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HOW CAN WE IMPROVE INFORMED CONSENT PROCESSES?

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EXECUTIVE SUMMARY

True informed consent is a conversation between a clinician and a patient involving a full disclosure of diagnosis, treatment options, as well as the risks, benefits and consequences of refusal. While this information should be provided in a way that patients understand and should be tailored to their values and goals, there is evidence to suggest that informed consent may be sub-optimal or not obtained at all in many circumstances. Failure to obtain fully-informed consent can contribute to decisional regret which can have negative impacts on quality of life, health outcomes and experiences within the health care system. Inadequate consent is also the basis of many medical malpractice claims. In the Victorian context, inadequate informed consent was identified as a critical factor in 10% of the Victorian Managed Insurance Authority's medical indemnity claims.

The aim of this project is to develop and test a strategy to improve informed consent processes between clinicians and patients or increase patient understanding of risks, benefits and alternative options and ultimately their ability to make an informed decision about their care. To unpack contributing factors to this problem, a literature review, practice review and citizen panel were conducted.

A rapid review of the literature identified seven systematic reviews and 16 primary studies. Collectively, the reviews found that:

- preoperative education, particularly using a multimedia format, can improve patients' recall of risks and understanding of procedures;
- the use of static visual aids to communicate risk may improve risk literacy, especially among individuals with lower levels of numeracy;
- question prompt lists may increase the amount of questions patients ask during consultations; and
- decision aids, particularly those that are computer-based, can improve knowledge and reduce decisional conflict.

Primary studies covered the following intervention categories: best case/worst case; additional conversations; framing and personalising; repeat back; testing with feedback; simplified information; standardised consent forms; training; and access to interpreters.

Consultation interviews with researchers, clinicians and a consumer representative reiterated the importance of providing patients with personalised information about risks, benefits and alternative options so that they can make choices that align with their values and goals. They identified a number of different ways to present risk information in order to aid patient understanding (e.g. diagrams, icon arrays and bar charts) and highlighted that training could improve clinicians' basic communication skills, communication of risk information and knowledge about the informed consent process.

We consulted with a panel of 13 Victorian community members to better understand their perspectives on informed consent processes. This highlighted that while they understood the concept of informed consent, more education surrounding patient rights and what to expect during this process could be provided. Citizens emphasised the importance of adequate time to engage in detailed conversations and consider the information prior to making a decision, therefore suggesting that informed consent discussions should begin as early as possible. They reported that the provision of information should be tailored based on individual preferences and identified a number of ways in which multimedia could be used to enhance the delivery of information.

Collectively, the review and consultation activities provide basis for deliberations on how research evidence and practice insights can assist in the identification of feasible and testable behaviour change strategies.

AIMS

The aim of this project is to develop and test a behavioural strategy to improve informed consent processes. We applied the Forum method[1,2] which takes a structured approach to evidence review and stakeholder dialogue.

Table 2 outlines this approach. This briefing document contains findings from the evidence and practice review. The Briefing Document is directed towards groups with expertise in or experience in informed consent. These include clinicians, health service organisations, consumers and consumer representatives, researchers, the Victorian Department of Health and Human Services (DHHS) and the Victorian Managed Insurance Authority (VMIA). Details of the research methods employed in producing this briefing document can be found in Appendix 1.

Table 2. Project overview

EVIDENCE AND PRACTICE REVIEW
Rapid review of evidence into the effectiveness of strategies to improve communication of informed consent between clinicians and patients and increase patient understanding of the risks, benefits and alternative options when consenting to medical treatments. Examination of current practice and key issues in informed consent processes through: • A day-long citizen panel in which members of the Victorian community discuss key challenges; and • One-on-one interviews with clinicians, researchers and other experts in the field.
STAKEHOLDER DIALOGUE
Convene a representative stakeholder group to: • Gain a shared understanding of key issues in informed consent processes; • Identify and prioritise behavioural interventions that are feasible, can be trialled within 6 months and are scaleable across various Victorian health settings and services; • Determine broad characteristics of a high-priority trial for further development. A day-long structured stakeholder dialogue will be held on May 10, 2019. The dialogue aims to connect the information from this briefing document with the people who can make change happen and deliberate upon this shared challenge. Collective problem solving through multi-stakeholder dialogue has been used around the world to address healthcare policy and practice challenges. Participants consistently demonstrate high satisfaction and high intention to act upon evidence discussed in dialogues. Specific questions for deliberation at this stakeholder dialogue are presented at the end of this briefing document.
TRIAL IMPLEMENTATION
The BehaviourWorks research team, in collaboration with VMIA, DHHS and participating health services, will develop, implement and evaluate a pilot trial of a high-priority intervention in a Victorian hospital setting. The pilot trial is anticipated to be conducted in 2019.

INTRODUCTION

"A person must not be subject to medical treatment without his or her full, free and informed consent"
Charter of Human Rights and Responsibilities Act 2006[3]

INTRODUCTION TO INFORMED CONSENT

In the healthcare setting, consent must be obtained before anything is done to a patient[4]. Informed consent is a person's agreement for something to happen to them (e.g. surgery or an invasive diagnostic test)[5]. Consent must be given voluntarily and based on sufficient information provided by a clinician, including a complete explanation of a patient's diagnosis and treatment options, as well as a full disclosure of the risks, benefits and consequences of refusal, in a way that the patient can understand[5,6]. This must occur before the commencement of any medical treatment and the patient must have the capacity to provide consent[4,7,8]. Informed consent has ethical, legal and practical implications. These implications are outlined below[6,9].

