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What is This?
How Should Effectiveness of Risk Communication to Aid Patients’ Decisions Be Judged?

A Review of the Literature

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Risk-communication interventions are associated with benefits at both the individual and the public health level. However, the types of outcomes used to assess the effectiveness of risk-communication interventions vary greatly. This makes synthesis of the research in systematic review difficult, and limits both the implementation of advances in clinical practice and further research. This article reviews the outcomes used in risk-communication publications, particularly those addressing individual decisions about treatment. From the traditional cognitive and behavioral research outcomes of patient knowledge, risk perception, and compliance, the emphasis has shifted towards more affective outcomes, including satisfaction, assessment of the information provided and the decision-making process, and certainty about whether the best option has been chosen. These affective outcomes may be more specific and sensitive measures for risk-communication research. Further development and validation of measurement scales to address these issues is needed. Key words: risk communication; physician–patient communication; outcome assessment; affective outcomes. (Med Decis Making 1999;19:428–434)

Effective risk communication is a necessary step in any attempt to share clinical decisions with patients. Risk communications may be subdivided into those between agencies and the public (mass communication) and those from individual communicators. This individual, or one-to-one risk communication is of great interest to public and professionals alike, representing as it does an opportunity to develop medical encounters in ways that are more patient-centered and in keeping with moves to enhance patient participation in health care.

We have reviewed one-to-one risk communication to identify key contexts and contents of risk communication that appear to be most effective. Developing existing definitions in the literature, the review sought to accommodate the range of communication delivery modes that may be relevant to practicing clinicians, including the use of written and audiovisual media. The definition of risk communication adopted was: one-to-one communication in which the intervention includes a stimulus to patients to weigh the risks and benefits of a treatment choice or behavioral [risk reducing] change.

Within the 97 studies of risk communication identified, the clinical context of making treatment choices was an area where interventions could have greater effects on key outcomes, such as patient knowledge, risk perception, anxiety, or behavioral change (the treatment choices made). This derives from the goal’s usually being an informed patient choice where the clinician is nearer to equipoise (no clear preference) regarding the actual choice made, as in the treatment of benign prostatic hyperplasia, where the management options include watchful waiting, medical therapy, and surgery. In contrast, studies aiming for behavioral changes (e.g., smoking cessation, reduced alcohol consumption) or increased participation in screening (e.g., mammography, Pap tests) have professional-led desired outcomes: to reduce risky behaviors or improve compliance. Such studies were not associated with such large changes in key outcomes.

In addition to contextual differences, differences in the contents of risk-communication interventions are also associated with variations in outcomes. The
use of individualized (calculated) risk estimates was associated with larger effect sizes than were other types of intervention. However, closer examination of this debate suggests that the situation is not as simple as these findings may suggest. These findings probably reflect different aims of studies and different outcome evaluations made, as well as a potentially genuine effect-modifying influences of these context and content variables.

Other issues also arise. First, there is a challenge to demonstrate these effect sizes in real practice (particularly in family practice) rather than in the hypothetical situations often studied to date (especially in the treatment-choice studies). Studies based in practice could then assess clinical and economic outcomes such as actual adherence to treatments or care chosen, rather than the intentions to take treatments evaluated in hypothetical studies to date.

Second, and more important, further issues arise about what constitutes "effectiveness" of risk communication. Should effectiveness be judged by outcome criteria perceived (and researched) by professionals as important? These frequently include "cognitive" outcomes, such as knowledge or accurate risk perception, or "physical/behavioral" changes. For example, even a review of patient participation in decision making, by definition a patient-centered paradigm, still examined outcomes in terms of these more traditional measures of pain, recovery duration and compliance.

Patients might attach greater value to different aspects of effectiveness. These could include satisfaction with the communication process, actual involvement in the decision making, a better understanding of the risks and benefits of the different options, helpfulness of the information to the decision-making process, or certainty that the best choice has been made. These "softer" outcomes have been called "affective." They may be more specific for assessing risk communication, particularly in certain contexts or with certain types of interventions. These outcomes could also be more sensitive to change than the cognitive or behavioral outcomes, which in general have shown fairly modest changes in research to date.

There is an increasing consensus that research should evaluate patient-perceived values rather than provider perceptions of the importance of interventions. There is, however, little consistency in the literature about the particular types of outcomes that should be measured to assess the effectiveness of risk-communication interventions. There is much variability even for the cognitive and behavioral outcomes chosen, but it is greater still for the affective outcomes. Reviewing and synthesizing the available research to judge the effectiveness of interventions is therefore difficult. This limits both the implementation of research findings in clinical practice and further research itself.

