Welcome to this learning module on Informed consent.

Welcome to the module about the important topic of informed consent – something that is essential for all health practitioners to understand and practice. In this module, we will review the basics of informed consent and also the process of obtaining informed consent. We also discuss how to tailor medical information to match the patient’s need.

So, firstly the basics……...

A strong underlying premise of all health care is that patient has the right to make decisions about their health care. This right includes or extends to the right to consent to or decline the offer of certain healthcare and to change that decision. Respect for patient’s autonomy in relation to health care decisions is seen when competent patients can make their own health care decisions.

Those who are not competent are protected from harm but are allowed to participate in decision-making to the full extent that they are able. A person is also deemed to have capacity to make decisions until you prove that they cannot make them.

This is echoed in the Australian Charter of Health Rights which states that patients have the rights to be informed about services, treatment, options and costs in a clear and open way. They are also entitled to receive open, timely and appropriate communication about their health care in a way they can understand and to be included in decisions and choices about their care.

So why do you need to gain consent? Ethically, gaining consent acknowledges the patient’s right to make their own decisions. Legally, if you do not obtain consent for health-care, you may be in breach of the law. You may be criminally liable or open to a civil breach allegation. In only a few prescribed circumstances such as an emergency and necessity etc. is consent waived.
Slide 7 – Types of consent

There are 3 key types of consent: verbal, written and implied.

Verbal consent is a form of express consent where a patient says they agree to healthcare. Generally, the law does not require consent to be in writing and in many cases it can be verbal or simply implied. Verbal consent may be appropriate for healthcare that carries no significant risks to the patient, for example, the insertion of an intravenous cannula into a peripheral vein, or a dental filling under local anaesthetic.

Written consent is where the patient or decision-maker provides written evidence of their agreement to healthcare, for example, by signing a consent form. A key fact to note about written consent is that the signature on a consent form is NOT considered to be enough to show the consent is valid and informed. A signed consent form needs to be supported by appropriately specific and detailed information, written either on the form or documented in the patient’s clinical record, to provide the best evidence of the communication process followed to obtain the patient’s consent.

Implicit consent

It is preferable to always gain at least verbal consent to assessment, intervention or treatment or all procedures. In limited cases, the patient indicates their agreement through their actions or by complying with the health practitioner's instructions.

In the case of healthcare without significant risk to the patient, it is usually sufficient to rely on a demonstration of the patient’s implied consent by their actions. E.g. routine blood sample for testing when a patient may give implied consent by extending their arm for the insertion of the needle. However, this may not be acceptable where there may be a significant consequence in light of the test result. For example: a practitioner asking for a HIV status test.

Particular care is taken when relying on implied consent as there is the possibility of a misunderstanding leading to an adverse outcome for patient, staff, students and Queensland Health. After all, how is a patient supposed to give informed consent if you have not discussed the reason for the procedure with them?

Slide 8 – When do I need to obtain it?

This slide reviews the timing of gaining consent and when to obtain consent to health care.

Essentially, all health practitioners and students must obtain consent before touching (examining) or providing healthcare to adult and child patients. Healthcare is broadly defined as a ‘range of activities related to the care or treatment of a patient, or a service or a procedure to diagnose, maintain, or treat the patient’s physical or mental condition, carried out by, or under the direction or supervision of, a health practitioner.’ Put simply, everyone who engages in health service should obtain informed consent prior to working with patients.

Slide 9 – Students seeking consent

If you are a student, it is important to know the following:
Just being a patient in a teaching hospital, centre or clinic does not imply that they consent to being examined or receiving healthcare from a trainee or student health practitioner. The patient must specifically consent to a student participating in their health care.

Some important things to remember:

1. Trainee/student health practitioners must be introduced in a way that makes it clear that they are trainees/students and not registered health practitioners (misleading terms such as ‘doctor/physiotherapist in training’ are not to used).
2. Patients must be told that they have a right to say no to the student providing health care.
3. Student health practitioners must work within the limits of their professional competence and be appropriately supervised at all times.
4. The responsibility for ensuring patients give valid informed consent rests with the health practitioner.
5. Any interaction about consent between the patient and trainee/student should take place in the presence of the treating health practitioner, so they can become involved as necessary.