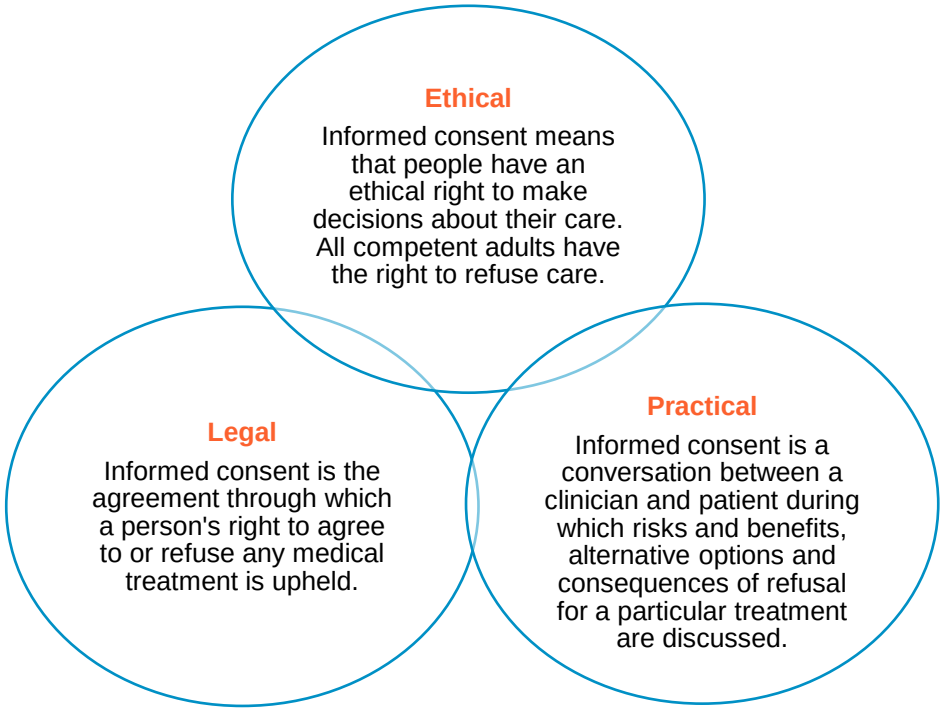

Figure 1. Ethical, legal and practical implications of informed consent.

The responsibility to obtain consent is on the clinician who will perform a procedure or investigation[4]. A conversation between a patient and a clinician is the actual process of obtaining informed consent while the consent form documents the occurrence of the conversation, providing proof that the conversation took place and that the patient understood and agreed to the procedure or treatment[9]. In other words, obtaining informed consent is a legal duty of healthcare providers and the consent form is the legal paperwork to demonstrate that they have fulfilled this obligation[9]. It is imperative that the practical element of informed consent, the conversation, is fulfilled before a consent form is signed[9].

While a lot of work that healthcare professionals do is based on implied consent (e.g. patients holding out their arm for a blood pressure measurement), for invasive or uncommon treatments, explicit

consent needs to be obtained[6]. The focus of this project is on invasive treatments which may be associated with potential complications or irreversible side effects and require explicit informed consent.

It is important that patients are able to make informed decisions about the care and treatments that are right for them. In order to do this, they need to be aware of the options available to them, including alternative treatment options. It is also worth noting that treatment option presentation and subsequent decisions can be influenced by the clinician patients choose to see[10]. For patients, understanding what their life will be like after the treatment or procedure is important to their decision-making process, but often discussions are centred on acute risks.

Failure to obtain fully informed consent has resulted in a number of significant legal judgements in relation to the provision of information. In the case of Rogers v Whitaker (1992), the Australian High Court ruled against a surgeon who was considered to have provided inadequate information. Whitaker, the plaintiff, was left essentially blind after an unsuccessful operation on her right eye caused sympathetic ophthalmia in her left eye. Although the surgery was performed appropriately, the surgeon failed to inform Whitaker of the possibility of sympathetic ophthalmia, despite the patient expressing concerns about risks to her 'good eye'. The court ruled that doctors have a duty to disclose 'material' risks. They defined a risk as material if "in the circumstances of the particular case, a reasonable person in the patient's position, if warned of the risk, would be likely to attach significance to it, or if the medical practitioner is, or should be aware that the particular patient, if warned of the risk, would be likely to attach significance to it"[11].

Following the more recent UK Supreme Court case of Montgomery vs Lanarkshire Health Board in 2015[12] (See Box 1), there has been a shift from passive disclosure of information, to a more collaborative, patient-centred experience in which patients and clinicians work together to arrive at a mutually acceptable treatment plan[13,14].

MONTGOMERY VS NHS LANARKSHIRE case

- In 1999, Nadine Montgomery's baby boy suffered brain damage during birth
- As an insulin-dependent diabetic, Mrs. Montgomery was at increased risk of having a larger than average baby, which increases the risk of vaginal birth complications, including shoulder dystocia
- Mrs. Montgomery's baby's shoulder got stuck during birth, which resulted in severe fetal brain anoxia and led to cerebral palsy
- Mrs. Montgomery claimed that her obstetrician failed to communicate the risk of shoulder dystocia associated with vaginal delivery
- The obstetrician claimed that the risk was small and therefore did not communicate it as caesarean section delivery is not in the maternal interest
- Montgomery said that if she had been told of the risk, she would have elected to have a caesarean section
- In 2015, Montgomery was awarded £5.25m compensation after a 16-year legal fight in which her claim was upheld by the Supreme court

Shared decision making is one approach in which patients can be further engaged and given more responsibility during the informed consent process. It involves clinicians and patients working together to make decisions based on best available evidence and patients' values, goals and concerns. Clinicians support patients to consider options and communicate their preferences in order to achieve fully informed consent[15].

