Informed Consent

Standard 1: Governance for Safety and Quality in Health Service Organisations

State Government Victoria
Cabrini
Department of Health

Published by Sector Performance, Quality and Rural Health, Victorian Government, Department of Health

June 2014

Acknowledgements

The Department of Health Victoria acknowledges the contribution of medical and health specialists, Victorian health services, and members of the *National Safety and Quality Health Service Standards: Educational Resources Project* project team, Steering Group and Advisory Committee.

The Educational Resources Project Steering Group members comprised:

- Associate Professor Leanne Boyd, Steering Group Chair; Director of Education, Cabrini Education and Research Precinct, Cabrini Health
- Ms Madeleine Cosgrave, Project Manager
- Ms Susan Biggar, Senior Manager, Consumer Partnerships, Health Issues Centre
- Mr. David Brown, Consumer representative
- Dr Jason Goh, Medical Administration Registrar - Cabrini Health
- Mr Matthew Johnson, Simulation Manager, Cabrini Education and Research Precinct, Cabrini Health
- Ms Tanya Warren, Educator, Cabrini Education and Research Precinct, Cabrini Health
- Ms Marg Way, Director, Clinical Governance, Alfred Health
- Mr Ben Witham, Senior Policy Officer, Quality and Safety, Department of Health Victoria

The Educational Resources Project Advisory Committee members comprised:

- Associate Professor Leanne Boyd, Advisory Committee Chair; Director of Education, Cabrini Education and Research Precinct, Cabrini Health
- Ms Madeleine Cosgrave, Project Manager
- Ms Margaret Banks, Senior Program Director, Australian Commission on Safety and Quality in Health Care
- Ms Marrianne Beaty, Oral Health National Standards Advisor, Dental Health Services Victoria)
- Ms Susan Biggar, Senior Manager, Consumer Partnerships, Health Issues Centre
- Mr David Brown, Consumer representative
- Dr Jason Goh, Medical Administration Registrar, Cabrini Health
- Ms Catherine Harmer, Manager, Consumer Partnerships and Quality Standards, Department of Health, Victoria
- Ms Cindy Hawkins, Director, Monash Innovation and Quality, Monash Health
- Ms Karen James, Quality and Safety Manager, Hepburn Health Service
- Mr Matthew Johnson, Simulation Manager, Cabrini Health
- Ms Annette Penney, Director ,Quality and Risk, Goulburn Valley Health
- Ms Gayle Stone, Project Officer, Quality Programs, Commission for Hospital Improvement, Department of Health Victoria
- Ms Deb Sudano, Senior Policy Officer, Quality and Safety, Department of Health Victoria
- Ms Tanya Warren, Educator, Cabrini Health
- Ms Marg Way, Director, Clinical Governance, Alfred Health
- Mr Ben Witham, Senior Policy Officer, Quality and Safety, Department of Health Victoria

Contents

Informed Consent

Introduction

This module relates to The National Safety and Quality Health Service (NSQHS) - Standard 1: Governance for Safety and Quality in Health Service Organisations.

Learning outcomes

On completion of this module, clinicians will be able to:

1. Differentiate between the types of consent.
2. Discuss informed consent.
3. Explain the importance of good communication between clinicians and patients or carers in relation to informed consent.
4. Describe valid refusal.
5. Discuss issues associated with consent.

National Safety and Quality Health Service Standards

The Australian Commission on Safety and Quality in Health Care (ACSQHC) developed the 10 NSQHS Standards to reduce the risk of patient harm and improve the quality of health service provision in Australia. The Standards focus on governance, consumer involvement and clinically related areas and provide a nationally consistent statement of the level of care consumers should be able to expect from health services.

Aim of Standard 1

The aim of Standard 1 is to ensure that healthcare organisations establish and maintain a governance structure and systems to sustain and improve the reliability and quality of patient care.

A governance system sets out safety and quality policies, protocols and procedures and assigns roles, responsibility and accountability for patient safety and quality.

The principles in *Standard 1: Governance for Safety and Quality in Health Service Organisations* and *Standard 2: Partnering with Consumers* are fundamental to all Standards and provide a framework for their implementation.

ACSQHC, 2012

Criteria to achieve Standard 1
Governance and quality improvement systems
There are integrated systems of governance to actively manage patient safety and quality risks.
Clinical practice
Care provided by the clinical workforce is guided by current best practice.
Performance and skills management
Managers and the clinical workforce have the right qualifications, skills, and approach to provide, safe, high-quality health care
Incident and complaints management
Patient safety and quality incidents are recognised, reported and analysed and this information is used to improve safety systems.
Patient rights and engagement
Patient rights are respected and their engagement in their care is supported.

