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Enhancing Informed Choice to Undergo Health Screening: A Systematic Review

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Abstract

Objective—To assess the effectiveness of health screening interventions aimed at enhancing informed choice.

Methods—Studies were selected if (1) they were randomized controlled trials conducted between January 1, 2000, and March 30, 2010, (2) participants in one arm underwent a prescreening intervention aimed at improving informed choice, and (3) informed choice was the primary outcome.

Results—Eight studies that met the inclusion criteria involved screening for prostate, colorectal and breast cancer, and diabetes. Five of the 8 prescreening interventions led to greater informed choice.

Conclusions—With researchers mindful of the limited number of studies, findings were encouraging, but conclusions regarding the most effective ways of facilitating informed choice for screening are at best tentative.

Keywords

prescreening interventions; health screening; randomized control trials; informed choice; systematic review

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Health screening tests aim to identify and prevent or treat diseases in unsuspecting individuals. They are justified by their potential benefits to the population. There is a consensus that when screening tests are offered, individuals should be provided with the tools to make informed choice.¹ Yet there remains little consensus on what constitutes an informed choice.

This review summarizes data from randomized controlled trials (RCTs) of prescreening interventions aimed at improving informed choices about undergoing health-screening tests.

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Human Subjects Statement

This review was exempt from human subjects review.

A similar systematic literature review was published in 2000 summarizing evidence of informed choice about screening uptake.² Six RCTs met Jepson's inclusion criteria for informed uptake: the prescreening intervention was described in sufficient detail; information was provided on the benefits and risks of screening; knowledge and uptake and informed decision making were assessed. Jepson and colleagues concluded that there was some evidence that changing the format of informed-choice interventions (videos, leaflets with decision trees or computer programs) from well-prepared leaflets does not increase knowledge, satisfaction, or test uptake. They also concluded that it remained unclear whether enhancing informed choice affects screening uptake. Over the ensuing decade, informed choice has been defined and measured more systematically; and additional predictors and outcomes related to decision quality, identified.

One definition of informed choice states that it results from having sufficient understanding of relevant information and choosing a course of action that is consistent with one's values and beliefs.³ Informed choice defined as such can be measured using the Multidimensional Measure of Informed Choice and includes knowledge, attitudes, and test choice.³ Similarly it can be measured as an *integrated decision*: having sufficient relevant knowledge and values clarity as assessed by the Values subscale of the Decisional Conflict Scale.⁴⁻⁶

A core component of informed choice is relevant knowledge, often described as understanding the potential risks and benefits of a screening test. It is not easy to arrive at consensus, even among informed experts, about what constitutes sufficient and balanced (risks and benefits) knowledge. Thus, for most prescreening interventions, development of the accompanying information needs to be systematically collected and reviewed not only by experts but also importantly by the intended participants. Literacy level and format of presenting information need to be taken into account to ensure that that target population can understand the relevant information. Essentially all interventions aimed at enhancing informed choice about health screening convey relevant knowledge, and many have been shown to be effective in increasing understanding.

Another core component of informed choice is attitudes toward the behavior, in this case a health screening test. Attitudes reflect one's values and may be defined as a person's thoughts or feelings of favorableness or unfavorableness toward a choice.³ Attitudes most predictive of intentions or behavior are positive towards undertaking the behavior. Less commonly, prescreening interventions address attitudes or their underlying values and beliefs. There is no consensus on the primacy of values and their resultant attitudes in enhancing informed choice.

O'Connor and colleagues define *decisional conflict* as a state of uncertainty about a course of action.⁴ Uncertainty occurs more often when faced with decisions that involve risk or uncertain outcomes, exacerbated by feeling uninformed, unclear about one's values, and unsupported in making a decision. Making an informed choice is theoretically associated with reduced decisional conflict.⁷ Thus, the primary outcomes selected for this review were informed choice and/or decisional conflict.