A systematic review conducted by Makoul & Clayman identified nine essential elements of shared decision making that should be considered during consultations with patients[16]:

- Provide a definition and explanation of the healthcare problem
- Present a range of options
- Discuss the benefits, risks and costs of each option
- Understand patient values and preferences
- Discuss patient ability and self-efficacy
- Present evidence about treatment options and make recommendations
- Check that the patient has understood
- Make or clearly defer a decision
- Arrange a follow-up consultation

There is evidence to suggest that shared decision making is associated with reduced decisional regret and improved decision quality and patient knowledge related to treatment options and risks[17,18].

PROBLEMS WITH INFORMED CONSENT

A number of factors contribute to the success of informed consent processes.

Patient factors include, but are not limited to, health literacy, language barriers and willingness to be involved[19-21]. It has been reported that one in seven surgical patients experience decisional regret about surgery decisions, which can have significant negative impacts on quality of life, health outcomes and experience with the health care system[22-24].

The numerical literacy and experience level of clinicians, as well the time available to obtain informed consent impact on clinicians' ability to obtain informed consent[20,25]. While Australian courts have held doctors negligent for failure to disclose risks in a number of cases and issued guidelines to help doctors inform their patients, there is evidence to suggest that best practice is often not followed[26]. There is also considerable variation in practice. A survey of Australian junior medical officers found that 11% had conducted a significant procedure and 22% had witnessed a significant procedure for which informed consent had not been taken[27]. Furthermore, 56% stated that they consented patients for a procedure for which they did not have adequate knowledge of the risks involved. Many respondents also believed that medical school training and ongoing education related to informed consent processes is inadequate. A review of negligence claims and complaints in Australia highlighted that doctors are often uncertain about which risks they should disclose to patients during informed consent discussions[28]. Among 481 disputes over informed consent, 45 were disagreements between patients and clinicians related to whether a particular clinical risk should have been disclosed before treatment. Clinicians commonly justified non-disclosure by suggesting that risks were too rare or that specific risks were encompassed by more general risks that were discussed.

In the Victorian context, inadequate informed consent was identified as a critical factor in 10% of VMIA claims. Strategies to address barriers to informed consent and improve informed consent processes may empower patients to make more informed choices about their health care.

WHAT DOES THE EVIDENCE SAY? RAPID REVIEW FINDINGS

A rapid literature review was undertaken to identify, evaluate and synthesise published literature investigating interventions that improve informed consent processes.

Rapid reviews are an emerging method of efficiently synthesising research evidence in health policy and other settings where a broad overview of research evidence is required in a short timeframe. *Caution needs to be applied when interpreting rapid review findings, as more comprehensive review approaches may elucidate further information and insights, which would influence review interpretation and conclusions [29]. Therefore, systematic reviews remain the definitive method of literature review, and we recommend systematic reviews be undertaken whenever possible. Further details of the review and other methods employed in producing this briefing document can be found in Appendix 1.*

The literature search yielded a total of 3774 citations after the removal of duplicates. Following screening, seven systematic reviews were eligible for inclusion in the rapid review. In addition, 16 primary studies were included to supplement the evidence review. Quality appraisal of these reviews using the recognised AMSTAR 2 tool showed that three reviews were of reasonable to high quality, satisfying a majority of applicable quality criteria (See Appendix 2). This means that reasonable confidence can be placed in the findings of these reviews. The remaining four reviews satisfied less than half of the AMSTAR 2 criteria, and caution should be applied when interpreting these findings.

Collectively, the included evidence covers pre-operative education, question prompt lists and decision aids. A synthesis of this evidence is presented below.

Pre-operative education aids

Four systematic reviews evaluated interventions using different formats of pre-operative education on informed consent processes.

A review of 22 studies found that providing additional written information improved risk recall and understanding of procedures[30]. Similarly, static visual aids are beneficial and tended to result in larger improvements in risk literacy and decision making among less numerate participants[31]. While static visual aids may be helpful, less numerate people may still have difficulties interpreting and using visually represented numerical concepts such as icon arrays[31]. Interventions to provide written information about risks and benefits of treatment drugs in MS were moderately successful in improving understanding, however there was no effect found on decisions[32]. In addition to improving patient knowledge of the procedure and risks and improving recall over time, procedure-specific written information, with or without pictures and interactive multimedia interventions can reduce variability in the information discussed during routine informed consent consultations[30].

The use of multimedia resources was also consistently effective in improving risk recall [30], immediate recall, especially when resources were adjusted for patient reading age,[33] and understanding of procedures[30]. However, one review found that whilst improving recall, the interventions did not improve satisfaction with informed consent or anxiety levels[33]. While one review concluded that interactive multimedia interventions appear to have the most potential to enhance pre-operative education for patients[30], another review found that there was

Multimedia interventions appear to have the most potential to enhance pre-operative education for patients

no additional benefit to more interactive interventions compared with passive information such as a leaflet[32]. Furthermore, a small number of studies comparing static and dynamic or interactive icon arrays found that interactive and dynamic elements do not necessarily contribute to improvements in risk comprehension and decision making[31]. Audio-visual aids seem to encourage patients to listen to and review information in their own time, reinforcing information provided during informed consent conversations[33].

Collectively, these reviews indicate that pre-operative education delivered using written information or multimedia/audio-visual aids can enhance risk recall and understanding of procedures. However, there doesn't seem to be evidence to suggest which types of interventions within these categories are most effective. Findings were mixed in relation to the additional benefits of interactivity to deliver pre-operative education, however static presentation may be best for the presentation of risk information.

Decision aids

Decision aids are one method clinicians can use to standardise shared decision making during informed consent discussions. They go beyond the provision of information by prompting patients to think about what is important to them, so that they can make choices that reflect their own values and preferences[34,35]. A systematic review of 105 studies found that, compared to usual care across a wide range of decision contexts and delivery modes, patients exposed to decision aids during or prior to a consultation felt more knowledgeable, better informed and established clearer personal values for treatment[36]. They were also more likely to play an active role in decision making and have increased risk perception accuracy. The authors reported that decision aids reduced the proportion of undecided patients and appeared to have a positive impact on patient-clinician communication, despite only adding a median of 2.6 minutes to the length of the consultation.