There is a need for standardized outcomes and measurement tools. In this study we aimed to identify the categories of outcomes that have been used in one-to-one risk-communication studies to date, particularly those in which the context is that of making treatment choices. We do not report the levels of effectiveness of the interventions identified, but identify common patterns that emerge from these different studies. We summarize where validated measures exist, and identify categories where further development of measures is needed. Particular attention is paid to the affective outcome measures, on which future risk-communication research should concentrate if it is to keep in step with current (mainly patient-led) moves towards patient-centeredness.

### Method

We undertook a systematic literature search of the Medline, Embase, CINAHL, PsycLit, SCI, SSCI, ASSIA, and CancerLit databases from the start of the databases to 1997. The principal search topics related to communication about risks in one-to-one health care encounters. The search strategy used layers of subject headings for risk (health behavior or life style or risk or risk taking or risk factors) and communication (communication or counseling or genetic counseling or health education or health promotion or patient compliance or patient education or persuasive communication). The search strategy did not attempt to cover the field of shared decision making or decision supports in a systematic way, although several risk-communication publications overlap with this field. In addition to electronic searches, key review articles and reference lists of included studies were examined for further potential references. Full details of the search and its output are given elsewhere.

The papers identified were examined further regarding the various types of outcome measures assessed. Risk-communication studies of screening or behavioral changes (reducing risky behaviors such as smoking, unsafe sexual practices, etc.) tend to have a narrower range of outcome measures to assess the effectiveness of their interventions. These generally focus on the goal of increasing screening utilization or reducing risky behaviors. While these outcomes are clearly of great clinical and health-economic importance (and appropriate to these studies), these publications do not shed as much light on the affective outcomes being particularly addressed here, so they are not examined in depth.
Table 1 • Types of Outcomes Reported in Risk Communication Literature

<table>
<thead>
<tr>
<th>Theme</th>
<th>Category</th>
</tr>
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<tbody>
<tr>
<td>Cognitive</td>
<td>1. Patient's knowledge change after intervention</td>
</tr>
<tr>
<td></td>
<td>2. Correct risk perception</td>
</tr>
<tr>
<td>Behavioral/physical</td>
<td>1. Compliance (intended or actual; with treatment or use of information package)</td>
</tr>
<tr>
<td>Affective</td>
<td>1. Anxiety ratings (general, state, and trait)</td>
</tr>
<tr>
<td></td>
<td>2. Satisfaction</td>
</tr>
<tr>
<td></td>
<td>3. Certainty about option chosen</td>
</tr>
<tr>
<td></td>
<td>4. Assessment of decision-making process</td>
</tr>
<tr>
<td></td>
<td>5. Assessment of information given</td>
</tr>
</tbody>
</table>

We have concentrated on studies that address treatment choices. These include those where the risk-communication intervention aimed to facilitate an individual’s decision making regarding whether to take a specific treatment (such as for prostatism or mild hypertension) or immunization, to enable an informed choice to be made regarding entry into a clinical trial, or to improve adherence to a management plan.

The articles were examined by the authors to identify apparent categories of outcomes. The categories were identified inductively in a process similar to qualitative research methods.21 The authors undertook this independently initially and then agreed upon the final categories by discussion. These categories were then organized under the broader themes identified earlier by Llewellyn-Thomas.13 Within each outcome category, the specific outcome measures reported were reviewed to identify the range of different measures available and whether validated measures were apparent.

Results

The types of outcomes reported by the identified studies are summarized in table 1.

COGNITIVE OUTCOMES

Patient knowledge. Several studies assessed patients' knowledge of risks,11,12,15,25–26 including the risks of radiologic22,23 or anesthetic procedures,24 the number of side effects of medication recalled,25 and risks and benefits of medication11 or screening procedures.26 This outcome also featured in some screening studies, such as an educational intervention to enhance mammography use.27,28

Risk perception. Risk perception was also assessed in various studies, usually in terms of whether subjects' perceptions of personal risk were modified by an intervention to make them more accurate in terms of epidemiologically calculated risk.10,17,29,30 This outcome was also used in screening studies where efforts were made to reduce perceptions of risk (and consequent anxiety) regarding breast,31–33 cervical,34 or skin cancer.35 Other studies sought to heighten perceived vulnerability to breast cancer as a means of increasing the utilization of mammography.36 The studies were limited in their interpretation of risk perception, focusing only on the magnitude of the chances that x would happen, rather than addressing also the level of adversity or burden that would be associated with x's occurrence.37,38 Only the former can realistically be judged to be accurate in comparison with epidemiologically derived data.

