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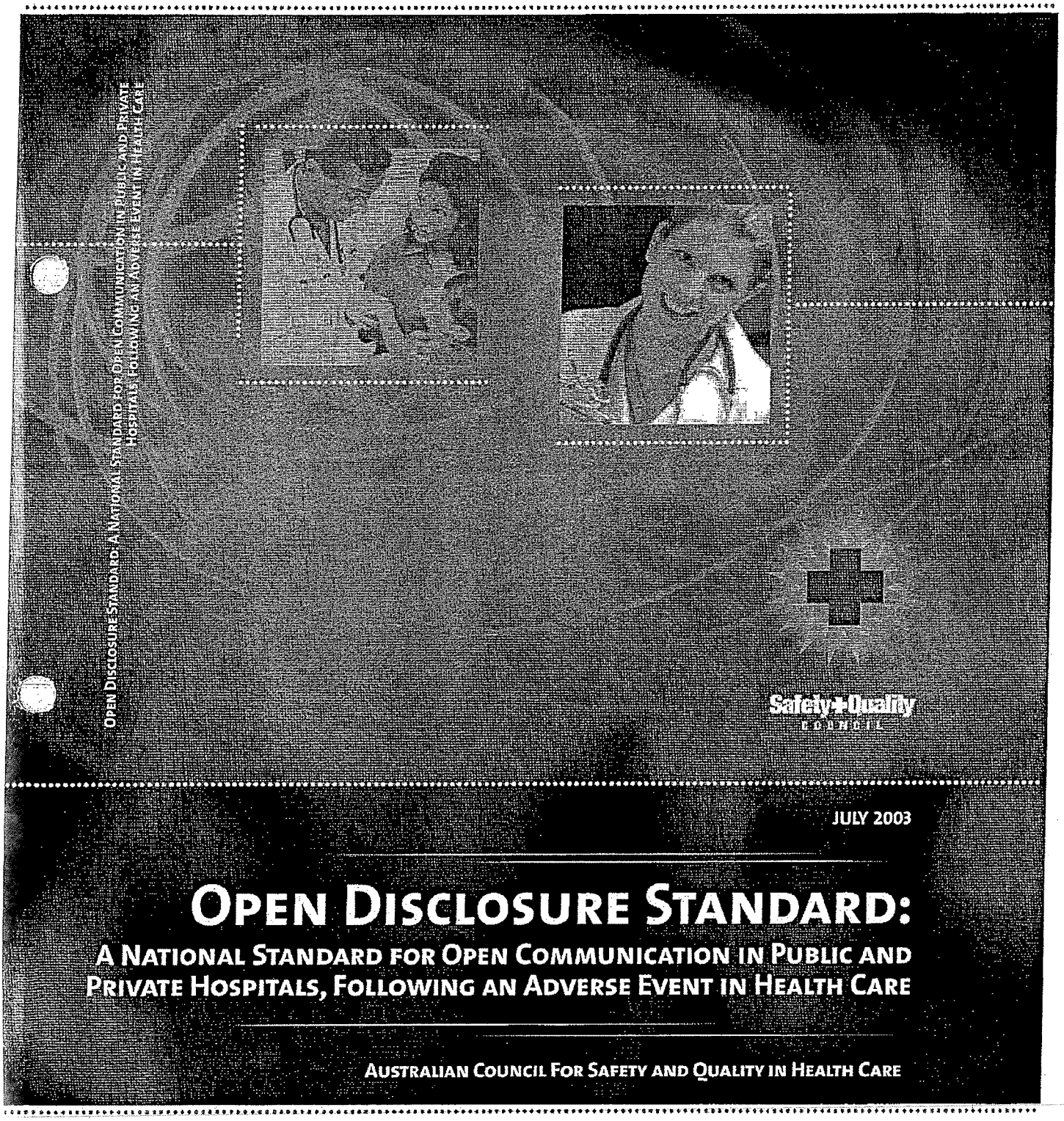

JULY 2003

OPEN DISCLOSURE STANDARD:

A NATIONAL STANDARD FOR OPEN COMMUNICATION IN PUBLIC AND PRIVATE HOSPITALS, FOLLOWING AN ADVERSE EVENT IN HEALTH CARE

AUSTRALIAN COUNCIL FOR SAFETY AND QUALITY IN HEALTH CARE

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A NATIONAL STANDARD FOR OPEN COMMUNICATION IN PUBLIC AND PRIVATE HOSPITALS, FOLLOWING AN ADVERSE EVENT IN HEALTH CARE

July 2003

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The Australian Council for Safety and Quality in Health Care was established in January 2000 by all Australian Health Ministers to lead national efforts to improve the safety and quality of health care, with a particular focus on minimising the likelihood and effects of error. The Council reports annually to Health Ministers.

This document is an attachment to the Council's fourth annual report to Health Ministers, *Patient Safety: Towards Sustainable Improvement, Fourth Report to the Australian Health Ministers' Conference, 31 July 2003*.

Acknowledgements

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Disclaimer

While this document gives some guidance on legal issues, it does not claim to provide legal advice. Hospitals and other organisations implementing the Standard will need to seek their own legal advice on implementing the Standard. Organisations implementing the Standard remain fully responsible for managing their legal risks

Publications Number 3320

The following organisations were voting members of the Standards Development Committee who participated in the development and endorsement of this standard:

Association for Teachers of Ethics and Law in Australia and New Zealand Medical Schools

Australian College of Health Service Executives

Australian Council on Healthcare Standards

Australian Health Ministers' Advisory Council

Australian Insurance Law Association

Australian Medical Association

Committee of Presidents of Colleges

Commonwealth Department of Health and Ageing

Consumers' Health Forum

Health Consumers Council

Health Professions Council of Australia

Maternity Alliance

Medical Defence Association of South Australia

Medical Error Action Group

National Council of Health Complaints Commissioners

National Rural Health Alliance

Australian Nursing Federation

Pharmaceutical Society of Australia

Plaintiff's Lawyers Association

Private Healthcare Industry Quality and Safety Committee (PHIQS)

Royal Australian College of General Practitioners (NSW)

Royal College of Nursing, Australia

Royal Australasian College of Medical Administrators

PREFACE

The Open Disclosure Standard is an initiative of the Australian Council for Safety and Quality in Health Care. The Standard aims to promote a clear and consistent approach by hospitals (and other organisations where appropriate) to open communication with patients and their nominated support person following an adverse event. This includes a discussion about what has happened, why it happened and what is being done to prevent it from happening again. It also aims to provide guidance on minimising the risk of recurrence of an adverse event through the use of information to generate systems improvement and promotion of a culture that focuses on health care safety. The Standard was prepared by the Standards Australia Committee on Open Disclosure and informed by extensive national consultation undertaken during 2002.

The Standard provides a framework designed to be used in the development, or upgrading, of an organisation's internal policies, processes and practices regarding adverse events and open communication. The framework has been developed initially for application in hospitals. It may require some modification before it is appropriate for implementation in other health care environments. Organisations will need to consider implementing the process outlined in this Standard within their existing internal policies, which may need to be changed or upgraded to facilitate the open disclosure process, and with due consideration given to legal and insurance requirements and risks.

The Standard is divided into two sections.

Section A provides an overview of the Standard. It also includes a brief discussion on why the Standard was developed, key issues for consideration when implementing open disclosure and the scope of the Standard.

Section B describes the open disclosure process.

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SECTION A KEY ISSUES FOR CONSIDERATION

1 INTRODUCTION

1.1 Background

Open disclosure is the open discussion of incidents that result in harm to a patient while receiving health care. The elements of open disclosure are an expression of regret, a factual explanation of what happened, the potential consequences and the steps being taken to manage the event and prevent recurrence.

The Open Disclosure Standard forms part of a wider national initiative of Commonwealth, State and Territory governments, through the Australian Council for Safety and Quality in Health Care, to promote a safer and better health care system. Australia's health care system provides high quality services. As knowledge about health grows and the use of new technologies increases, the provision of health care is becoming more complex and sometimes things go wrong.

In working towards an environment that is as free as possible from adverse events, there is a need to move away from blaming individuals to focussing on establishing systems of organisational responsibility while at the same time maintaining professional accountability. In this context, health care organisations need to foster an environment where people feel supported and are encouraged to identify and report adverse events so that opportunities for systems improvements can be identified and acted on.

Ensuring that communication is open and honest, and that it is immediate is important to improving patient safety. While open disclosure is already occurring in many areas of the health system, this Standard is about facilitating more consistent and effective communication following adverse events. This includes communication between the following:

a) Health care professionals.

b) Health care professionals and patients and their support person.

c) Health care professionals, health care managers and all staff.

Effective communication for patients commences from the beginning of an episode of health care and continues throughout the entire episode.

For health care professionals, there is an ethical responsibility to maintain honest communication with patients and their support person, even when things go wrong. By ensuring that there is good communication when an adverse event occurs, we can begin to look at ways to prevent them from recurring.

The Standard also aims to foster commitment from health care organisations to –

d) provide an environment where patients and their support person receive the information they need to understand what happened;

e) create an environment where patients, their support person, health care professionals and managers all feel supported when things go wrong;

f) build investigative processes to identify why adverse events occur; and

g) bring about any necessary changes in systems of clinical care, based on the lessons learned.

In implementing open disclosure, each organisation will operate –

h) within its own policies, procedures and processes;

i) within existing or upgraded integrated risk management frameworks and quality improvement processes;

j) in accordance with applicable Commonwealth State/Territory laws and regulatory regimes; and

k) within particular requirements of insurance and employment contracts.

1.2 Principles for open disclosure

This Standard was developed within complex and dynamic processes. It attempts to address the interests of consumers, health care professionals, managers and organisations, and other key stakeholder groups. Several themes were consistently raised and have become principles on which the Standard is built. They include the following:

1. **Openness and timeliness of communication** – When things go wrong, the patient and their support person should be provided with information about what happened, in an open and honest manner at all times. The open disclosure process is fluid and may involve the provision of ongoing information.
2. **Acknowledgment** – All adverse events should be acknowledged to the patient and their support person as soon as practicable. Health care organisations should acknowledge when an adverse event has occurred and initiate the open disclosure process.
3. **Expression of regret** – As early as possible, the patient and their support person should receive an expression of regret for any harm that resulted from an adverse event.
4. **Recognition of the reasonable expectations of patients and their support person** – The patient and their support person may reasonably expect to be fully informed of the facts surrounding an adverse event and its consequence, treated with empathy, respect and consideration and provided with support in a manner appropriate to their needs.
5. **Staff support** – Health care organisations should create an environment in which all staff are able and encouraged to recognise and report adverse events and are supported through the open disclosure process.
6. **Integrated risk management and systems improvement** – Investigation of adverse events and outcomes are to be conducted through processes that focus on the management of risk (see AS/NZS 4360[1]). Outcomes of investigations are to focus on improving systems of care and will be reviewed for their effectiveness.
7. **Good governance** – Open disclosure requires the creation of clinical risk and quality improvement processes through governance frameworks where adverse events are investigated and analysed to find out what can be done to prevent their recurrence. It involves a system of accountability through the

[1] Australian/New Zealand Standard for Risk Management

organisation's chief executive officer or governing body to ensure that these changes are implemented and their effectiveness reviewed.