Computer-based decision aids may have an additional benefit in improving knowledge and reducing decisional conflict

Further investigation of computer-based decision aids found that compared to usual care or alternative decision aids, computer-based decision aids were associated with significant improvements in knowledge and reduced decision conflict. This systematic review and meta-analysis of 26 randomised controlled trials conducted by Syrowatka et al. concluded that integrating media-rich and/or interactive features into computer-based decision aids can improve the quality of decision making when considering a number of clinically appropriate options. Providing clarity around evidence, optional in-depth information and access to external resources improved knowledge and reduced decisional conflict. In contrast, presentation of patient stories, providing feedback and tailoring to patient context negatively affected knowledge and increased decisional conflict[37].

Collectively, these reviews highlight that decision aids can improve knowledge and reduce decisional conflict and computer-based decision aids may have an additional benefit. There is also evidence to suggest that interactive elements may improve the quality of decision making.

Question prompt lists

A rapid review of 50 studies conducted by Sansoni, Grootemaat & Duncan examined the use and effectiveness of question prompt lists as communication aids to increase the number of questions asked by patients, improve information provision and enhance patient participation in medical consultations. The authors concluded that there was some evidence to suggest that an appropriately designed and relevant question prompt list, which is endorsed (i.e. explicit encouragement to ask questions and discussion about question prompt list) by a clinician, may contribute to increased patient question asking during consultations, which may result in increased information provision by the clinician. There were no consistent findings concerning the effects of question prompt lists on patient knowledge, recall, anxiety or satisfaction[38].

Question prompt lists may contribute to increased patient question asking and potentially increased information provision by the clinician

PRIMARY STUDIES

A short synthesis of primary studies of potential interest found in the rapid review is presented below. The studies have not been quality appraised, but may be of interest in developing behaviour change interventions.

Best case/Worst case

Taylor et al. evaluated an intervention to teach surgeons to use a novel decision support tool, Best Case/Worst Case as a way to change communication and promote shared decision making. The tool requires clinicians to draw a diagram (See Figure 2) to present different options and possible outcomes. Prior to training, surgeons described the patient's problem in addition to an operative solution, led deliberation over options and did not incorporate patient preferences into treatment recommendations. Following training, surgeons using the Best Case/Worst Case tool clearly highlighted that patients have a choice between treatments, described a range of postoperative outcomes and involved patients and their families in deliberations[39].

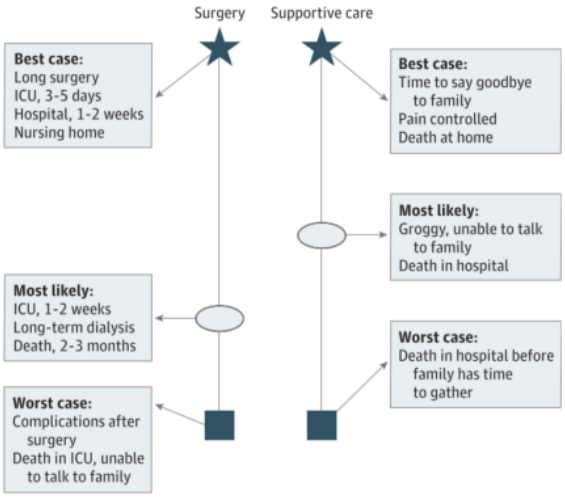

Figure 2. Best Case/Worst Case example

Additional conversations

Junior medical staff represent an additional resource through which informed consent information can be reinforced to patients. A randomised controlled trial conducted by Kam et al. found that patient risk recall was better among patients who received an additional phone call (covering upcoming operation, risks, planned outcomes and postoperative care) from junior medical staff after undergoing the initial informed consent process, compared to those who underwent standard consent processes. Furthermore, 35% more patients in the intervention group rated their understanding of the procedure as good or very good.

Framing and personalising

Heisig et al. investigated the effect of different informed consent procedures on expectations about breast cancer treatments. The authors reported that positively framing (i.e. providing treatment benefit information) and personalising informed consent (i.e. providing individual explanations and encouraging questions and discussion) can positively influence treatment expectations and reduce decisional conflicts, compared to standardised interactions (i.e. short, businesslike) [40].

Repeat back

In a secondary analysis of a randomised trial, Prochazka et al. found that patients who repeated back key elements of informed consent (i.e. diagnosis, nature of surgery, anatomical location, risks, benefits and alternatives) felt more likely to have received the right information about alternative options than those who underwent standard consent processes[41].

Testing with feedback

Given the positive impacts that multimedia educational resources have on patient recall, Roberts et al. investigated whether applying an educational testing approach can further enhance the effect. Participants who were tested on their knowledge of the material provided in an informed consent video for a medical procedure and provided with feedback on the correct answer during the video had significantly greater recall than those were tested but not provided with feedback and those who were not tested at all[42].

Simplified information

Five studies evaluated the impact of simplifying various elements of consent forms. Providing simplified, personalised letters[43] or structured materials[44] increased recall of information. Structuring information also helped participants to concentrate and they rated the information as easier to understand[44]. While simplified consent forms (accompanied by verbal explanations) did not increase understanding or satisfaction[45], simplifying complex sentences and providing explanations of medico-legal language resulted in higher comprehension and less uncertainty, especially among those with low health literacy[46]. To further support this, another study found that simplifying language with accompanying educational diagrams increased understanding compared with traditional consent forms[47].

