Health Knowledge Network

EVIDENCE BULLETIN

May 2014

Interventions to promote informed consent for patients undergoing surgical and other invasive health care procedures

Review question

What is the effect on patients, clinicians and the healthcare system of interventions to promote informed consent for patients undergoing surgical and other invasive healthcare treatments and procedures?

What are interventions to promote informed consent?

Interventions to promote informed consent generally provide information about the treatment options, associated benefits and harms, probabilities and scientific uncertainties. They may involve face-to-face contact, or online, video, telephone or leaflet-based information. They may also be organisational, such as providing more time for the patient to ask questions.

Key findings

Interventions to promote informed consent for surgery and other invasive procedures were found to:

- Improve knowledge immediately after delivery of the intervention, and in the short and longer term (> 15 days later)
- Improve satisfaction with decision-making and reduce decisional conflict
- Increase consultation length
- Make no difference to generalised anxiety, anxiety with the consent process or satisfaction with consent process

Full citation for this review:
Kinnersley P, Phillips K, Savage K, Kelly MJ, Farrell E, Morgan B, Whistance R, Lewis V, Mann MK, Stephens BL, Blazeby J, Elwyn G, Edwards AGK. Interventions to promote informed consent for patients undergoing surgical and other invasive healthcare procedures. *Cochrane Database of Systematic Reviews* 2013, Issue 7. Art. No.: CD009445. DOI: 10.1002/14651858.CD009445.pub2.

This summary is relevant for:

This evidence bulletin can be used by decision makers and clinicians involved in the informed consent process for surgery and other invasive health care procedures.

This summary includes:

Not included:

- Additional evidence
- Detailed descriptions of the intervention or how to implement it in practice
- Recommendations

What is a systematic review?

A systematic review aims to locate, appraise and synthesise all of the available evidence related to a specific research question. Authors adopt rigorous methods to minimise bias as a way of producing reliable findings with the ultimate goal of making the evidence more useful for practice. See navigatingeffectivetreatments.org.au for more information.

Relevance to the health care context in Victoria, Australia

The broader policy and clinical context	The Victorian Charter of Human Rights and Responsibilities Act 2006 asserts that full, free and informed consent must be given by patients before a medical treatment is provided. This is reflected in the Australian Charter of Healthcare Rights in Victoria and is a standard component of medical intervention internationally.
The populations and settings in which this relevant	The results of this review are highly relevant to Australian hospital settings, with the studies being set primarily in hospital or secondary care settings (63/65) and almost all studies taking place in high income countries (eight in Australia). While most studies (60/65) included adults consenting for a procedures for themselves, five studies considered consent for minors. The results are applicable to a wide range of clinical procedures including surgery, invasive procedures and anaesthetics.
Implications for decision makers	A range of interventions exist to enhance informed consent for people considering surgery or other invasive procedures. This review identified that audio-visual, multimedia, written, structured consent and decision aids are all generally effective in improving knowledge but their relative effectiveness for other outcomes is unclear. Thus the selection of an informed consent procedure can be made on the basis of practical considerations and preferences. There were insufficient studies to provide conclusions about the impact of interventions to promote informed consent on clinicians, health care organisations and uptake of procedures.
Implications for clinicians	As clinicians take responsibility for the consenting of patients, they could also take responsibility for improving this process. Clinicians wanting to promote informed consent can choose from a wide range of consent interventions (see Implications for decision makers). Some may require special equipment (i.e. multimedia) and others may require extensive development and piloting. The authors advocate for making informed consent a process rather than an event and suggest that providing consent information before, rather than at, admission is important.

Related Resources

Examples of interventions to promote informed consent

- Temple health. A practical guide to informed consent
- Queensland Health. Guide to informed decision-making in health care

Related systematic reviews

- Hon 2012. Extended discussion of information for informed consent for participation in clinical trials
- Ryan 2009. Audio-visual presentation of information for informed consent for participation in clinical trials
- Stacey 2014. Decision aids for people considering health treatment or screening decisions

Related evidence bulletins

- Audio-visual presentation of information for informed consent for participation in clinical trials
- Personalised risk communication
- Decision aids for people considering health treatment decisions

Available at the Health Knowledge Network

Background

Information about this review

The authors of this systematic review conducted a detailed search of studies published up to July 2011. They used the following criteria to determine which studies to include:

Types of studies

- Randomised controlled trials and cluster randomised controlled trials

Participants

- People aged 16 years and over being asked to give consent for a surgical or other invasive healthcare treatment or procedure, either for themselves or on behalf of someone for whom they have responsibility.

