are not homogenous and statistical integration of findings is not possible. Little can be said, therefore, about how anxiety varies across different health contexts by type of decision and decision maker; except that there appear to be patterns of responses by decision type and sex. The limitation of the review is that only studies employing a randomised controlled trial design were included. It is likely that articles reporting the results of a randomised controlled trial design to assess the effectiveness of decision aid would not include the analyses required to investigate the relationship between affect and decision process, even if measures of process were included. The relationship between affect and decision making are more likely to be described in articles reporting multivariate regression analyses and/or studies employing cross-sectional designs. Broadening the inclusion criteria to include these designs in future reviews would increase the likelihood of statistical analyses being employed to integrate findings on the affect-cognition relationship.

One of the main questions to arise from this review, then, is, 'What measure should be employed to evaluate decision aid effectiveness?' There is no definitive 'decision aid effectiveness' measure but there are questionnaire-based measures evaluating: the amount of conflict experienced during decision making [4]; satisfaction with the decision made [5]; degree of systematic processing required to make the decision [6]; whether or not the choice was consistent with the decision maker's attitudes and knowledge [34]. Which measure researchers choose to employ depends primarily on the purpose of the intervention. So, aids aiming to facilitate patient satisfaction with treatment choice should

assess decisional satisfaction. However, it is likely that some well-defined concepts currently have no validated measures. For example, there are definitions of informed and shared patient decision making and their component parts have been identified [1,35,36] yet there are currently no published, validated questionnaire measures of informed or shared patient decision making. In addition, within the medical decision making literature, there are aspects of effective decision making that can be operationalised and used to evaluate decision aids capacity to encourage the making of more effective decisions. For example, more realistic interpretations of decision relevant information like risk perceptions and greater analysis of the options and consequences of the decision rather than contextual elements such as searching for information on what other patients do. In these situations concepts require operationalisation and the development of validated measures.

4.1. Conclusions

Anxiety is an insufficient measure to employ when evaluating the effectiveness of decision aid interventions in non-psychiatric patient populations. In addition, anxiety is an unsuitable measure to assess whether or not decision aids have associated iatrogenic consequences. Measures of anxiety are useful in understanding the relationship between level of arousal and (in) effective decision making strategies. Indeed the systematic review results suggested some patterns are emerging between anxiety levels and decision complexity but it remains an empirical question as to how these levels are useful to either changing healthcare services and/or facilitating effective decision making. The implications for primary and secondary decision aid research are (a) to ensure methodological consistency in subsequent studies in order to enable integration of findings across health contexts, decision characteristics and decision makers, (b) avoid designing studies that employ anxiety as an estimate of iatrogenic consequence, (c) further understanding of the relationship between affect, cognitions and decision aids, (d) develop validated measures of effective decision making, and (e) employ measures of decision effectiveness that reflect the purpose of the intervention.

4.2. Practice implications

The main implication for health care practice is that decision aids should be used to help patients make difficult health screening and treatment choices. Providing complete information about the consequences and risks of health screening and treatment choices in the form of a decision aid does not increase patient anxiety. Further, the use of decision aids encourages patients to use more of this decision-relevant information when making their healthcare choices [7] and leads to patients making more effective decisions [2,7].

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