Standardised consent forms

One way to improve the documentation of informed consent discussions is to use technology to produce standardised templates. Khan et al. found that the use of pre-printed template stickers ensured 100% documentation of risks, benefits and post-operative recovery details compared to handwritten consent forms[48]. Similarly, St John et al. found that procedure-specific forms generated using a web-based system have no variation in the documentation of potential complications[49].

Training

Three primary studies evaluated informed consent training programs for doctors. Training programs increased collaborative communication[50], confidence in ability to describe and complete consent processes[51], and skills in discussing and documenting consent[52]. However, in one study, participants still documented significantly fewer items than they discussed with patients[52]. Training programs included written and oral materials, video modelling, role-play, individualised feedback, lectures and targeted discussions.

Access to interpreters

Language barriers can impede informed consent processes. A pre-post intervention conducted by Lee et al. found that, for patients with limited English proficiency, installation of dual-handset interpreter phones at every bedside resulted in a higher likelihood of meeting criteria for adequately informed consent. However, compared to English-speakers, patients with limited English proficiency still had lower adjusted odds of adequately informed consent[19].

WHAT CAN WE LEARN FROM THE EXPERIENCES OF EXPERTS?

Interviews were conducted with a Patient Advocate, a Director of Surgery, a Health Lawyer, a Risk and Evidence Communication Researcher and a Health Systems and Safety Researcher. The key themes of these interviews are outlined below:

PATIENT RIGHTS DURING INFORMED CONSENT PROCESSES

Interview participants emphasised the importance of patients understanding the purpose of informed consent discussions and their rights throughout the process. It was suggested that patients may not be aware that they have a choice when it comes to undergoing medical treatment and that they can refuse treatment and/or change their mind. They highlighted that obtaining informed consent should be viewed as a series of two-way conversations of increasing depth and detail, rather than as a legal obligation. More value should be placed on patients' understanding of the information discussed during these conversations than on the information documented on a consent form. They should be provided with relevant information and then exercise their right to consider this information in order to make their decision, free from coercion.

> *"It has to really be made clear that the patient has a choice".*

AMOUNT AND TYPE OF INFORMATION PROVIDED TO PATIENTS

All participants reported that informed consent discussions should include information about diagnosis, what the relevant treatments/procedures involve, the associated risks and benefits, potential outcomes and what to expect after the procedure. Patients should be made aware of the potential consequences of treatment refusal and should be informed about all alternatives, including non-surgical alternatives. This was seen as particularly important given that there is a financial incentive associated with performing surgery.

> *"We will very commonly see patients who've had a recommendation that they have a knee joint replacement and yet if they seek a second opinion from a non-surgical provider, it turns out that losing weight and engaging in physiotherapy can actually be a more effective treatment for their knee pain… yet the orthopaedic surgeon has recommended the surgical approach without really talking to them about non-surgical options that are less costly and often have better outcomes for patients".*

To avoid overwhelming patients, it was suggested that, while options should be presented, patients should only be provided with information about treatments or procedures that they are currently considering. It was also highlighted that patients who desire further information can find it online.

> *"We do have a tendency to want to give people all the information at once. And they might not be considering all three of these therapies at this precise moment in time. So we need to be able to give them just the information they need for that decision at that moment. And they do need the risks and benefits".*

The amount and type of information presented to patients can also be altered based on patients' current knowledge about a particular procedure.

> *"It's always obvious as to who's done some background research or not… you can curtail the explanation or expand it depending on where the gaps are in the person's knowledge".*

PRESENTATION OF INFORMATION

There are a number of ways in which clinicians can present information about risks and benefits. These include graphics, icon arrays, decision aids, framing in the positive and negative, bar charts, risk ladders, percentages, natural frequencies, diagrams and audiovisual presentations. It was suggested that clinicians should have the ability to be flexible and present information in a variety of different ways to aid patient understanding, as different formats resonate with different people.

> *"Knowing some key skills that you can employ at any time. Knowing how to make a quick graphic and having a few examples of how to describe something so that if someone is not understanding one way you can try another".*

While participants mentioned using case studies in which previous patients describe what a procedure was like, they highlighted that this method can be extremely persuasive and needs to be carefully balanced with facts.

> *"Using things like narrative and storytelling can completely persuade people in one direction or another because as soon as you engage the emotions, it is very difficult to help… essentially you're being very persuasive by whatever you show".*

There were also varying views when it came to discussing risks and benefits in terms of percentages and frequencies.

> *"A lot of the research has shown that patients understand percentages better than frequencies".*

> *"I try not to give a lot of percentages because people often get stuck on percentages".*

One participant recommended discussing what would happen if a particular risk eventuated, as a way of assisting patients to contextualise risks.

> *"I think you can kind of rattle through those risks of bleeding and infection and nerve damage and so on and when you hear them it's kind of terrifying but then to actually hear that for each of those risks there is a clear plan about how you would be cared for".*

TIMING OF INFORMED CONSENT

Participants acknowledged that there is often not enough time to have in-depth conversations with patients. They suggested that informed consent discussions should begin as soon as patients start speaking to their GP about potential treatments/procedures and are referred to see a surgeon. It was suggested that for different specialties, there could be a standardised timeline around when patients would be informed. This timeline could build in time for multiple detailed conversations between the patient and clinician, as well as time for patients to consider the information on their own.

> *"Along that journey, you will have talked about different aspects to different depths and you would have a chance to go away in between and come back with different questions and hopefully explore some material outside of the consultations as well".*

TAILORING INFORMED CONSENT

Taking into account what matters to patients and tailoring information provision accordingly was highlighted as an important component of informed consent discussions. It was suggested that

patients should be provided with personalised information about risks and benefits so that they can make choices that align with their values and goals.

