



**Informed Consent in Healthcare:
An Issues Paper**

March 2013

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Introduction

The Consumers Health Forum of Australia (CHF) is the national peak body representing the interests of Australian healthcare consumers. CHF works to achieve safe, quality, timely healthcare for all Australians, supported by accessible health information and systems.

CHF has been funded by the Bupa Health Foundation to identify gaps in the information currently available to consumers about informed consent, and to develop resources to empower them to make informed choices about their healthcare.

In consultations conducted by the CHF over many years, consumers have raised concerns over the lack of informed consent and informed financial consent processes when making decisions about their healthcare. This is of particular concern in the context of rising out-of-pocket healthcare costs and increasing rates of chronic illness in the community.

The purpose of this paper is to explore issues relating to consumers and informed consent in healthcare. The paper also provides a snapshot of the current literature, research and policy debate surrounding informed consent.

What is Informed Consent?

Informed consent is a key concept in the provision of health care which has ethical, legal and practical dimensions. From an ethical perspective, informed consent forms an essential component of the moral right of individuals to autonomy over their own bodies and is based on the principle of free agency.

From a legal perspective, informed consent is defined in terms of an agreement or process by which the rights of individuals to agree or to refuse treatment are upheld. In practical terms, informed consent refers to the process by which a health care provider informs a consumer of their treatment options, and associated risks and benefits, and supports them to make a decision about their care.

Definitions of Informed Consent

There are a broad range of definitions of informed consent, which reflect the ethical, legal and practical conceptions of this term. Many of the definitions focus on the provision of information on treatment options, including the possible side effects, risks and benefits. For example, the Victorian Charter of Human Rights states that informed consent:

must be voluntary and the person concerned must have been given sufficient information for an informed decision to be made. This would include information such as the nature of the person's condition and the treatment options available, including explanations of possible risks, side effects and benefits of the treatment.¹

In its *Consent to Treatment: Procedures* document, the ACT Government identifies four criteria that must be satisfied if informed consent is to be achieved:

¹ Victorian Charter of Human Rights and Responsibilities Act 2006 (Vic)

*the patient is competent to give consent; full information of risks, benefits, alternatives and costs has been provided; consent is freely given; and consent is specific to the procedure.*²

The Queensland Government, in its *Health Informed Decision-making in Healthcare Policy*, moves away from the use of the term ‘consent’, as this term itself implies a more passive role for consumers than for providers. Instead, this policy focuses on ‘informed decision-making’ which it describes as reflecting:

*that the aim is for the patient to make the right decision about healthcare (or for the decision-maker acting on their behalf to do so), considering all circumstances of their life. It is still a successful outcome if a patient receives and understands all information appropriate for them to make a decision, and then decides to decline consent to the healthcare, even if it is considered by the health practitioner to offer the best clinical outcome.*³

Discussion Questions

1. Are you aware of any definitions of informed consent that are missing from this paper?

2. Do you have a preferred definition of informed consent?

CHF notes that there are circumstances in which consumers are unable to provide informed consent, such as emergency treatment situations, or in the case of consumers with cognitive illnesses, such as dementia. These issues are explored in greater detail in subsequent sections.

The Importance of Informed Consent

Almost all individuals will, at some point in their lives, require some medical or healthcare treatment. Medical treatment typically involves some risk or possible harm, which may include physical pain and suffering or other costs, such as time away from work. The need to balance the risks and the benefits of treatment options makes the decision-making process complex and very individual. Even with the same information, two individuals could make a different treatment decision based on their unique perspective on the situation.

In practical terms, informed consent processes should support the role of consumers as genuine partners in healthcare and promote consumer involvement in decision making. This is a more consumer-centred definition of health care than the traditional doctor-led model.

To the general community, informed consent is an important issue which in many ways defines the commitment of the health system to genuine consumer engagement beyond diagnostic services. At a broader level, consent processes help deliver services that are more closely aligned with the priorities and concerns of the community. This has a range of benefits, including improved health outcomes and a more efficient allocation of resources. In this way, informed consent processes are important in developing a genuinely consumer-focussed health system.

