Waitematā
District Health Board
Best Care for Everyone

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05 October 2020

[redacted]

Dear [redacted]

Re: OIA request – Endoscopy procedures

Thank you for your Official Information Act request to the Ministry of Health seeking information on endoscopy procedures.

On 15 September, the Ministry of Health formally transferred your request to Waitematā District Health Board in accordance with section 14 of the Official Information Act 1982.

Before responding to your specific questions, it may be useful to provide some context about our services.

Waitematā DHB serves a population of more than 630,000 across the North Shore, Waitakere and Rodney areas, the largest and one of the most rapidly growing DHBs in the country. We are the largest employer in the district, employing around 8,500 people across more than 80 locations.

In addition to providing services to our own population, we are also the metropolitan Auckland provider of forensic psychiatry, child disability services, child community dental services and community alcohol and drug services.

In response to your request, we can provide the following information:

1. **In the last five years, how many endoscopy consents were undertaken by nurses and could I please get a breakdown of the procedures these consents related to (e.g. gastroscopy, colonoscopy, ERCP (endoscopic retrograde cholangiopancreatography), etc? I also want to know who conducted the procedure.**

At Waitematā DHB, nurses do not undertake consents for any endoscopy procedures. This has been consistent within our hospitals for more than five years.

2. **In the last five years, how many endoscopy consents were done by doctors and could I please get a breakdown of the procedures these consents related to? I also want to know who conducted the procedure.**

All endoscopy consents were done by medical or surgical endoscopists who are involved with performing the procedures.

A breakdown of our endoscopy procedures for the last five years is as follows:

Year	Colonoscopy	Colonoscopy of Post-surgical Anatomy	ERCP	Flexible Sigmoidoscopy	Upper EUS	Upper GI endoscopy
2015	4273	132	313	596	168	3644
2016	4631	138	296	700	183	4159
2017	4169	156	408	685	217	4461
2018	4430	202	471	606	229	4710
2019	5099	213	419	711	248	4981

3. For the last five years, can you please state how many high-risk endoscopy procedures (based on what you classify as high-risk procedures) nurses consented patients to?

As per our response to question 1, Waitematā DHB nurses do not consent patients for any endoscopy procedures.

4. In the last five years, how many deaths have been attributed to endoscopy procedures?

Of the SAC1 events (Severity Assessment Code where the outcome is death or severe loss of function) reported to the Health Quality and Safety Commission by Waitematā DHB over the past five years, none have been attributed to endoscopy procedures.

5. What is best practice in terms of who (i.e. doctors or nurses) should be consenting patients to endoscopy procedures? Should consent be obtained by the clinician conducting the procedure?

It is best practice for the registered health professional conducting the procedure to obtain the consent and this is our practice at Waitematā DHB. Please see our Informed Consent policy attached – **Attachment 1**.

I trust that this information is helpful.

Waitematā DHB supports the open disclosure of information to assist community understanding of how we are delivering publicly funded healthcare. This includes the proactive publication of anonymised Official Information Act responses on our website from 10 working days after they have been released.

If you consider there are good reasons why this response should not be made publicly available, we will be happy to consider your views.

Yours sincerely

Mark Shepherd
Director Provider Healthcare Services
Waitematā District Health Board

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1. General

Purpose

This document contains detailed information about Informed Consent and its application at Waitematā DHB and provides a framework for staff to work within to encourage positive safe practice.

It is intended to act as a reference document for staff when determining how the various Acts and Codes influence decision making regarding the obtaining and verification of informed consent at Waitematā DHB.

In facilitating informed consent, staff are asked to do what is reasonable in the circumstance of a busy clinical setting to ensure that patients are respected, that patients are informed and able to give consent to the procedures required by their care plan.

Patients will be informed Waitematā DHB is a learning environment using posters and patient information sheets or paragraphs in letters

Students are encouraged to be present for learning and should not be actively excluded unless the patient refuses consent. The supervising registered health professional is expected to discreetly advise the patient of the student presence and ensure that their presence is not intrusive to the treatment experience.

In communicating with patients, they will be:

- assured that each registered health professional employee involved in their care plan is competent and complies with the legal and policy expectations of the employer. Employees who are trainees are part of a training programme which ensures that they competent before working in indirect supervision care delivery
- advised of the designation of those looking after them
- advised that students or unqualified staff are directly supervised and supported by DHB staff in their learning

Scope

All Waitematā DHB staff, agents, and representatives are required to work within the framework set out in this document. Health professionals must justify any variations.

1.1 Definitions

Clinical Teaching	Clinical teaching for the purposes of this policy applies to the situation where teaching [including assessment, discussion or observation] occurs that is additional to normal clinical requirements, or involves someone not qualified to undertake the procedures on their own.
Explicit Consent	In relation to the removal, retention and disposal of body parts, explicit consent is written consent signed by the patient or the legal representative of the patient. If this is not possible, a health professional may act in the best interests of the patient taking into account the views of those who are available with an interest in the patient's welfare.

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Healthcare Procedures	"Services" are defined in clause 4 of the Code of Rights to include "health care procedures". Healthcare procedure is defined in section 2 of the Health and Disability Commissioner Act 1994 to mean "*any health treatment, health examination, health teaching, or health research carried out on or in respect of any person by any health care provider*".
Informed Acceptance	In relation to the removal, retention and disposal of body parts, informed acceptance is the provision of information that a reasonable consumer would expect in the circumstances about the standard procedures with the opportunity to question or reject the procedure or practice.
Informed Consent	Informed consent may be defined as the process whereby someone who has the capacity and competence to consent to a given treatment or procedure, having been given sufficient information which he or she has understood, voluntarily arrives at a reasoned decision as to whether or not to agree to the proposed treatment or procedure. This should be a process which is responsible to the needs, wishes, capabilities and expressed concerns of the particular patient.
Registered Health Professional	"Registered Health Professional" is defined as: a health practitioner who practises in a regulated profession in New Zealand and must be registered with the relevant responsible authority and hold an Annual Practising Certificate (APC) issued by that authority.
Observer	"Observers" [including students] are defined as those additional to the normal medical/midwifery/nursing / allied health professional team immediately involved in the procedure and staff directly concerned with the on-going care.
Patient	The term "consumer" is used in the Code of Health and Disability Services Consumers Rights when referring to individuals who receive health or disability services. Services in Waitematā DHB usually refer to patients, clients or service users according to the type of service. **For consistency, the term "patient" has been used in this document.**
Services / Treatment	"Services" are defined in clause 4 of the Code of Rights as: "Health services or disability services, or both; and includes health care procedures". The term "treatment" is also used; both include allied health services.
Student	Student refers to someone not employed by Waitematā DHB and who is enrolled in a recognised health professional training programme and who is not ordinarily part of the health care team and works under the direction of a registered health professional who is responsible for the patient and the expected outcome.
Supervision	The active process of directing, guiding, oversight, co-ordinating, monitoring and influencing the outcome of a task/function delegated to ensure that the expected standard of safe care is provided Supervision may be: • direct (registered health professional [RHP] is present, observes work, and directs • indirect (RHP is easily contactable and does not directly observe the activities because the staff member or RHP Trainee has been assessed as competent and knows when to call for assistance
Trainee	A registered health professional, who is employed by the DHB, has been assessed as competent and is enrolled in a training programme which will lead to a specialist qualification. They work in an indirect supervision arrangement with the training programme supervisor to meet advanced learning outcomes.

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1.2 What is Informed Consent?

Informed consent is founded upon the principles of self-determination, veracity, responsibility and accountability.

Informed consent assumes three key elements:

- Effective communication [Right 5]
- Provision of all necessary information to the consumer [Right 6] and
- The consumers freely given and competent consent [Right 7]

Notably, the informed consent process applies not only to procedures but to the provision of all health services.

Informed consent is **not** the process of filling out forms, but rather the exchange of information so that the person can make an informed decision about the healthcare options, including the option of refusing the service.

Consent may be given verbally or in writing however the process i.e. discussion and decision should always be well documented in the clinical record. [Refer: *When is Written Consent Required?]*

1.3 Why is Informed Consent Necessary?

The patient has the right to be accurately and adequately informed about a proposed treatment, procedure or intervention and to agree or refuse to have that treatment, procedure or intervention.