BEHAVIORAL/PHYSICAL OUTCOMES

Compliance. Compliance covers a variety of outcomes. It usually refers to compliance with a chosen treatment or agreement to participate in a therapeutic trial, but may also include use of the information package itself being studied. Most of these studies in the treatment-choice context were in fact hypothetical, and hence reports describe intentions to comply with treatments, tests, or trials.14–16,28,30,39–43 Some describe actual patient compliance10,22,26 or related issues, such as citing specific side effects as a reason for discontinuing medication7 or giving reasons for refusing to enter a clinical trial.41

“Compliance” is becoming outmoded, in favor of “adherence” or, more recently, “concordance.”44 In keeping with this shift in emphasis, there has also been a move towards assessing adherence in relation to the patient's own treatment plan rather than a doctor-determined management strategy.11 In this respect, this outcome category appears to be evolving towards a more patient-centered concept, in parallel with the following affective outcome categories.

AFFECTIVE OUTCOMES

Anxiety ratings. Many studies have assessed patient anxiety, including general anxiety or concern,15,17,23,45,46 or measurement of “state” or “trait”24 anxiety levels. State and trait anxiety are usually assessed by validated methods.47,48 One related outcome was “feelings towards medication.”49 Other studies would have interpreted refusal to undergo a (radiologic) procedure as evidence of increased patient anxiety due to the provision of risk information if any change in utilization had been documented.22
Satisfaction. Patient satisfaction has been reported in terms of a number of different aspects of the health care encounter. Some authors view satisfaction as a general outcome of the consultation, while specific satisfaction has been reported concerning the consent process, the drug-information insert or the health care provider. The usual focus is on satisfaction with the information given, but another aspect concerns the patient’s personal sense of accomplishment at having negotiated a package, such as a computerized videodisk, with which he or she may be highly unfamiliar. Another aspect concerns satisfaction with the decision-making process, but this is described below.

Certainty about option chosen. The patient’s level of certainty or confidence that the therapeutic option chosen was the best one for him or her personally appears intuitively to be an important outcome category. This has been described in some risk-communication studies, but the validity of simple measures is questioned by the findings of Hux and Naylor, in which high degrees of certainty were reported even by people who subsequently changed their minds in response to presentation of alternative information.

Uncertainty has, however, also been assessed by means of a decisional conflict scale covering the same concepts, and validated in the contexts of immunizations and breast cancer screening. The factors contributing towards uncertainty include feeling uninformed about options and the risks and benefits of each option, having unclear personal values, and anticipating difficulty carrying out the decision. Decisional conflict is likely when making choices involving risk or uncertainty of outcomes, high stakes in terms of potential gains and losses, the need to make tradeoffs in selecting a course of action, and anticipated regret over the positive aspects of rejected options.

Assessment of decision-making process. The decision-making process has been assessed in terms of preferences for involvement in the decision. Scales to identify the patient’s preference for involvement or perceived actual involvement have been developed. The influence of the information provided on the decision making has been explored, as has the process of making the decision, including aspects such as discussion with other family members, the amount of time spent deliberating, and whether the individual feels more supported in the decision.

General satisfaction with the decision made has been described, and scales have been developed for this purpose and validated in the contexts of antenatal screening, hormone replacement therapy (HRT), and immunizations. Patients’ perceptions of their involvement in the decisions made do not feature in the risk-communication research reviewed here, though there are scales of perceived involvement in the literature focusing more specifically on patient participation.

Assessment of information given. Several aspects of the value of information have been used as outcome measures, often as part of an overall group of questions or ratings. The correlations of the responses within these groups have not been reported.

Regarding individual elements of the information sharing, studies have assessed whether patients felt an adequate explanation of the information had been provided and whether they perceived the information to be accurate. Further aspects studied include whether information was found clear and easy to understand, whether it was consistent with patients’ personal values, and whether it was interesting or more accessible than usual sources of information. Perhaps of more importance, however, other studies have focused on whether enough information had been provided, and whether the information had actually been useful or helpful in making the treatment decision.

Discussion

The articles identified in this review demonstrate a wide range of outcome measures used. These can be grouped into eight broad categories. Some, particularly the cognitive and behavioral outcomes (knowledge, risk perception, and compliance), have been used over long periods of time in research. Others, including the affective outcomes, are gaining in prominence. These reflect a more patient-centered philosophy that is emerging in parallel with developments in risk communication itself.

However, there is no consensus about what constitutes a good decision, and little empirical evidence exists. O’Connor defines effective decisions as informed, consistent with personal values, and acted upon, and the affective outcomes reflect this: satisfaction, assessment of the information given and the decision-making process, and certainty about the treatment choice made. Kits are becoming available to aid patient choices about therapy, for example, weighing the risks and benefits of hormone-replacement therapy, the management of benign prostatic hyperplasia, or genetic screening for breast cancer susceptibility. Any decision aids or alternative risk-communication strategy should reduce uncertainty and confusion in choosing a
course of action and increase the likelihood that consumers will make “effective” decisions. These affective outcomes complement but do not render obsolete the more traditional cognitive and behavioral research outcomes, which still have clinical and health-economic importance.