The current review is aimed at expanding our understanding of the empirical evidence of prescreening interventions aimed at enhancing informed choice in health screening decisions since 2000.

Objective

The goal of this systematic review is to assess the effectiveness of prescreening interventions published since the Jepson review of 2000 that aim to enhance informed choice.

METHODS

Search Methods for Identification of Studies

An electronic literature search was conducted using MEDLINE via PubMed (2000 to February 2010), EMBASE (2000 to February 2010), PsychINFO (2000 to February 2010) via OVID SP, CINAHL (2000 to February 2010) via EBSCO, Cochrane Database of Systematic Reviews, Cochrane Central Register of Controlled Trials, and the National Research Register. Initial searches used MEDLINE Major Topics terms [Majr] Genetic Screening or Mass Screening or Screening or (Antenatal/Prenatal screening or testing) which were combined with information or education or informed choice or informed uptake or informed decision* or shared decision* combined with randomized-controlled-trials or rct* or randomized controlled trial* or controlled clinical trial* or evaluation study or evaluation studies.

Inclusion criteria—Studies were selected for inclusion if they were (1) randomized controlled trials conducted between January 1, 2000, and March 30, 2010; (2) participants in one arm underwent a prescreening intervention aimed at improving informed choice, and (3) the primary outcome was informed choice, operationalized by one of 4 different measures: (1) the Multidimensional Measure of Informed Choice (MMIC), (2) a self-assessment of one's ability to make an informed choice, (3) an integrated decision, or (4) decisional conflict using the Decisional Conflict Scale (DCS). Secondary outcomes included knowledge, attitudes, intentions, and uptake. Eligible populations were adults aged 18 years and over, contacted about participating in a health-screening test.

Exclusion criteria—Studies reported in languages other than English were excluded. Studies reported in non-peer-review publications (grey literature) were also excluded.

Data Collection and Analysis

Risk of bias—A majority of the studies included met a high standard for minimizing risk of bias. All 8 studies used computer-generated randomization; 7 concealed allocation to the intervention from participants; 5 were blinded to the investigators (one was not and 2 did not specify); all 7 were equivalent in participant characteristics at baseline; all 8 had a follow-up rate that exceeded 80%, and 5 used validated measures to assess their primary outcomes. In one study the measures were not validated and in 2, no information was provided on validity or reliability.

Quality criteria—Institutional ethics boards approved all of the studies for the protection of human subjects and in each study participants were consented. In 3 of the studies, consumers were involved in the development of the interventions.

Sensitivity analysis—Seven of the prescreening interventions tested were of low intensity, consisting of leaflets or other written materials. In one, the intervention was of medium intensity, involving an interactive computer website. Randomization was successful in all studies resulting in high relevance of the control group; with no differences other than the type of intervention at baseline.

Missing data—There was insufficient detail on the analyses in 6 of the studies to allow comparisons among study outcomes. Only 3 analyzed the data with an intention to treat. The fidelity of the interventions was variably checked. In 2 studies, there was fidelity of the use of the intervention; and in 6, fidelity could not be discerned from the descriptions. For example, several studies sent a leaflet intervention by post and failed to ask whether the participants read it.

Attrition rates did not vary among the intervention groups. In 3 studies, comparisons between the demographic characteristics of participants and those lost to follow-up were made; but in the majority, no comparison was conducted. The majority of these studies had very low dropout rates that may explain why a comparison was not reported. Overall there was variability in how missing data were managed, the most notable being the lack of confirmation of use of the intervention.

RESULTS

Study Selection

Following inspection of 2995 abstracts, 26 studies were identified that appeared to meet the inclusion criteria. These papers were subject to a full-text evaluation, and 17 were excluded because informed choice was not assessed.⁸⁻²⁴ Another one was eliminated because the intervention aimed at enhancing informed choice in decisions of maternity care did not include the offer of a screening test.²⁵ See review schema in Figure 1.