All health professionals have a responsibility and obligation to inform patients about proposed treatments, procedures and interventions and to gain consent to them. This is one facet of the duty of care that they owe to their patients.

1.4 When is Consent Required?

Generally, informed consent must be obtained for each treatment or procedures proposed e.g. anaesthesia and surgery are separate procedures. There are, however, situations when a group of procedures or treatments are closely linked and consent for each individual treatment or procedure would be inappropriate [Refer: *Composite Procedures*].

In situations where a series of similar treatments is undertaken [e.g. dialysis, counseling], it is expected that a full explanation / discussion is held prior to or at commencement of care provision. On subsequent visits / appointments, agreement to proceed should be confirmed and any new questions/issues covered. If the plan previously agreed changes significantly, a new consent process should be undertaken [including new written consent if applicable].

There are some limited situations in which individuals may be treated without consent. Acts of Parliament such as the Mental Health [Compulsory Assessment and Treatment] Act 1992, control the conditions under which this may happen. [Refer: *Laws Relating to Procedures where Patient Consent is Not Required*].

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1.5 Levels of Consent - Implied, Verbal or Written

For routine minor interventions e.g. taking of blood pressure or observations, the patient should be informed of what is happening and implied consent can be taken from their agreement. This may also be covered by the patient's agreement to a package of care, e.g. their agreement to be admitted and monitored.

Consent for secondary purposes e.g. blood testing in case of needle stick injury, should be documented.

Consent must be in writing if:

- The patient is to be placed under general anaesthetic or sedation; or
- There is a significant risk of adverse effects on the patient; or
- The procedure is experimental; or
- The patient is to participate in any research; or
- Body parts or tissue are to be removed [information provided must cover removal, retention, return or disposal]; or
- Blood components and products are to be used ; or
- A student is to perform an intimate examination; or
- When either party requests it.

All staff are supported to challenge other Registered Health Professionals where consent has not been obtained or this policy has not been followed. Staff should also escalate concerns to their clinical leader.

Explicit verbal consent is required in all other circumstances.

1.6 Documentation of Consent or Written Consent

Written consent has two main purposes:

- ***The protection of the patient and their rights*** by ensuring that health professionals do take steps to secure informed consent and to alert the patient to the fact that some procedures are more significant than others. The issue of significance must include an assessment from the patient's perspective.
- ***The protection of the health professional and the institution*** as evidence that the legal and ethical requirements for gaining informed consent have been carried out.

If there is any doubt as to the level of consent required, written consent must be obtained. Signed consent forms are first base evidence that a patient consented to the treatment of procedure described. Verbal consent should be noted in the clinical record.

In any circumstances involving apparently contentious issues of informed consent, or if the patient does not consent, relevant information is to be clearly documented in the clinical record.

In situations in which a patient cannot consent for himself or herself, it should be recorded who gave consent and their relationship to the patient. These situations include children under 16, and those whose mental state leaves them [temporarily or permanently] without the capacity to consent [Refer: Legal issues relating to children and Diminished capacity and competence to consent].

Children under the age of 16 giving birth should have their views taken into consideration, but can only consent if they have sufficient maturity to understand the clinical issues and treatment options including risks and benefits and are able to express their wishes.

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Documentation of the consent discussion and decision is to be made in the clinical record, including as appropriate:

- Notes of information provided [including written material]
- Specific issues of concern and/or wishes of the patient
- Important questions asked by the patient and answers given/who was present
- Who gave consent

Note: Where a surgical procedure involves laterality, the words "left" and "right" are used rather than abbreviations "L" and "R".

1.7 What and How Much Information

The test of what and how much information is required is that which "a reasonable patient, in that patient's circumstances, would expect to receive" in order to make an informed decision.

Every patient has the right to receive:

- An explanation of their condition; and
- An explanation of the options available, including an assessment of the expected risks [including likely consequences if the treatment is not provided] and side effects, benefits and costs of each options [options include alternative treatments and/or a second option]; and
- Advice of the estimated time within which the services will be provided: and
- Notification of any proposed participation in teaching or research, including whether the research requires and has received ethical approval; and
- Any other information required by legal, professional, ethical and other relevant standards; and
- The results of tests; and
- The results of procedures.

Every patient has the right to honest and accurate answers to questions relating to services, including:

- The identity and the qualifications of the provider; and
- The recommendation of the provider; and
- How to obtain an opinion from another provider; and
- The results of research.

Every patient has the right to receive, on request, a written summary of the information provided.

The higher the probability of risk or the greater the magnitude of harm, the more care and detail in giving information is required. There is no fixed threshold [e.g. occurs in >1% of cases] for defining what must be discussed. For example: a 1 in 1000 chance of death should be discussed but not necessarily a 1 in 5-chance of minor discomfort.

Patients should be informed of rare risks that are more likely because of their particular circumstances, or which would have greater significance for that particular patient e.g. risk of bleeding in someone taking anticoagulants or the consequences of arm nerve damage for a carpenter.

Enabling informed consent involves some level of checking that the patient has understood what he or she has been told. No consent should be requested until the health professional is satisfied that the patient has demonstrated an adequate understanding of what is proposed.

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It is accepted that patients may refuse information or will not want detailed information about complications. The clinician still has an obligation to ensure the patient has had core information on the procedure and its implications.

1.8 Primary Responsibility for Information, Consent and Delegation

The primary responsibility for ensuring information is imparted and for obtaining consent lies with the Registered Health Professional who is to carry out the treatment or procedure.

In some situations it is impracticable for all **information** to come from the Registered Health Professional conducting the treatment or procedure.

- In such cases the appropriate Registered Health Professional familiar with the treatment or procedure and with adequate knowledge of the risks and benefits of the treatment or procedures should impart the information.

Where it is impracticable for consent to be **obtained** by the Registered Health Professional conducting the procedure, an appropriate Registered Health Professional may delegate this responsibility.

The Registered Health Professional doing the procedure must ensure that this is only delegated to another Registered Health Professional who is familiar with the issues noted above but who also fully understands the associated risks and benefits for **that particular patient.**

1.9 How Should Information be Given?

Registered Health Professionals must try to reduce in all possible ways, any feelings of excessive dependency, vulnerability or discomfort the patient may have about asking questions or suggesting alternative points of view.

There should be privacy for discussions of diagnosis and treatment options. Where practical, for example in outpatient clinics, patients should be encouraged to dress in their own clothes and be comfortably seated before discussion of diagnosis or treatment options is held.

Information should be given in a language, style and form that the patient can easily understand. Where necessary and reasonably practicable it should be translated into the patient's own language by a competent interpreter.

Patients should be advised that they have a right to have another person or persons present during the discussion related to the proposed treatment or procedure. A Health Advocate may attend at the request of the patient.

Any available written or audio-visual material should be included where it could be helpful in providing the information needed and supporting the discussion. Patients should also be referred to any other relevant and reliable resources e.g. websites.

Sufficient time should be allowed for the patient to read the written information and discuss this and any verbal information with whomever he/she wishes.

Patients should be advised of how any further questions can be addressed and who to contact.

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1.10 Team Approach to Providing Information

In situations where a team is involved in management or treatment, the process of imparting information may be shared between various members of the team. Each team member should document the information/discussion covered.

Anyone involved in the care or treatment of a patient who believes the patent is not being kept adequately informed should convey this to the person responsible either directly or through another member of the team.

1.11 Team Approach to Obtaining Consent

Where the situation arises where obtaining consent is delegated, the patient should be told the reason why the person carrying out the treatment or procedure could not personally obtain consent.

Any Registered Health Professional delegated the task of obtaining informed consent who does not have the knowledge of the procedure/treatment and risks and benefits has a responsibility to inform their consultant/supervisor so that alternative arrangements to get consent can be made.

1.12 Right to Refuse

Under section 11 of the New Zealand Bill of Rights Act 1990 ad Right 7[7] of the Code, every competent person has the right to refuse or withdraw consent to services.

It should be made clear to the patient that he or she has the right to refuse or withdraw from treatment without fear of recrimination or penalty [Refer: Refusal of Treatment].

The section titles ‘Laws relating to Procedures where consent is not required’ summarises situations where this right does not apply.

1.13 How Long is Consent Valid?

Verbal consent should be reaffirmed immediately prior to a procedure or intervention. Where written [evidence of] consent is required, the length of time that written consent may still be considered valid is dependent on:

- The nature of the procedure
- Likelihood of change in health status between consent and procedure
- Progression of condition
- Change in competence
- Significant change in the patient’s personal circumstances.