8. **Confidentiality** – Policies and procedures are to be developed by health care organisations with full consideration of the patient's, carer's and staff's privacy and confidentiality, in compliance with relevant law, including Commonwealth and State/Territory Privacy and health records legislation.

1.3 Development of local policies

The Open Disclosure Standard provides a flexible framework designed to be used by organisations, health care professionals and managers when developing or amending policies and procedures for open disclosure. It is essential that each organisation's policy and procedure meets its unique needs and resource availability, while reflecting the specific legal, regulatory, institutional and cultural considerations relevant to them.

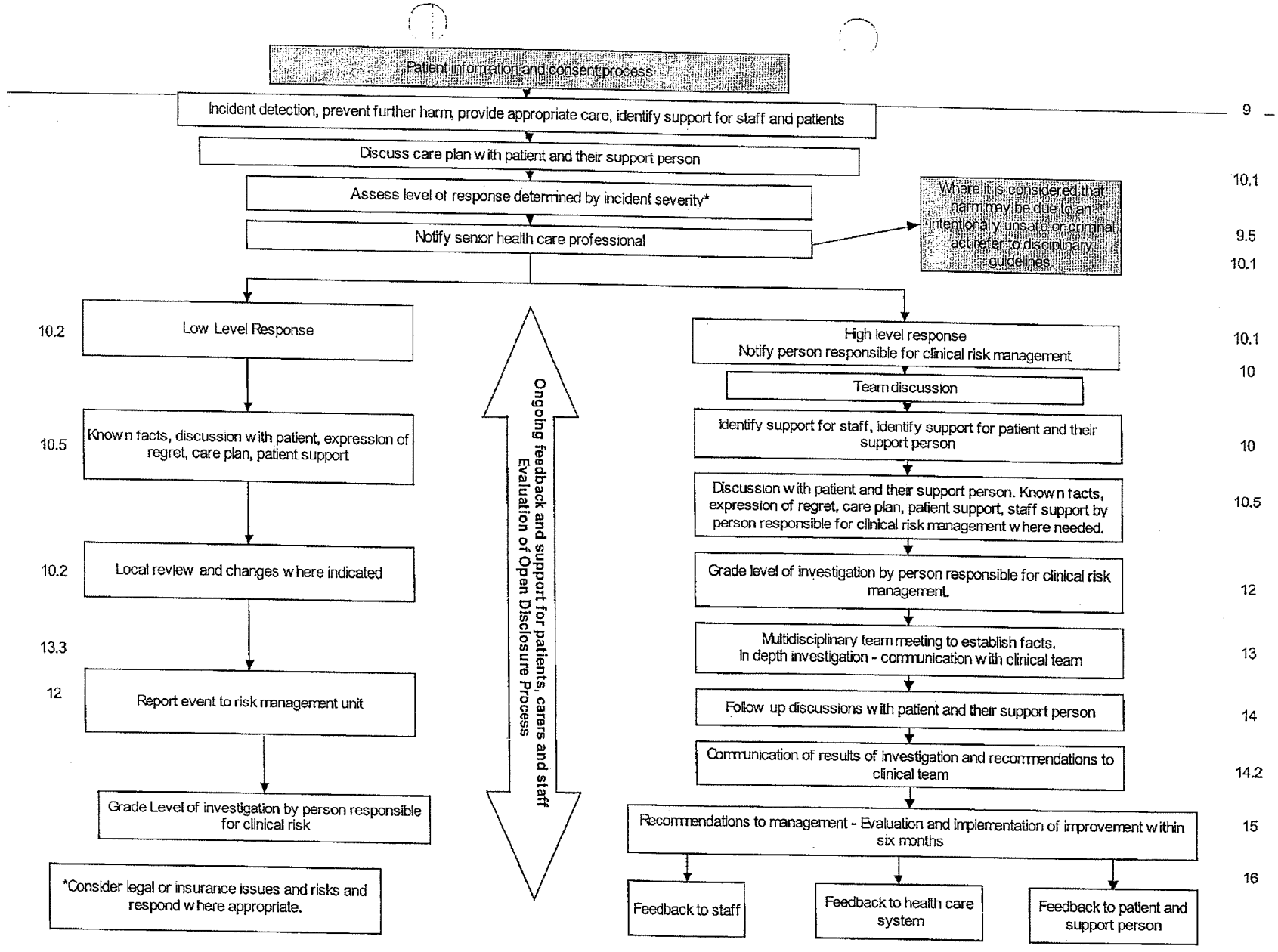
In particular, policies need to take into account the following:

a) The requirements of those who provide insurance to health care organisations and professionals, both of which should be involved in the policy development at an early stage including pro-actively educating their constituents involved in open disclosure.

b) The necessity of appropriate training and education for relevant staff to ensure a coordinated and informed approach to open disclosure and avoid admissions of liability (in either verbal or documentary form).

c) The need for involvement of consumers and health care professionals in developing policies and processes.

A summary of the open disclosure process is demonstrated in the flow chart on the next page.


Patient information and consent process
Incident detection, prevent further harm, provide appropriate care, identify support for staff and patients
9
Discuss care plan with patient and their support person
Assess level of response determined by incident severity*
Notify senior health care professional
Where it is considered that harm may be due to an intentionally unsafe or criminal act refer to disciplinary guidelines
10.1
9.5
10.1
10.2
Low Level Response
10.5
Known facts, discussion with patient, expression of regret, care plan, patient support
10.2
Local review and changes where indicated
13.3
12
Report event to risk management unit
Grade Level of investigation by person responsible for clinical risk
*Consider legal or insurance issues and risks and respond where appropriate.
Ongoing feedback and support for patients, carers and staff
Evaluation of Open Disclosure Process
High level response
Notify person responsible for clinical risk management
10.1
Team discussion
10
identify support for staff, identify support for patient and their support person
10
Discussion with patient and their support person. Known facts, expression of regret, care plan, patient support, staff support by person responsible for clinical risk management where needed.
10.5
Grade level of investigation by person responsible for clinical risk management.
12
Multidisciplinary team meeting to establish facts.
In depth investigation - communication with clinical team
13
Follow up discussions with patient and their support person
14
Communication of results of investigation and recommendations to clinical team
14.2
Recommendations to management - Evaluation and implementation of improvement within six months
15
16
Feedback to staff
Feedback to health care system
Feedback to patient and support person

2 SCOPE

The Open Disclosure Standard provides a framework for communication with patients and their support person following an adverse event. This framework is designed to be used by public and private hospitals, health care professionals and managers when developing or amending their policies and procedures for open disclosure to patients and their support person, following an adverse event. The Standard is based on concepts and principles that should be broadly applicable to other health care and community settings.

There is no agreed universal definition of "adverse event". For the purposes of this Standard, the Australian Council for Safety and Quality in Health Care has defined "adverse event" as "an incident in which unintended harm resulted to a person receiving health care". Adverse events also include harm to patients arising from the environment of care for which the hospital is responsible. At times, the patient's perspective on whether he or she has suffered "harm" may differ from the views of the health care professional or the organisation. In this instance, the patient's view should trigger the open disclosure process, regardless of whether an initial assessment suggests a recognised complication, or clinical or system error.

The following factors are outside the scope of this Standard:

a) Consent process

Consent by a patient for treatment is a major legal issue for all health care professionals. There is a body of law on what does and does not constitute consent. There is also legislation in the States and Territories dealing with the issue in relation to particular people, e.g. children. The law imposes on health care professionals the duty to warn of risks and options, and discussion of potential outcomes. While the consent process is integral to the patient/provider relationship, it is not considered necessary to discuss this issue in detail as "consent" in the open disclosure process will be no different to what is required in the ordinary health care context.

b) Costs incurred by patients

General suggestions about managing costs incurred by the patient are made in Appendix B.

c) *Disciplinary processes*

Disciplinary processes vary between jurisdictions and particular organisations. Information about disciplinary processes is outside the scope of this Standard. However, it is important to ensure that the open disclosure investigation is continued, even when a referral is made to a disciplinary process, as useful information for system improvement may emerge.

Organisations should have guidelines in place on how and when to make a referral to a disciplinary process. In developing and amending these guidelines, care should be taken to avoid potential conflict between disciplinary and open disclosure investigations. This includes ensuring that the rights of the person subject to the disciplinary process are recognised and respected, such as the right to be given an opportunity to respond to findings by the open disclosure investigation and to have legal, union or other representation.

3 KEY TERMS

A full Glossary of terms used in this Standard is included at the end of this document (Appendix A). For the purpose of this Standard, the following terms are defined as indicated.

a) Adverse event

An incident in which unintended harm resulted to a person receiving health care[2].

b) Expression of regret

An expression of sorrow for the harm experienced by the patient.

c) Individual responsible for clinical risk

Health care organisations need to designate responsibility for the management of risks associated with the delivery of clinical care. The person responsible needs to be of sufficient seniority to have credibility and be able to drive change to effect improvements. He or she will oversee the implementation of the open disclosure process within the organisation.

d) Support person

Information about an adverse event will be given to a patient's nominated "support" person in appropriate circumstances, taking account of the patient's wishes, Confidentiality and privacy requirements and the organisation's internal policies. The nominated support person/persons may be any individual, identified by the patient as a nominated recipient of information regarding their care. This may include family, friend, partner or those who care for the patient.

In cases of a dispute between, say, family and partners or friends about who should receive information, the patient's wishes, expressed on the admission form, should be paramount. In addition, some people have a legal relationship which entitles them to receive information (for example, in some cases, a parent, legal guardian or an executor).

Given the complexities, references in this Standard to "support person" should be read with the words, "where appropriate".

However, it is highly recommended that nominated support persons be involved in the open disclosure process from the outset so as to be able to give appropriate support and care to the patient.