2 ACT Health (2011) *Consent to Treatment: Procedures*. ACT Health: Canberra.

3 Queensland Health (2012) *Health Informed Decision-making in Healthcare Policy*. Queensland Health: Brisbane.

There is little research on the link, if any, between informed consent processes and clinical outcomes. However, the findings of the small number of available studies indicate that there is a positive association. Some studies support the position that improved communication between clinicians and consumers overall contributes to both increased adherence to treatment regimes,⁴ improved long-term health outcomes,⁵ increased patient satisfaction, faster recovery, reduced emotional distress, a lower level of pain relief used and in some cases a reduced length of stay in hospital.⁶ There is also some evidence that when fully informed, consumers make better use of services, which may result in lower overall health costs.⁷ A number of studies also demonstrate that improving communication can reduce the level of medical errors,⁸ and reduce complaints against providers and services.⁹

However, there is no conclusive evidence supporting a consistent link between improved informed consent processes and better health outcomes. The research on the impact of informed consent resources and processes generally focusses on one aspect of the informed consent process, such as consumer recall of the material, perception of its quality and the relationship with the clinician. A hypothesis of improved clinical outcomes is made on the basis of an improvement in any of these areas.¹⁰

Discussion Questions

3. Are there any other reasons why informed consent is important?

4. In your view, are there any areas that warrant additional research?

The Consequences of Poor Informed Consent

A range of problems may stem from poor informed consent processes. At an individual level, poor informed consent processes can result in consumers undergoing unnecessary treatment and incurring a preventable harm. Even in the absence of physical harm, decisions occurring in the absence of informed consent can undermine the autonomy of the patient.

Poor informed consent processes can also impact on the health system as a whole. The potential for medical errors and malpractice claims, for example, has significant cost implications. The literature also suggests that problems with informed consent are a significant component of medical litigation. One study found that:

4 Bull, S.A., Hu, X.H. and Hunkeler, E.M. (2002) 'Discontinuation of Use and Switching of Antidepressants: Influence of Patient-Physician Communication.' *Journal of the American Medical Association*. 288: 1403-1409.

5 Stewart, M.A. (1995) 'Effective Physician-Patient Communication and Health Outcomes: A Review.' *Canadian Medical Association Journal*. 15: 1423-1433.

6 Egbert, L.D., Battit, G.E., Welch, C.E. and Bartlett, M.K. (1964) 'Reduction of Postoperative Pain by Encouragement and Instruction of Patients: A Study of Doctor-Patient Rapport.' *New England Journal of Medicine*. 270: 825-827; Hall, J.A. and Dornan, M.C. (1988) 'What Patients Like About Their Medical Care and How Often They Are Asked: A Meta-Analysis of the Satisfaction Literature.' *Social Science in Medicine*. 27(9): 935-939; Roter, D.L. and Hall, J.A. (2006) *Doctors Talking to Patients/Patients Talking to Doctors: Improving Communication in Medical Visits*. 2nd Edition. Westport: Praeger Publishing.

7 Kennedy, A.D., Sculpher, M.J., Coulter, A., Dwyer, N., Rees, M. and Abrams, K.R. (2002) 'Effects of Decision Aids for Menorrhagia on Treatment Choices, Health Outcomes, and Costs: A Randomized Controlled Trial.' *Journal of the American Medical Association*. 288(21): 2701-2908.

8 Sutcliffe, K.M., Lewton, E. and Rosenthal, M.M. (2004) 'Communication Failures: An Insidious Contributor to Medical Mishaps.' *Academic Medicine*. 79: 186-194.

9 Levinson, W., Roter, D.L., Mullooly, J.P., Dull, V.T. and Frankel, R.M. (1997) 'Physician-Patient Communication. The Relationship with Malpractice Claims Among Primary Care Physicians and Surgeons.' *Journal of the American Medical Association*. 277: 553-559.

10 Pizzi, L.T., Goldfarb, N.I. and Nash, D.B. (2001) 'Procedures For Obtaining Informed Consent,' in Shojania, K., Duncan, B., McDonald, K. and Wachter, R.M., eds. *Making Health Care Safer: A Critical Analysis of Patient Safety Practices*. Agency for Healthcare Research and Quality: Rockville. 546-554.

Of nearly 10 000 Australian medicolegal cases resolved in the 7 years 2002–2008, around one in 30 medical negligence claims and one in nine conciliated complaints included allegations of problems with informed consent.”

Given that the costs, in both monetary and non-monetary terms, associated with making a medical negligence claim can be high, it can be assumed that these figures do not represent all consumers who are unhappy with their informed consent processes.