The 8 remaining studies tested the effect of a clinical intervention on informed choice about a screening test for one of 3 types of cancer (prostate, colorectal, and breast) or diabetes. Interventions varied from enhanced leaflets or decision aids to videos and Internet materials. See Table 1 for a synthesis of the study designs.

Outcome Variables

Informed choice was measured in 6 of the studies, in 3 using the MMIC.²⁶⁻²⁸ An indirect measure of informed choice used in 2 of the studies was the perception of the decision makers' ability to make an informed choice, assessed using a single item.^{5,6} This measure was developed for the studies reported in the review and had not been validated. Another study operationalized informed choice as an integrated decision. This measure included having sufficient relevant knowledge and values clarity, as assessed by the Values subscale of the DCS.⁴ Although distinct from the MMIC, this measure similarly aims to capture both knowledge and values that lead to attitude formation. The measure appears to have been developed for this study and had not been validated.

An indirect index of informed choice is post intervention perceptions of decisional conflict. This construct was measured using some combination of the 5 subscales of the Decisional Conflict Scale (DCS). Two studies included decisional conflict as their primary assessment of informed choice and used the entire 16-item DCS.^{29,30} Four studies in this review supplemented their measures of informed choice with assessment of residual decisional conflict.^{5,6,26,28} Gattellari and colleagues assessed "factors contributing to decisional uncertainty" (a subscale that was later divided into 3 subscales of 3 items each: Informed, Values, and Support).^{5,6} Mathieu and colleagues used the Informed and Values subscales.²⁶

The secondary outcomes as defined by this review were measured in most of the studies: knowledge (N = 8), attitudes (N = 6), intentions (N = 7), and screening uptake (N = 4). The use of these variables as predictors of informed choice suggests the Theory of Planned Behavior was used to design most of the studies,^{31,32} although no mention of a theoretical framework was made in any of the papers.

Main Findings

Primary outcomes—Effects of the prescreening interventions on the primary outcomes compared to usual care or no education (control) are listed in Table 2. Informed choice improved using the enhanced prescreening interventions in 5 out of 8 studies. In 3 of the studies, informed choice was operationalized using the MMIC, in one self-assessment of the

decision maker's ability to make an informed choice and in the fourth, making an integrated decision. In the 2 studies that assessed decreased decisional conflict as an indirect measure of informed choice, no effect of the intervention was found.

A meta-analysis of the effects on informed consent was thwarted by the use of different outcome measures and the lack of details provided on the results of measures of differences between the means (chi-square, t- and Mann-Whitney U tests). See Table 3 for a summary of the analysis.

In those studies of prescreening interventions that successfully enhanced informed choice, one found that greater values clarity was associated with an increase in informed choice about screening for colorectal cancer.²⁶ In another study, perceived ability to make an informed choice was associated with both increased knowledge and less positive attitudes toward screening for prostate cancer risk. In 2 other studies, the acquisition of relevant knowledge increased informed choice given there was no change in attitudes,^{27,33} and in one, an increase in knowledge and less positive attitudes led to more informed choices.²⁸ Variables that may have been associated with a decrease in decisional conflict were not explored in the 4 studies that identified a reduction post intervention.

Secondary outcomes—All the studies in the review reported on knowledge acquisition. In all but one, it increased above usual or no education. All studies measured knowledge using an investigator-generated measure specific to the screening disease target. The comparative changes in attitudes towards screening varied among the studies, with 2 studies finding no change in attitudes towards screening, 2 decreasing positive attitudes toward prostate cancer screening (as intended by the intervention), one decreasing positive attitudes toward fecal occult blood screening (not as intended by the intervention), and one resulting in more positive attitudes toward screening for breast cancer (as intended). These studies used different measures for assessing attitudes, and several instead measured values clarity, making it difficult to consider the results in aggregate. The disparity in findings may reflect the discrepancy in how attitudes were measured or may reflect varied effects of the interventions. These results add little to clarifying the role of attitudes in enhancing informed choice.