Services may have in place processes that assume a set period consent is considered valid. The factors above need to be considered in establishing such a timeframe and also considered on an individual patient basis.

Once given, it is only when the patient’s condition or circumstances have materially changed that information or consent may no longer be considered valid.

Where there has been a delay of two months or more between the point where the information was provided and the procedure takes place, the critical clinical information should be reiterated and this discussion documented.

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Services must have in place appropriate processes to continue to engage with the patient so there is an opportunity for any changes in the patients circumstances [clinical and personal as above] to be discussed and addressed. When the consent form was signed is less important], particularly in a case when significant surgical intervention is involved,

Regardless of when a consent form is signed, what is important is the patient's voluntary, competent and informed consent ***at the time*** of the procedure.

1.14 Advance Directive

Every patient may use an advance directive to give informed consent or, or refuse, a healthcare procedure.

An advance directive is the patient's instruction to consent to or to refuse treatment given at a time when the patient was competent, for use when they are subsequently of diminished competency.

An advance directive can be verbal or written, however a patient making an advance directive should always be asked to document that directive, and where that is not possible it should be documented in the clinical record and signed by the patient.

Issues to consider are:

- An undocumented verbal advance directive may be difficult to substantiate. Written advance directives are preferable.
- Was the patient competent to make the directive at the time it was given?
- Whether the patient's consent/refusal was likely to be on an informed basis
- Was the patient free from undue influence in making the directive?
- Whether the advance directive is likely to have become out of date\whether the patient is likely to have changed their mind
- Did the patient intend the directive to apply to the present circumstances?

1.15 Effective Communication – Specific Requirements

Registered Health Professionals must exercise special care when patients may have difficulties in understanding what is proposed or in making their own views known. Patients who may have such difficulties include:

- **Those from a different cultural background**: Cultural differences in decision-making should be respected. This process may require involvement of family members in the information giving and decision making.
- **Those not proficient in English:** Patients must have an adequate understanding of what is proposed in order to give informed consent. The involvement of a recognised interpreter may be necessary, particularly for situations involving written consent.
- **Those disabled by confusion, an altered state of consciousness, mental incompetence, speech or understanding difficulties or hearing problems**: Information may need to be presented in a facilitated way or by alternative means e.g. non-verbally. Clinicians should seek and take into account the views and advice of families and/or paid caregivers who are familiar with the patient's means of expression and communication.

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- **Those who have literacy disabilities**: Health services still have a high expectation of literacy amongst patients which is unsubstantiated; all information should be provided at a level that a 12 year old could be expected to understand. All written information should be at a level of an 8 year old understanding and be vetted by consumer groups.

  Some patients will require a formal assessment of their communication [receptive or expressive] so that the Registered Health Professional gaining consent can be confident the patient understands the information or expresses their requirement adequately. Any such assessment by e.g. Speech Language Therapist, Occupational Therapist is to be clearly documented.

1.16 Children's & Young Persons

The Code of Health & Disability Services Consumer Rights applies to children as it does to adults. The general provisions outlined in this policy apply to children and young people.

There are however specific provisions regarding who can consent on behalf of a child and in what circumstances a child or young person may consent.

1.17 Involving Children in Information Giving

In addition to imparting information in order for parents/guardians to make a decision on the child's behalf, information should, where practicable, be given to the child in a way that the child can understand and, where possible, the child's agreement should also be sought. Of course this will vary with the age of the child, but the general principle is to involve the child as much as possible.

Under the Code of Health and Disability Services Consumers' Rights everyone is presumed competent to give informed consent unless there are reasonable grounds for believing the person is not competent (Right 7(2)).

The Code is subject to section 36 of the Care of Children Act. Section 36 provides that a young person over the age of 16 to medical, surgical or dental procedures (including blood transfusions) has effect as if the child was of full age.

For children and young people under the age of 16, Section 36(3) states that consent may be given:
(a) by a guardian of the child
(b) by a person who has been acting in the place of a parent, if there is no guardian in NZ or no guardian who can be found with reasonable diligence who is capable of giving consent
(c) by a District Court Judge or the chief executive of Child, Youth and Family, if there is no person in NZ who has been so acting.

Section 36 does not state that a child or young person under 16 cannot give a valid consent and it is likely that the NZ courts would follow the English case of *Gillick v West Norfolk & Wisbech Area Health Authority* [1985] 3 All ER 402. In the *Gillick* case the highest English court held that children and young person may consent to medical treatment when they are old enough and mature enough to decide for themselves. Provided the child or young person is capable of understanding what is proposed and of expressing his or her wishes.

The test of whether a child or young person under 16 years can give consent is whether they have sufficient maturity to understand their condition, the options for treatment and any risks or benefits associated with each treatment option and are able to express their decision with respect to treatment. Where a child or

young person has sufficient maturity and can express their decision, the child or young person's decision will prevail over the parents' wishes.

Even though children and young persons may legally be able to give valid consent, parents should be involved in the decision making process wherever possible.

2. Teaching and Observers

All healthcare settings should be learning environments where clinical teaching and learning occur as part of day to day practice. Additionally, as a teaching institution, formal teaching occurs. This includes further education for registered and employed clinical staff and training for unqualified students.

Patients, however, have a right to consent to or decline involvement in teaching including the presence of observers during treatment or examination. The primary obligation is to provide the patient with sufficient information for them to give or withhold their informed consent. This includes being informed of the identity and qualifications of the provider.

Patients also have the right to be treated with respect and to receive effective communication.

Teaching of qualified staff occurs in a range of situations from undertaking of procedures under supervision to directly observing procedures to discussion of case studies. Teaching therefore covers both the provision of healthcare services and the use and disclosure of health information.

2.1 Core principles

Consent for involvement in teaching applies not only to interventional procedures but also to observation of them.

Some teaching occurs within the clinical team as part of the optimal provision of care for that patient e.g. case discussion or assistance with a procedure. Teaching is simply a secondary element of sound care provision. The basic provisions of common courtesy and respect apply, however specific patient consent is not required.

Where teaching [including assessment, or discussion or observation] occurs that is additional to normal clinical requirements or involves someone not qualified to undertake the procedure on their own. In this case, an explanation is to be given to the patient and their explicit permission sought.

This section applies to:

- Students in training
- Staff in recognised training programmes
- Registered and employed clinical staff undertaking on the job training and further education
- All teaching staff

2.2 Principles for Clinical Teaching

Where teaching [including assessment or discussion or observations] occurs that is **additional to normal clinical requirements for that patient in that patient's circumstance,** or involves someone not qualified to undertake the **procedures on their own,** an explanation is to be given to the patient and their explicit permission sought.

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Common courtesy indicates that there should be an appropriate introduction of the student and identification of their role. An explanation of what is occurring and why, should be given as part of the **usual interaction with the patient**.

Patients who are not able to give informed consent on their own behalf should not generally be involved in procedural teaching without the consent of their representative.

Where practicable, the request to the patient should be made without the student present so the patient is able to freely decide whether or not to be involved in the teaching situation. However, where the trainee/student attends on their own they must obtain the patient's agreement.

Every patient has the right to withdraw from the teaching session at any stage and must receive a clear prior assurance that refusal to participate in teaching or withdrawing from teaching will not jeopardise his or her care in any way.

Patients have the right to have a support person present at any time including during intimate examinations such as rectal or vaginal examinations.

Verbal discussions about involvement in teaching should be recorded in the clinical record for reference.

There are further obligations in regard to involvement of students in training.

2.3 Intimate Examinations

Such examinations are of critical importance and need to be properly learned by health professionals. The commonest cancers (prostate and breast) for both men and women are disclosed by such examinations.

Responsibility for eliciting the essential consent to teach these procedures rests with the supervising clinical teacher.

Multiple intimate examinations on one patient by a group of students is prohibited.

Intimate examinations by students under general anaesthetic require the same consent process i.e. the patient MUST consent for teaching BEFORE anaesthesia or pre-medication is given.

- Multiple examinations are, as in the general setting, prohibited.

Clinical teachers should use chaperones appropriately when teaching intimate examinations.

Patients have the right to have a support person present particularly during intimate examinations such as rectal or vaginal examinations.