> *"I think probably the primary thing is whether or not a treatment option is going to help them achieve their goals. And I think we end up having so much focus on some of these incredibly rare side effects and sometimes don't spend enough time talking about the more common things. I think to give people a realistic sense of what to expect in terms of the common side effects and then really just following their lead if there are additional things that they're particularly worried about or curious about".*

MEASURING INFORMED CONSENT

Participants acknowledged that it can be difficult to measure whether a patient has understood the information provided and given true informed consent. One participant mentioned that many evaluations of informed consent are retrospective, i.e. asking patients about their satisfaction/regret post-operatively. Other retrospective measures include asking patients whether they felt that they had all of the information required to make their decision, or whether they would make the same decision again (i.e. decision consistency). Pre-operatively, patients may be asked to repeat back the information, which can test knowledge, but doesn't necessarily test understanding.

> *"There's more to it even than just knowing the facts. It's about having a representation of that. And having imagined the consequences of that in your mind. And that requires opening people's imagination in a way that numbers on a page don't".*

One participant suggested that asking patients to talk through and provide a rationale for their decision may be the best way to measure pre-operative informed consent.

> *"Asking patients to talk through their decision and what they considered is one of the few things that does seem to help patients think through things and rationalise them".*

Clinicians should also ensure that they are looking for non-verbal cues suggestive of poor patient understanding and allow questions so that patients can clarify information.

> *"You open up for questions and that's when you gauge how well the process has gone".*

One participant also reported using nurses to confirm patient understanding about a procedure prior to commencing any surgery.

> *"I think the best part is when someone comes to the operating theatre and says to the nurses 'I'm having this done and that's what basically happens and this is my understanding of it' and that's often a confirmation that the explanation was reasonable".*

EDUCATION AND TRAINING

Participants suggested that education surrounding informed consent processes is currently lacking. Further education could be built into medical training about the importance of using a patient centred approach, welcoming questions and using plain English when providing information. Clinicians may also require further opportunities to practice non-verbal communication skills in order to identify the level of patient understanding.

> *"It's all practice and it's having those real communication skills so that you know when somebody, you're actually engaging with them, you're seeing from their face, whether they're looking a bit blank now".*

Communication of risk information was also identified as an area which requires more emphasis during training. The 'Helping Patients Make Informed Decisions: Communicating benefits and risks' e-learning module developed by the Australian Commission on Safety and Quality in Health Care was identified as a good resource which could be promoted to upskill clinicians.

> *"There is the knowledge of how to communicate risk information and the importance of it. A lot of the time that isn't part of the medical training… I think it needs to be emphasised in the clinician training and then I think it needs to be in professional practice"*

Participants acknowledged that junior staff often learn how to obtain informed consent through watching senior doctors, therefore it is important that they model appropriate behaviours.

> *"So much of it is being role modelled so trainees are learning from their senior consultants all the time. So I think trying to influence the behaviour of consultants who are very involved in training junior doctors can be really helpful so they get good role modelling".*

IMPORTANCE OF SUPPORT PEOPLE DURING INFORMED CONSENT PROCESSES

Participants suggested that, where possible, patients should bring a support person to appointments where treatment options are being discussed, particularly if they are older, don't speak English or have low levels of health literacy. Having an additional person in the room could help patients to remember more information about a procedure and the associated risks, as well as think of additional questions.

> *"When you go back and ask people three days later or a week later that they haven't remembered a lot of that content and that's where I think having a support person who is present so that the patient can go back and talk through what was discussed with somebody else who was there and remembered it".*

WHAT DO CITIZENS THINK?

During a citizen panel convened on the 26th of March 2019, 13 socio-demographically diverse Victorian community members were provided with a plain language version of this briefing document. One-third of the participants represented the general population, one-third had recently undergone elective surgery and one-third had a family member who had recently undergone elective surgery. During the deliberation about the problem, citizens were asked to share what they view as the key challenges when providing informed consent. Citizens were asked to reflect on their own experiences and those of family and friends to consider the underlying challenges and inform the types of interventions which may be appropriate. The key themes of the discussion from the perspective of participants are summarised below.

Theme	Details
What is informed consent?	• Duty of full disclosure about any medical treatments or tests that you are undertaking • The doctor should provide you with all of the information so that you understand what will happen when you undergo a procedure • Patients should also be provided with information about risks and complications, particularly potential severe, long-lasting side effects
Timing of informed consent conversations	• Informed consent processes should start as early as possible • It could start immediately post-diagnosis, when patients are first starting to consider necessary procedures i.e. the first or second time patients meet with the doctor or the consultation prior to the procedure • Doctors could stagger information provision to avoid overwhelm
What factors influence informed consent processes?	• Poor interpersonal skills of doctors • Poor understanding of the patient context and what matters to them • Cultural and religious differences of patients • Varied patient preferences for information amount, content, presentation, and explanation

How can we improve informed consent?	<u>Patients</u>
	
	• Patients should be educated on their informed consent rights
	  ○ They need to be aware that it is their right to know certain things about a procedure and if they are not explained, patients have a right to ask about them
	• Patients could be given a summary of what they will be asked to provide consent for before attending a consultation
	  ○ This could include the main items for discussion during the informed consent conversation
	  ○ It would give patients a chance to consider the information before the conversation and raise any questions before going through all of the information
	• Patients should be able to take information and consent forms home to read and think about any questions that they might like to raise
	• Question prompt lists may be useful
	
	<u>Doctors</u>

	• Doctors need to make a judgement about how much information a particular person might want
	• Doctors could provide basic information and advise patients on where they can find additional information
	• They should list all of the risks and provide statistics about the likelihood of these risks occurring, no matter how likely they are
	• Doctors should ask patients what their post-surgery expectations are so that they can bring these in line with what is likely to occur
	  ○ Discovery questions could be used to guide this process
	• Doctors should provide visual presentations of procedures, however this should complement a conversation
	• Doctors could consider using alternative mediums to present information to patients, including videos, DVDs, YouTube, websites, FAQ sheets and podcasts
	• Videos could be shown at the hospital, with staff on hand to answer any questions that arise
	• Doctors should receive interpersonal relations/compassion training to improve how they relate to patients and convey information
	• Doctors could ask patients to repeat back what they understand to measure informed consent
	