In 2 of 7 studies that measured intentions to undergo screening, intentions decreased after use of the enhanced prescreening interventions. Both studies involved undergoing prostate screening where the interventions aimed to decrease intentions and ultimately prostate cancer screening. There were no other changes in intentions. Uptake decreased from usual care in 2 of the 4 studies in which it was assessed, in one for prostate cancer screening as intended. The majority of interventions resulted in no change in screening intentions or uptake, providing some evidence that enhancing informed choice may have little effect on screening uptake.

DISCUSSION

Five of the 8 interventions aimed at improving informed choice about screening tests above usual care did so. The heterogeneity of the interventions and screening disease target preclude drawing firm conclusions about how this was accomplished. Those that did enhance informed choice involved screening for breast cancer, colorectal cancer, Type 2 diabetes, and prostate cancer. Three different decision aids, an “evidence bases” booklet, and an informed choice-based invitation constituted the enhanced interventions. All 3 decision aids resulted in more informed choices as measured by the MMIC. It is unclear whether these interventions enhanced informed choice because of better understanding of relevant information alone as effects on attitudes toward screening were inconsistent.

Although decision aids have been shown repeatedly to increase relevant knowledge, it remains unclear from the published literature whether and how decision aids affect values clarification as related to attitudes toward the behavioral decision.³⁴ With the limited evidence kept in mind, the pattern of findings suggests that the most promising prescreening interventions may be decision aids, regardless of limited understanding of how they achieve more informed choice.

In 7 of the 8 studies, the screening interventions increased knowledge about the screening test and condition above usual or no education. The measures of knowledge were investigator developed for each study, except in each of 2 cases in which the investigators conducted a subsequent study using the same measure.^{5,6,28,33} The investigators often used the content of government leaflets to inform the development of the interventions. Two solicited input from members of the target population. There was no consistency among the studies for the type or extent of the information included. Further, the criteria by which the investigators determined that sufficient knowledge had been acquired varied. Regardless of the notable finding that 7 of the 8 studies increased knowledge, it remains unknown whether the information learned was the most relevant or sufficient to making a screening test decision.

Attitudes were assessed in 6 studies, and results were inconsistent: they became more negative with use of the enhanced interventions in 3, more positive in one, and unchanged in 2. Intentions were assessed in 7 of the 8 studies: they were unchanged in 5 and decreased in 2. Screening up-take was assessed in 4 studies: it was unchanged in 2, increased in one, and decreased in another. The limited evidence did not suggest that increasing informed choice affects screening uptake.

The aim of the current review was to extend and update the Jepson review of 6 randomized controlled trials of health screening decisions in which knowledge, uptake, and informed decision making were assessed. Jepson and colleagues concluded that there was some evidence that changing the format of informed-choice interventions (videos, leaflets with decision trees, or computer programs) from well-prepared leaflets does not increase knowledge, satisfaction, or test uptake. They also concluded that it remained unclear whether enhancing informed choice affects screening uptake. With the addition of these 8 studies, there is now limited evidence to suggest that moving beyond well-prepared leaflets to decision aids may lead to interventions that more consistently enhance knowledge and result in more informed choice. Further, there is some additional evidence to suggest that enhancing informed choice does not affect screening uptake.

In the studies summarized by Jepson and colleagues, informed choice was a less well-defined construct that had been used to inform the design of leaflet interventions aimed at increasing screening behavior. The construct was inconsistently defined and interpreted in the design of the interventions. Study outcomes were limited to components of, and proxies for, the more contemporary definition of informed choice. Although significant variation remained among the studies in the current review, informed choice was described using the definition proposed by Marteau and colleagues⁷ in 4 of the studies; and in 3 studies, the MMIC was used to measure informed choice. Six used subscales of the decisional conflict scale to measure constructs that might be considered a consequence of informed choice. Yet despite a decade of more consistent thinking about the elements of informed choice along with publication of a validated measure, progress has been slow in answering important research questions about how interventions can be designed to effectively increase informed choice and in doing so whether they change screening behavior.