In fact, best practice is for the practitioner to meet with the patient first and ask them in the absence of the student. At this point, you should also make it known that their refusal to consent will not affect their treatment plan in any negative way.

Slide 10 – The process

These next slides review the process of obtaining informed consent.

Slide 11 – Two components of informed consent

There are two key components of informed consent – informing the patient = fully informed + consent.

To meet the criteria to be informed consent, just obtaining a patient’s signature on a piece of paper is not enough. Patients may agree to something because they trust you or because of your role but this does not mean that they understand what you are going to do to them or why. This is particularly true in cases where people are extremely unwell or come from culturally or linguistically diverse backgrounds. To make the consent informed, you have to provide enough information about the health decision needed for the patient to make a ‘fully informed’ consent.

Slide 12 – Conditions that must exist

Also, for the patient’s informed consent to be valid, certain conditions must exist:

1. Capacity to consent

The patient has to have the capacity (ability) to make a decision and not be affected by therapeutic, anaesthetic or other drugs or alcohol. If there is any evidence to suggest the patient might not have capacity to provide consent to the particular healthcare concerned, the treating medical practitioner (treating health practitioner in the case of community and primary care settings) is recommended to undertake a thorough assessment of the patient’s ability to make a decision.
2. Consent is decision-specific
The patient must be able to agree to a specific process at the specific time that the decision has to be made. Also note that if the proposed treatment or process alters after consent has been given, then the process of informed consent must re-occur.

3. Voluntary consent
The consent is voluntarily given, and free from manipulation by or undue influence from family, medical staff or other social coercive influences.

4. Nature of the information provided
The discussion between the patient and the health practitioner is transparent, well balanced, and involves two-way communication which is sensitive to the situation.

The patient is able to clearly understand the information because it is provided in a language or by other means the patient can understand.

Slide 13 – Remember
Another important fact to remember is that for the consent to be valid, the healthcare itself must be lawful.

The fact that a patient consents to the healthcare does not allow a health practitioner to carry out an unlawful act, for example, an unlawful sterilization of a woman with impaired capacity. The law provides protection to vulnerable adults and children in such cases.

Slide 14 – How do I obtain consent?
The National Health and Medical Research Council (NHMRC) has published detailed guidance to medical practitioners on communicating with patients, and the minimum level of information that should be provided to patients to gain consent:

1. Engage the patient in a two way discussion
2. Ensure that the patient understands the proposed healthcare and has, where appropriate, supportive information to make an informed decision whether to agree or not.
3. Ensure that the patient is able to give informed consent
4. Consistent with good clinical practice, provide information and education in simple, non medical jargon terms
5. Used shared decision-making tools when available.

Slide 15 – What information do I need to give to the patient?
This slide reviews the type of information that must be provided to the patient. In simple terms that are tailored to fit the patient’s comprehension level, the patient must be told the:

1. Diagnosis
2. Prognosis [including degree of uncertainty about this]
3. Options for investigations/treatments
4. Burdens and benefits of investigations/treatments
5. Whether the invention is conventional/experimental
6. Who will perform the intervention
7. Consequences of choosing the test/treatment
8. Significant expected short-term and long-term outcomes
9. Time and cost involved

The patient should be encouraged to ask questions about this information and moreover, you should be aware of how you present to the patient! For example, is the patient likely to feel free to ask you questions if you come across as busy or disinterested or dismissive?

**Slide 16 – Most importantly, ask yourself**

Most importantly, ask yourself:

- Was the patient given enough time to consider and ask more questions in order to make an informed decision? Of course, the context e.g. acute emergencies versus ward decisions make a difference here.

- Did the information provided, and the consent given, relate to the specific healthcare actually provided? For example, you may know that the patient needs to have an amputation to remain alive and how to amputate a leg but do you know enough about the consequences for the patient or the likelihood of the patient receiving prosthesis, if they consent to the amputation? If the patient cannot get a prosthesis and you guarantee this until rehabilitation, then saying that they will get one if irresponsible and generates false hope. This patient may still have agreed to the amputation despite the lack of guarantee but you have not met the standard for informed consent.