2.4 Clinical Teaching of Students in Training

In the partnership between patients, teaching staff and student, the paramount consideration must always be the welfare and interests of the patient/

Patients are not to be involved in clinical teaching of students without their being fully informed and their freely given consent. Verbal discussion about involvement in teaching must be recorded in the clinical record for reference.

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Teachers and students must ensure that other requirements of this policy are met in clinical teaching situations. This includes the requirements for Effective Communication – Specific Requirements.

Physical examination or specific procedures undertaken by a student must not be repeated unreasonably on any patient, or to the patients detriment and must not produce or prolong unreasonably any distress, embarrassment or pain.

Students should comply with any other policy requirements including the presence of a chaperone where indicated.

Students are entitled to question or challenge their supervisor / other staff if they believe these provisions are not being met appropriately. If on challenging their supervisor, the students receive a response that they consider unhelpful or inadequate, advice should then be sought from their teaching institution.

2.5 Supervision of Student Experience

An effective healthcare setting needs a continuing supply of qualified staff. An essential requirement for training health professionals is access to well-planned and properly supervised practical experience.

Good quality experience for students is based on a three-way partnership between:

- the patient who agrees to be part of teaching/learning processes
- teaching staff
- and the student

This involves cooperation between the teacher and other qualified staff.

The quality of patient care is the responsibility of the clinical team and not the student.

Students providing aspects of clinical care and treatment must be supervised by their clinical team and supported by the teaching staff.

2.6 Consent for Involvement of Students

Every patient has the right to decide whether he or she agrees to an interview, examination or other specific procedure carried out by a student or in the presence of a student.

Every patient has the right to withdraw from the teaching session at any stage and must receive a clear prior assurance that refusal to participate or withdrawing from teaching will not jeopardise his or her care in any way.

It is generally not necessary for student to get written consent for their participation in specific interventions. **Students must get written consent to perform intimate examinations.**

Patients have the right to know the name and professional status of any person who wishes to interview them for teaching purposes and /or examine them, or to carry out specific treatment or investigation procedures. **Students must introduce themselves to the patient and must on each occasion explain clearly their role e.g. observing, assisting under supervision.**

Teachers must obtain a patients permission to involve him or her in group teaching or clinical demonstration session and explain exactly what will be involved and how many students will be present.

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2.7 Consent for all Students in Theatre / Operating Room / Procedure Room

In theatres /operating room/ procedure room, supervising consultants and registrars must inform patients that a student is assisting or observing as part of the anaesthetic or surgical team and that any practical task undertaken by that student will be directly and closely supervised. Verbal consent must be obtained. The consent and the student role should be documented on the consent form by the Registered Health Professional responsible. The consent should be obtained before premedication is given.

A student must get written consent to perform intimate examinations with the guidance of the supervising consultant and registrar.

Where prior consent could not be obtained e.g. opportunity to observe an unusual or an unexpected finding, and there was a clear teaching purpose, the patient or their representative must be notified as soon afterwards as practicable.

Consent to Perform Intimate Examination must always be Supervised

Senior staff members [consultant, senior registrar] are responsible for obtaining consent. Student needs to ensure that consent has been obtained and to document that verbal consent has been obtained in the patient notes. Student must always have a senior staff member present [consultant, senior registrar or nurse with GTA teaching] when performing any intimate examination e.g. breast, pelvic, speculum examinations.

2.8 Confidentiality

Students are responsible for ensuring that personal information acquired by them about a patient remains confidential.

2.9 Case Studies

Consent for case studies should be specifically obtained and recoded in the patient notes, recording that the patient is aware of who is likely to hear or see the information in the case study, and their consent to this.

In some situations, a patient will agree to have the student involved in supervised management or teaching, but not give consent for involvement in a case study.

2.10 Observers Not Involved in Clinical Care

On occasion, an observer may be present who is not directly involved in the patients immediate clinical care team e.g. Company representative on introduction of new equipment or visiting clinician.

The Registered Health Professional responsible for the patient must explain the observer's role and seek the patient's permission for the observer to be present. The consent must be documented in the clinical record.

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2.11 Academic Advice to Medical Students

Consent for Taking a History in Clinic

Senior staff members [consultant, senior registrar] are responsible for obtaining consent. Students need to ensure that consent has been obtained and to document that verbal consent has been obtained in the patient notes. It is of course the patient's right to decide whether to agree to an interview, examination or procedure by a student

Consent to Perform Intimate Examination under Anaesthetic in Theatre

Senior staff members [consultant, senior registrar] are responsible for obtaining consent. This is written consent.

Consent to Use Patient Information in Case Studies or Presentations

As part of clinical education process, patient based case studies may be used to provide examples of health scenarios for teaching and learning purposes. It is essential to ensure that identifying information, or combination of information that could identify the patient, is deleted from any case study material. It is essential to gain the patient's consent for the use of their information for teaching purposes. Verbal consent recorded in the patients file is appropriate.

All staff and students on placement in the Waitematā DHB are bound by the Health Information Privacy Act and the Waitematā DHB privacy policy in relation to the use of patient information.

3. Research

3.1 Principles for Research

[Refer: DHB policy "*Obtaining Informed Consent for Participation in Research, Feb 2013*"]
Patients have a right to consent to or decline involvement in or to take part in research.

Any research involving patients must have Health & Disability Ethics Committee (HDEC) approval or an Independent/Institutional EC approval where required (refer to NEAC guidelines July 2012). Additionally Locality Management approval must be sought to ensure that appropriate mechanisms are in place for identifying patient and gaining informed consent (refer to Awhina Research and Knowledge StaffNet site for guidance).

The Code of Health and Disability Services Consumer Rights extends to those occasions when a consumer is participating in or it is proposed that a consumer participate in research.

Patients must not be included in research without their written informed consent. Patients not able to give informed consent on their own behalf should not be involved in research without the consent of their representative and should not be involved in research where patients who can give consent could be approached instead.

Every patient has the right to withdraw from the research at any stage and must receive a clear prior assurance that refusal to participate in research or withdrawing will not jeopardise his or her care in any way.

Informed Consent

Patients have the right to know the name and professional status of any person who wishes to interview and / or examine them, or to carry out specific treatment or investigation procedures.

Researchers are responsible for ensuring that personal information acquired by them about a patient remains confidential.

4. Composite Procedures

Introduction

Patients should give informed consent for each treatment or procedures before it begins. However, there are times when a group of procedures or treatments are closely linked and should be discussed as a composite procedure for the purpose of gaining consent.

4.1 Interdependent Treatments

Interdependent treatments are when treatments are routine and necessarily interdependent, for example, administration of general anaesthetic, endotracheal intubation and the insertion of intravascular lines, which accompanies major surgical procedures, to be followed by a period of mechanical ventilation.

In such cases, all the component procedures should be obtained to the patient as part of the explanation of the treatment for which she/he is being asked to consent.

4.2 Conventional Treatments for Complications

There are conventional treatments used for the immediate management of acknowledged common potential complications related to a procedure for which consent has been obtained. In this case, it may not be possible to gain the patient's informed consent to that of his/her representative for the specific treatment because of the complexity or urgency of the situation.

4.3 Potential Pathology Confirmed during Surgery

Consent can be given by the patient for appropriate further action in the event of potential pathology being confirmed during the procedure for which he/she has given consent. For example, the surgeon may proceed to a more extensive operation following a biopsy that is confirmed as malignancy during frozen section analysis.

The patient should be informed as the possible nature of the additional surgery and the consequences of non-consent e.g. further surgery. If the patient is unable to make an informed decision without a confirmed diagnosis, consent to a composite procedure should not be sought.

4.4 Limitations on Composite Procedures Consent

Consent to composite procedures should never be used to imply prior consent to treatment or procedures that are not routinely used in the clinical procedure for which the patient has consented and / or unproven in the situation, event in an emergency.

Informed consent from the patient or his/her representative should always be sought for the use of extreme measures or unconventional treatment.

Informed Consent

4.5 Unforeseen Pathology during Surgery

In the event of unforeseen pathology being discovered during the procedure for which the patient consented, the surgeon should not perform a definitive procedure for that pathology during that procedure. The diagnosis should be considered separately and separate consent to treatment gained from the patient, except where this approach significantly increases procedural risk to the patient.