Table 1: Criteria to meet Standard 1 (ACSQHC, 2012)

Policies and procedures

There are numerous policies, procedures and resources within health care services to assist you in meeting your responsibilities in relation to consent. It is important to access, read and adhere to systems, policies and procedures within your organisation.

Background

In the healthcare setting, clinicians can do nothing to a patient without first obtaining consent.

It is therefore essential that clinicians are aware of their obligations as well as patient's rights.

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 (Vic).

Informed consent is a person's agreement to allow something to happen to them (e.g. surgery or an invasive diagnostic procedure) based on a full disclosure of risks, benefits, alternatives and consequences of refusal.

This conversation must occur before the consent form is signed. The conversation between the clinician and the patient or carer is the true process of obtaining informed consent. The signature on the consent form is proof that the conversation took place and that the patient understood and agreed.

Obtaining informed consent is a legal duty of healthcare providers. The consent form constitutes the legal paperwork.

Consumers Health Forum of Australia, 2013

Types of Consent

IMPLIED CONSENT

Implied consent is consent which is not explicitly given by the individual, but is inferred from the person's actions or inactions.
They indicate their wishes, without necessarily stating them.

An example commonly seen in the health care setting is a patient holding their arm out for a blood pressure cuff to be applied. Although the patient has not expressly consented to the intervention, their action (holding out their arm) clearly indicates that they are willing for the procedure (blood pressure measurement) to occur.

Much of what a clinician does each day is based on an understanding of implied consent. It is considered common for a patient to supply their medical history on admission, undergo a nursing assessment and have vital signs taken whilst in hospital. The patient implies, through their participation, that they have consented to these common procedures.

However for uncommon or invasive treatments, specific consent needs to be obtained. For example, although consent may be implied for a skin assessment on admission, verbal consent should be obtained prior to examination of breasts or genitals.

Implied consent does not negate the need to provide the patient with an appropriate explanation of, and information about, the procedure, investigation, treatment or examination. If ever there is any doubt whether the actions or inactions of a patient imply consent or not, verbal or written consent must be obtained.

VERBAL CONSENT

Verbal consent is when an individual clearly states their agreement to an intervention or procedure.

An example would be a patient stating "Yes, you can put in a catheter."

Verbal consent should be obtained if there is any doubt of a person's implied consent to minor procedures. It should also be obtained if the intervention is invasive, likely to be more than mildly uncomfortable or entails mild to moderate risk.

Examples include, but are not limited to:

- venepuncture
- insertion of an indwelling catheter
- chest X-ray
- insertion of an intravenous cannula
- removal of drain tubes
- wound dressings
- examination of genitals, rectum or breasts

Verbal consent should be documented in the patient's medical record.

WRITTEN CONSENT

Written consent must be obtained when the treatment, investigation or procedure:

- is invasive or has significant potential complications or side effects including, but not limited to, death or permanent disability
- has significant irreversible side effects (e.g. scarring)
- requires surgical, medical, invasive radiology, oncology or endoscopy treatments
- requires the use of a general/epidural/ spinal/regional anaesthetic or intravenous sedation
- may adversely affect a patient's employment, personal relationships or hobbies/interests
- involves the administration of medications which are newly developed or have known high risk complications
- is complex and/or involves multiple components
- is required by law to have written consent
- involves potential risk to a foetus
- may affect current or future fertility
- involves a new technology or clinical procedure, including participation in clinical trials or medical research

Where a treatment involves any of the above, written consent must be obtained.

Minor procedures may only require verbal consent. If unsure, refer to your organisation's policies and protocols.

Office of the Public Advocate, 2013

Queensland Health, 2011

What is informed consent?

Informed consent is an agreement from a patient or their carer to undertake specific treatment.

Consent is a key element in healthcare. It has ethical, legal and practical implications.

Ethically, consent represents an individual's moral right to make decisions about themselves and their care.

Legally, consent represents an agreement or process by which the individual's right to agree to, or refuse, medical treatment is upheld.

Practically, consent represents the conversation in which the patient and clinician discuss the options, risks and benefits of treatment and any consequences of refusal. It is vital that people are given all the information they need in order to choose what is right for them. The patient and carer must be given an opportunity to ask questions and have them answered.