The outcome categories may also be particularly important over different time scales. The cognitive and behavioral outcomes are suited to short-term evaluation, providing immediate results from studies. The affective outcomes also have some immediate importance, but also have longer-term effects and significance: only if the patient is satisfied, and understands the choice made and why, is individual adherence to such a personal decision likely to continue.

The assessment of most of these outcomes is somewhat imprecise science at present. Among the cognitive outcomes, risk perception may be assessed by means of analog scales for risk values, but is usually assessed along with knowledge by a test of factual recall. However, recall does not necessarily indicate understanding. Assessments of recall are also prone to error, as people’s interpretations of the risk information given vary widely—different expressions (framing) of the same risk, whether as percentages, gambling odds, or other formats, have different meanings for different individuals.

Among the affective outcomes, validated scales exist for the assessment of anxiety, satisfaction with the process of making a treatment decision, and the level of patient certainty about the decision’s being the best one for the individual. Apart from anxiety, affective outcomes require assessment of their validity and reliability when used in clinical contexts outside the narrow range so far examined. The authors of one scale have indicated that they plan to evaluate whether the acceptable reliability and validity found in two contexts (influenza immunization and breast cancer screening) can be replicated in other decision-making contexts that involve higher stakes and value tradeoffs, such as genetic screening and the risk of stroke vs bleeding with anticoagulation for atrial fibrillation.

There is clearly much scope also for the development of specific questions or scales that can assess the other affective outcomes: satisfaction with the elements of the consultation, or patients’ assessment of the information given. Where some authors have used groups of questions to elicit such assessments about the information, these can provide the basis for further research into the internal consistency, validity, and reliability of a measurement scale. Such research may identify which factors in a scale are most valuable as evidence of effective decisions resulting from the risk-communication intervention. For risk communication in the treatment-choice context, we speculate at this stage that these might be understanding of the information, whether sufficient information has been provided, and whether the information was helpful in arriving at the decision.

In studies of screening or behavioral changes, the behavioral outcomes feature prominently, especially compliance with utilization of screening tests or reducing risky behavior. This is appropriate to the aims of those studies. We have identified a broader range of outcomes assessed in the studies of treatment choices. These include the affective outcomes and could be viewed as showing a more patient-centered approach to evaluation. Many of these outcomes, such as patient evaluation of the risk information or certainty about making the right choice of treatment option, would, however, be appropriate outcome measures in the other screening or behavioral-change studies. For example, in an intervention to improve adherence to mammography programs, it would be appropriate to measure the increase in utilization and also how women rated the information given to them, and their levels of certainty about utilization’s being the best choice for them personally. Then any overall increase in utilization could be interpreted as reflecting effective risk communication rather than simply the effects of arousing fear or anxiety among the women receiving the intervention.

The use of affective outcome measures is haphazard at present, and consistency is required with respect to both which outcome measures should be used, for which types of studies, at which time intervals, and also how long after interventions they should be applied. This study has identified categories of outcomes within previously identified groups. Awareness of the categories should enable researchers to focus on the outcomes relevant to the aims, contexts, and contents of their particular risk-communication interventions.

If the affective outcomes are evaluated consistently alongside the cognitive and behavioral outcomes in future studies, this should provide more specific measures with which to judge the effectiveness of risk-communication interventions, particularly for studies addressing treatment choices for patients. The affective outcomes identified may also be more sensitive measures of the effectiveness of risk communication than the research ones, which have often been resistant to change. Increasing adoption of these affective outcomes to evaluate effectiveness of risk-communication interventions is in keeping with the moves towards greater patient-centeredness now expected in medicine. Moving from evaluation of compliance to assessing adherence to the patient’s own chosen plan is also consistent with this proposed shift.
Conclusion

Affective outcomes are a valuable and necessary complement to the cognitive and behavioral outcomes of knowledge, risk perception, and compliance. They may be more specific and sensitive measures of the effectiveness of risk-communication interventions. We need a consensus about the most important affective outcomes, which in the current literature include anxiety, satisfaction, assessment of the information given and the decision-making process, and certainty about the option chosen. The consensus should be informed and validated by both quantitative and qualitative research methods with patients. This should culminate ideally in accepted and valid scales for measuring different aspects of the effectiveness of risk communication. These will have relevance also to the specific areas of decision making and decision supports. Rigorous development of such outcome measures is needed, as few validated scales currently exist.

Future risk-communication research should be undertaken in real practice rather than in the many hypothetical situations studied to date, and must address these affective outcome measures, matched to the aims, contexts, and contents of the interventions. Consistency in the use of outcome measures will also help advance the understanding and practice of risk communication by making comparisons between studies possible, and their lessons easier to learn.

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