5. Blood Components and Products

[Refer: *Blood Component/Product Administration Policy*]

5.1 Prescribing

Blood components and products are registered medicines in New Zealand [Medicines Act 1981]. They must be prescribed by a registered medical practitioner or where appropriate a registered midwife and this must be recorded in the patient's clinical record.

5.2 Information

As with any other prescribed drug, the patient must receive adequate information on the reasons for the transfusion, the risks, the benefits and the adverse sequelae that may result if the transfusion is not received.

All patients must receive the relevant New Zealand Blood Service information brochure on the blood components or products prior to giving informed consent. This should be documented in the clinical record.

5.3 Consent

The patient or their representative must normally agree to the transfusion before it is carried out. **Written consent must be obtained for the use of blood components and products.**

The patient's decision to refuse blood components and products should be clearly documented in the patient's record. This documentation should include details of the advice given to the patient, including discussion of alternative courses of action e.g. not performing surgery and their implications.

In circumstances where the patient cannot give informed consent [e.g. under anaesthesia], blood components and products may be given if required unless there is knowledge that the patient would not agree.

As a general rule, when consent is being obtained for an anesthetic, consent would also be obtained for the use of blood components and products if in the particular circumstances there is a significant risk, of 1% or more, of these products being required.

5.4 Refusal of Blood Components and Products

Where blood components and products are refused by an adult for any reason [e.g. religious beliefs], this decision must be respected; ensuring that those making the decision fully understand the implications this may have on the clinical outcomes.

Informed Consent

When this decision is made by one or more people on behalf of another who is not capable of making the decision, such as in the case of a minor, there is provision for the decision to be legally challenged. [Refer: Diminished Capacity & Competence to Consent]. When situations such as this occur, advice should be sought from the Medical Advisor and/or DHB Legal Counsel.

In both situations, it is recommended discussions be held with the Clinical Director/Medical Director of the unit/hospital, exercising the 'one up' authority principle.

5.5 Information brochures

The patient brochures on blood components and products, prepared by the New Zealand Blood Service, should be widely available, particularly in areas where blood components and products are regularly given. [Refer: *Blood Component/Product Administration Policy*].

6. Diminished Capacity and Competence to Consent

Introduction

While the principles of this section apply to all patients, specific provisions for children and young people are covered in relevant documents relating to legal issues relating to children.

For consent to be valid it must be voluntary, knowing or informed and competently given. Illness, medication, intellectual disability, dementia, mental illness, delirium, inebriation or head injury and other physical injuries all may affect the informed consent process.

Right 7 (2) of the Code of Rights provides that everyone must be presumed competent to give informed consent, unless there are reasonable grounds for believing that the person is not competent.

As stated in Right [3] of the Code of Rights a patient with diminished competence retains the right to give informed consent appropriate to that patient's level of competence.

6.1 Capacity to Consent

Individuals with the above conditions may lack the capacity to fully give or withhold consent. In the case of intellectual disability this is a permanent state. In other cases it is an acquired state which may be brief or prolonged.

A person may be competent in some respects e.g. to manage their financial affairs and incompetent in others e.g. to understand the effect if illness upon them or to assess the value of treatment. Medication can alter the mental state and may either improve or impair competence.

6.2 Determining Competence

Clinicians are often called on to determine competence i.e. to form an opinion as to whether a patient has the capacity to give informed consent. By definition it is not possible to know in advance of assessing a patient whether s/he is competent or not and so able to consent to the assessment. However, in such situations, the willingness of the person to participate combined with sensitivity on the part of the clinician performing the assessment is likely to be sufficient given that the assessment process usually involves

either passive observation or purely verbal engagements which the patient can decline to cooperate with or withdraw from if they change their mind about taking part in the assessment.

The courts have identified a number of factors relevant to determining competence. These are the patient's ability to:

- Understand and retain relevant information
- Understand the nature and consequences of options
- Weigh the information, balance the risks and benefits and arrive at a choice
- To communicate their choice
- Give reasons for their choice.

Note that an imprudent decision is not the same as an incompetent decision**.**

A person with partial capacity retains the right to make a decision to the degree to which they are competent to do so.

If the patient is both legally and clinically competent, the usual guidelines for informed consent apply.

6.3 When a patient lacks capacity to give or withhold consent

Where an adult patient lacks, wholly or partly, the capacity to understand the nature and to foresee the consequences, of decisions in respect of matters relating to his/her personal care and welfare, the right to consent to treatment rests with:

- An attorney under an enduring power of attorney ("EPOA") in respect of welfare. The EPOA must be activated by a medical practitioner. The EPOA and certificate of activation should always be sighted and a copy taken for the patient record.
- A welfare guardian appointed under the Protection of Personal and Property Rights Act 1988. The order appointing the welfare guardian should always be sighted and a copy taken for the patient record.

If there is neither an EPOA nor a welfare guardian, then treatment may be provided under Right 7(4) of the Code of Health and Disability Services Consumers' Rights. For treatment to be provided under Right 7(4) the following conditions must be met:

- Treatment must be in the patient's best interests. This is a clinical decision which must take into account the benefits and risks of the proposed treatment.
- Reasonable steps must be taken to ascertain the patient's views; and
- Either, if the patient's views have been ascertained, treatment must be believed to be consistent with the choice the patient would have made if s/he were competent or
- If the patient's views have not been ascertained, the views of other people interested in the patient's welfare and available to advise must be taken into account.

Where Right 7(4) is relied on, no-one is entitled to sign the consent form. The senior clinician should document the steps taken to establish capacity and to seek the patient's views and the clinical justification for the treatment.

In some circumstances e.g. where an incompetent patient is refusing treatment and there is likely to be an ongoing need for treatment, it may be appropriate to apply for a personal order under the Protection of Personal and Property Rights Act 1988. Advice should be sought from a Legal Advisor.

Informed Consent

Notes:

- An attorney under an EPOA and a welfare guardian are not entitled to withhold consent to a standard medical treatment or procedure intended to save the patient's life or prevent serious damage to their health.
- These requirements apply equally to a patient who has an intellectual disability and is in the care of an organisation which provides accommodation and other services to people who have intellectual disabilities. Employees of these organisations will generally not have the authority to consent to treatment for their clients. They can however be consulted where treatment under Right 7(4) is being considered.

6.4 Compulsory Assessment & Treatment – Mental Health

If the treatment is for a mental disorder, an application under the Mental Health [Compulsory Assessment and Treatment] Act should be considered.

Responsibility for the treatment of a compulsory patient under the Mental Health [Compulsory Assessment and Treatment] Act is vested in the responsible Clinician in terms of the Act. Such patients are subject to a compulsory treatment process under the Act.

If a patient under the Mental Health Act requires medical treatment and lacks capacity to give or withhold consent, the Protection of Personal and Property Rights Act procedure applies as above.

There is a clear philosophy in the Mental Health Act that requires the patient and/or his principal caregivers to be fully informed at all stages. This is particularly relevant when informed consent cannot be given.

6.5 Medication & Competence to Consent

Medication given for pain relief, in anaesthesia, or to treat psychiatric illness may affect conscious awareness and competence to consent. This is a complex issue.

Although consciousness may sometimes be impaired, there is often an improvement in concentration and thinking ability with the relief of symptoms such as pain, anxiety and depression. Conversely, unrelieved pain, anxiety or depression may of themselves impair competence.

Where practicable, discussion about treatment should take place before administration of medication liable to affect consciousness. When a patient's competence clearly has been impaired by medication and the procedure is not urgent, recovery should be allowed before consent to further treatment is sought.

In principle, consent should not be sought when a patient is drowsy or unable to concentrate. In practice however, consent for further treatment will sometimes be necessary from patients who have for instance received medication for pain relief. In no circumstances should written consent be obtained once sedation or pre anaesthetic medication has been administered.

It would be impracticable to suggest that consent should never be sought from patients on any medication with the potential to affect concentration and thinking. Sound clinical judgment and common sense should always be exercised.

Informed Consent

7. Refusal of Treatment

Introduction

Refusal of treatment is contained within the Health and Disability Code of Rights. A competent and informed decision to refuse treatment must be respected with no change in the standard of care provided.