4 PATIENT ISSUES

4.1 Communication

Health care organisations need to create an environment that facilitates open and effective communication. Policies and practices should address the following:

[2] Wilson, Runciman, Gibberd (1995) *Quality in Health Care Study,* Medical Journal of Australia 163 (9): 458-471.

a) They should ensure early identification of the patient's needs including, but not limited to, documentation at the time of admission of –

- the names of particular individuals to provide assistance and support to the patient;
- the names of those individuals (who may be different to the patient's next of kin or those identified above) that the patient has chosen to receive information about their health care, and any restrictions on disclosure; and
- whether an interpreter service may be required for the patient. (See Appendix C.7 and C.9).

b) They should encourage patients to notify the clinical team of any issues or conditions that may affect their care.

c) Where an adverse event has occurred, policies and practices should provide assurance that an ongoing care plan will be developed in consultation with the patient and their support person, and that the plan will be followed through; facilitate inclusion of the patient's support person in discussions about an adverse event where the patient agrees.

d) Policies, processes and practices should provide appropriate opportunities for the patient and their support person to obtain information about the adverse event.

e) They should provide information about the open disclosure process to patients and their support person in verbal and written format. For low level response events where requested and for high level response events as a matter of course.

f) Where a patient has died as a result of an adverse event, subject to the requirements of the coroner and legislation, policies and practices should ensure that the support person is provided with known information, care and support. The support person should also be referred to the coroner for more detailed information.

4.2 Advocacy and support

Patients and their support persons may need considerable help and support after experiencing an adverse event. Support may be provided by families, other support persons, social workers, religious representatives and, where available and appropriate, trained patient advocates. Where a patient needs more detailed long-term emotional support, the organisation should provide advice to the patient on how to gain access to appropriate counselling services.

Health care organisations should provide the following to patients:

a) Information including contact details on services provided by social workers, religious representatives and trained patient advocates who can provide emotional support, help patients identify the issues of concern, support patients at meetings with staff and provide information about appropriate community services.

b) Contact details of a staff member who will maintain an ongoing relationship with the patient. Where possible restrict telephone use to arranging meetings or relaying specific information. More detailed discussion or explanation should be conducted via face-to-face meetings where appropriate.

c) Information on how to make a complaint, including contact details for the relevant State/Territory health complaints agency (see AS 4269–1995 *Complaints handling*) and on rights to access their medical records.

4.3 Particular patient circumstances

When considering open disclosure, the approach may be modified by consideration of the patient's personal circumstances. Appendix C provides advice on managing –

a) when a patient dies;

b) patients who are children;

c) patients with mental health issues;

d) patients with cognitive impairment;

e) patients who do not agree with the information provided;

f) patients with special language or cultural considerations (including recent migrants and visitors);

g) patients from Aboriginal and Torres Strait Islander communities; and

h) other patients with special communication needs (eg, hearing, sight or mobility impaired).

5 STAFF ISSUES

When a patient suffers an adverse event, individual staff members involved in the clinical care of the patient may also require emotional support and advice. Staff involved in the open disclosure process should be provided with access to assistance, support and the information they need to fulfil the role required of them.

To support staff, health care organisations should –

a) provide advice and training on the management of adverse events, communication skills and the need for practical, social and psychological support, as part of a general training program in the management of clinical risk for all staff, as well as particular training on the open disclosure process;

b) actively promote an environment that fosters peer support and discourages the attribution of blame;

c) ensure that staff are not discriminated against because of their involvement in open disclosure processes;

d) provide facilities for formal or informal debriefing of the staff involved in an adverse event, where appropriate, as part of the support system and separate from the requirement to provide statements for the purposes of investigation. (see clauses 7.5, 7.6, 7.8);

e) provide information to staff involved in the adverse event on the investigation and its outcomes (see clause 14.2);

f) provide information on the support systems currently available for staff distressed by adverse events (Doctors Health Advisory Service, medical defence organisations, professional and collegiate associations and trade unions, hospital counsellors, employee assistance scheme, referral to

specialised mental health care where appropriate) and encourage timely consultation with these organisations and advisers; and

g) give consideration to developing specific systems of support in their own institutions or in collaboration with neighbouring facilities.

The interests and circumstances of individual staff may not be the same as the organisations or of other staff, particularly where it appears that the incident may lead to disciplinary proceedings or give rise to legal liability. Organisations must also take into account in their policies and practices the rights of health care professionals. This should include ensuring in policies and practices that –

h) the open disclosure process focuses on safety and not attributing blame, leaving issues relating to individuals to disciplinary processes, if this is considered appropriate;

i) criticism and adverse findings against individual professionals is avoided. If adverse findings do have to be made, treat the professional fairly and afford natural justice, including giving the person the opportunity to comment on any adverse findings and taking those comments into account. This will also help to avoid defamatory statements (both verbal and written); and

j) recognise the obligation and/or right of professionals to seek appropriate advice and guidance from their indemnifiers and other relevant advisers and to act in accordance with such advice.

6 ORGANISATIONAL ISSUES

6.1 General

Good governance and quality assurance require that organisations shall be able to demonstrate that they learn from and improve their performance through continuous monitoring, and by reviewing the systems and processes in place for meeting their objectives and delivering appropriate outcomes. Health care organisations need to ensure appropriate direction and internal control through a system of governance. It is imperative that each facility and its management, including boards of governance and quality councils, show the capacity and willingness to learn from adverse events and to disseminate learning for the wider good of the community.

Health care organisations should –

a) acknowledge that health care is inherently risky and that there is a need to reduce risk wherever possible;

b) create a culture and system to encourage notification and open and honest communication of adverse events;

c) avoid unnecessary punitive action against those involved in an adverse event, while ensuring appropriate professional accountability; and

d) foster community awareness of the occurrence of adverse events to users of the health service and promote open disclosure to patients.

The organisation will need to determine whether the open disclosure process is to be implemented into existing systems and policies, such as risk management and identification of adverse events, or whether those systems need to be amended to take account of the open disclosure process.

6.2 Organisational responsibilities

Health care organisations should ensure that they –

a) have in place integrated risk management and quality improvement processes;

b) provide training and support to staff in communication skills, investigation and grading of adverse events, risk management and management of legal issues;

c) actively promote and disseminate information about open disclosure policy and procedures to staff and patients;

d) designate key staff to participate in and have responsibility for patient safety, quality improvement and risk management;

e) have established systems to identify adverse events;

f) have in place mechanisms for investigation of adverse events and analysis of factors causing adverse events;

g) have in place processes for implementing change to improve health care safety; and

h) implement appropriate monitoring and review mechanisms for the open disclosure process.

6.3 Responsibility of the governing body and chief executive officer (CEO)

A health care organisation's governing body, through the CEO, will have ultimate responsibility for ensuring that appropriate policies, processes and practices are in place and that, if necessary, changes occur to improve patient safety. They should also ensure that those with operational responsibility for an organisation have the means to implement recommended changes.

7 LEGAL CONSIDERATIONS

7.1 General introductory

It is not considered that these legal issues should inhibit implementation of the Open Disclosure Standard, but facilitate its practical application.

7.2 General

An organisation's internal open disclosure policy and training materials need to pay due regard to and be consistent with relevant legal obligations. Insurance issues will also need to be taken into account. In a hospital setting there is a complex web of relationships, with attendant rights, roles and responsibilities. A range of health care professionals are likely to be involved in an adverse event. Responsibilities will be owed to the patient and the organisation, although the specific legal basis of the relationship with the organisation will vary depending on whether the health care professional is regarded at law as an employee or as an independent contractor.

These legal issues need to be considered prior to and during the investigation.

The legal implications of the open disclosure process will vary between jurisdictions and types of organisations (eg, public and private). Organisations need to consider the legislation applying to them, both Commonwealth and State/Territory and general law principles.

Key legal and insurance issues are discussed in the following clauses.

7.3 Admission of liability

In discussions with the patient and their support person under the open disclosure process, health care professionals may –

a) acknowledge that an adverse event has occurred;

b) acknowledge that the patient is unhappy with the outcome;

c) express regret for what has occurred;

d) provide *known* clinical facts and discuss ongoing care (including any side effects to look out for);

e) indicate that an investigation is being, or will be undertaken to determine what happened and prevent such an adverse event happening again;

f) agree to provide feedback information from the investigation when available; and

g) provide contact details of a person or persons within the health care organisation whom the patient can contact to discuss on-going care (see clause 16.1).

Health care professionals need to be aware of the risk of making an admission of liability during the open disclosure process. In any discussion with the patient and their support person during the open disclosure process, the health care professional should take care not to –

h) state or agree that they are liable for the harm caused to the patient;

i) state or agree that another health care professional is liable for the harm caused to the patient; or

j) state or agree that the health care organisation is liable for the harm caused to the patient.

7.4 Protection of communications and documents from disclosure

Communications and documents (including emails) produced in response to an adverse event may have to be disclosed later in any legal proceedings or, for public hospitals, in response to a freedom of information application.

It is therefore important that care is taken in all communications and documents, stating as fact, only what is known to be correct.

In some circumstances, which should be detailed in the organisation's open disclosure policy, it may be necessary to undertake the open disclosure process in tandem with other legal or investigative processes so as to appropriately utilise –

a) legal professional privilege; or

b) qualified privilege legislation.

7.5 Legal professional privilege

It may be that the organisation or legal adviser requires particular documents to be created (e.g, reports, witness statements) for the purpose of obtaining or giving legal advice on the incident or for use in legal proceedings, should this eventuate. If so, the organisation should be able to claim that those communications and documents attract legal professional privilege and do not have to be disclosed to a third party (usually the patient in any legal proceedings) or in a freedom of information application.

However legal professional privilege applies only in limited circumstances and a number of important principles need to be considered:

a) The principle provides that confidential communications, including documents, between a lawyer and client made for the *dominant* purpose of the client obtaining, or the lawyer giving legal advice, or for use in existing or contemplated litigation, are protected from disclosure.

b) A communication can be verbal or in writing.

c) Legal professional privilege belongs to the client (not the lawyer) who is receiving the legal advice or legal services. This is the organisation which is obtaining the legal advice. Health care professionals, both those employed by the organisation or who are independent contractors, may have sought their own legal advice and then claimed legal professional privilege for communications between them and their lawyers.

d) The client can waive legal professional privilege so that the protection no longer applies. A waiver can be express or implied. If protection is sought, it is important not to do anything that inadvertently discloses the communication or document so that it is no longer confidential.

7.6 Qualified privilege legislation

The Commonwealth and all States and the ACT have enacted legislation that protects from disclosure to third parties certain information generated as a result of particular quality assurance activities.[3]

The Commonwealth and State legislation (but not the ACT's) requires that persons who acquire information solely as a result of their membership of or an association with a committee or project that attracts qualified privilege, must not make a record of or divulge information to any person, with limited exceptions.