Informed Consent and Consumer Information Needs

As noted above, the majority of definitions of informed consent focus on the content of the information provided to consumers by health care practitioners. Some commentators¹¹ describe three standards by which the information provided to consumers can be assessed. These are:

- The ‘health professionals standard’ – information provided should be that which would be supported by the majority of professional peers of good standing
- The ‘reasonable person standard’ – information provided should be that which would be considered relevant by a reasonable person
- The ‘subjective person standard’ – information provided should be that which is considered relevant by the individual involved in the treatment decision.

Most definitions of informed consent either implicitly or explicitly rely on one of these standards.

There are also a number of guidelines published which define more specifically the content of information that should be provided to consumers. For example, the *National Health and Medical Research Council (NHMRC) Guidelines: Communicating with Patients* states that:

The patient needs to be advised of the possible or likely nature of the procedure or treatment [and] the proposed approach, including:

- *what the proposed approach entails;*
- *the expected benefits;*
- *common side effects and material risks;*
- *whether the procedure is conventional or experimental;*
- *who will perform the procedure or treatment;*
- *other options for management of the complaint;*
- *the realistic expectations for the outcome of the procedure or treatment; and*
- *the time and cost involved including any out of pocket expenses and any potential costs should further surgery be required.*¹²

Another approach to information provision in health care consultations is based on a decision-making model, used in a number of non-health industries.¹³ This model reflects the fact that when making decisions that involve a degree of uncertainty, consumers require not only information about their range of choices, but also about the likely outcomes of each one.

¹¹ Mazur, D.J. (2009) ‘Medical-Legal Aspects of Evidence-Based Choice and Shared Decision-Making.’ In: Edwards, A. and Elwyn, G., eds. *Shared Decision-Making in Healthcare: Achieving Evidence-Based Patient Choice*. 2nd Edition. Oxford University Press: Oxford. 165-70.

¹² National Health and Medical Research Council (2011) *NHMRC Guidelines: Communicating with Patients: Advice for Medical Practitioners*. National Health and Medical Research Council: Canberra.

¹³ Carey, K. (2006) ‘Improving Patient Information and Decision-Making.’ *The Australian Health Consumer*. 1: 21-22.

Applying this to a health consumer informed consent model, informed consent would require that consumers are given information about:

- *Options* – available options, including the option to defer treatment on a ‘wait and watch’ basis.
- *Outcomes* – expected outcomes associated with each option including the known complications or side-effects.
- *Incidence* – statistical rates at which the treatment is successful and known complications occur.

The differing needs of individual consumers in relation to information are not discussed extensively in the literature. This is a key issue, as both providing too much and too little information to a consumer can compromise their comprehension.

Discussion Questions

5. What information would you require in order to provide informed consent?

6. In your view, would informed consent processes be improved by a minimum standard of information requirements?

Other Mechanisms to Support Informed Consent

There is an emerging body of research on how consumers process health and medical data. This research has found that communicating medical information effectively is difficult as many people, from all educational backgrounds, find it difficult to understand explanations and remember medical information. One study concluded that “being exposed to facts is not the same thing as being informed.”¹⁴ This raises issues around the presentation of information, the conditions under which the information is provided and how health care providers, and others, can assess consumers’ understanding of information.

A Cochrane Review into individual decision making in relation to health care found that there are different ways of supporting decision-making in health, and often, these do not rely on facts and figures. On this basis, the authors argue that:

*there is a vast disconnect, in other words, between the way health information is commonly presented and the way real people make decisions based on that information. The answer, however, is not to change the way people make judgments by getting them to pay more attention to the precise facts. It won’t work—and it won’t lead to better choices.*¹⁵

The literature highlights a number of other factors that are required in order for consumers to provide informed consent. These include:

- Consumers must understand the information provided.
- Consumers must not feel under pressure or coerced into making a decision.
- Consumers must have time to consider their options.

14 Renya, V.E. and Hamilton, F. (2006) ‘Physician Decision Making and Cardiac Risk: Effects of Knowledge, Risk Perception, Risk Tolerance and Fuzzy Processing.’ *Journal of Experimental Psychology: Applied*. 12: 179-195.

15 Kinnarsley, P., Edwards, A.G.K., Hood, K., Cadbury, N., Ryan, R. and Prout, H (2007) ‘Interventions Before Consultations for Helping Patients Address Their Information Needs.’ *Cochrane Database of Systematic Reviews*. Issue 3.

- Consumers must be empowered to ask for any additional information they feel is relevant.
- Consumers must understand that they have the right to make a decision, including refusing treatment.