- Did I check that they understand what I said – did I use an interpreter or audio or other assistance device if needed?

Don’t make assumptions about what the patient or decision-maker might want or needs to know or their ability to understand it. It is recommended that health practitioners carry out an appropriate and full psycho-social assessment of the patient (including a review of the patient’s clinical record and discussion with the patient or substitute decision-maker). This will enable them to provide information relevant to the specific circumstances of that patient.

**Slide 17**

Documentation: When must I obtain the consent in writing rather than verbally?

It is Queensland Health policy that, as a minimum, written consent be obtained for all healthcare where there are known significant risks or complications. Written consent is advisable for:

- any healthcare which carries significant risks to the patient
- where doubt exists about the patient’s capacity to consent
- where the healthcare is controversial.
It is important to recognise that some discussions need to be sensitively managed, for example, the available end of life treatments and the plan agreed with the patient. In these situations, it is preferable for the health practitioner to have comprehensive documentation of the discussions held and the decision reached, [with supporting evidence] to put in the patient’s clinical record.

Slide 18

Documentation: What should I do with the consent form?

All signed consent forms and any supplementary documents are to be filed in the patient’s Queensland Health clinical record at the facility where the healthcare is provided. All original consent forms are to be retained as part of the patient’s clinical record in accordance with Queensland Health Retention and Disposal of Clinical Records Policy. If the patient lacks capacity and you needed to obtain consent from someone, then you should also make a note of who consented and the authority under which they did so e.g. Statutory Health Attorney. A Social Worker will be able to help you understand the substitute decision-making options and documentation.

Slide 19 – Can a person refuse health care?

Sometime we are asked if a person can refuse health care? The answer is simple:

• Any patient who has capacity to consent may decline any or all healthcare at any time, even when this is contrary to medical recommendations and in circumstances where such a decision to decline healthcare may result in the death of the patient.
• A patient may also change their mind or withdraw consent at any time, for example, they may want to delay the whole or part of their treatment.
• The declining or withdrawal of consent can be orally or in writing. This declining or withdrawal of consent may be on the grounds of religious, cultural or other personal beliefs or any other reason.

Slide 20 – What should I do if they refuse health care?

If the person refuses health care, you should ensure that you check the following:

☑ The patient has capacity to make the decision
☑ The patient really understands what is intended and has had time to ask questions and think about options
☑ There is nothing preventing understanding e.g. sight or hearing or written comprehension issues
☑ You have spent time exploring the reasons for the refusal or decline. Sometimes it can just be a misunderstanding. They may be embarrassed to tell you that they cannot read the consent form or that they have never learnt to sign their name. Sometimes fear prevents agreement.

For example, in one case, a woman refused an operation that was critical on the basis that her mother had died under anaesthetic. Thankfully, once this was known, we were able to talk to her about the changes in medicine and anaesthetic in the last 70 years and she agreed to the operation. Some people refuse on religious or cultural grounds and it is good to know this as there may be alternatives or options that are acceptable to use instead.
Slide 21 – The information supplied must match patient need.

To ensure that a patient really understands something that they are consenting to, you may need to tailor the information to match the patient’s disability, diversity or level of comprehension.

Slide 22 – Patients who lack capacity

Within health contexts, we often come across people who lack capacity to make decisions. Most patients do NOT lose capacity to make all decisions and may be able to understand and consent to simple things e.g. to a flu vaccination but not to more complex matters. All patients should be encouraged and assisted to make their own decisions to the full extent that they are able.

Ask yourself whether the patient lacks capacity in relation to the specific decision at the specific time that the decision is needed – E.G it is not relevant whether they have capacity to make decisions around complex financial matters if they are asked to consent to a simple operation. Remember that they can have capacity for one and not the other. If the patient is not able to consent to treatment, then you will need to look to a substitute decision-maker. At this point of time, unless you know the correct legal process for this, you should contact a social worker or the hospital legal advisor.