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3 *Health Act 1993* (ACT), *Health Administration Act 1982* (NSW) (ss.20D-20K), *Health Services Act 1991* (Qld) (ss. 30-38), *Health Commission Act 1976* (SA) (s. 64D), *Health Act 1997* (Tas), *Health Services Act 1988* (Vic) (s. 139), *Health Services (Quality Improvement) Act 1994* (WA) and *Health Insurance Act 1973* (Cth) (Part VC)

Many of the adverse events which trigger the open disclosure process will not trigger a quality assurance activity under the legislation (assuming that the legislation applies in a particular case), and accordingly, in many cases of an adverse event, that legislation and the qualified privilege will not apply. In these circumstances, the open disclosure process will not be affected by the quality assurance legislation.

Where the quality assurance legislation does apply, however, information and documentation arising as part of the quality assurance investigation may not be disclosed under the open disclosure process. Accordingly, in those circumstances where qualified privilege will apply to the investigation, organisations and health care professionals need to be aware that their ability to disclose information to a patient or support person pursuant to the open disclosure process will be restricted. In some jurisdictions it is possible to release some information. In developing open disclosure policy, organisations need to consider specific conditions on release of information covered by qualified privilege legislation.

A health care organisation which has the qualified privilege legislation available to it should include in its internal open disclosure policy, the circumstances where it is likely that a quality assurance activity under the legislation will be invoked.

7.7 Freedom of information (FOI) legislation

Public hospitals are subject to FOI legislation, which varies across jurisdictions. The Commonwealth, the States and the ACT (but not the Northern Territory) have enacted FOI Legislation[4]. Generally, FOI legislation creates a right to access information contained on records held by government agencies (subject to some exceptions and exemptions) and a right to bring about amendments to records containing personal information which is incomplete, out of date or misleading. Health care professionals should take into consideration, when creating documents as part of the open disclosure process, that the document may become available to the patient. Every effort should be made to ensure that the documents are accurate and are written in appropriate language.

In particular, documents should restrict themselves to clinical facts which have been verified, as far as is possible, as accurate and should not –

a) attribute blame to any health care professional or the health care organisation;

b) record opinions about staff, patients, support persons or others, unless those are expert opinions with supporting evidence for the opinion recorded; or

c) contain statements about another person which are, or are likely to be, defamatory.

[4] *Freedom of Information Act* 1982 (Cth), *Freedom of Information Act* 1989 (NSW), *Freedom of Information Act* 1982 (Vic), *Freedom of Information Act* 1992 (Qld), *Freedom of Information Act* 1991 (SA), *Freedom of Information Act* 1992 (WA), *Freedom of Information Act* 1991 (Tas), *Freedom of Information Act* 1989 (ACT),

7.8 Privacy and confidentiality

In some jurisdictions, patients have rights to privacy and confidentiality of personal information or health records by virtue of legislation.[5]

There is also an implied obligation of confidentiality at common law (owing to the nature of the relationship between a health care professional and a patient) although legal rights to confidentiality are difficult to enforce, and some breaches of confidence are without legal remedy.

Organisations and health care professionals will have to have regard to obligations of privacy of patients, staff and others, when conducting investigations, creating reports and making any disclosures under the open disclosure process. Care will also have to be taken to ensure that any information obtained as part of the open disclosure investigation is recorded and stored in accordance with the legislation.

Organisations should develop their own guidelines to ensure that the relevant privacy principles and other obligations of confidentiality are adhered to during the open disclosure process. It is important to note that this legislation also provides patients with the right to access information about their care such as their medical record.

The safest way to ensure there is not a breach of privacy or confidentiality is to obtain the consent of the patient to disclose specified information to nominated persons. This can be done at the time of admission.

7.9 Defamation

In the context of open disclosure it is possible that a health care professional or other person could be defamed by virtue of a statement, either verbal or written, "published" by, for example, an organisation or health care professional to another person. For example, this could occur by a health care professional alleging that another is incompetent.

It is only necessary, for an action for defamation to arise, for the communication to be made to one other person.

It is not even necessary for a person to be referred to by name, in order to be defamed, if it can be shown that the person could be readily identified.

Accordingly, health care organisations should ensure that health care professionals, in their training in open disclosure, are informed that they must be careful about information recorded and what is said to and about others during the open disclosure process.

7.10 Insurance considerations

An adverse event may involve more than one insurer because of the range of health care professionals that may make up a multidisciplinary team. The interests of these parties may be conflicting and therefore it is important that those involved

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5 *Privacy Act 1988* (Cth), *Privacy and Personal Information Protection Act 1988* (NSW), *Information Privacy Act 2000* (Vic) and *Health Records Privacy and Access Act 1997* (ACT). The Western Australian Government has stated that it intends to introduce privacy legislation to apply to Government bodies in 2003. NSW's *Health Records and Information Privacy Act 2002* is expected to come into force in 2003.

in the adverse event are fully aware of their own responsibilities in regard to their relevant insurance policies.

Medical defence organisations and other indemnifiers may provide medico-legal advisory services to their members (and those insured) and may wish to discuss and assist in the open disclosure process.

Many policies of insurance granted by insurers and medical defence organisations will require the insured to notify and take early advice from the insurer of an adverse event, usually within a certain period of time following the adverse event ("**the notification requirement**").

These policies may also set out other requirements which the indemnifiers impose on the organisation, such as what can or cannot be said by staff before the insurer is notified of the adverse event (if the event is one requiring such notification). Each health care organisation should, in order to ensure that the organisation complies with the indemnifier's requirements, ensure that –

a) their insurers are consulted regarding notification requirements prior to implementing an open disclosure policy;

b) the manager responsible for overseeing the management of adverse events is aware of what events are to be notified under an insurance policy in force in respect of that organisation and the requirements for the timing of relevant notifications; and

c) health care professionals are instructed to report adverse events to the manager promptly.

SECTION B THE OPEN DISCLOSURE PROCESS

8 PRIVACY AND CONFIDENTIALITY

All discussions should occur with regard to ethical and legal requirements relating to Confidentiality and Privacy of patients and staff (see clause 7).

9 INCIDENT DETECTION OR RECOGNITION

9.1 General

The open disclosure process commences with the recognition that the patient has suffered unintended harm during their treatment. Hospitals must develop appropriate mechanisms to identify adverse events.

9.2 Identifying an adverse event

An adverse event might be identified –

a) by a staff member at the time of the incident;

b) by staff retrospectively when an unexpected outcome is detected;

c) by a patient or carer who expresses concern or dissatisfaction with the patient's health care, either at the time of the Incident or retrospectively;

d) through established complaints mechanisms;

e) through incident detection systems, such as Incident reporting or medical record review; and

f) from other sources, such as detection by other patients, visitors, students or other hospital staff.

9.3 Priority

As soon as an adverse event is identified, the first priority is prompt and appropriate clinical care and prevention of further harm. Where additional treatment is required this should occur, where reasonably practical, after a discussion and with the agreement of the patient. Responsible managers should be advised and should gather any evidence that will assist in investigating the event.

9.4 Adverse events occurring elsewhere

An adverse event may have occurred in an organisation other than that in which it is identified. The individual who first identifies the possibility of an earlier adverse event should notify the individual responsible for clinical risk in the organisation in which it was identified. That person should establish whether –

a) the adverse event has already been recognised;

b) the process of open disclosure has commenced elsewhere; and

c) investigations are in progress.

If the open disclosure process has not already commenced in the other organisation, the open disclosure process should be initiated. The investigation of the adverse event and the disclosure process should occur, where possible, in the health care organisation where the adverse event took place.

9.5 Criminal or intentionally unsafe act

Adverse events are almost always unintentional. If, at any stage following an adverse event, it is considered that the harm may be the result of a criminal or intentionally unsafe act, then the initial response should proceed as follows:

a) The individual responsible for clinical risk and the chief executive officer (CEO) should be notified immediately.

b) Management should follow their local complaints and disciplinary process and/or refer the matter to the appropriate authority. (The disciplinary process is outside the scope of this Standard).

10 INITIATING THE OPEN DISCLOSURE PROCESS

10.1 Initial assessment to determine level of response

All incidents should be assessed initially by the first member of the clinical team to detect the incident. He/she will do an initial assessment of the level of response required and notify a senior health care professional to confirm their evaluation.

For a low-level incident, this senior health care professional may be a nurse manager, nurse specialist, staff specialist, registrar, resident medical officer or allied health care professional. This should be determined by the type of event and the organisation's particular policy. For a high-level incident, this will be the senior health care professional responsible for the patient. The organisation's policy should also specify when to notify and involve the CEO and other management.

The level of response required will be determined by the impact or consequence of the incident. (See Appendix D for an example of a decision matrix to determine the level of response).

a) Low-level response

A low-level response should be used for those adverse events where there is no permanent injury or increased level of care (eg transfer to operating theatre or intensive care unit) required.

b) High-level response

A high level response will be determined by the impact or consequences of the incident, that is –

- death or major permanent loss of function;
- permanent lessening of body function; or
- a need for surgical intervention, transfer to a higher level of care (eg transfer to intensive care unit) or major change in clinical management.

The individual responsible for clinical risk should be notified immediately of a high-level response and be available to provide support and advice during the open disclosure process if required.

10.2 Management of low-level incident

The person detecting the incident and the senior health care professional will decide who should manage the disclosure discussion with the patient and if support is required.

It is likely that in most cases where a low-level response is indicated, the disclosure process will be completed with the initial disclosure discussion with the patient. The content of this discussion is set out in clause 10.5. Unless there are specific indications or the patient requests it, the disclosure process and the investigation and implementation of changes will occur at local service delivery level, with participation of those directly involved in the event. Reporting to management will occur through standard incident reporting mechanisms and will be analysed to detect high-frequency events. Review will occur through aggregated trend data, local investigation or, where trend data indicates a pattern of related events, an in-depth investigation. (For grading the level of investigation see clause 12)

10.3 Management of high-level incidents

10.3.1 Preliminary team discussion

The multi-disciplinary team and all other staff involved in the adverse event, including the most senior health care professional, will communicate as soon as possible after the event to –

a) establish the basic clinical and other facts;

b) assess the event to determine the level of response;

c) identify who will take responsibility for discussion with the patient and their support person;

d) consider the appropriateness of engaging patient support at this early stage, including the use of a facilitator or a patient advocate (see clause 4.2);

e) identify immediate support needs for staff involved;

f) ensure that all team members maintain a consistent approach in any discussions with the patient and their support person; and

g) consider legal and insurance issues, both for the organisation and health care professionals, and notification to relevant people (see clause 10.6).