In the literature, these issues are discussed in the context of the power imbalance that often characterises health care consultations, and how this can affect informed consent. For example, Walker et al describe how easy it is for consumers to feel disempowered in health care settings and that health care providers can assist by outlining treatment options as an invitation to involve consumers in the decision-making process.¹⁶

There is also some literature on consumers' differing perceptions of risk and how health care providers can effectively communicate information about probabilities associated with health care treatment.¹⁷

Discussion Questions

7. Are there any additional factors which are required for informed consent?

Barriers to Improving Informed Consent

There are a number of challenges identified relating to the establishment of consistently high quality informed consent processes across the health system. These relate to consumers, providers and the health system more broadly.

Consumer Issues

There are specific groups of consumers for whom standard informed consent processes may not be appropriate. These scenarios may require a more targeted approach, and are discussed in greater detail below.

Other issues identified through consumer consultations and surveys include confusion about the purpose of the consent process, a feeling of intimidation, and stress or time pressure during the consultation. Some research also found that many consumers see informed consent as simply a legal process undertaken by providers to prevent consumers from suing doctors.¹⁸ These consumers may not engage with the process, or see it as useful in providing them with any information in making treatment decisions.

When asked about informed consent processes, consumers often report feeling pressure to make a decision without having had time to reflect or deliberate.¹⁹ The power imbalance that is experienced in many healthcare settings can restrict the capacity of patients to seek further relevant information and ask questions about their treatment options.²⁰

16 Walker, B. (2004) 'Risk Management for Chiropractors and Osteopaths: Informed Consent. A Common Law Requirement.' *Australasian Chiropractic and Osteopathy*. 12(1): 19–23.

17 Edwards, A., Elwyn, G. and Mulley, A. (2002) 'Explaining Risks: Turning Numerical Data into Meaningful Pictures.' *British Medical Journal*. 324(7341): 827-30.

18 Bottrell, M.M., Alpert, H., Fischbach, R.L. and Emanuel, L.L. (2000) 'Hospital Informed Consent for Procedure Forms: Facilitating Quality Patient-Physician Interaction.' *Archives of Surgery*. 135(1): 26-33.

19 Dixon-Woods, M., Williams, S.J., Jackson, C.J., Akkad, A., Kenyon, S. and Habiba, M. (2006) 'Why Women Consent to Surgery, Even When They Don't Want To: A Qualitative Study.' *Clinical Ethics*. 1(3): 153.

20 Akkad, A., Jackson, C., Kenyon, S., Dixon-Woods, M., Taub, N. and Habiba, M. (2004) 'Informed Consent for Elective and Emergency Surgery: Questionnaire Study.' *British Journal of Obstetrics and Gynaecology*. 111(10): 1133-8.

Provider Issues

Challenges identified at the provider level include:

- A lack of clinician time for adequate explanation and discussion
- Confusion about when informed consent is required
- Concerns about providing too much information around minor risks
- Poor understanding of risks, or an inability to communicate these risks effectively
- An inability to assess a patient's level of comprehension, particularly in the case of adult patients with intellectual, cognitive or mental impairment.

Although effective communication between providers and consumers is essential to informed consent, there is a wide body of research highlighting the difficulties experienced by many clinicians in this area. For example, there is evidence that they often overestimate the amount of information they provide,²¹ and many find it difficult to present information without using technical language and medical terminology.²²

Other challenges relate to informing consumers of individual risks based on population-wide estimates. Many clinicians find it difficult to interpret statistics, and may not provide accurate information.²³ Differences in perceptions of risk and differing levels of tolerance for uncertainty also play into this confusion.

In some situations, clinicians may focus on very rare but serious complications, placing less emphasis on more likely but less serious side effects. Important consumer issues may have less clinical relevance, such as anticipated levels of pain and time needed off work, and are often not communicated to consumers.

Broader Health System and Organisational Issues

Underlying many of the challenges surrounding informed consent are systemic issues. These include remuneration systems that provide incentives for shorter consultations, workforce practices that do not support team approaches to providing care, and a culture in which doctors are considered authority figures and consumers are not empowered to raise questions.

In addition to this, there are organisational barriers to improving informed consent processes in some hospitals and health services, such as poor communication systems with patients and a lack of supporting infrastructure.

Discussion Questions

8. Are there any other additional barriers to improving informed consent processes?

Legal Issues in Informed Consent

From a legal perspective in Australia, the treatment of informed consent is based on the legal precedent set by *Rogers V Whitaker* in 1992. This evolved from the Bolam standard in 1957 and the Sidaway standard in 1985, and represents a move away from a clinician-centred approach to defining information requirements to a more consumer-centred one.