Types of intervention

- Interventions targeted at healthcare professionals, or patients, or both, who were participating in the consent process for a surgical or other invasive procedure or
- Interventions targeted organisational change of the consenting of these patients
- Interventions were required to have the intention of improving patients' understanding of their treatment options and procedure, evaluating their options, or helping them retain and recall the information provided, and thus their ability to provide informed consent

Comparison

- Interventions were compared with usual care (controls)

Outcomes

The following outcomes were examined:

- Informed consent
- Patient understanding
- Knowledge/retention/recall
- Deliberation (weighing up)
- Communication of decision
- Other patient outcomes (including satisfaction and anxiety)
- Clinician outcomes (including satisfaction, ease of use and confidence in patient's decision)
- System outcomes (including rates of uptake of procedures, delay in decision making, complaints and litigation, adverse procedural outcomes and economic/resource use)

Main results

This review included 9,021 participants in 65 studies.

About the studies

The majority of studies were conducted in hospital/ secondary care settings in high income countries (eight in Australia). Participants were considering a range of clinical decisions, including surgery, invasive procedures (e.g. endoscopy) and anaesthetics.

The types of interventions were mixed, including audio-recorded (n = 2), non-interactive audio-visual (n = 19), interactive multimedia (n = 6) and written information (n = 27).

Effects of interventions

Interventions to promote informed consent were found to:

- Improve knowledge immediately after delivery of the intervention, and in the short and longer term (> 15 days later)
- Improve satisfaction with decision-making and reduce decisional conflict
- Increase consultation length
- Make no difference to generalised anxiety, anxiety with the consent process and satisfaction with the consent process

What this review does not show

This review provides little information about the Impact of interventions to promote informed consent on clinicians, health care organisations and uptake of procedures.

The authors concluded that results should be interpreted with caution due to the high levels of heterogeneity associated with many of the main analyses although they believe there is broad evidence of beneficial outcomes for patients with the pragmatic application of interventions.

Results table: intervention to promote informed consent versus control

Outcome		Relative effect* (95% CI)*	No of Participants (studies/comparisons)
1	**Knowledge**		
	Immediate knowledge (<24 hours)	SMD 0.53 (95% CI 0.37 to 0.69) RR 1.17 (95% CI 0.85 to 1.60)	2852 (26 studies) 331 (3 studies)
	Short-term knowledge (1 to 14 days)	SMD 0.68 (95% CI 0.42 to 0.93)	2106 (16 studies)
	Long-term knowledge (≥ 15 days)	SMD 0.78 (95% CI 0.50 to 1.06)	1353 (17 studies)
2	**Satisfaction**		
	Satisfaction with decision making	SMD 2.25 (95% CI 1.36 to 3.15)	2144 (8 studies)
	Satisfaction with the consent process	SMD 0.12 (95% CI –0.09 to 0.32)	2024 (15 studies)
3	**Decisional conflict**	SMD –1.80 (95% CI –3.46 to –0.14)	837 (3 studies)
4	**Anxiety**		
	Generalised anxiety	SMD –0.11 (95% CI –0.35 to 0.13)	2069 (14 studies)
	Anxiety with the consent process	SMD 0.01 (95% CI –0.21 to 0.23)	1407 (13 studies)
5	**Consultation length**	MD 1.66 minutes (95% CI 0.82 to 2.50)	517 (6 studies)

* Relative effect is measured as Relative Risk (RR), Standardised Mean Difference (SMD), or Mean Difference (MD) followed by a 95% confidence interval (95% CI)

This evidence bulletin draws on the format developed for SUPPORT summaries (for more information on SUPPORT summaries see www.supportsummaries.org).

Health Knowledge Network

The Health Knowledge Network is the knowledge transfer arm of the Centre for Health Communication and Participation. The Centre is funded by the Quality, Safety and Patient Experience Branch, Department of Health, Victoria, Australia.

The Health Knowledge Network summarises reviews published by the Cochrane Consumers and Communication Review Group.

Contact Us

Health Knowledge Network, Centre for Health Communication and Participation, La Trobe University, Bundoora, VIC 3086, Australia. Ph: +61 3 9479 5730 E: hkn@latrobe.edu.au
W: http://www.latrobe.edu.au/aipca/about/chcp

Suggested citation

Synnot, A. 2014. Interventions to promote informed consent for patients undergoing surgical and other invasive healthcare procedures [Evidence Bulletin]. http://www.latrobe.edu.au/aipca/about/chcp/health-knowledge-network/bulletins