



## Informed Consent for Treatment/Intervention

VHA Clinical Governance in Community Health

Discussion Paper

March 2009

### Aim

The aim of this paper is to highlight the issues related to informed consent for treatment in the community health context and provide a set of recommended procedures for informed consent for treatment for discussion by the sector. This document may then be used as the basis for organisations to develop their own policies and procedures.

### Background

Informed consent for treatment/intervention was identified by the VHA Clinical Governance in Community Health project as an area that required further development in community health as part of strengthening service quality. Failure to obtain informed consent for treatment/intervention in community health services has been identified in complaints to bodies such as VMIA and the Health Services Commissioner and represents a risk to clients and organisations.

### Definitions

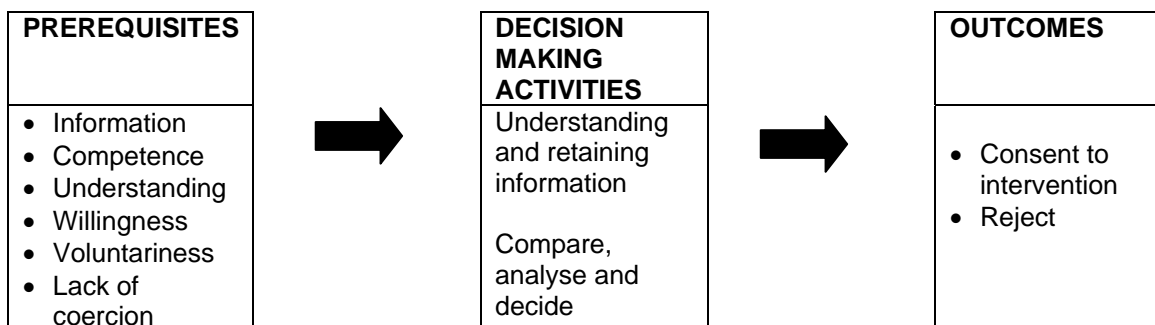
#### *Informed Consent*

Informed consent, in a health care setting, is the procedure whereby patients (clients) consent to, or refuse, an intervention based on information provided by a health care professional regarding the nature and potential risks (consequence and likelihood) of the proposed intervention (Coy, 1989). The Victorian Charter of Human Rights requires that consent for medical treatment be free, full and informed and states:

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

Beauchamp and Childress (1994) expand on the definition to add “consent to an intervention is informed if (and perhaps only if) one is competent to act, receives a thorough disclosure, comprehends the disclosure and acts voluntarily”.

Informed consent for treatment/intervention while following the principles for gaining consumer consent for use and disclosure of personal information is a distinct process.



Modified from Leino-Kilpi 2000:112



### *Nominated Representative*

A nominated representative is a person the consumer has nominated to represent them at a time when the consumer had legal capacity e.g. the common form is enduring power of guardianship. This differs from enduring power of attorney (under the instruments ACT) for financial and legal matters and enduring power of attorney (medical treatment) under the Medical Treatment Act.

### *Appointed Representative*

An appointed representative is a person appointed by an authorised body such e.g. VCAT statutory orders for a guardian to be appointed.

## **Legislation and Guidelines**

*The Victorian Charter of Human Rights and Responsibilities Act 2006*

*DHS Language Services Policy March 2005*

*Guardianship and Administration Act 1986*

## **Why informed consent for treatment?**

- Ethical right of every individual to make decisions about their own body
- Legal protection against
  - claims of trespass (assault and battery) due to failure to obtain valid consent
  - claims of negligence due to consent given on the basis of inadequate information
- Improved outcome with client cooperation and understanding
- Provide a bottom up demand for evidence based information

## **Ethical issues**

The main ethical principle serving as the basis for informed consent is that of autonomy. The principle of autonomy highlights that competent adults “always have the right to decide what ought or ought not be done to them, providing that the exercising of that right does not infringe on the comparable rights of others.”(Coy, 1989). When the principle of autonomy is used as the basis for informed consent, consent is required because it helps clients right to self-determination. When promoting self determination the act of gaining informed consent applies to a wide range of interventions, including those considered low risk or not harmful.

The philosophy of primary health care is grounded in social justice. The principle of autonomy is consistent with the community health philosophy of active participation of the client in decisions about their own health care. However research demonstrates that health care professionals interpretation of the ethical obligation to obtain informed consent is often “underpinned by an overriding motivation to obtain a (therapist determined) beneficial outcome for the patient, rather than by a primary concern for respecting patient autonomy” (Delaney, 2007:176). The principle of beneficence is the duty of health care providers to be of a benefit to a client /patient and emphasises the importance of producing good outcomes. Under the principle of beneficence, when the intervention does not have a potential for harmful outcomes, informed consent is not perceived to be necessary. The right for clients to make decisions about interventions is only acknowledged in relation to those interventions that are potentially harmful.