10.3.2 Timing

The initial disclosure discussion with the patient and their support person should occur as soon as possible after recognition of the adverse event. Factors to consider when considering timing of the disclosure discussion include –

a) clinical condition of the patient;

b) availability of key staff;

c) availability of the patient's support person;

d) availability of support staff;

e) patient preference;

f) privacy and comfort of the patient; and

g) emotional and psychological state of the patient.

10.4 Choosing the individual to make the disclosure

10.4.1 General

The individual making the disclosure should be the most senior health care professional who is responsible for the care of the patient. For high-level incidents, that person should have the support of a senior staff member with good communication skills. The person disclosing should ideally have the following characteristics –

a) be known to the patient;

b) be familiar with the facts of the incident and care of the patient;

c) be of sufficient seniority to be credible;

d) have received training in open disclosure;

e) have good interpersonal skills;

f) be able to communicate clearly in everyday language;

g) be able and willing to offer reassurance and feedback to the patient and his/her support persons; and

h) be willing to maintain a medium to long-term relationship with the patient where possible.

In all cases that require a high-level response, the decision on who will make the disclosure should be made in consultation with the person responsible for clinical risk. If for any reason the senior health care professional is unable to make the disclosure, a substitute will need to be selected but, ideally, the senior health care professional should still be present at the discussion.

10.4.2 Use of a substitute health care professional to disclose

In exceptional circumstances, where it is not possible for the most senior health care professional responsible for the clinical care of the patient to be present, an appropriately senior person, trained in open disclosure processes, should take responsibility for the disclosure discussion.

The qualifications, training and scope of responsibility of the substitute person should be well delineated. This will assist effective communication with the patient or their support person without jeopardising the rights of health care professionals, or their relationship with the patient. The substitute person may be the individual responsible for clinical risk or someone of similar expertise.

10.4.3 Assistance with initial disclosure discussion

The person who will be disclosing should be able to nominate someone to assist them with the disclosure interview. Ideally this would be someone with experience or training in communication and open disclosure.

10.4.4 Consultation with patient regarding the individual to make the disclosure

If, for any reason, it becomes clear during the initial disclosure discussion that the patient would prefer to speak to a different health care professional, the patient's wishes should be respected and a substitute, in consultation with the patient, should be provided.

10.4.5 Responsibilities of junior health care professional

Junior clinical staff or those in training should not carry out the disclosure except where –

a) the incident is minor;

b) the senior health care professional responsible for the care of the patient is present for support;

c) the patient agrees;

d) the junior staff member has received adequate training to undertake the disclosure; and

e) the junior staff member is willing to participate in the process.

10.4.6 Adverse events related to the physical environment of care

In a case relating to injury within the environment of care, a senior manager of the relevant service will be responsible for disclosure (relating of the accident). A senior member of the multi-disciplinary team should be present to assist at the initial disclosure discussion (e.g. domestic supervisor assisted by the senior nurse manager in a case where a patient has slipped on a wet floor). The health care professional responsible for treating the injury should also be present to assist in providing information on what will happen next and the likely effects of the injury.

10.5 Content of initial disclosure discussion with the patient

The initial disclosure discussion is the first part of an ongoing communication process. Many of the points raised in the initial disclosure discussion may need to be expanded upon in any subsequent meetings with the patient and their support person.

It is important not to speculate, attribute blame to yourself or other individuals, criticise individuals or admit liability. All known facts relevant to the adverse event can be made available to the patient and their support person, subject to any legal restrictions that may apply (see clause 7).

The discussion should include –

a) an introduction of all people attending, including their role;

b) an expression of empathy and regret for the harm that has occurred;

c) disclosure only of facts known at that time as agreed between the multidisciplinary team;

d) listening to the patient's and/or their support person's understanding of what happened and address any questions or concerns they may have;

e) indicating to the patient and their support person that their views and concerns are being heard and considered seriously;

f) a discussion about what will happen next (return to operating theatre, need for more investigations, see another specialist etc);

g) information on likely short-term effects (and long-term effects if known, however this information may need to be delayed to a second or subsequent meeting);

h) assurance to the patient and their support person that they will be informed of further investigation that will take place to determine why the adverse event occurred, the nature of the proposed process and expected timeframe. Also provide information on how feedback will be provided on the findings of the investigation any changes made to prevent recurrence and if delays in the process are experienced the reasons for those delays;

i) an offer of support to the patient and their support person; and

j) information to the patient and/or support person on how to take the matter further, including any complaint processes available to them.

10.6 Notification

10.6.1 Individual/manager with designated responsibility for clinical risk

In all cases the individual with responsibility for management of clinical risk within the organisation should be informed of an adverse event by telephone, electronically or by completion of an incident form depending on the level of response decided upon. This person will then grade the incident to determine the level of investigation.

10.6.2 Insurers

Insurers of organisations and insurers of individual practitioners will have to be notified in accordance with the particular contractual obligations for timely notification.

10.6.3 Management

Notification of management will usually occur via the individual responsible for clinical risk. However, when a major incident occurs that may attract media attention or where a criminal act is suspected, the CEO should be notified immediately, in accordance with the organisation's incident policy.

10.6.4 General Practitioner(GP), residential facility and other community care providers

The referring GP, residential facility or other community care provider should be contacted at an early stage so that he/she is informed and can offer their support and continuing care to the patient and carer. This should be with the patient's agreement.

10.6.5 Unexpected or untimely death – the coroner

Cases of untimely or unexplained death and suspected unnatural deaths must be reported to the coroner as required by State or Territory legislation. A coroner may request that the case not be discussed with other parties until he/she has

considered the facts. It may be that this will not preclude an Expression of Regret from the organisation to the patient's Support Person/family (however advice should be sought from the coroner as to whether this will breach the requirement not to discuss the matter). In this situation, it should be made clear to the family that a discussion of the facts and any further concerns will be arranged at a date to suit both parties, after the coroner's assessment is finished.

10.6.6 Notification to relevant statutory and other appropriate authorities

Where there are adverse outcomes health care organisations may need to respond to a variety of external requirements, reviews or queries, including requirements of State, Territory and Commonwealth regulatory bodies. The organisation's policy on adverse events and open disclosure should clearly state these requirements to ensure that an organisation's legal and insurance needs are met.

11 DOCUMENTATION

11.1 General

The disclosure of an adverse event and the facts relevant to it must be properly recorded. Documentation includes medical records, incident reports and records of the investigation process.

11.2 Health care records

Medical records should document –

a) the time, place, date of the disclosure discussion and the name and relationships of those present;

b) the plan for providing further information to the patient and their support person;

c) offers of support and the response received;

d) questions posed by the patient or their support person and the answers given;

e) plans for follow up as discussed with the patient;

f) progress notes relating to the clinical situation and accurate summary of all points explained to the patient and their support person; and

g) copies of letters sent to the patient, their support person and GP.

11.3 Incident report

Clinical or other staff should submit an initial incident report in accordance with the organisation's policy on adverse events or incident reporting.

12 GRADING THE EVENT TO DETERMINE THE LEVEL OF INVESTIGATION

All adverse events should be subjected to an appropriate level of investigation and analysis to determine the cause. Not all adverse events require a major investigative process. Many will be resolved with a limited internal management process. Cumulated data for both high level and low level incidents should be reviewed centrally. Incidents should be graded by the person responsible for clinical risk and according to –

a) the extent of the injury including its physical and where appropriate financial consequences; and

b) the likelihood of recurrence of the incident.

The matrix obtained by correlating these parameters will determine the potential risk to patients and the organisation. A sample grading matrix is provided in Appendix E.

13 THE INVESTIGATION

If the investigation is being carried out under qualified privilege legislation, legal advice should be taken on the extent of protection provided for documents and communications, as well as whether, and how, any information collected or findings made can be disclosed to patients or others.

If the investigation is being conducted with the involvement of lawyers (sometimes at the instigation of insurers), advice should also be sought on whether documents or communications as part of the investigations are privileged from disclosure and what can be properly disclosed without inadvertently losing the privileged protection.

13.1 The investigation and analysis

The investigation will take place within an appropriate framework (eg clinical governance/clinical risk/quality improvement), as follows:

a) Once the preliminary decisions relating to initial disclosure are made, the investigation process should proceed according to how the adverse event has been graded and should be commenced immediately. It is important that the investigation begins promptly while memories are fresh and before evidence is lost or destroyed.

b) In serious adverse events (major or sentinel health event), a root cause analysis, or another investigation method of similar intensity, should be considered. In these circumstances, the services of outside experts may also be used. Cases of moderate severity may be investigated by a small number of designated people. Low-risk cases may be investigated by a small team or subjected only to aggregate review (data trending). The decision about the level of investigation should be determined by grading the event to determine the level of investigation (see clause 12) and be in accordance with the organisation's policy.

c) If there is concern about the capacity to obtain detailed information in the absence of protection of communications and documents from disclosure, the investigating team should consider seeking appropriate legal advice as soon as

the adverse event occurs and/or invoking qualified privilege legislation if this is appropriate. (see clause 7.6).

d) The incident investigation should –

- identify the reasons for the adverse outcome;
- identify underlying systems failures;
- make recommendations that indicate that "lessons have been learned";
- identify improvement strategies to reduce the risk of future harm;
- identify reasons why no improvement can be made, if this is the case; and
- satisfy obligatory reporting requirements.

13.2 The personnel to be involved

13.2.1 General

An individual who has the knowledge and status to make authoritative recommendations should conduct the investigation in association with appropriate clinical advisers. This will usually be a senior health care professional or manager (as designated in the organisation's policy). All health care professionals involved in the incident should be given the opportunity to have input into the investigation.

13.2.2 Investigator's role

The investigator will –

a) actively plan and manage the investigation, and determine the scope of the investigation and issues raised;

b) be impartial and not advocate for any parties associated with the investigation;

c) collect the facts (staff, patient, carer statements or interviews) retain damaged equipment and arrange for an inspection or make direct observation of the scene;

d) identify appropriate standards, policies, processes and practice of care relevant to the case;

e) review available information from audit, Incident reporting or other sources that relate to the subject matter of the investigation;

f) assemble and analyse the information, and seek advice on matters outside their expertise; and

g) as far as possible make findings of fact, root causes and recommendations to support system changes to prevent recurrence of such adverse events.

13.2.3 Multi-disciplinary team

In most cases, a multi-disciplinary group will be involved in the investigation, the determination of the causes of the event and in recommending improvement strategies.