It is important that they not only hear, but also understand this information. Ensuring they understand is a key aspect of consent and is the responsibility of the clinician obtaining consent.

Patients who are not proficient in English (including deaf or hearing impaired patients) have a high risk of ineffective communication during the consent process. A professional interpreter should be used in these situations to ensure that the patient can give fully informed consent.

Health care organisations must ensure that patients have given their informed consent to medical treatment (implied, verbal or written) before that treatment is initiated.

This applies to all health interventions performed on patients, in accordance with legal and ethical requirements.

Office of the Public Advocate, 2013; Consumers Health Forum of Australia, 2013; ACSQHC, 2012

Principles of informed consent

There are general principles that apply to all consent for medical treatment which are outlined under the following headings.

COMPETENT

Under the Victoria *Medical Treatment Act 1988*, a patient must be of sound mind and over 18 years of age in order to give or refuse valid informed consent. Competency is to be assumed unless there is clear evidence to the contrary. If there are any questions around a patient's competence, an assessment should be undertaken by the treating doctor or other appropriate personnel, e.g. psychiatrist.

Medical Treatment Act, 1988
Office of the Public Advocate, 2011

INFORMED

The patient must be provided with sufficient information upon which to make their decision. This should include the details, nature, benefits, alternatives and material risks of the proposed health intervention or treatment.

This will enable them to make an informed decision regarding their own health care. Information about the proposed health intervention or treatment should be provided in a way that the patient can understand.

The patient should be encouraged to ask questions and provide input into the conversation. It is important that the patient fully understands everything that has been said and the implications of their decision. It is the clinician's responsibility to make sure the patient understands and isn't just passively agreeing.

Office of the Public Advocate, 2013

VOLUNTARY

Consent must be given freely and voluntarily. The clinician may advise the patient what they believe is the best option for their care. A clinician must not exert pressure on, coerce, or force the patient to take their advice.

The patient has the right to choose between available treatment options. They also have the right to withdraw their consent at any time before or during a procedure, investigation, examination or treatment. This must be documented and communicated to all involved.

Office of the Public Advocate, 2013

TIMING

Consent must occur prior to the commencement of the procedure and any pre medication.

SPECIFIC

Consent given by the patient:

- must be specific to the medical treatment for which the patient has been informed
- is only valid for that medical treatment

Questions like "Can you explain to me in your own words what procedure you are having and why?" can help to ensure that the patient fully understands and agrees to the treatment. Any documentation should clearly state the treatment that the patient is agreeing to. Where relevant, the site and side of any procedure must be stated on written documentation of informed consent.

The clinician must not exceed the 'scope of authority' given by the patient.

Johnstone, 2009; NHMRC, 2013; Queensland Health, 2011

Why is informed consent important?

Most people will require medical treatment at some point. This treatment may involve significant risks, costs or pain.

For one individual, those risks and costs may be worth it, while for another individual, they may not be. It is important that people have the right to choose.

Consumers Health Forum of Australia, 2013

Your role in consent

It is the responsibility of the clinician who will carry out the procedure or investigation to obtain informed patient consent. This means that nurses obtain consent for nursing interventions, surgeons obtain consent for surgical interventions, physiotherapists obtain consent for physiotherapy interventions etc.

Consent for anaesthesia is the responsibility of the anaesthetist. It should be obtained in accordance with 'Australian and New Zealand College of Anaesthetists: Guidelines on Consent for Anaesthesia or Sedation' and documented on the consent form.

When is a consent form NOT consent?

Always!

A consent form is not, in itself, the 'consent.'

The patient must choose the proposed treatment following a conversation with the clinician. This choice or agreement constitutes consent.

The consent form documents evidence that the conversation occurred and that the patient agreed to the proposed treatment.

Documentation

CONSENT FORMS

There needs to be documentation which provides evidence of informed consent. You should follow your organisation's policy and protocols.

Consumers Health Forum of Australia, 2013

DURATION OF CONSENT

Consent remains valid as long as there is no change in the patient's condition or to the nature, extent or reason for the medical treatment. Development of new treatment options should be discussed with the patient.

Exceptions

TREATMENTS AUTHORISED BY LAW

Where a treatment is authorised or required by statute or court order, consent is not required.

PATIENTS UNDER 18 YEARS OF AGE

Legally a person is not termed an adult until they are 18 years of age. Therefore a parent (or legal guardian) is required to consent to their child's medical treatment.

However, Australian law recognises that teenagers become more competent as they get older and may be able to provide informed consent for themselves.