	<u>Nurses</u>
	
	• Nurses could discuss information with patients, as they may have more time and discussions with the doctor can be overwhelming
	• Specially-trained nurses could also have a post-consultation conversation with patients to answer any additional questions
	
	<u>Processes</u>
	
	• The informed consent process should be standardised so that every patient goes through the same steps before a procedure
	  ○ This would allow patients to have expectations about what should happen and when
	  ○ Nurses could ensure that this procedure is followed
	• More time should be provided for the informed consent process so that patients can digest the information and make a decision
	• There should always be a follow-up consultation, as patients may have additional questions
	• The informed consent process should be documented
	  ○ Initialing each page of information could improve this process
	• The consent form could be first signed in the doctor's rooms, and then again at hospital admission, thus requiring duplicate signatures
	
	<u>Information provision</u>
	
	• Information should be simplified and specific to the procedure
	  ○ Jargon should be broken down into layperson's terms
	  ○ Doctors should not just read directly from a document
	• Standardised information about a procedure could be provided, but there could also be a section where individually-tailored information could be provided

QUESTIONS FOR DELIBERATION

1. What are the biggest challenges in the informed consent process including communication between clinicians and patients, clinician skills and patient skills?

2. Is there a specific target population, process, environment, or other potential focus for behaviour change?

3. What identified behaviour change interventions are:
    a. Feasible
    b. Testable in the short term i.e. 6 months
    c. Scalable across Victoria
    d. Measureable (i.e. sufficient volume in timeframe for key outcomes)
    e. Sustainable?

4. Which is the highest priority for a pilot study and why?

5. What are appropriate success measures for a pilot study?

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APPENDIX 1: PROJECT METHODS

THE FORUM APPROACH

This project is based on the Forum approach, an established method of promoting evidence-informed practice change, which involves four key activities:

1. Defining a major challenge through consultation with key stakeholders to understand the issues and complexities;
2. Gathering from published literature and further consultation the information necessary to properly consider the challenge, and presenting this in a briefing document (i.e. this document);
3. Convening a structured stakeholder dialogue to connect the information from the briefing document with the people representing key stakeholder groups who can make change happen; and
4. Reporting outcomes through a dialogue summary and related academic publications and briefing the organisations and individuals who can affect change about their role in developed strategies.

The Forum approach of evidence review and structured stakeholder dialogue was established by John Lavis in Canada in 2009. Subsequently Dr Peter Bragge and Professor Russell Gruen were funded by the Victoria Transport Accident Commission from 2012 - 2015 to lead the first Australian-based Forum program, which focused on addressing high-priority challenges in brain and spinal cord injury care, research and policy. Outputs of the NTRI Forum program have been published online and in peer-reviewed literature. Satisfaction in the NTRI Forum process was high based up on participant surveys, with a mean score of 6.4 / 7 (where 1 is 'Failed' and 7 is 'Achieved') for ranking of how well the briefing document achieved its purpose (N =114, response rate 45%) and 6.0 / 7 for the stakeholder dialogue (N=192, RR 76%).

RAPID REVIEW METHODS

Search strategy

A comprehensive search of the following databases was undertaken: PsycINFO via Ovid, Medline via Ovid, Web of Science, Cochrane Library via Wiley and Health Systems Evidence. The search strategy is reproduced below:

Table 3. Search strategy

	Search string
1	patient* OR client* OR doctor* OR clinic* OR intern* OR registrar* OR consultant* OR specialist* OR surgeon* OR "general practitioner" OR "medical practitioner" OR physician*
2	communicat* OR educat* OR teach* OR learn* OR train* OR skill* OR "online educat*" OR medical informat* OR informatics* OR staff develop* OR "decision support technique*" OR counsel* OR cultural* competen* OR "hospital patient relation" OR information service* OR information disseminat* OR "access to information" OR (information adj (service OR system OR disseminat* OR seek* OR provis* OR aid OR material OR sheet OR package)) OR ((patient OR client OR written OR print OR visual OR provid*) adj information)
3	consent OR e-consent OR (informed adj2 (consent OR decision OR choice)) OR informed decision making OR consent comprehension OR "informed choice" OR informed consent recall OR (consent adj (process OR form OR document)) OR improving informed consent OR (improve* adj2 consent) OR (understanding adj2 consent) OR consent process

4	"medical treatment" OR surgery

Screening and selection

Two reviewers screened the citations against the inclusion and exclusion criteria listed in Table 4. Data extracted from the included articles was used to inform a commentary on strategies to improve informed consent processes. Data extraction tables are available on request.

Table 4. Inclusion and exclusion criteria

	Include	Exclude
Study Type	• Systematic or narrative reviews (of quantitative or qualitative studies) and primary studies	
Population	• Health professionals, patients and families	
Study Design	• Qualitative, observational or interventional	
Study Setting	• Hospital settings or pre-hospital settings or community healthcare	
Intervention	• Factors influencing consent procedures or documentation of consent	
Outcome	• Patient informed consent	
Publication Status	• English language • Peer-reviewed journal publications or reports • Published from 2014-2019	

CITIZEN PANEL METHODS

Facilitation framework

Understanding informed consent

- What perspective do you bring to today? What experiences or challenges have you encountered with informed consent?
- What does informed consent mean to you?

How could we improve the communication of informed consent between doctors and patients?

- At what point should patients be having conversations about informed consent with their doctor?
- Are patients currently being provided with all of the information that they required to provide informed consent for medical treatments?
- Based on your experience, what do you think could be done to improve how doctors discuss informed consent with patients?
- What role should patients and families play in the informed consent process?