21 Makoul, G., Arntson, P. and Schofield, T. (1995) 'Health Promotion in Primary Care: Physician-Patient Communication and Decision Making about Prescription Medications.' *Social Science and Medicine*. 41(9): 1241-54.

22 Jenkins, V.A., Fallowfield, L.J., Souhami, A. and Sawtell, M. (1999) 'How Do Doctors Explain Randomised Clinical Trials to Their Patients?' *European Journal of Cancer*. 35(8): 1187-93.

23 Op cit Edwards et al.

The *Rogers v Whitaker* decision resulted in a penalty against a surgeon who was considered to have provided inadequate information. The court stated that it is part of the doctor's duty to disclose 'material' risks. A risk is held to be material if:

*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.*²⁴

Since 1992, the Courts have focused on defining the minimum amount of information that the patient needs in order to make an informed choice, and have emphasised the need to warn patients of the risks involved in any proposed procedure.

In the view of some commentators, this approach can result in informed consent processes being seen as a set of criteria or series of tasks that the healthcare professional must complete, rather than as an interactive dialogue with a patient.

Other factors influencing informed consent from a legal perspective may include cognitive impairment, issues surrounding end-of-life care and other scenarios in which consumers may not be able to provide consent. In these cases, informed consent may be aided through the appointment of substitute decision-makers, who make decisions on behalf of consumers who have lost capacity to do so for themselves.²⁵ Advance care planning, where consumers can prepare for their future care, can also help ensure that wishes and preferences are known when consumers can no longer make decisions or legally complete documents.²⁶

Discussion Questions

9. Are you aware of any other legal issues affecting informed consent?

Informed Consent in Practice

The evidence suggests that informed consent processes often do not meet the needs of consumers in practice. This is supported by the large number of complaints made against health care providers which involve informed consent issues.

One retrospective review of negligence claims complaints lodged with the Office of the Health Services Commissioner of Victoria between 2002 and 2008 found that a total of 3.4 percent (263 of 7846) of medical negligence claims and 11.5 percent (218 of 1898) of conciliated complaints involved allegations of deficiencies in the consent process.²⁷ Other qualitative research shows that the consent process often fails to meet the needs of the patient.²⁸ These reports suggest that patients do not receive sufficient information, that the information is not understandable, and that it is not tailored to their needs.²⁹

24 *Rogers v Whitaker* (1992) 175 CLR 479

25 Cartwright, C. (2011) *Planning for the End-of-Life for People with Dementia: A Report for Alzheimer's Australia*. 23(1). Alzheimer's Australia: Canberra.

26 Ibid.

27 Gogos, A.J., Clark, R.B., Bismark, M.M., Gruen, R.L. and Studdert, D.M. (2011) 'When Informed Consent Goes Poorly: A Descriptive Study of Medical Negligence Claims and Patient Complaints.' *Medical Journal of Australia*. 195(6): 340-344.

28 Op cit Akkad et al.

29 Schattner, A., Bronstein, A. and Jellin, N. (2006) 'Information and Shared Decision-Making are Top Patients' Priorities.' *BMC Health Services Research*. 6(1): 21.

There is less research conducted on other issues which may undermine informed consent, such as cultural factors, power relations and the dynamics of the consultation process. Specific types of health care and health care providers attract more complaints about informed consent than others. One study found that more than half of the cases involving informed consent problems were against surgeons and that collectively, surgeons, obstetrician-gynaecologists and general practitioners were involved in 82 percent of cases. This study also found that the rate of complaints against plastic surgeons was significantly higher than that against any other type of specialist.³⁰

In relation to the details of complaints made, in 71 percent of cases, the primary allegation concerned a complication of treatment that had not been canvassed or fully understood prior to treatment. The next most common types of complaints related to the scope of the consent process and whether it had been exceeded. In these cases, the risk that the procedure would confer no benefit, as opposed to harm, had not been raised with the consumer, and the process by which consent was obtained was unsatisfactory. Process allegations involved situations in which patients felt rushed, pressured to proceed, or regarded the language used as incomprehensible.