Slide 23 – Patient with difficulties in communication

Some patients will have difficulties with verbal or written communication. You should confirm the patient’s level of understanding by asking the patient or decision-maker to explain in their own words what they have understood about the nature of the proposed healthcare and the consequences of accepting or declining the proposed healthcare options. Note that low English proficiency does not in itself indicate low literacy, education or intelligence.

When a patient has limited health literacy, low or no English proficiency, is visually or hearing impaired, or has an intellectual disability, health practitioners should use communication methods appropriate to the situation and the patient’s level of communication. These might include simple, language free of medical jargon audio, diagrams and illustrations, and video or multimedia material. All staff and students will have access to devices that will aid in communication but you may need to ask your supervisor where these devices are kept or how they are obtained. Any limitations in communication and methods used to assist decision-making should be documented in the patient’s clinical record, with sufficient detail to provide evidence the patient understood the information.

Psychologists, social workers, liaison officers, speech pathologists, teachers, carers or others who know the patient well may be able to offer advice, or support the communication process most appropriate for an individual patient. Documents supporting the consenting process are available in several languages on the Queensland Health Informed Consent website. Visit [www.health.qld.gov.au/consent/html/for_clinicians.asp](http://www.health.qld.gov.au/consent/html/for_clinicians.asp) [Online: accessed 16 November 2011]

Slide 24 – Patients with culturally and linguistically different backgrounds

It is beyond the scope of this guide to address all issues related to communicating with patients from a CALD background. Documents supporting the consenting process are available in several languages on
the Queensland Health Informed Consent website. Visit

Further essential resources can be found in the information for health workers section of the Queensland Health Multicultural Health website. Visit

Slide 25 – Use of interpreters

Health practitioners are to comply with the prevailing Queensland Health policy regarding the use of interpreters.

Patients who have difficulty communicating in English are offered an accredited or recognised interpreter during the informed consent process.

Be aware!

The ability to speak English does not necessarily indicate that a person has the proficiency necessary to comprehend complex medical concepts or instructions.

If any doubt, exercise respect and caution and engage an interpreter. Using family members is not suitable as you want the information exchanged to be impartial and regulated.

Check out the Queensland Government Multicultural website: It states that non-professional interpreters should not be used unless the situation is urgent and a professional interpreter is unavailable.

Friends and family members are not used as professional interpreters> children and young relatives are not appropriate in any context

If an on-site interpreter is not available, a video remote (video conference) or telephone interpreter can be engaged.

Slide 26 – Final notes

When using interpreters:

• It is not acceptable to simply provide booklets and pamphlets for the patient and/or interpreter to read alone.

• The interpreter should be asked to ‘sight translate’ the content of the consent form and additional information, for example, medications or post-operative care, to the patient. The information required to be ‘sight translated’ should only be 200-300 words long.

• Both the interpreter and health practitioner/delegate are to be present at the time the information is translated and provided to the patient, so that the health practitioner/ delegate can clarify questions that may arise and obtain valid informed consent while the interpreter is present.

• It is the responsibility of the health practitioner/delegate to ascertain that the patient has understood the content of the consent form and other information, not the interpreter’s responsibility.
• If you cannot use an interpreter (e.g. in a case of emergency), you should clearly document in the patient’s record why the circumstances justified you not using an accredited interpreter.

Slide 27 – Children and youth

In Queensland, anyone under the age of 18 is considered a ‘minor’. In cases involving younger children who are likely to lack the maturity and understanding to make important health decisions, their parents will most likely be the decision-makers unless guardianship rests with someone else. Children and young persons under the age of 18 years are able to consent to healthcare where they have sufficient capacity to do so. However, unlike adults, a child or young person is presumed not to have capacity to give their own consent, unless there is sufficient evidence they have such capacity. This is often referred to as ‘Gillick competence’ after a legal case in the United Kingdom.

Slide 28 – Summary

This has been a very brief review of the basics in relation to informed consent and the processes that you should follow when seeking it. As a practitioner/student, you will come into contact with a diverse range of situations and so you are directed to a few key references that were used to develop these powerpoints.

For more comprehensive information about informed consent, you are referred to the following references – used to develop this resource:

