Interventions to improve patient comprehension in informed consent for medical and surgical procedures: a systematic review

Schenker Y, Fernandez A, Sudore R, Schillinger D

CRD summary
This review assessed the effectiveness of communication interventions to increase patient understanding in informed consent for medical and surgical procedures and concluded that a wide range of communication interventions improve comprehension in clinical informed consent. The lack of detail on the magnitude of effects makes interpretation of the conclusions difficult and publication bias may be possible.

Authors' objectives
To assess the effectiveness of communication interventions to increase patient understanding in informed consent for medical and surgical procedures.

Searching
MEDLINE and EMBASE were searched to November 2008 for studies published in English. Search terms were reported. Reference lists of relevant articles retrieved and a published bibliography of empirical research on informed consent were examined for further studies. The full search strategy was available as a web appendix.

Study selection
Eligible randomised controlled trials (RCTs) and non-randomised controlled trials compared a standard informed consent process for a high risk and/or invasive medical process with an enhanced process designed to improve comprehension in patients undergoing medical or surgical procedures. Studies had to report a quantitative, objective measure to assess comprehension or recall key elements of informed consent for inclusion.

Studies addressed informed consent for a wide variety of medical and surgical procedures and more than half took place in an in-patient setting. Most of the studies were conducted in the United States; the remainder were in the United Kingdom, Australia, Canada and New Zealand. The informed consent interventions were categorised as additional written information, audiovisual/multimedia interventions, extended informed consent discussions and test/feedback technique. The outcomes reported varied between studies, but most assessed understanding of the risks of the procedure; patient understanding of potential benefits/indications, alternatives and general knowledge about the procedure were also assessed. A variety of instruments were used to measure outcomes. Most studies assessed comprehension before the medical/surgical procedure.

One reviewer selected studies for inclusion. Where eligibility was unclear, four reviewers determined eligibility for inclusion by consensus.

Assessment of study quality
Methodological quality was assessed by one reviewer using a tool developed based on the domains recommended in a previously published AHRQ report in terms of description of study population, randomisation, description of intervention, outcome measurement and results to obtain a quality score out of five. Papers that scored 0 to 2 were considered poor quality; those with a score of 3 were considered fair and those scoring 4 or 5 were considered good quality.

A subsample of 21 papers was assessed by two reviewers to refine the quality criteria and disagreements were resolved by consensus.

Data extraction
Data were extracted independently by two reviewers for the outcomes reported onto a standardised data extraction form. Disagreements were resolved by consensus.

Methods of synthesis
The studies were presented in a narrative synthesis grouped by type of intervention and outcome measure. A table of study characteristics was presented in the text.

**Results of the review**

Forty-four studies were included in the review (5,419 patients; range 18 to 269). Twenty-three were RCTs (3,029 patients) and 21 were non-RCTs (2,388 patients). Eighteen studies were rated good quality, 10 were fair and 16 were poor. None of the studies were double-blinded and other limitations included poor reporting of randomisation method and non-blinded outcome measures.

Thirty-nine studies measured understanding of risks associated with a procedure; 28 of these found that the intervention improved comprehension. Fourteen of 20 studies showed that the intervention improved understanding of potential benefits/indications, seven of ten studies showed improved comprehension of alternatives and 22 of 28 showed improved comprehension of general knowledge about the procedure.

Sixteen of 21 studies reported improvement in comprehension with the addition of written information. Eleven of 15 studies reported improved comprehension with audiovisual interventions. Two of five studies showed improved comprehension with extended informed consent discussion. All three studies that investigated test/feedback techniques found that this was associated with improved understanding of informed consent.

**Authors' conclusions**

A wide range of communication interventions improve comprehension in clinical informed consent.

**CRD commentary**

The research question was supported by inclusion criteria for participants, interventions, outcomes and study design. Only two databases were searched for studies published in English; it was possible that relevant studies were missed and publication and language bias cannot be ruled out. Two independent reviewers were involved in data extraction which reduced the possibility of error and bias. The extent of involvement of a second reviewer was limited for study selection and quality assessment, so these processes may have been prone to bias and error. Some aspects of study quality were considered, however there was little detail regarding the quality domains assessed. Narrative synthesis appeared appropriate considering the heterogeneity of the study populations, interventions and outcomes. However, there was little numerical data available in the synthesis.

The authors' conclusions are supported by the data presented, however their reliability is limited by possible publication bias and the lack of detail on the magnitude of effects makes interpretation of the conclusions difficult.

**Implications of the review for practice and research**

**Practice:** The authors stated that communication interventions should be promoted and decisions to enhance informed consent should consider the importance of different elements of understanding beyond procedural risks, as well as feasibility and acceptability of the intervention to clinician and patients. Interventions that are accessible to patients with limited literacy and/or English proficiency should be implemented.

**Research:** The authors stated that conceptual clarity regarding key elements of informed consent knowledge would help to focus improvements and standardise interventions. The authors also suggested that: future studies should implement measures to reduce bias; outcome measures should consider more than procedural risk (such as benefits/indications, alternatives); studies should include patients with limited literacy and English proficiency; more research is required to assess the comparative effectiveness of interventions and the potential for combining methods; and cost-effectiveness studies are needed.

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