This study also found that problems with informed consent often occurred in association with other problems in the delivery of care. This demonstrates how informed consent issues are embedded within the broader context of health care provision, such as the relationship between the clinician and consumer and the consumer's perception of the outcomes of the treatment. Studdert concludes that the relationship between problems with informed consent and other aspects of care is complex, with:

the most likely scenario [being that] a mix of concerns operate synergistically, producing a sufficiently negative perception of the overall care experience to move patients to complain or litigate.³¹

Discussion Questions

10. Given the research on consumer experiences, what are the key issues that need to be addressed to improve informed consent processes?

Informed Consent Resources

There are a broad range of resources available to support informed consent processes. These can be grouped together as follows:

- Material providing generic information about consumer rights and entitlement to informed consent
- Support for consumers in relation to specific diseases, conditions and procedures
- Resources for clinicians which provide them with information about their obligations and practical strategies to obtain informed consent
- Interactive resources targeting both providers and consumers which support the decision making process.

³⁰ Op cit Gogos et al.

³¹ Studdert, D.M., Mello, M.M. and Gawande, A.A. (2006) 'Claims, Errors, and Compensation Payments in Medical Malpractice Litigation.' *New England Journal of Medicine*. 354: 2024-2033.

The most common type of informed consent resources are those which target consumers and provide information about a recommended procedure or a range of treatment options, including details of the risks, benefits, evidence base and probable outcomes. These resources are typically paper-based, although many can be provided in alternative formats, including as audio recordings or DVDs.

Resources for clinicians generally focus on legal obligations and the skills required to provide information in a way that is meaningful to consumers. They are generally produced by medical colleges and medical indemnity funds.

Interactive resources, such as decision aids and other shared decision making tools, aim to support a more collaborative approach to making treatment decisions. There is evidence that when used correctly, these can increase consumers' knowledge of their options and associated risks and benefits, and assist them in making a decision.³²

There are a large number of decision aids that have been developed for use in health care. However, most are specific to particular type of practices or clinical conditions.³³ There are also generic decision aids which can be used to support decision making on any treatment options which may have broader application, for example, in primary care. One example of this is an decision aid developed by the Ottawa Health Research Institute, designed to help with any major decision.³⁴

Discussion Questions

11. Are you aware of any other informed consent resources?

12. Should a standardised decision aid be developed and promoted for use in the Australian health system? What should this include?

The Role of Consent Forms

Informed consent processes are often reduced to a formal consent form, although these are only required for certain types of procedures. Consent forms can be required for legal reasons or may be implemented as part of routine practice by health care providers or services.

Consent forms can be generic and cover all different types of procedures and health care settings, or they may be specific to a particular type of treatment or service. Evidence suggests that improving consent forms can result in improved patient comprehension and recall, although many studies show mixed results.³⁵

One review of the literature concluded that consent forms were a necessary tool in obtaining informed consent, but that they are not effective when used as a stand-alone solution. Other tools are also required to increase consumer involvement in the decision-making process, such as information supporting consumers to question health care providers.³⁶

32 Stacey, D., Bennett, C.L., Barry, M.J., Col, N.F., Eden, K.B. and Holmes-Rovner, M. (2011) 'Decision Aids for People Facing Health Treatment or Screening Decisions.' *Cochrane Database of Systematic Reviews*. Issue 10.

33 For example, Foundation for Informed Medical Decision Making (1996) *Hormone Replacement Therapy: A Shared Decision Making Program. Clinician's Guide*. Foundation for Informed Medical Decision Making: Boston.

34 Ottawa Hospital Research Institute (2013) 'Patient Decision Aids.' Available online: <http://decisionaid.ohri.ca/> Accessed 27 February 2013.

35 Temple Health (2013) 'A Practical Guide to Informed Consent.' Available online: <http://www.templehealth.org/ICTOOLKIT/html/ictoolkitpage1.html> Accessed 27 February 2013.

36 Ibid.

Some disadvantages of consent forms relate to their focus on consultations, and their potential to hinder a more spontaneous dialogue between clinicians and consumers. One author writes that standardised consent forms can contribute to informed consent processes becoming ritualistic and formulaic, which can lead to clinicians becoming desensitised to consumers' fears and concerns³⁷ and reduce consumer autonomy.³⁸

When surveyed, consumers do not demonstrate strong support for consent forms. For example, one poll found that only 41 percent of patients believed that the use of consent forms made their wishes known, and 46 percent believed that the primary function of the consent form was to protect the hospital.³⁹

Discussion Questions

13. What is the role of informed consent forms? How and when should they be used?

Gaps in the Available Resources and Interventions

Unequal power relations within the health care setting

While this is identified by consumers as an important issue, it is rarely directly addressed in informed consent resources. Information targeted at consumers frequently includes details of the rights of consumers to ask questions, refuse treatment and seek a second opinion. This may go some way toward empowering consumers within the consultation environment but it does not explicitly address the power imbalance that can act as a barrier to informed consent processes.

The right to hear all treatment options

Many of the resources focus on specific recommended treatments and while they provide comprehensive information about those procedures, they do not provide information about the range of other alternative treatment options that may be available. This makes it difficult or impossible for consumers to make an informed choice which balances the risks and benefits of all treatment and non-treatment options.

The right to refuse treatment

Many informed consent resources also do not explain that consumers have the right to refuse or delay treatment. Where this issue is raised, it is presented as a black and white choice with no information provided on 'watchful waiting' and how this can occur in practice.

The deliberative process

Providing informed consent requires more than just obtaining relevant information. This information then has to be used by the consumer to consider how it fits within their individual circumstances, values and beliefs.⁴⁰ With the exception of decision aids and similar tools, most resources are focussed on the provision of relevant facts about procedures, but do not contain any guidance on how these facts can be used by consumers to make a decision about their treatment options.

37 Picano, E. (2004) 'Informed Consent and Communication of Risk from Radiological and Nuclear Medicine Examinations: How to Escape from a Communication Inferno.' *British Medical Journal*. 329 (7470): 849-851.

38 Habiba, M., Jackson, C., Akkad, A., Kenyon, S. and Dixon-Woods, M. (2004) 'Women's Accounts of Consenting to Surgery: Is Consent a Quality Problem?' *Quality and Safety in Health Care*. 13(6): 422.

39 Akkad, A., Jackson, C., Kenyon, S., Dixon-Woods, M., Taub, N. and Habiba, M. (2006) 'Patients' Perceptions of Written Consent: Questionnaire Study.' *British Medical Journal*. 333: 528.

40 Elwyn, G. (2008) 'Patient Consent: Decision or Assumption?' *British Medical Journal*. 336(7656): 1259.

Systemic and organisational change

There were no identified resources or interventions to support systemic or organisational changes which would facilitate improved informed consent processes. For example, moving away from a time-based remuneration system for clinicians could reduce the time pressures often experienced in a consultation.

Discussion Questions

14. Are there any other gaps in the identified resources?

15. How can these gaps best be addressed?

Specific Challenges

There are a number of areas of health care and population groups that may raise additional issues in relation to informed consent and may need specific strategies.

Healthcare Areas

Cosmetic surgery is an area of particular concern for informed consent.⁴¹ Cosmetic surgery differs from almost all other forms of health care as it is undertaken for cosmetic purposes rather than to cure a physical problem causing harm, pain or dysfunction. This impacts upon the way in which the risks and the benefits of procedures are assessed as the lack of medical necessity reduces the tolerance for risk. The more subjective nature of the potential benefits also makes consent more difficult to assess objectively, raising the possibility of exploitation of consumers.

Cosmetic surgery is the subject of a disproportionate number of complaints stemming from informed consent issues, largely due to the perceived failure of clinicians to communicate the likely outcomes of the procedure and the expected side effects.⁴² This suggests that there is significant scope for improvement in informed consent processes in this area.

Live donation, for example donating a kidney to a family member, also requires special consideration in relation to informed consent processes. This is related to the lack of medical necessity and the altruistic intent of the donor. As is the case with cosmetic surgery, when there is no medical necessity for a procedure, the level of risk that is considered reasonable is significantly reduced. When donation is made to a family member, there is also the potential for undue pressure to be exerted on an individual who is a suitable donor. Informed consent processes need to take account of both of these issues.

Research issues can also often arise in the course of medical treatment. For example, consumers may be asked if a tissue sample or other genetic material obtained as part of the treatment can be used for medical research purposes. This is a separate process from the provision of treatment and therefore requires consent to be obtained specifically for this purpose, ideally prior to the treatment occurring. The consent process for participation in medical research must also make clear that refusing consent for this process will not in any way impact upon the provision of medical treatment.

41 Cosmetic surgery in this context is defined as surgery undertaken for purely cosmetic, as opposed to therapeutic, reasons.

42 Leclercq, W.K.G. Keulers, B.J. Scheltinga, M.R.M. Spauwen, P.H.M. Van Der Wilt. G.J. (2010) 'A Review of Surgical Informed Consent: Past, Present, and Future. A Quest to Help Patients Make Better Decisions.' *World Journal of Surgery*. 34(7): 1406-1415.