As a result, parents and their teenage children hold concurrent rights to consent to treatment for a patient under 18 years of age. The clinician and health care organisation will need to determine each case individually, based on the capacity of the teenager to provide their own consent.

The Gillick test is used to help clinicians determine if a minor has capacity to give informed consent. Further information can be found at the Office of the Health Services Commissioner at: http://www.health.vic.gov.au/hsc/

This does not apply to refusal of treatment.

Guardianship and Administration Act, 1986; Medical Treatment Act, 1988; Health Records Act, 2001; Office of the Health Services Commissioner, 2003

EMERGENCY SITUATIONS

Emergency treatment is defined as treatment that the medical practitioner believes is necessary as a matter of urgency to:

- save the patient's life
- prevent serious damage to the patient's health
- prevent the patient from suffering or continuing to suffer significant pain or distress

Every effort should be made to have the patient or their next of kin provide written or verbal consent to treatment.

If that is not possible, the doctor may proceed with the intended treatment and document the reasons for this decision in the progress notes.

If the treatment has been clearly refused by the patient, it should not be administered.

Office of the Public Advocate, 2013

CONFUSED OR INCOMPETENT PATIENTS

In situations where a patient is not competent to give consent, it must be provided by their nominated representative.

Office of the Public Advocate, 2013; Medical Treatment Act 1988; Mental Health Act 1986

Refusal of Medical Treatment

All competent adults have the right to refuse treatment in relation to a current illness.

In situations where a patient is not deemed to be competent, refusal of treatment can be provided by their nominated representative. The nominated representative has the right to refuse treatment on the patient's behalf but cannot refuse palliative care.

VALID REFUSAL OF TREATMENT

For there to be a valid refusal of medical treatment, the patient and treating doctor must, by law, complete a *Refusal of Treatment* form. This form can be found at the Office of the Public Advocate at:

http://www.publicadvocate.vic.gov.au/medical-consent/177/

Clinicians have a legal and moral duty to the patient to respect and act on their informed refusal, irrespective of their personal beliefs and opinions.

Consumers Health Forum of Australia, 2013

LEGAL IMPLICATIONS

When a patient has refused treatment, the law protects clinicians from any wrongdoing in not providing that treatment.

However, if a clinician ignores a patient's refusal of treatment, they can be charged with medical trespass.

Medical Treatment Act, 1988

WITHDRAWAL OF REFUSAL OF TREATMENT

A patient, or their legal representative, may withdraw their decision to refuse treatment at any time. This must be documented and communicated to all involved.

Consumers Health Forum of Australia, 2013;
Medical Treatment Act, 1988

Engaging with patients and carers

Patients and carers should be educated about the need for informed consent and their role and rights in the process.

You should consider the following when obtaining informed consent from patients or carers:

- explaining the need for informed consent
- explaining the patient's rights regarding consent or refusal for treatment
- explaining their right to change their mind about decisions
- providing relevant, easy to understand information
- enabling them to discuss their needs and preferences
- offering information in languages other than English and not assuming literacy
- providing an opportunity for patients and carers to ask questions and have them answered

You should ensure that the patient and carer understand the consent process.

ACSQHC, 2012

Reporting adverse events

All adverse events relating to poor or absent consent should be reported to the nurse/midwife in charge, the attending medical officer (if necessary) and be documented in the clinical record. They should also be reported on your organisation's risk or incident management system.

Patients and carers should be fully informed of any adverse events and the organisation's open disclosure processes implemented.

Information trends can then be used to inform quality improvement activities such as system, policy, protocol and equipment improvements and education and training activities.

ACSQHC, 2012

Summary

Informed consent is an important aspect of Standard 1 in the National Safety and Quality Health Service Standards.

The key messages are:

1. In the health care setting, clinicians can do nothing to a patient without first obtaining consent.
2. Informed consent is a person's agreement to allow something to happen to them (e.g. surgery or an invasive diagnostic procedure) based on a full disclosure of risks, benefits, alternatives and consequences of refusal.
3. The conversation between the clinician and the patient or carer is the true process of obtaining informed consent.
4. A professional interpreter should be used for patients who are not proficient in English and for the deaf or hearing impaired.
5. The signature on the consent form is proof that the conversation took place and that the patient agreed and understood.
6. Implied consent is consent which is not explicitly given by the individual, but is inferred from the person's actions or inactions.
7. Verbal consent is when an individual clearly states their agreement to an intervention or procedure.
8. Written consent is required for certain procedures.
9. Ethically, consent represents an individual's moral right to make decisions about themselves and their care.
10. Legally, consent represents an agreement or process by which the individual's right to agree to, or refuse, medical treatment is upheld.
11. Practically, consent represents the conversation in which the patient and clinician discuss the options, risks and benefits of treatment and any consequences of refusal.
12. It is the responsibility of the clinician who will carry out the procedure or investigation to obtain informed patient consent.
13. There needs to be documentation which provides evidence of informed consent. You should follow your organisation's policy and protocols.
14. A parent or guardian is required to give informed consent for patients under 18 years of age unless the patient is deemed to have capacity.
15. All competent adults have the right to refuse treatment in relation to a current illness.
16. All adverse events relating to poor or absent consent should be reported on your organisation's risk or incident management system.

Test Yourself

Pair each number to the appropriate letter to complete the sentences.

1. In implied consent	**a.** the conversation in which the patient and clinician discuss the options, risks and benefits of treatment and any consequences of refusal.	1. ____
2. Verbal consent	**b.** palliative care.	2. ____
3. Written Consent	**c.** freely and voluntarily.	3. ____
4. Practically, consent represents	**d.** there is no change in the patient's condition or to the nature, extent or reason for the medical treatment.	4. ____
5. Ethically, consent represents	**e.** only for the specific medical treatment that has been consented to.	5. ____
6. Legally, consent represents	**f.** an individual's moral right to make decisions about themselves and their care.	6. ____
7. Competency	**g.** must have consent provided by a parent or guardian unless they are deemed to hold capacity themselves.	7. ____
8. Consent must be given	**h.** the clinician who will carry out the procedure or investigation.	8. ____
9. The clinician who obtains consent is	**i.** should be obtained if there is any doubt of a person's implied consent to minor procedures.	9. ____
10. Consent must be obtained	**j.** an agreement or process by which the individual's right to agree to, or refuse, medical treatment is upheld.	10. ____
11. Consent is valid	**k.** the patient's wishes are clearly indicated, without needing to be stated.	11. ____
12. Consent remains valid as long as	**l.** must be obtained if the procedure has significant irreversible side effects.	12. ____
13. Patient's under 18 of age	**m.** is to be assumed unless there is clear evidence to the contrary.	13. ____
14. Treatment can be refused by a nominated representative, except for	**n.** prior to the commencement of the procedure and any pre medication.	14. ____

Answers

1. K
2. I
3. L
4. A
5. F
6. J
7. M
8. C
9. H
10. N
11. E
12. D
13. G
14. B

References

Australian Commission on Safety and Quality in Health Care. (2012). Safety and Quality Improvement Guide Standard 1: Governance for Safety and Quality in Health Service Organisation. Sydney: Commonwealth of Australia

Consumers Health Forum of Australia. (2013). Informed Consent in Healthcare: An Issues Paper. Accessed at: https://www.chf.org.au/pdfs/chf/Informed-Consent-Issues-Paper.pdf

Department of Health Victoria. (2013). Human Resources: Charter of Human Rights and Responsibilities Implementation Guide for DEECD Policy Officers. Accessed at: http://www.education.vic.gov.au/hrweb/Documents/Charter-Implementation-Guide-DEECD.pdf

Guardianship and Administration Act, 1986 (Vic)

Health Records Act, 2001 (Vic)

Johnstone, M.J. (2009). Bioethics: A Nursing Perspective. 5th ed. Sydney: Elsevier

National Health and Medical Research Council. (2013). National Statement on Ethical Conduct in Human Research. Accessed at: http://www.nhmrc.gov.au/book/national-statement-ethical-conduct-human-research

Medical Treatment Act 1988 (Enduring Power of Attorney)

Mental Health Act 1986 (Vic)

Office of the Health Services Commissioner. (2003). Information Sheet No. 5 – Minors, Privacy Laws & Consent. Accessed at: http://www.health.vic.gov.au/hsc/infosheets/minors.pdf

Office of the Public Advocate. (2013). Medical Consent. Accessed at: www.publicadvocate.vic.gov.au/medical-consent/

Office of the Public Advocate. (2011). Section 42K Notice. Accessed at: http://www.publicadvocate.vic.gov.au/file/file/Medical/interactive%20PDFs/Section42KNotice2011.pdf

Queensland Health. (2011). Guide to Informed Decision-making in Healthcare. Accessed at: http://www.health.qld.gov.au/consent/documents/ic-guide.pdf

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