These principles clash when a client decision may not produce, in the service provider’s opinion, the best outcome for the client. When the principle of beneficence is dominant the service provider will act paternalistically to try to protect the client from the perceived harm inherent in the clients own decisions. Recognition needs to be made that the service providers goal of optimising health may not be the goal of the client. Generally where the client is competent to provide consent the clients right to autonomy overrides the beneficence of the service provider (Devereux 2002:7).



As J.A. Coy (1989) states

“Failure to obtain informed consent in any situation in which options for the patient are available constitutes a failure to respect the autonomy of the patient. Even when only one type of medical treatment exists for a given problem, at least two options are available to the patient: treatment or non treatment.”

### **Principles of Informed Consent**

The principles informing the practice of informed consent for intervention can be summarised as follows:

- Clients are entitled to make their own decisions about interventions and should be given adequate information on which to base these decisions
- Competence: consent is only valid if the client is competent to understand and authorise the intervention.
- The provision of adequate information on the issue and intervention options on which to make a decision
- Information is provided in a form appropriate to the clients circumstances, personality, expectations, fears, beliefs, values and cultural background
- Voluntariness: there should be no coercion and the client is free to accept or reject the advice
- Frank & honest information exchange from both parties
- A continual process – clients may change their decision about interventions after commencement of the intervention

### **Values and Informed Consent**

There needs to be recognition that individual and organisational experience, beliefs and values influence the understanding of best outcomes. Service providers need to be aware of when their own values/beliefs/expectations, or those of their organisation, conflict with their client's in determining the preferred option for intervention. For example a home based palliative care service is centred on providing clients with the opportunity to remain in their homes as long as possible. However some individuals may feel less anxious in a hospital environment closer to medical attention.

### **Funding Guidelines, Best Practice and Informed Consent**

Service providers may occasionally be placed in a situation where clients request services that are outside the bounds of their scope of practice, practice/funding guidelines or are known by service providers, based on evidence based practice, to be ineffective. The service provider is not required to provide a service that is not part of their scope of practice or that they believe, based on reasonable grounds, is not in the best interests of the client. The service provider, in these circumstances, can present the options for intervention that they can assist the client with and give information about external services if the client wishes to pursue an intervention which the service provider can not provide.

### **Capacity to Consent**

Informed consent for treatment is only valid if the individual has capacity to consent at that time. All adults (18 years and over) are assumed to have the capacity to consent unless otherwise proven. There are no numeric measures or tests which can be done to determine if an individual has capacity to consent. Capacity is a judgement of an individual's ability to understand the consequences and nature of a specific decision. People with mild intellectual disabilities may still be capable of consenting. Similarly people with more significant intellectual disabilities may be capable of consenting to simple procedures. Individuals may also lose capacity temporarily, for example while suffering from an illness, but later recover from it.



Capacity for consent requires that a person must be able to understand the information given, remember the information and analyse it to make a decision to give consent.

**Example**

An individual may have the capacity to make a decision about whether to be treated for a particular health problem, because they can understand what is wrong with them, what the treatment will involve, and what the long term consequences of the treatment will be, but at the same time not have capacity to manage their financial affairs, because they are not capable of understanding the extent and nature of their finances, and the consequences of the decisions made about their finances.

Every endeavour should be made to communicate with clients with alternate methods, where required, to ensure understanding of the issues. It is important to weigh up the nature and complexity of the proposed intervention and avoid the situation where a determination of incapacity to consent becomes an unnecessary barrier to service access. The process of determining capacity to consent should be consistent with the complexity of the procedure proposed.

### **Under 18 years**

In Victoria there is no statutory law around the specific age at which a child becomes competent to consent. The principles governing determination of capacity are whether the child has sufficient understanding and intelligence to enable them to understand what is being proposed. Where a child lacks the relevant capacity to consent to the intervention parental or guardian consent is required.

### **No Capacity to Consent**

In circumstances when an adult does not have the capacity to consent the Victorian Guardianship and Administration Act 1986 (G&A Act) outlines the process for substitute consent in the case of medical treatment only. This covers the responsible person for treatment by general practitioners and dentists (see appendix 1). The G&A Act provides that a 'person responsible' may consent to medical treatment for an adult who is unable to consent to the treatment. The person responsible is the first person listed below who is reasonably willing and able to make a decision:

1. A person appointed by a patient under the *Medical Treatment Act 1988 (Vic)*.
2. A person appointed by the Victorian Civil and Administrative Tribunal to make decisions in relation to the proposed treatment.
3. A person appointed under a guardianship order with power to make decisions regarding medical treatment.
4. An enduring guardian appointed by the patient while competent, and given the power to make decisions regarding medical treatment.
5. A person appointed in writing by the patient with power to make such decisions.
6. The patient's spouse or domestic partner.
7. The patient's primary carer.
8. The patient's nearest relative.