In the situation where a patient disagrees with the advice of clinical staff in regard to his/her care and staff are concerned about the implications of this, the following principles apply:

- The patient has the right to make an informed choice
- If she/he is competent to make an informed choice and no other legal constraints apply, the patients choice cannot be overruled and must be respected
- Deciding that a patient is not competent to make an informed choice is a significant step and requires careful consideration and consultation [Refer: Diminished Capacity and Competence to Consent and Incompetent Patient Guideline]

Where a patient is competent and refuses treatment, appropriate risk assessment should be made and appropriate further action taken e.g. referral of care and protection or safety concerns to an external agency, case review with senior colleagues or notifying referrer.

7.1 Clinician Responsibilities

The clinician's responsibilities are to:

- Clarify competence
- Document assessment of competence
- Provide patient with full explanation of and information on the proposed treatment, risks and likely consequences if the treatment is not provided; and options including alternative treatments and / or second opinion
- Document the patient decision
- Involve family/support persons as appropriate
- Seek advice from Clinical Director / Professional Advisor / DHB Clinical Ethics Advisory Committee / DHB Legal Counsel where required.

7.2 Assessment of Capacity for Consent or refusal of Treatment

[Refer: *Incompetent Patient Guideline and Effective Communication – Specific Requirements*]

If there are concerns that the mental health of a patient in a general clinical area has an effect on his/her competence, the Liaison Psychiatry team should receive a referral and requested to assess.

Where there may be language difficulties, an official interpreter, [contacted through WATIS] must be utilised as part of the process to assess competence.

7.3 Documentation – including patient statement

The documentation in the patient's clinical record must include:

- an assessment of the patient's competence to make an informed decision to refuse treatment
- advice given to the patient and concerns of the clinician including a full explanation of consequences, risks and options.

Informed Consent

This is to be completed by the person with prime responsibility for care / or who has given the advice. The advice provided should be documented in detail.

If relevant, the Discharge at Own Risk form is also used in adult [non mental health] inpatient services [Refer: Self Discharging Patient policy]

Should an interpreter be used to assist with communicating with the patient, they should sign the clinical record detailing what was told to the patient

If the patient's condition is serious and persists and resolution is not imminent, the patient should be asked to sign a formal statement in the clinical record. The statement should state the patient:

- Understands the concerns of his/her clinicians
- Understands the advice given [in particular the nature of the proposed treatment/intervention and the risks if that is not provided].
- Has received all information that he/she requires
- Accepts responsibility for the consequences of his/her decision.

If the patient refuses to sign the statement, two staff should sign confirming that they have heard the information the patient was given.

7.4 Ongoing Care

Where possible, an agreed plan should be developed, maintaining communication with the patient and with their family/whanau as appropriate. Detailed entries should be made in the clinical record as the situation develops.

A high standard of care should continue. In some circumstances, a change of clinician may be indicated. Care must be handed over to the subsequent clinician and an explanation given to the patient.

The Duty Nurse Manager / Team Leader or other appropriate manager / senior colleague must be informed.

7.5 If a Pregnant Woman or Foetus is At Risk

Special consideration is to be made in the situation where a pregnant woman refuses treatment.

Should the life of a pregnant woman and consequently her foetus or the life of the foetus be at risk because of the woman's refusal of treatment, the DHB Legal Counsel should be consulted.

7.6 Legal Advice

In other situations where clinicians have ongoing concerns about a patient's refusal of treatment, the DHB Legal Counsel should be consulted.

Informed Consent

8. Laws Relating to Procedures where Patient Consent is Not Required

Introduction

A number of Acts of Parliament provide for overriding the individual's right to decide whether or not to consent to procedures, in cases where the right is seen to work against the public good. The following Acts apply:

8.1 Alcoholism and Drug Additional Act 1996

A judge may issue orders for the detention and treatment of alcoholics and drug addicts

8.2 Care of Children Act 2004

Of considerable importance in hospitals is section 38, which safeguards doctors who administer blood transfusions to persons under the age of 20 years in emergencies where consent to the procedure has been refused.

8.3 Children, Young Persons and Their Families Act 1989, s49, s53

A family Court Judge has the power to order medical examinations and reports in respect of children and young persons. The report must be provided forthwith following the examination. In limited circumstances social workers have the power to require medical examinations.

8.4 Coroners Act 2006

This statute empowers coroners to require an autopsy which the family of the deceased has no right to refuse.

8.5 Crimes Act 1961

Section 41 expressly authorises the use of "such force as may be reasonably necessary" to prevent the commission of suicide, or of an offence likely to cause immediate and serious injury to the person or property of anyone. This allows restraint without consent in the circumstances specified in the section.

8.6 Crimes Investigations [Bodily Samples] Act 1995

This Act provides for a High Court Judge to make orders for the taking of bodily samples from suspects in police investigations when the suspects decline consent.

8.7 Health Act 1956

Under the Health Act 1956 a Medical Officer of Health may impose measures to prevent the spread of infectious disease.

Informed Consent

8.8 Health & Disability Commissioner [Code of Health & Disability Services Consumers Rights regulations 1996]

Where a patient is not competent to give informed consent and there is no one available who is legally entitled to consent on their behalf, treatment may be provided, where it is in the best interests of the patient and reasonable steps have been taken to ascertain the views of the patient or other suitable persons who are interested in the welfare of the patent. Right 7[4]. [Refer: *Diminished Capacity & Competence to Consent*].

8.9 Human Tissue Act 2008

The Human Tissue Act prescribes consent processes for management of deceased person and tissue removed from living people now deceased.

8.10 Land Transport Act 1998

Section 73 of this Act authorises the hospital doctor who has immediate charge of the patient to take a blood specimen, whether or not the person being tested has consented or is event capable of giving consent.

The conditions to be complied with are:

- That the doctor is requested by an enforcement officer to take the blood specimen
- That the doctor has reasonable grounds to believe that the person is there as the result of a motor vehicle accident
- That the doctor is satisfied that taking the sample would not prejudice the person's care and treatment
- The doctor may direct another doctor, nurse or medical laboratory technologist or any employee whose duties includes the taking of blood specimens
- The medical practitioner or medical officer who takes the specimen must tell the person [unless the person is unconsciousness] that the blood specimen is being or was taken for evidential purposes or must notify the person in writing as soon as practicable that the specimen was taken for evidential purposes.

8.11 Mental Health [Compulsory Assessment & Treatment] Act 1992

This Act provides for assessment and treatment of mental disorders. The Act does not provide for compulsory treatment of medical conditions. [Refer: Diminished Capacity & Competence to Consent]

8.12 Protection of Personal & Property Rights Act 1988

Under this Act, a competent individual may appoint an Enduring Power of attorney [EPOA] who has (in general) authority to consent once the patient loses capacity.

Where there is no EPOA, a Family Court may be asked to appoint a welfare guardian with authority for particular aspects of that person's personal care and welfare – including consent to treatment or a personal order authorising specific treatment, or care placement or to order specific treatments. Section 18 of the Act prohibits an EPOA or welfare guardian from making specific decisions, notably consent to ECT, brain surgery designed to change the person's behaviour and participation in any medical experiment other than for the purpose of saving the person's life or preventing serious damage to the person's health.

Informed Consent

Section 18 of the Act obliges a welfare guardian to have, as the paramount consideration, the promotion and protection of the welfare and best interests of the person for whom the guardian is acting.

The Protection of Personal and Property Rights Act 1998 also allow a person to appoint an attorney under an Enduring Power of Attorney. The attorney can make any decision specified in the empowering document, subject to the same restrictions as a welfare guardian.

8.13 Privacy Act 1993

Consent must be obtained for clinical recordings unless staff reasonably believes that:

- Obtaining authorisation would prejudice the interests of the individual concerned or prejudice the purposes of collection
- Obtaining authorisation is not desirable or practicable in the circumstances of the particular case

Not obtaining authorisation is necessary to avoid prejudice to the maintenance of the law by any public sector agency, including the prevention, detection, investigation, prosecution and punishment of offences.

8.14 Tuberculosis Act 1948

A Medical Officer of Health may require the examination of a person suspected to have TB or measures to prevent the spread of TB. A District Court Judge may, under section 16, order a person to be detained in an institution for the purposes of treating TB.