What factors make it hard to solve issues with informed consent?

- What are the main challenges to obtaining informed consent?

How could we improve patient understanding of risks, benefits and alternative options?

- Do you understand the information provided by doctors about risks, benefits and alternative options?

- How should information about risks, benefits and alternative options be presented?

Participants

Socio-demographically diverse Victorian community members were recruited through ACI research services.

Procedure

The citizen panel was convened on the 26th of March 2019 and participants gave informed consent. Citizens were provided with a plain language version of this briefing document. During the deliberation of the problem, citizens were asked to share their perceptions about informed consent processes. Citizens were asked to reflect on their own experiences and those of family and friends to consider the underlying challenges and inform the types of interventions which may be appropriate.

CONSULTATION INTERVIEW METHODS

Interview framework

The interviews were semi-structured, allowing the interviewer to explore emerging themes as well as salient issues[53]. The interview framework was as follows:

1. Can you provide a brief introduction and outline your role, including how long you have been in this role? In what capacity/context do you engage with informed consent?

2. From your perspective and experience, what are the key issues that need to be addressed in order to improve the informed consent process?

3. What are the barriers to informed consent in the hospital, pre-hospital or community healthcare contexts?
    a. What are the key issues with communication between patients and clinicians about treatment options, risks and benefits and consent?
    b. How could clinicians/hospitals improve how they communicate the consent procedure/risks and benefits/shared decision making?
    c. What are the key issues with patient understanding of treatment options, risks and benefits? *What information do patients require to make an informed decision about their care? Do patients understand the information that is currently presented to them during the informed consent procedure?*
    d. Are patients currently presented with all their alternative options?
    e. What are the key issues with the documentation of the consent process?

4. What strategies are you aware of that have been employed in the past to improve the communication of consent between clinicians?

5. What strategies are you aware of that have been employed in the past to increase patient understanding of treatment options, risks and benefits?
    a. (if answered 5) How successful have these strategies been?
    b. (if answered 5a) What factors do you think have contributed to the success or failure of previous strategies?

6. Do you have any other comments about informed consent processes?

Participants

Participants were purposively selected based upon their experience and/or expertise in the area of informed consent[54].

Procedure

Participants were contacted by BehaviourWorks Australia and invited to take part. Research aims and procedures were outlined in an Explanatory Statement given to all participants prior to the interview. All interviews were conducted via telephone. Interviews lasted between 29 and 45 minutes. Interviews were conducted by AL in February 2019. Interviews were digitally audio-recorded, transcribed verbatim, anonymised and stored securely.

Analysis

Interview transcripts were coded and analysed thematically[55] using a computer-assisted qualitative data analysis software program (NVivo 11, QSR International Pty Ltd 2014, Doncaster). Interview transcripts were coded according to emergent themes relevant to the topic. Direct quotations from interview transcripts were used to illustrate key themes. The participant categories (i.e. role and responsibilities) have been de-identified.

APPENDIX 2: RAPID REVIEW QUALITY APPRAISAL

Criterion (AMSTAR 2)	Farrell et al. (2014)	Garcia-Retamero et al. (2017)	Reen et al. (2017)	Sansoni et al. (2015)	Stacey et al. (2017)	Syrowatka et al. (2016)	Villanueva et al. (2018)
1. Did the research questions and inclusion criteria for the review include the components of PICO?	Yes	Yes	Yes	No	Yes	Yes	Yes
2. Did the report of the review contain an explicit statement that the review methods were established prior to the conduct of the review and did the report justify any significant deviations from the protocol?	No	No	No	No	Yes	No	No
3. Did the review authors explain their selection of study designs for inclusion in the review?	No	No	No	No	No	No	No
4. Did the review authors use a comprehensive literature search strategy?	Partial yes	Partial yes	Partial yes	Partial yes	Partial yes	Partial yes	Partial yes
5. Did the review authors perform the study selection in duplicate?	Yes	No	No	Yes	Yes	Yes	Yes
6. Did the review authors perform data extraction in duplicate?	Yes	No	Yes	Yes	Yes	No	No
7. Did the review authors provide a list of excluded studies and justify the exclusion?	No	No	No	No	Yes	No	No
8. Did the review authors describe the included studies in adequate detail?	Partial yes	Partial yes	Partial yes	No	Partial yes	Partial yes	Partial yes
9. Did the review authors use a satisfactory technique for assessing the risk of bias in individual studies that were included in the review?	Yes	No	No	No	Yes	No	No
10. Did the review authors report on the sources of funding for the studies included in the review?	No	No	No	No	No	No	No

11. If meta-analysis was performed, did the review authors use appropriate methods for statistical combination of results?	Yes	N/A	N/A	N/A	Yes	Yes	N/A
12. If meta-analysis was performed, did the review authors assess the potential impact of risk of bias in individual studies on the results of the meta-analyses or other evidence synthesis?	Yes	N/A	N/A	N/A	Yes	No	N/A
13. Did the authors account for risk of bias in individual studies when interpreting/discussing the results of the review?	Yes	No	Yes	No	Yes	No	No
14. Did the review authors provide a satisfactory explanation for and discussion of heterogeneity observed in the results of the review?	Yes	No	Yes	No	Yes	Yes	No
15. If they performed quantitative synthesis, did the review authors carry out an adequate investigation of publication bias (small study bias and discuss its likely impact on the results of the review)?	No	N/A	N/A	N/A	Yes	No	N/A
16. Did the review authors report any potential sources of conflict of interest, including any funding they received for conducting the review?	Yes	Yes	Yes	Yes	Yes	Yes	Yes
TOTAL yes / applicable items	11/16	4/13	7/13	4/13	14/16	7/16	5/13