14 PRELIMINARY FOLLOW-UP

14.1 Preliminary follow-up with the patient and their support person

The preliminary follow-up discussion with the patient and their support person is an important step in the open disclosure process (unless the incident is minor and where no follow-up is required) and should be guided by the following:

a) The senior health care professional involved in the adverse event should be involved in the follow up discussion.

b) The discussion should occur at the earliest practical opportunity and may vary from a few days after the event to the first follow-up appointment.

c) Feedback should be given on the progress to date and should provide information on the investigation process. In some instances the process may be completed at this time.

d) There should be no speculation or attribution of blame. Similarly, the person disclosing the adverse event must not criticise others or comment on matters outside their own experience.

e) The patient and support person should be offered an opportunity to discuss the situation with another relevant professional, where appropriate.

f) A written record of the discussion should be made and filed, according to internal policy and legal requirements.

g) All queries should be responded to appropriately within an environment that encourages and supports the patient and their support person, and addresses their concerns.

h) If completing the process at this point, the patient and their support person should be asked if they are satisfied by the investigation and explanation, and a note of this made in the patient's records (see clause 11.2). Written information about the adverse event and its management should be provided to the patient and their support person for all high level incidents and where requested for low level incidents (see clause 16.1).

i) Consideration should be given to involving with the patient's permission, the GP, residential facility or community care provider in the discussion.

j) The patient should be provided with details of a person to contact if further issues arise.

14.2 Preliminary follow-up with staff

The results of the investigation and recommendations for improvement should be communicated to the multi-disciplinary team involved in the incident (see clause 5).

15 RECOMMENDATIONS AND IMPLEMENTATION

15.1 Communication of recommendations to management

On completion of the investigation, the investigator or committee (in conjunction with clinical advisers) will make recommendations for action to management and clinical staff, based on an assessment of causation.

Recommendations to improve public health and safety may also be generated through a coroner's inquest or other external inquiries. These should also be incorporated into outcomes of other investigation processes.

15.2 Responsibility of management

15.2.1 General

It is the responsibility of management to –

a) consider all recommendations for improvement;

b) decide which recommendations are to be implemented;

c) delegate responsibility for implementation;

d) allocate adequate resources to make changes required;

e) implement a mechanism for reporting on changes made and outcomes of these changes; and

f) document reasons for a decision not to implement recommendations.

15.2.2 Governing body

The organisation's governing body will have ultimate responsibility for ensuring the safety of patients and that resources are made available for implementing recommended changes.

15.2.3 Chief executive officer

The CEO has operational responsibility for ensuring that the organisation has appropriate adverse event detection, investigation, support and improvement processes in place.

Organisations will ensure that the CEO has the authority to –

a) implement recommendations of the investigation team where appropriate; and

b) effect change through the operational management system.

15.3 Implementation of recommendations

15.3.1 General

Systems improvements based on the accepted recommendations will be implemented through the framework for achieving improved outcomes. This may be a committee designated to oversee quality assurance, clinical risk and/or patient safety, or the clinical governance unit. Any recommendations accepted by

management for implementation should be the subject of a detailed action plan that lists –

a) actions to be taken;

b) those responsible for implementing the changes;

c) the timeframe for completion; and

d) mechanisms for monitoring and evaluating improvement.

Some recommendations may first require trialing to evaluate their effectiveness. All changes should be made within six months of management receiving recommendations.

15.3.2 Implementation of urgent changes

Where information comes to light at an early stage which requires immediate action to prevent further damage occurring, the hospital will have a mechanism in place for its urgent implementation.

16 COMPLETING THE PROCESS

16.1 Communication to patient

After completion of the investigation, feedback to the patient may take the form of a face-to-face interview, a letter or both. The interview and/or letter will include –

a) reference to the clinical and other relevant facts;

b) reference to details of the concerns or complaints of the patient and support person;

c) an expression of regret for the harm suffered;

d) a summary of the factors contributing to the adverse event; and

e) information on what has been and will be done to avoid repetition of the adverse event, and how these improvements will be monitored.

It is expected that in most cases there will be complete disclosure of the findings of the investigations. In some cases, information may be withheld or restricted. This may occur for example where it is considered that disclosure of information will adversely affect the health of the patient; where investigations are pending coronial processes; where contractual arrangements with insurers preclude disclosure of specific information or where information is protected from disclosure (see clause 7). In this case, the patient will be informed of the reasons for the restriction.

16.2 Continuity of care

When a patient has been harmed during the course of treatment and requires further therapeutic management or rehabilitation, discussion should be held with the patient to ensure that they are clearly informed of their proposed ongoing clinical management. Discharge planning should ensure ongoing care is provided where it is required as a consequence of the adverse event.

16.3 Communication with the GP, residential facility and other community care providers

When the patient is leaving the care of the organisation, the patient should be asked if he or she agrees to a discharge letter being forwarded to the GP, residential facility or community care provider. Subject to the patient's consent, the letter should contain summary details of –

a) the nature of the adverse event and the continuing care and treatment;

b) the current condition of the patient;

c) clinical investigations; and

d) recent results.

16.4 Monitoring improvements

Any recommendations for systems improvements and changes implemented should be monitored for effectiveness in preventing recurrence. The individual with responsibility for management of clinical risk should develop a plan for monitoring implementation and effectiveness of changes.

16.5 Communication of changes to staff

Effective communication with staff is a vital step in ensuring that recommended changes are fully implemented and monitored. It will also facilitate the move towards increased awareness of patient safety issues and the value of open disclosure.

16.6 Communication of lessons learned throughout the health system

The health care industry should provide a mechanism to ensure that health care organisations can disseminate information about factors that cause adverse events in a meaningful and useable format to prevent recurrence across organisational boundaries.

APPENDIX A GLOSSARY

There is a valid ongoing discussion on the meaning of some of the terms used in the Standard. However, for the purpose of this Standard, the following meanings have been used.

Admission of liability — An "admission" of liability is a statement by a person that proves, or tends to prove a person's or organisation's liability in negligence for harm or damage caused by another. There is a clear distinction between an admission of fact on the one hand ("we lacerated your liver during the course of the operation"), versus an admission of liability for negligence (" the liver laceration constitutes a breach of my duty of care to you and that breach has caused you injury") on the other.

Adverse event – An incident in which unintended harm resulted to a person receiving health care[6].

Adverse outcome – An outcome of an illness or its treatment which has not met the health care professional's or the patient's expectation for improvement or cure.

Carer(s) – Family, friend or those identified by the patient as providing care for them.

Circumstance – All the factors connected with or influencing an event, agent or person.

Clinical risk management – The process of risk management as it relates to clinical care.

Complication – An adverse event related to medical intervention or disease, especially an event that is a known potential consequence of, or that sometimes occurs in relation to, the patient's disease or its treatment.

Disability – Any type of impairment of body structure or function, activity limitation and/or restriction of participation in society.

Event – Something that happens to or with a person. (See Incident).

Expression of regret – An expression of sorrow for the harm experienced by the patient.

Harm – Death, disease, injury, suffering, and/or disability experienced by a person.

Hazard – The potential for harm arising from an intrinsic property or circumstance

Health care professional – A doctor, dentist, nurse, pharmacist, allied health care professional, or registered alternative health care practitioner. They may be employed by the hospital or self employed.

Health care record – A collection of data and information gathered or generated to record clinical care rendered to an individual. A comprehensive, structured set of clinical, demographic, environmental, social, and financial data and information, documenting the health care given to a single individual.

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[6] Wilson, Runciman, Gibberd (1995) *Quality in Health Care Study* Medical Journal of Australia 163 (9):458-471.

Hospital – An institution or organisation in which health care is the main service provided.

Incident – An event or circumstance which could have, or did lead to unintended and/or unnecessary harm to a person, and/or a complaint, loss or damage.

Injury – Damage to tissues caused by an agent or circumstance.

Integrated risk management – a process of assessing all of an organisation's risks and developing strategies to coordinate the management of those risks, including financial, operational, and clinical. It uses a structured and disciplined approach with a key focus of aligning strategy, processes, people, technology and knowledge and should be integral to the culture of the organisation

Liability – Responsibility for an action in a legal sense.

Morbidity – The negative consequences (symptoms, disabilities or impaired physiological state) resulting from disease, injury or its treatment.

Mortality – Death from disease or injury.

Open disclosure – The process of open discussion of adverse events that result in unintended harm to a patient while receiving health care and the associated investigation and recommendations for improvement.

Qualified privilege legislation – Qualified privilege legislation varies between jurisdictions but generally protects the confidentiality of individually identified information that became known solely as a result of a declared safety and quality activity. Certain conditions apply to the dissemination of information under qualified privilege. [7]

Risk – The likelihood that someone or something that is valued will be harmed by a particular hazard.

Root cause analysis – A systematic process whereby the factors which contributed to an incident are identified.

Safety – A state in which risk has been reduced to an acceptable level.

Sentinel health event – Events in which death or serious harm to a patient has occurred, for example:

a) An unexpected occurrence involving death or serious physical or psychological injury, or the risk thereof.

b) An incident with actual or potential serious harm, or death.

c) A condition that can be used to assess the stability or change in health levels of a population, usually by monitoring mortality statistics. Thus, death due to acute head injury is a sentinel health event for a class of severe traffic injury that may be reduced by such preventive measures as use of seat belts and crash helmets.

Staff – Any one working within a hospital, including self-employed professionals such as visiting medical officers.

Standard – Sets out agreed specifications and/or procedures designed to ensure that a material, product, method or service is fit for the purpose and consistently performs the way in which it was intended.

[7] The Public Interest in Qualified Privilege. Australian Council for Safety and Quality in Health Care 2001

Suffering – Experiencing anything subjectively unpleasant. This may include pain, malaise, nausea and/or vomiting, loss, depression, agitation, alarm, fear, grief or humiliation.

Support person – Information about an adverse event will be given to a patient's nominated "support" person in appropriate circumstances, taking account of the patient's wishes, confidentiality and privacy requirements and the organisation's internal policies. The nominated support person/persons may be any individual, identified by the patient as a nominated recipient of information regarding their care This may include family, friend, partner or those who care for the patient. (see Clause 3 for further clarification)

System failure – A fault, breakdown or dysfunction within operational methods, processes or infrastructure.

Systems improvement – The changes made to dysfunctional operational methods processes and infrastructure to ensure improved quality and safety.

Treatment – The way an illness or disability is managed by drugs, surgery, physiotherapy or other intervention to affect an improvement in or cure of the patient's condition.

APPENDIX B FINANCIAL SUPPORT

Patients experiencing an adverse event often indicate that bearing the costs of care is the determining factor in initiating litigation, particularly if they are also faced with loss of earnings.

Health care organisations should develop guidelines in consultation with insurers and other relevant agencies for providing assistance to patients who have experienced adverse events and where preliminary investigation indicates that this would be appropriate. For example, health care organisations may consider offering financial or other support at an early stage.

It is recommended that any of the above only be undertaken on written legal advice and with prior consultation with the insurer (particularly if the insurer is to meet the cost).