9. Where to Go for Help

9.1 Avenues for Assistance

Where the issue of informed consent is still unclear or the staff member is unsure about the appropriate action to take the following steps should be considered:

- Discuss the matter with any or all of:
  - Experienced colleagues and/or the relevant Clinical Director/ Professional Advisor
  - Director of Nursing and Midwifery
  - Chief Medical Advisor
  - Duty Nurse Manager (available 24 hours)
- Seek advice from Waitematā DHB Legal Advisor
- Consult Waitematā Clinical Ethics Advisory Committee
- Seek the advice of a consumer/patient advocate organisation (e.g. the IHC)
- Contact the office of the Health and Disability Commissioner
- Contact the office of the Privacy Commissioner

10. Post Mortem Examination - Autopsy

Introduction

Post-mortem examinations may be required under the Coroner's Act 2006 or may be requested by the clinician who has responsible for the care and treatment of the patient.

Informed Consent

10.1 Information to be Provided

Appropriate information is to be given to patients / family / whanau according to the circumstances of the procedure or autopsy. [Refer: Body Parts – Autopsy]

10.2 Coronial Autopsy

If a death is reported to the Coroner, the decision whether or not to order a post-mortem examination rests entirely with the Coroner.

The categories of death which must be reported to the Coroner are summarised in the Death of a Patient policy.

10.3 Non-Coronial Autopsy

Requests for non-coronial post-mortem examination must come from the doctors directly involved in the care of the patient and requests are made by direct discussion with the family.

Only with the informed consent of the family may an autopsy proceed. Telephone discussion and requests are acceptable if family is not present. The form "Post Mortem Consent [Non Coroners]" must be completed.

Doctors can ask the family for permission to perform an autopsy for the purposes of research or clarification of diagnosis beyond that required for completion of the Medical Certificate of Cause of Death e.g. implications for management of future pregnancies.

Permission cannot be sought to perform an autopsy to determine the causes of death, as this is a category of death that has to be reported to the Coroner. If in doubt, contact the Coroner.

It is recommended that the doctor directly involved in the case discusses the findings with the family, both at the preliminary stage, and at the final report stage.

11. Tissues / Organs for Transplant and Other Purposes

Introduction

There are specific requirements for consent for removal and use of organs or tissues for therapeutic purposes and for purposes such as education or research. This is governed by the Human Tissue Act 2008.

11.1 Removal of Tissues / Organs at Autopsy

A person may request in writing, or orally before two or more witnesses during his/her last illness, that his/her body [or some part thereof] be used for therapeutic purposes, research or education after his/her death, under the Human Tissue Act 2008.

However, no tissue is removed for therapy, research or education without the consent of specific family members, even where the deceased has indicated prior permission i.e. staff must also ensure there is no overriding objection to the consent given. Specific written consent is sought for any tissue retrieved for these purposes.

Informed Consent

Liaison with the family or patient representative is managed by the Donor Tissue Coordinator [Coroners Office] or Organ Donation NZ Donor Coordinator. Any queries about these situations should be made to Organ Donation NZ.

In coronial autopsies, it is for the Coroner's Office to inform families regarding any removal or retention of body parts or tissue for ongoing examination.

11.2 Consent for Post Mortem Tissues / Organs for Transplant

There are specific requirements for consent and clinical criteria for suitability for organs or issues for transplant. This is also governed by the Human Tissue Act 2008.

Specific consent of the family for removal of organs must be obtained. This consent should be sought by the Intensive Care team caring for the patient. Requests are never made by the 'transplant team'.

In addition, if the death is in a category reportable to the Coroner, the consent of the Coroner will be requested prior to any removal. In practical terms, the Intensive Care team will discuss the case with the Coroner. If the death occurs in the community the request may be made by the Donor Tissue coordinator of the Coroner's office or Organ Donation NZ.

If a patient or family volunteer tissue or organ donation, advice should be sought from Organ Donation New Zealand in the first instance due to the specific clinical criteria and requirements for consent.

11.3 Consent for Living Donation

Living donation of e.g. kidney or liver is facilitated by the IntraAbdominal Transplant Unit. If a patient or family volunteer a living organ donation, advice should be sought from the Transplant Unit due to the specific clinical and ethical criteria and requirements for consent.

12. Photography, Video, Audio & Related Clinical Recordings

Introduction

Patient information is routinely collected as part of the provision of healthcare and does not require explicit consent. Taking a photographic, video or audio recording is collecting patient information in the same way as writing a description of what is seen or heard.

However, it is often outside what patients might expect and may also be perceived as being more invasive and will in some situations be more identifiable.

The Health Information Privacy Code [HIPC] only requires that the patient is informed of the purpose of collection of information; however it is a courtesy in all cases to inform the patient of the intention to collect information in this way. Doing so verbally is required as a minimum. In some cases it is appropriate to get the patients written agreement. In all cases discussion with the patients should be documented.

The use or disclosure of a photographic, video or audio recording is subject to the same restriction as the use or disclosure of other patient or personal information.

Photographic, video or audio recordings of patients or staff occur in five situations:

Informed Consent

- Clinical recordings as part of patient diagnosis and management [including radiology or related imagery]
- Secondary use of Clinical recordings for non-clinical purposes e.g. education and/or research
- Recordings by staff e.g. promotional, media, information
- Recordings by external agencies e.g. promotional, media
- Private recordings [made by patients or their relatives]

12.1 Controlled storage, transmission and access

It is preferred that photographic, video and audio clinical recordings are made by specialist medical photography / technical staff to ensure the quality of image and appropriate storage. It is recognised there are situations where it is appropriate for clinical staff to make these recordings however the same principles and policy statements apply.

Photographic, video and audio clinical recordings should not be made on personal equipment, should be stored in a particular way (health record for access by MDT) and should not be messaged i.e. may only be sent by secure WDHB email if needed.

Having made a record this must be documented in the clinical record.

The use and purpose of any photographic, video and audio clinical recording should be included in the explanation given to the patient of what is proposed to be done to any recording taking place. The level of information to be provided is that which a reasonable consumer in that consumer's circumstances would expect. Relevant information could include who is making the recording; and how the recording will be used and stored e.g. retained within the clinical record.

Where staff or relatives are to be included in the recording their written consent must be obtained for recordings.

Where a clinical recording is an interdependent part of the procedure e.g. colposcopy, all the component procedures should be outlined to the patient as part of the explanation of the treatment/procedure for which she/he is being asked to consent [Refer: *Composite Procedures*]

Every patient subject to the Mental Health [Compulsory Assessment and Treatment] Act 1992 is entitled to be informed where it is intended to make or use a videotape or other visual or audio recording of any interview with or any other part of their treatment [s68].

The requirements of the Privacy Act 1993 and the Health Information Privacy Code 1994 must be observed.

12.2 Agreement / Notification for Photographic, Video or Audio Recordings

In the case of children, notification/agreement should occur with the parent/guardian. Where an adult patient is not competent to understand or agree to collection this may be discussed with somebody acting lawfully, or on behalf of, or in the best interests of the patient.

Where the patient is deceased, see the following section.

In other cases where it is not practicable or appropriate to obtain agreement, discuss with the DHB Legal Counsel.

Informed Consent

Agreement must be obtained for photographic, video or audio clinical recordings **unless** staff reasonably believes that:

- Obtaining authorisation would prejudice the interests of the individual concerned or prejudice the purposes of collection e.g. would cause unreasonable delay
- Obtaining authorisation is not reasonably practicable in the circumstances of the particular case
- Not obtaining authorisation is necessary to avoid prejudice to the maintenance of the law by any public sector agency, including the prevention, detection, investigation, prosecution and punishment of offences e.g. in the case of suspected non-accidental injury of a child or dependent person where it is unlikely that the parent, guardian, patient or care-giver will give authorisation.

12.3 Deceased Patients - Photography

Where the patient is deceased, photographs may be taken where required as an integral part of the autopsy. The taking and use of photographic recordings should be discussed as part of the consent for autopsy. Consent for photography must be obtained.

Stillborn babies and neonatal deaths – photographs may be taken on verbal consent from the parents for the benefit of the parents, these photographs are gifted to the families or stored in the clinical record of the infant should the family wish to review them at a later date.

The consent of the executor/administrator [or next of kin where there is no executor] is required to use or disclose photographs for secondary purposes.

In Coroner's cases, any information collected as part of the autopsy, including photographs, is collected as an agent of the Coroner. Use or disclosure for a secondary purpose requires the consent of the Coroner [to release] and the executor/administrator [to use].

Photographs may also be taken [for secondary purposes] with the executors/administrators consent after the body has been released by the Coroner.