The G&A Act specifically applies to registered medical and dental practitioners administering medical and dental treatments, The remainder of interventions provided in community health would come under the term 'health care'. There is no list of persons legislated to provide substitute consent for general health care procedures. For service providers other than medical and dental practitioners in community health, the service provider must use their discretion in ensuring the nature of and risks involved with the intervention are weighed up against the level of substitute consent required. For example procedures that were invasive, such as nail avulsion or wound debridement, would require investigation of the most appropriate person to provide substitute consent. For invasive investigations the substitute consent required would preferably be from the first person listed who is willing and able to make a decision from the list provided by the G&A Act above. Incapacity to consent should not become an added barrier to service access for clients unless there are real concerns regarding the obtaining of substitute consent for the proposed intervention.



It is worth noting that the list of authorised representatives outlined in relation to consent to sharing of health records is specified under the Health Records Act (Section 85,2001) and pertains specifically to categories of people who can make decisions about health information not health interventions .

## Other Issues

### Mental Health

The Mental Health Act 1986(Vic) provides for the giving of consent to non psychiatric treatment (surgical operation or procedure) for involuntary, security or forensic clients who are incapable of giving consent. The list of those who may give consent can be found in Appendix 1

### Disability

The Victorian and Civil Administrative Tribunal (VCAT) has power under the *Guardianship and Administration Act 1986* and other legislation to make orders including orders appointing a Guardian or Administrator for a person aged 18 years or over who has a disability. If a patient has a disability and cannot give informed consent, a 'person responsible' may give consent on their behalf to medical and dental treatment. The person responsible is the first person willing and able to consent as listed under the no capacity to consent section of this document.

## Procedure for Informed Consent

The following recommended procedure for informed consent for intervention is outlined below:

### 1) Provide Information and Discuss Options

Prior to providing information on intervention options there is an expectation that there has been a discussion of the client's goals. The staff member is then required to give a clear explanation regarding interventions options before a client can make a decision. The information provided should include:

- The nature of the condition
- Proposed Intervention
- Benefits and how likely those benefits are
- Disclosure of any likely material risk. A risk is material if:
  - A reasonable person if warned of the risk would attach significance to the risk
  - A practitioner should be aware that the patient/consumer if warned of the risk would attach significance to it
- Who will be involved?
- Other Intervention options including the no intervention option
- Time
- Costs

To ensure a client understands the information a service provider should:

- Use language the client understands
- Allow the client to ask questions
- Repeat information when necessary
- Give the client time to make a decision
- Use a qualified interpreter when needed. The DHS Language Service Policy, 2005 requires as a minimum that clients who are not able to communicate though written or spoken English have access to information in their preferred language at critical points including when needing to give informed consent. Additional requirement include that language services are provided by qualified professionals and not family members, friends or carers.

### 2) Determine Capacity for Informed Consent

All clients (over 18) are assumed to have the capacity to consent unless otherwise proven. Where any doubt exists about a client's capacity for informed consent, the health professional or an appropriate colleague should assess the capacity of the person to take the decision in question, with the assistance of other workers where needed. Assessing capacity may involve investigating a client's ability to:



- Understand and Retain Information: Explore the client's ability to explain their presenting problem/issue
- Analyse Information and Decide: Explore whether the client is able to compare the options available and the risks of those options

This assessment of capacity to consent should be recorded in the client's file (DH, 2009). If a client is deemed incapable of consent then a person responsible must be found to provide substitute consent as described above.

### 3) Record Evidence of Informed Consent

Consent for routine assessment is implied by the attendance of the client at the appointment. Informed Consent is required for any additional interventions. Authorisation by the client to have an agreed intervention may take a variety of forms: expressed, implied, verbal, nonverbal or written.

Documentation of consent is evidence that the client has agreed to the intervention but does not prove the consent was informed or valid. Additional evidence is required to demonstrate that the consent was informed and can be a summary of the information provided to the client or by a form indicating clearly the information that was given to the client on this occasion. While there is no legal requirement for consent to be documented, documentation enables service providers to demonstrate that the processes involved in obtaining informed consent have been followed.

Documentation of informed consent should include:

- Client identification
- Service provider who obtained consent
- Date of consent
- Diagnosis
- Intervention Options
- The benefits and risks
- The alternatives
- Time and costs
- The exact treatment to which the client is consenting
- The name of the service provider performing the intervention
- Notes about opportunity for clients to ask questions
- Client signature

### 4) Duration of Consent

The process of informed consent should occur as close as possible to the clients receiving the intervention proposed. Consent remains valid until it is withdrawn by the client or if there is a change in the client circumstances. It is suggested that the validity of the consent be affirmed with the client at a new episodes of care. If there has been any significant changes in health status then a new consent must be sought to reflect any changes in material risk. Organisations may set a timeframe for mandatory review of informed consent for treatment in their own procedures.