The diversity in content, format, and platform makes it challenging to compare outcomes across the studies. Even within each study, it is unknown how the interventions increased knowledge, or in some cases, informed choice. Several mailed the intervention to homes of the target population and failed to assess whether participants read or used the intervention, jeopardizing the fidelity of the intervention. Although the quality of the studies varied as well, in some cases it was poor.

Overall, the continuation of inconsistency in definitions of informed choice and sufficient relevant knowledge, the use of different types of interventions, and the diversity in outcome measures suggest that data from this review add little to our understanding of the effectiveness of screening interventions in enhancing informed choice. The impact of the increasing informed choice appears to date not to have an effect on screening behavior, but this is supported by limited data.

Strengths

The strength of this review lies in updating the findings by Jepson published a decade earlier, providing new evidence that informed-choice interventions can increase acquisition of relevant knowledge and enhance informed choice above usual care but not affect screening uptake.

Limitations

There are 2 key limitations of this review. One is a potential failure to identify all relevant research for inclusions. Efforts were undertaken to avoid this pitfall by reviewing the reference lists of all identified studies. The second is the potential for publication bias. All studies included were published in journals, and the grey literature was not reviewed.

Conclusions

Despite progress in defining and measuring informed choice, the findings of this review fall short of furthering our understanding about the effective components of interventions designed to facilitate making informed choices about screening. Although a large literature was identified over the past decade on health screening interventions aimed at increasing knowledge, only 8 studies met the criteria for inclusion, a randomized control design of an intervention aimed at enhancing informed choice. Only a subset of 4 used a validated measure of the primary outcome, informed choice.^{26-28,33} These 4 studies included interventions to enhance screening for breast cancer, Type 2 diabetes, and colorectal cancer, the diversity making it inadvisable to draw conclusions on the role of health screening interventions in enhancing informed choice.

The quantity and quality of evidence will hopefully expand over the coming decade, given the availability of a formal definition for informed choice and publication of a validated measure. However, the small number of studies identified in this review and the remaining inconsistencies in design and measures suggest cautious optimism is warranted.

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Figure 1.
Flow Chart of Manuscript Selection

Table 1

Study Design Synthesis

Disease/Screening Test	Author/Year	Country	Intervention	Ind and Dep Variables	Groups	Follow-up
Prostate CA Screening/PSA	Gattellari 2003	Australia	"Evidence-based" booklet v Conventional information	Knowledge Attitudes Intentions Worry Dec Conflict Perceived ability to make an IC	1. Booklet (n=126) Men 2. Conventional info (n=122) Men	12 months
	Gattellari 2005	Australia	Leaflet v Video v "Evidence-based" booklet	Knowledge Attitudes Intentions Decisional conflict Perceived ability to make an IC	1. Leaflet (n=140) Men 2. Video (n=141) Men 3. Booklet (n=140) Men	On average 21 days after the intervention
	Illic 2008	Australia	Leaflet v Web site v Video	Knowledge Intentions Anxiety Dec Conflict Role in Dec PSA uptake	1. Leaflet (n=50) Men 2. Web-based (n=56) Men 3. Video (n=55) Men	One week
	Krist 2007	USA	Web site Decision aid v Paper Decision aid	Knowledge Shared decision responsibility PSA uptake	1. Web site DA (n=226) Men 2. Paper DA (n=196) Men 3. Usual care (n=75) Men	Immediately following physician visit
Breast CA Screening/Mammography	Mathieu 2007	Australia	Decision aid v Usual care	Knowledge Attitudes Intentions Mammo uptake Informed choice BrCa worries Anxiety Decisional conflict	1. Decision Aid (n=367) Women 2. Usual Care (n=367) Women	One month
Colorectal CA Screening/FOBT	Trevena 2008	Australia	Decision aid booklet (6 versions) v Government consumer guidelines	Knowledge Values clarity FOBT uptake Informed choice Integrated decisions	1. Decision aid (n=157) 2. Aus. Gov't Consumer Guidelines (n=157)	One month
	Smith 2010	Australia	Decision aid (and DVD) v Government consumer guidelines	Knowledge Attitudes FOBT uptake Informed Choice Decisional Conflict	1. Decision aid (n=357) 2. Aus. Gov't Consumer Guidelines (n=172)	Two weeks and 3 months
Diabetes/Serum Glucose screening	Kellar 2008	UK	Invitation to facilitate IC v Standard invitation	Knowledge Attitudes Intentions Informed Choice	1. IC Invitation (n=273) 2. Standard Invite (n=134)	Two weeks