Verbal consent must be documented and the clinical form "Consent to Disclosure / Use of Photographic or Recorded Information" used to document consent for disclosure / use.

Where it is not practicable or desirable to obtain the consent of the executor or administrator e.g. due to the passage of time, photographs or recordings may be used for directly related purposes, such as education and training in a form that does not identify the individual [HIPC Rule 11 [2] [c]]

12.4 Clinical Recordings for Diagnosis and Management

Where photographic, video or audio recordings are made as an integral and necessary part of patient treatment or management, the patient should be informed and their verbal consent obtained – see table below.

Where a patient is clearly identifiable and the material would be considered sensitive e.g. videotape of counselling session, the patient's written agreement is required.

The patient should be advised as soon as possible in cases where prior notification/ agreement could not reasonably be obtained e.g. recording of an unexpected finding during surgery.

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The recording and / or report summarising the findings / results must be held as part of the patient's clinical record. This includes any clinical recordings made on personal devices e.g. mobile phones, PDAs or recordings made using e.g. ward/unit digital camera.

The recording clinical purpose may not be on personal devices at all – only DHB devices.

A copy of the recording may be retained locally in the department for agreed purposes. **These must be held with appropriate security and not retained longer than required**. Units must have clear processes in place to manage these recordings and copies.

All recordings must be identified by patient NHI, surname, date of birth and date of recording
The recordings must be used for patient diagnosis and management. In no circumstances may these recordings be used for education or research purposes unless appropriate consent is given or disclosure allowed under the Health Information Privacy Code.

12.5 Levels of Notification / Agreement

Levels of notification and/or agreement for various photographic, video and audio recordings made as part of diagnosis and clinical management are given as examples in the table below:

Example	Level of Notification/ Agreement	Rationale
Imaging – Radiology	Verbal	Clinical procedures are recording. Integral part of diagnosis and/or clinical management.
Photography for chronological monitoring e.g. wound care	Verbal	Integral part of diagnosis and/or clinical management. Explanation of purpose given to patient.
Photography for patient identification	Verbal	Explanation of clinical management purpose given to patient.
Video – physical healthcare setting gait analysis	Verbal	Integral part of diagnosis and/or clinical management. Explanation of recording given as part of overall explanation of procedure
Endoscopy procedures	Notification as part of consent for overall procedure	Composite procedure requiring written consent. Explanation of recording given as part of overall explanation of procedure.
Surgical photography	Notification as part of consent for overall procedure	Composite procedure requiring written consent. Explanation of recording given as part of overall explanation of procedure.
Audio/video of patient interview or interaction with others – all settings e.g. group or individual counselling, therapy	Written Could be obtained as part of the video – the person stating their name and consent.	Identifiable and potentially more sensitive than summary recording of interview/interaction.
Photography in sensitive cases e.g. sexual or physical abuse	Made as part of normal process of care and treatment. Written unless exceptions outlines above apply.	Identifiable and potentially more sensitive than summary recording.

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12.6 Use / Disclosure of Photographic, Video or Audio Recordings for Education or Publication

Where a photographic, video or audio clinical recording made for clinical purposes is to be used for the purpose of education within the clinical team, disclosure is permitted [HIPC Rule 10 [1] [b] as it is directly related to the purpose in connection with which the information was obtained i.e. as part of the provision of clinical care.

For wider education within the organisation e.g. grand round, the information must be used in a form in which the individual concerned is not identifiable [HIPC Rule [10] [e] [i]

In the case of disclosure for education purposes outside the organisation e.g. conference presentation, **the expectation is that consent is sought**. However under HIPC Rule 11 [2] [c] if it is not desirable or practicable to gain consent the information may be used in a context in which the individual is not identifiable.

Publication provisions below may also apply if the presentation is to be subsequently circulated or published [including online].

Where photographic, video or audio recordings made for patient treatment or management are subsequently to be used for reproduction in a journal or text book, inclusion in a display presentation or any other form of publication, including electronic or digital media, specific consent using the appropriate consent form is required

No recordings may be used for any purpose other than the purpose or purposes specified in the agreement / consent obtained.

12.7 Photographic, Video or Audio Clinical Recordings made for Secondary Purposes

Written consent is required for photographic, video or audio clinical recordings which are made for clinical teaching, research, professional supervision, publication or other purposes. Consent may be taken verbally as part of the video record.

The written consent must cover the purpose and use the recording [intended recipients of the information], the agency that will hold the information, consequences [if any] of declining collection and the patients right to access to the recording [HIPC Rule 3].

The written consent form is immediately placed in the patient clinical record.

Recordings made for the purpose of research must comply with the guidelines and requirements of the DHB policy.

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12.8 Recordings by External Agencies

Any person or organisation requires approval for filming or photography within Waitematā DHB premises.

Proposals for recordings must be submitted verbally or in writing to the Communications Manager or General Manager and include:

- The purpose of the recording
- The proposed audience
- Statement that the proposed recording will fill a unique need and that there is no other suitable material available
- Where appropriate the script is to be submitted for approval.

The Communications Department will coordinate this process. Approval is given for the stated purpose only. [Refer: Media policy]. For all recordings by external agencies, written consent must be obtained for all children and verbal or written consent for all adults [including visitors and staff]. This must be obtained before any recording is made. Consent forms are available from the Communications Department.

12.9 Private Recordings

Private recordings include any photographs, video and audio recordings made in any Waitematā DHB premises by patients or their families/whanau or support person.

Patients, their families or support persons are entitled to make recordings, however, where this will encompass third parties, the person wishing to make the recording must seek the verbal consent of all those likely to be included.

Patients, visitors and staff member's rights to privacy of identification are to be respected. Staff may decline to be included in private recordings. Staff should be aware any private recordings could be placed in the public domain at any stage.

13.Procedure Specific Consent Forms

Waitematā DHB does not encourage the use of procedure specific consent forms.

It is recommended that services use the generic 'Consent to Treatment' form and include specific information in patient information leaflets; and document in the clinical record specific issues of concern discussed.

In limited and specific areas, it may be more appropriate to have procedure specific consent forms however this must be approved by the Health Information Manager and Legal Counsel. These situations could include e.g. course of treatment such as chemotherapy and haemodialysis and where other specific legal requirements apply. [Section 29: form is to be used for unregistered medicine].

The critical part of the process is the information imparted to the patient and documentation in the clinical record. Information sheets and service protocols can be developed to cover common complications and risks that are to be routinely covered with patients.

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14. Staff Education on How to Gain Consent & Communicate with Patients

Staff will be advised of the requirements of this policy in their orientation/induction.

Ongoing there will be regular reminders in inservice and other training sessions and where the document is updated/changed to reiterate expectations.

Staff who seek consent in accordance with this policy must have:

- appropriate knowledge and experience of the procedure being consented
- have received training in best approaches to communicate with patients and their family.

Students should have received training prior to entering the clinical placement and be assisted by DHB staff when seeking consent, in accordance with the requirements of this policy.

15. Audit of Policy Compliance

Audit of compliance with this policy will be scheduled and the findings of the audit discussed by the Clinical Governance Board.

16. References / Associated Documents

Type	Title/Description
Publications	• The Code of Health & Disability Services Consumers' Rights. • Ministry of Health, *Consent in Child and Youth Health* (1998) • Medical Council of New Zealand Guidelines on Informed Consent 1995
Policy	• Auckland DHB policy Informed Consent 2010 • Health Media • Informed Consent • Health Information/Privacy - Client Access • Health Information/Privacy - Accuracy & Correction • Health Information/Privacy - Third Party Requests
Legislation	• The New Zealand Bill of Rights Act 1990 • The Health Information Privacy Code 1994 • The Privacy Act 1993 • The Mental Health (Compulsory Assessment and Treatment) Act 1992 • The Health Act 1956 • The Health (Immunisation) Regulations 1995 • The Transport Act 1962 • The Land Transport Act 1998 • The Coroners Act 1988 • The Protection of Personal and Property Rights Act 1988 • The Children's, Young Persons and their Families Act 1989 • The Criminal Investigations (Blood Samples) Act 1995 • The Human Tissue Act 1964 • The Care of Children Act 2004 • The Alcoholism and Drug Addiction Act 1966 • The Contraception, Sterilisation and Abortion Act 1977 • The Tuberculosis Act 1948 • The Crimes Act 1961