Population Groups

Population groups with additional informed consent needs include:

- People with poor English skills
- People with low levels of literacy
- People with some forms of disability
- People with cognitive impairment
- People from culturally and linguistically diverse backgrounds.

While these groups are very diverse in terms of their health care needs, in relation to informed consent processes they can be divided into three main groups:

Language and Communication Issues

This includes consumers who have difficulty using standard communication methods, including people with poor English skills and with specific disabilities, such as hearing or vision impairment. Their needs can be addressed through the use of interpreters, translated materials, or through the provision of resources in alternative formats. CHF notes, however, that it is not always possible to provide this.

Cognitive Issues

This group includes those who may not be able to make an informed decision about their own best interests, or who lack legal capacity to do so due to their age (i.e., minors), a disability or an illness. It includes minors, people with intellectual disabilities and acquired brain injuries, people with certain mental health conditions and people with degenerative brain diseases. These groups may require targeted resources to address their specific information needs and cognitive capacities. In many cases, informed consent processes involving this group will include a guardian or carer in either a formal or informal role. People with degenerative conditions such as dementia that effect cognition are able to put in place advance directives, arrangements for substitute decision makers, and other decision instruments at a time when they do have cognitive capacity to consent to cover or guide medical decisions requiring informed consent at a future time when they may lack the capacity to do so.

Cultural Issues

This group includes consumers who may not be able to provide informed consent through standard processes for cultural reasons. This includes people from cultural backgrounds with significantly different practices in the provision of healthcare. For example, Aboriginal and Torres Strait Islander people may not feel culturally secure within a mainstream healthcare setting.⁴³ Another example is women from cultures where it is considered inappropriate to challenge men,⁴⁴ creating challenges in obtaining informed consent. These groups require targeted strategies to address the cultural barriers in providing informed consent. In some cases, this may include a role for an advocate or similar support person.

Discussion Questions

16. Are there any specific challenges that have not been outlined above?

17. How could these challenges be addressed?

43 North Coast Area Health Service (2009) Cultural Respect and Communication Guide. North Coast Area Health Service: Lismore.

44 Ibid.

Conclusion

Informed consent is a key issue for consumers of healthcare, and the foundation of a health system centred around the needs and priorities of consumers. There are a number of components to informed consent, including information provision as well as social, personal and cultural factors.

The majority of resources aimed at supporting informed consent focus on communicating information about procedures to consumers. However, there is a growing body of interactive techniques aimed at providing a framework within which consumers and clinicians can discuss, reflect and decide on the most appropriate treatment option.

Evaluations of these resources have shown some promising outcomes, however, there are still many unanswered questions about how and when they should be used to achieve maximum benefit. There is also a need for additional research into the specific needs of some population groups and for informed consent processes for particular types of treatment.

Developing a national standard or framework for informed consent within Australia could be the first step to progressing these issues in a coordinated and systematic manner to that this issue is recognised as a high priority in healthcare.

Next Steps

Comments and responses to this paper should be sent to m.azize@chf.org.au by Tuesday 30 April 2013. The questions asked in this paper are intended as a guide. Comments do not need to be restricted to the questions or issues that have been raised. Consumers are also encouraged to include examples and provide personal experiences.

Further information about CHF's work in this area can be found on the CHF website, www.chf.org.au. Alternatively, interested persons can contact CHF Policy Manager Maiy Azize at m.azize@chf.org.au or (02) 6273 5444.



The Consumers Health Forum of Australia (CHF) is the national peak body representing the interests of Australian healthcare consumers. CHF works to achieve safe, quality, timely healthcare for all Australians, supported by accessible health information and systems.

CHF does this by:

1. advocating for appropriate and equitable healthcare
2. undertaking consumer-based research and developing a strong consumer knowledge base
3. identifying key issues in safety and quality of health services for consumers
4. raising the health literacy of consumers, health professionals and stakeholders
5. providing a strong national voice for health consumers and supporting consumer participation in health policy and program decision making

CHF values:

- our members' knowledge, experience and involvement
- development of an integrated healthcare system that values the consumer experience
- prevention and early intervention
- collaborative integrated healthcare
- working in partnership

CHF member organisations reach millions of Australian health consumers across a wide range of health interests and health system experiences. CHF policy is developed through consultation with members, ensuring that CHF maintains a broad, representative, health consumer perspective.

CHF is committed to being an active advocate in the ongoing development of Australian health policy and practice.