APPENDIX C PARTICULAR PATIENT CIRCUMSTANCES

C.1 General

Knowing how to enable or enhance communication with a patient is important to facilitating an effective open disclosure process. In many ways, all these things are simply being "consumer-centred", thoughtful and respectful of the needs of each patient and their support person.

C.2 When a patient dies

Where an adverse event has resulted in a patient's death, it is crucial that communication is sensitive, empathic and open. Establishing open channels of communication may also allow the carer to indicate if he or she needs grief counselling assistance at any stage.

A death suspected to be a result of an "adverse event," maybe reportable to the coroner. It is necessary to ensure that family, carers or the patient's support person are kept up to date with what is happening and that personal contact is maintained by someone from the health care organisation throughout the coronial process. This will be subject to requirements of the coroner and legislative provisions. For example, the coroner may direct that the matter not be discussed.

There is considerable variation between State/Territory coronial legislation and individual coroners, including differences in disclosure or non-disclosure of information. Occasions may arise where an individual coroner requests that discussion of the case between hospital staff and family should not take place until he or she has considered the evidence. Directions for disclosure of information should be included in local guidelines. However, if the coroner so directs, it should be made clear to the family that a discussion of the facts and any residual concerns will be arranged at a date to suit both parties after the completion of the coronial inquiry which may include an inquest.

The functions of the coroner includes determination of the identity of the deceased person, as well as the manner and cause of death. The coroner has the power to require a post-mortem and to require the production of medical records, including private clinical records and hospital records, for the purpose of the coronial inquiry.

The coroner's brief (or coroner's file) is the file of information about the death collected by the police, on behalf of the coroner. It includes medical reports, the results of investigations, scientific reports, and witness statements. Relatives of the deceased are usually given a copy of the brief, except where the coroner or State/Territory legislation requires the investigation to remain confidential.

The coroner does not determine any criminal or civil liability. However, the investigation can provide valuable insight into causes of the adverse event. The coroner can make recommendations on public health and safety which should be channelled into the appropriate mechanisms for implementing changes for systems Improvement throughout the health sector.

C.3 Children

Where an adverse event involves children, the clinical team will, together with the parents/carers need to make informed but complex assessments of what the child should be told. In the case of young people close to the age of capacity, the involvement of parents in the process will be comparable to that of consent for treatment involving the child, weighing up the young person's maturity. There is often conflict between a young person asserting (or entitled to) autonomy and parental authority. States/Territories have legislation that generally protects health care professionals who act on the instructions of parents of children under 18 from civil liability for lack of consent by the young person. The involvement of young people in the open disclosure process will have to be assessed by the clinical team on a case-by-case basis, taking account of whether the child is mature enough to receive the information and having regard to the wishes of the young person and the parents where appropriate.

C.4 Patients with mental health issues

There are several main factors to consider in open disclosure to patients with mental health issues irrespective of whether the patient is subject to mental health legislation, which varies between jurisdictions. Disclosure of information relating to treatment issues, including open disclosure of adverse events, applies equally to people with a mental illness as to others. Patients are entitled to all relevant details concerning their treatment, including instances where an adverse event occurs, with the timing of the disclosure subject to the clinical team's assessment of how this will affect the health of the patient and the patient's ability to understand what is said (clause 10.3.2).

C.5 Patients with cognitive impairment

There are many individuals in the community with conditions that limit their ability to understand what is happening to them. Where possible, patients with a cognitive impairment should be involved directly in communications about what has happened to them, according to the level of their capacity to understand.

The person may have a legal guardian, or an attorney appointed under an enduring power of attorney. It should not be assumed that because a person is named in an order or power of attorney that that person has the legal right to act in all circumstances on behalf of the person. It will be necessary to determine the actual legal effect of any such relationships, which vary according to the terms of each guardianship order or power of attorney (only some jurisdictions permit a power of attorney to give the attorney right to consent to treatment on behalf of the person). These issues must be carefully considered in assessing whether disclosure of an adverse event and decisions to be taken can be made to or by a third party in the absence of the patient's informed consent to do so.

C.6 Patients who do not agree with the information provided

Sometimes, despite the best efforts of health care staff or others, the relationship between the patient and/or carer and the health care professional breaks down. The patient and/or their support person may not accept the information provided or may not wish to participate in the open disclosure process. In this case, the following strategies may assist:

a) Deal with the problem earlier rather than later.

b) Where the patient agrees, ensure that their support person is involved in discussions from the beginning.

c) Ensure the patient has access to support services, as described in clause 4.2.

d) Where the senior health care professional is not aware of the relationship breakdown, provide mechanisms for communicating early warning signs (eg patient communicating concern to other members of the team, lodging a Freedom of Information application).

e) Offer the patient and support person another contact person with whom they may feel more comfortable. This could be another member of the treating team or the individual with responsibility for clinical risk.

f) Use a mediation or conflict resolution service to help identify the issues between the health care organisation and the patient, and to look for a mutually agreeable solution.

g) Involve the services of the local health complaints office if the patient wants to lodge a formal complaint.

h) Assess whether sufficient weight has been given to the patient's version of events and whether reasonable efforts have been made to seek information from all key witnesses, including witnesses identified by the patient or carer.

Trust needs to be rebuilt where there has been a breakdown in the relationship between the patient and provider.

C.7 Patients with language or cultural diversity considerations

Where the patient and/or their support person come from linguistically or culturally different backgrounds to the service provider, communication can be more challenging. For example, if English is a patient's second language, they may have difficulty with medical terms, even if they otherwise are very proficient. The ability of health care professionals to communicate well can be similarly restricted. Equally, if a patient is from a background where people are particularly intimidated by authority figures, or she is a woman whose cultural or other experience makes it difficult for her to talk to a male about intimate issues, the selection of an inappropriate health care professional to provide information may significantly limit effective communication. These issues need to be considered when disclosing after an adverse event.

The need for interpreter services should be identified as soon as the patient makes contact with the service. A space on the admission sheet should be provided to identify the first language of all patients and also their preferred language of communication. For migrants and others who have been educated in English, there will be no need to consider translation services but care should be taken with those who have learned English later in life. When an adverse event occurs, the physical effects of the illness and the emotional impact may render a normally fluent speaker less able to communicate well.

Where someone has difficulty communicating in English or at the patient's request, a professional interpreter or a health care professional who can speak the patient's language should be used. The use of family (or other support person) to interpret should be avoided except in an emergency. An interpreter from the same language and cultural background may also be able to advise on other issues (e.g. whether the gender of the health care professional who makes the disclosure is an issue

that needs to be considered). These issues should be discussed with the interpreter beforehand so that the open disclosure process is culturally and linguistically appropriate from the outset.

C.8 Aboriginal or Torres Strait Islander patients

There are diverse cultural and linguistic groupings within the collective descriptor "Aboriginal and Torres Strait Islander people". The experience of Aboriginal people is that there are very real barriers to communication with health service providers not merely with respect to language but in the context of underlying principles and beliefs regarding health matters. Every effort needs to be made to ensure that the appropriate people in the context of the patient's needs are included in discussions, with the patient's agreement in relation to adverse events and their investigation and management.

C.9 Patients with other communication requirements

Other communication requirements are likely to arise. For example, an older person may have a hearing impairment or a memory or concentration impairment. People with disabilities may have communication difficulties. For example, a blind person will not be able to read a printed pamphlet; a deaf person may need an interpreter.

For someone with a mobility disability, the discussions should be held in a readily accessible place. For example, it is little use arranging a meeting, in a place that a person in a wheelchair cannot access, or where there are large distances to walk (as often occurs in hospitals) when the patient or support person has limited mobility.

APPENDIX D EXAMPLE OF MATRIX FOR INITIAL ASSESSMENT OF LEVEL OF RESPONSE

The following table is an example of a matrix to assess the level of response. The matrix used will vary depending on local policies.

Assessment of level of response

Level of Response	Consequence	Action
High	Death or major permanent loss of function not related to the natural condition of the patient	Immediately notify individual responsible for clinical risk management. Disclosure by senior medical practitioner or alternate with support where indicated
	Permanent lessening of bodily function not related to underlying condition of patient or where surgical intervention or transfer to higher level of care required (eg transfer to ICU)	
Low	No permanent Injury nor increased level of care required	Local management, incident report. Disclosure by senior health care professional

APPENDIX E EXAMPLE OF INCIDENT GRADING MATRIX

The following table is an example of a matrix for grading an Incident to determine the level of investigation required. The matrix used will vary depending on the policy of the organisation.

The tables are reproduced from AS/NZS 4360 *Risk management*. It is strongly recommended that users of the Open Disclosure Standard consult the complete AS/NZS 4360 for the context in which this table is presented and for detailed information on its use and application.

TABLE 1 QUALITATIVE MEASURES OF CONSEQUENCE OR IMPACT

Level	Descriptor	Example detail description
1	Insignificant	No injuries, low financial loss
2	Minor	First aid treatment, on-site release immediately contained, medium financial loss
3	Moderate	Medical treatment required, on-site release contained with outside assistance, high financial loss
4	Major	Extensive injuries, loss of production capability, off-site release with no detrimental effects, major financial loss
5	Catastrophic	Death, toxic release off-site with detrimental effect, huge financial loss

1 Measures used should reflect the needs and nature of the organisation and activity under study.

TABLE 2 QUALITATIVE MEASURES OF LIKELIHOOD

Level	Descriptor	Description
A	Almost certain	Is expected to occur in most circumstances
B	Likely	Will probably occur in most circumstances
C	Possible	Might occur at some time
D	Unlikely	Could occur at some time
E	Rare	May occur only in exceptional circumstances

2 These tables need to be tailored to meet the needs of an individual organisation.

TABLE 3 QUALITATIVE RISK ANALYSIS MATRIX—LEVEL OF RISK

Likelihood	Consequences				
	Insignificant 1	Minor 2	Moderate 3	Major 4	Catastrophic 5
A (almost certain)	H	H	E	E	E
B (likely)	M	H	H	E	E
C (moderate)	L	M	H	E	E
D (unlikely)	L	L	M	H	E
E (rare)	L	L	M	H	H

3 The number of categories should reflect the needs of the study.

Legend:

E extreme risk; immediate action required

H high risk; senior management attention needed

M moderate risk; management responsibility must be specified

L low risk; manage by routine procedures

'JGW-1P'

Safe Medication Practice Unit

Patient Safety Centre

Business Plan
2004-2005

Overview

Our mission	*'Promoting a healthier Queensland'*
Our values	Professionalism, teamwork, performance accountability, quality and recognition

Who we are

The aim of the Safe Medication Practice Unit is to improve the health of Queenslanders through quality use of medicines (QUM)[1], with a focus on the prevention of adverse drug events, by means of multidisciplinary enhancement of medication-related services and moving to best practice medication management. This goal will be obtained through FIVE major areas in the QH Medicines Management Program:

1. High Risk Medications and Systems
2. Medication Continuum
3. Medication Review
4. Electronic Medication Management Strategy
5. Data Management

The Safe Medication Practice Unit (SMPU) evolved and will build on successful work initiated by the Quality Use of Medicines (QUM) and Queensland Health Medication Management Services (QHMMS) Projects. These projects and the continuing goals of the SMPU will ensure safety initiatives outlined in the Health Minister's Joint Communique 23 April 2004. The SMPU reports directly to the Patient Safety Centre which has been established to implement and coordinate a patient safety reform agenda across the state.