Table 2

Intervention Effects on the Review's Primary and Secondary Outcomes

	Prescreening Intervention	Primary Outcomes		Secondary Outcomes		
		Informed Choice	Decisional Conflict	Knowledge	Attitudes	Intentions
Gattellari 2003	Evidence-based leaflet	+	-	+	+	0
	Evidence-based video	0		+		0
Gattellari 2005	Evidence-based leaflet	0		+		-
	Web site		0	0		0
Ilic 2008	Video		0	0		0
	Web site		0	+		-
Krist 2007	Leaflet			+		-
Mathieu 2007	Decision aid	+	0	+	^^	0
	Informed choice leaflet	+		+	+	0
Trevena 2008	Decision aid	^		+	0	0
	Decision aid	+	-	+	-	-

Note.

Compared to Usual Care Education or None

+ Increased, -Decreased, 0 No difference between/among the interventions

Informed choice was assessed using the MMIC, ability to make an informed choice or as an integrated decision or perceived ability to make an informed choice

[^] Measured as integrated decisions: sufficient understanding with clear values

^{^^} Measured as values clarity

Table 3**Informed Choice and Decisional Conflict**

Study	Informed Choice	Decisional Conflict	Statistical test
Gattellari (2003) Evidence-based booklet to enhance decision making about prostate cancer screening	Perceived ability to make an IC. $p = .008$	Factors contributing to decisional uncertainty (3 DCS subscales) $p < .001$	t tests No values given
Gattellari (2005) Evidence-based booklet to enhance decision making about prostate cancer screening	Perceived ability to make an IC. $p = .1$ nonsign. difference	Factors contributing to decisional uncertainty (3 DCS subscales) $F_2 = 3.3$ $p = .038$	Fisher's exact test
Krist (2007) Decision aid to increase informed choice about prostate cancer screening		All 16 items from the DCS Control 1.58 Leaflet 1.54 Web-based 1.55 No sign difference	t test No values given
Mathieu (2007) Decision aid to increase informed choice about breast cancer screening	MMIC Chi-square = 37.92 $p < .001$	Informed subscale of the DCS $p = .05$ Values subscale of the DCS $p = .02$	Chi-square and t tests No values given for t tests
Ilic (2008) Web-based computer intervention to increase informed choice about prostate cancer screening		All 16 items from the DCS Video v Computer -.06 Computer v leaflet .10 Video v leaflet .04 No sign difference	Chi-square test No values given
Trevena (2008) Decision aid to increase informed choice about colorectal cancer screening	Decisions integrating knowledge with values $p = .002$		Chi-square test No values given
Kellar (2008) IC invitation to facilitate informed choices for Type 2 diabetes screening	MMIC Chi-square = 41.1 $p < .001$		Chi-square test
Smith (2010) Decision aid to increase informed choice about colorectal cancer screening	MMIC Chi-square = 22.0 $p < .001$	All 16 items from the DCS (low lit version) Decision Aids 181 (51%) low DC Standard Info 65 (38%) $p = .02$	Mann-Whitney U test