It is worth noting that a client may withdraw their consent at any stage before, or during the course of the intervention.



Victorian Healthcare Association

## References

Beauchamp, T. L. Childress, C.F. (1994) Principles of Biomedical Ethics, (4th edition), Oxford University Press, Oxford

Coy, J., A. "Autonomy-based informed consent: ethical implications for patient non-compliance. " Physical Therapy. 69,10 (Oct 1989): 826(8).

Dental Practice Board of Victoria. Consent: Assisting patients to make well-informed decisions. Information Sheet No: I002 July 2007 Accessed from <http://www.dentprac.vic.gov.au/docs> March 2009

Dental Health Services Victoria (DHSV) Informed Consent Policy (PO-A029-02). November 2007 ( accessed via DHSV extranet)

Dental Health Services Victoria (DHSV) Informed Consent Procedure (PR-A018-02). November 2007

Delaney, C., M. 2007 In private practice, informed consent is interpreted as providing explanations rather than offering choices: a qualitative study. Australian Journal of Physiotherapy 2007 Vol. 53

Devereux J and Moore R, (2002) Medical Law (2<sup>nd</sup> edition) Routledge Cavendish, 2002 Sydney

Department of Human Services, 2005. Language Services Policy. Policy and Strategic Projects Division, Victorian Government Department of Human Services ,Melbourne Victoria, March 2005

DH (UK Department of Health) Seeking Consent: Working with older people. Accessed from [www.dh.gov.uk/en/Publicationsandstatistics/Publications](http://www.dh.gov.uk/en/Publicationsandstatistics/Publications) on March 2009

H. Leino-Kilpi, M., Valimaki and M. Arndt.2000. Patient's autonomy, privacy and informed consent. IOS Press

NHMRC. 2004. General Guidelines for Medical Practitioners on Providing Information to Patients. Commonwealth of Australia

## Appendix 1

### 1. Guardianship and Administration Act 1986

The definition of medical treatment under section 58 of the Guardianship and Administration Act 1986 No. 58 of 1986)

**Medical or dental treatment** means—

- (a) medical treatment (including any medical or surgical procedure, operation or examination and any prophylactic, palliative or rehabilitative care) normally carried out by, or under, the supervision of a registered practitioner; or
- (b) dental treatment (including any dental procedure, operation or examination) normally carried out by or under the supervision of a registered practitioner; or
- (c) any other treatment not referred to in paragraphs (a) and (b) that is prescribed by the regulations to be medical or dental treatment for the purposes of this Act—but does not include—
- (d) a special procedure; or a medical research procedure; or
- (e) any non-intrusive examination made for examination of the mouth, throat, nasal cavity, eyes or ears); or
- (f) first-aid treatment; or
- (g) the administration of a pharmaceutical drug for the purpose and in accordance with the dosage level—
- (i) if the drug is one for which a prescription is required, recommended by a registered practitioner; or

**S. 3(1) def. of medical or**

- (ii) if the drug is one for which a prescription is not required and which is normally self-administered, recommended in the manufacturer's instructions or by a registered practitioner; or (h) any other kind of treatment that is prescribed by the regulations not to be medical or dental treatment for the purposes of this Act;

### 2. Victorian Mental Health Act 1986

The following is a list of person's able to give consent for non psychiatric treatment ( surgical operation or procedure) for an involuntary, security or forensic patient under the Mental Health Act 1986.

- A person appointed by a patient under the *Medical Treatment Act 1988 (Vic)*.
- A person appointed by the Victorian Civil and Administrative Tribunal to make decisions concerning the proposed treatment.
- A guardian appointed by VCAT with power to make decisions regarding the proposed treatment.
- An enduring guardian with the power to make decisions regarding medical treatment.
- The authorised psychiatrist

For a patient under 18 years of age, consent may be given by any of the persons listed below who are reasonably available, willing and able to make a decision concerning the proposed treatment

- [A person with parental responsibility for the patient](#)
- A guardian with power to make decisions regarding the proposed treatment.
- A person who has authority under the Childrens and Young Person Act 1989 (VIC) to consent
- The authorised psychiatrist ( if non of the above is available, willing and able)

### 3. Victorian Health Records Act 2001 (HRA)

The following is a list of authorised representatives under the HRA: Section 85:

- A guardian within the meaning of the Guardianship and Administrative Act 1986 (GAA)
- An administrator or a person responsible within the meaning of the GAA
- An agent under the Medical Treatment Act 1988 (MTA)
- A parent, if the client is a child.