The SMPU intends on building on the success and lessons learned from the QUM and QHMMS Projects funded out of the previous health care agreement under the Quality Improvement and Enhancement Program.

Background

The medication use system involves multiple health care providers and is constituted of multiple steps (see figure 1); each with a risk of associated patient harm. This program aims to bring together a range of initiatives that focus on **improving safety** of the processes involved or **improve the effectiveness** of medicines use, or the **improving efficiency** of services – a systems approach. Each of the proposed projects is directly dependant on the other with common goals of QUM.

This program therefore, intends to use a **systems approach** to medicines management in addressing the proposed four areas for targeting in the following three-four years; ie

1. a strategy for electronic medicines management for QH
2. improving pharmaceutical review services across the state
3. improving the continuum of medicines use between hospital and community
4. targeted medication interventions on high risk medications.

Strategic Alignment

This program aligns with a number of important strategic directives and goals from a national level, state level, QH corporate level and locally for each health service district, including alignment with:

NATIONAL

National Medicines Policy
National Strategy for Quality Use of Medicines
National Medication Safety Taskforce
Health Minister's Joint Communiqué 23 April
Australian Pharmaceutical Advisory Council's National Guidelines to Achieve the Continuum of QUM between Hospital and Community
Pharmaceutical reform

STATE

QH Strategy Map

The program aligns with a number of the QH priorities for healthier Queenslanders, including by not exclusively:

C6 – Ensuring safe and quality health outcomes – all projects: Medication Safety, Pharmaceutical Review, Medication Continuum, E-medicines management

IP5 – Reduce risk in high risk consumers – Medication Safety Initiatives, Introduction of APAC continuum principles, Introduction of pharmaceutical review for prioritised high risk patients

WF1 – Encourage innovative and targeted research – Use of research into medication safety initiatives. Involvement in Centre for Research Excellence in Patient Safety submission

WF3- Recruit, develop and retain appropriately skilled workforce – Training in pharmaceutical review and medication safety risk awareness. Involvement in Medical / nursing / pharmacy schools undergraduate training to ensure "work-ready" workforce.

IP9 – Increased use of clinical evidence-based decisions – Development of guidelines for medication safety initiatives for use at point of prescribing for high risk medicines.

IP10 – Continuous improvement of key business processes – as determined by Electronic Medicines Management Strategy development, Introduction of APAC Continuum guidelines

IP2 – Improve community participation in the planning and delivery of health services. This is a fundamental principle of the APAC Continuum guidelines. Working with GPAC, General Practice and Community Pharmacy

C1 – Increase knowledge and skills for health – Fundamental requirements of APAC Continuum and pharmaceutical review

ELECTRONIC MEDICINES MANAGEMENT AGENDA (State and national)

Health Connect Program

- **Practice guidelines and standards**

State-wide incident management and integrated risk management

WORKFORCE ISSUES

Workforce strategic framework

The Medicines Management Program will utilise the following building blocks on which to base the proposed strategies:

1. Policy development and implementation
2. Facilitation and coordination of QUM initiatives
3. Provision of objective information and assurance of ethical promotion of medicines
4. Education and training
5. Provision of services and appropriate interventions
6. Strategic research, evaluation and routine data collection

Please see Table 1 for summary.

What we do

Preventing and addressing adverse drug events resulting in patient harm by improving medication-related practices in FOUR main areas:

1. High risk medicines and processes
   - standardised processes for ordering, supplying and administering of high risk medicines
   - increasing awareness of risk of patient harm in medication management
2. Medication continuum
   - ensuring transfer of accurate, comprehensive and complete, standardised information relating to medications on admission and discharge from QH facilities
3. Medication review
   - Reviewing therapy decision to ensure safe, effective medication treatment
4. Electronic Medicines Management Strategy
   - a strategy for the implementation of electronic solutions and standards to address medication safety issues

Table 1 - Medication Management framework and QH Strategies

	Medication Safety	Medication Continuum - APAC QUM Continuum Guidelines	Pharmaceutical review	eMedication Management.
Policy development	***Identification and prioritisation of FOUR medication safety implementation initiatives each year.*** *QHMSIG to develop policy on interventions for endorsement by Board* *Incident monitoring standard definitions for medication incidents* *Involvement in national Medication Safety Taskforce of ACSQHC*	***Development of policy for QH endorsement of new APAC continuum of QUM guidelines*** *Development and endorsement of minimum data sets & standards for QUM continuum guidelines*	***Develop standards for pharmaceutical review in line with national Health Minister's Joint Communiqué.*** *Development of policy on:* *1. implementation of pharmaceutical review.* *2. prioritisation of service provision* *3. remote supervision of medication services (including technicians roles and use of tele-pharmacy, indigenous QUM, Community Mental health* *Involvement in national working party on medication management*	***Development of e-Medication Management Strategy for QH*** • *(E-PALMS, Pyxis, Citrix etc see separate options paper)* • *Bar-coding* • *Telepharmacy* • *Wireless LAN for provision of clinical services at point of patient care* • *Electronic prescribing and decision support* • *Interfacing with pathology* • *Interfacing with Integrated Risk Management* *Involvement in National Electronic Prescribing & Decision support Working Party* *Involvement in development of minimum datasets for e-medicines management*
Facilitation of implementation	*Prioritise & coordinate initiatives to address the implementation of four medication safety initiatives each year in all QH districts*	*Work with QH districts to* ***facilitate the introduction of new APAC QUM continuum guidelines***	*Identification of resource implications for implementation of pharmaceutical review*	*Negotiate the use of QH drug catalogue for Commonwealth initiatives (eg Health Connect)*
Objective Information	*Use of QRMSA Services on selected topics*	*Updating of QH Medication Management Guidelines to support implementation* *e-PALMS implementation business interface and work practices* *Health Connect* *Endorsement of minimum data standards for medication related information transfer on admission and discharge*		*See APAC (Endorsement of minimum data standards for medication related information transfer on admission and discharge)*

Education	*Development and implementation of :* *1. Risk Awareness Education Program for QH and undergraduate medical, nursing and pharmacy staff.* *2. Prescribing module*	*See pharmaceutical review (training, competency assessment for undertaking activities associated with continuum eg medication history taking, pharmaceutical review, discharge medication liaison)* *Use of QH Skills Centre (RBH)* *Use of QRMSA Services for selected APAC QUM Continuum principles*	*Training, competency, credentialing (using UK NHS and Australian PSA/PGA frameworks)* *Clinical pharmacy training* • *Credentialing and Competency* *Pharmacy skills training in non-clinical domains:* • *Financial management* *Project management*	
Services / interventions (Workforce)	***Implement services and initiatives to address four medication safety initiatives each year in all QH districts*** *(eg palliative care, KCl, chemotherapy, etc)* *Facilitative implementation of National Medication Safety Alerts in QH districts* *Identification of deviation from evidence based best practice and implementation of interventions to address.* *(Eg* *1. National drug chart* *2. Infusion pumps etc)* *Identification of workforce implications*	***Facilitate districts in the implementation of APAC guidelines (prior to and following development of ePALMS)*** *Provision of consumer information* *Work practice design* *E-PALMS implementation* *Identification of workforce implications* *Work practice modelling and analysis for medication continuum*	***Facilitation of pharmaceutical review service implementation in QH districts*** *Tele-pharmacy* *Use of pharmacy support personnel work practice alignment with priorities* *Identification of workforce implications of Health Ministers' Joint Communiqué* *Clinical pharmacy service standards* *Prioritisation of services and interventions* *Remote supervision* *Pharmacist prescribing*	***Electronic Prescribing trial*** *Failure Modes and Effects Analysis for* *1. e-prescribing* *2. Bar coding of dispensing* *3. AMDS* *4. Interface with IRM* *5. Robotics* *6. Automated dispensing* *Identification of workforce implications*

Research, evaluation, data collection	*Act on data provided by Integrated Risk Management on RCA, or sentinel events.* *Development of performance indicators and monitoring of outcomes* *Benefits realisation*	*Undertake pilot with Bayside GPs /Nambour for the implementation of the APAC QUM continuum guidelines* *Involvement in Health Connect pilot* *Development of performance indicators and monitoring of outcomes* *Benefits realisation*	*Prescribing rights (nurse and pharmacist)* *Define and implement Clinical Pharmacy Intervention reporting and analysis (In consultation with Integrated Risk Management)* *Development of performance indicators and monitoring of outcomes* *Benefits realisation*	*Development of performance indicators and monitoring of outcomes* *Benefits realisation*
Shared Program Services	*Secretariat for QHMSIG and QHMMS Board* *Data analysis and reporting, project evaluation (Performance indicator data collection, economic evaluation* *Communication and liaison (Website, Factsheets, RARE moderated email, liaison, publishing of research)* *National representation on appropriate committees* *Financial management* *Event coordination (workshops, etc)* *Research (QUM student placements, CRE patient safety)*			

Work Plan

PROJECT AREA 1 - HIGH RISK MEDICINES AND SYSTEMS TEAM

Objective1

Address known harm associated with high risk medicines and systems

Reactive

Existing: Warfarin, medication chart, nurse risk awareness, potassium, IV fluids
New: Insulin, chronic pain, acute pain, vincristine, medical staff risk awareness packages

Proactive

1. Producing a safe workforce (risk awareness) through training program for (1) undergraduate medical, nursing and pharmacy and (2) QH staff
2. Input lessons learned into electronic prescribing
3. Incidents and risks identified by state-wide incident monitoring to be referred to Medication Safety project to be addressed (according to priority)

Key performance indicator/s

1. Observational audits of prescribing and administration
2. Number of strategies introduced to address high risk causes of patient harm associated with medications (Up to 4 per year)
3. Process analyses (failure modes effects analysis) undertaken for proposed system changes
4. 80% of sites using forms and systems developed within 12 months of approval/endorsement by QHMSIG
5. Training (complete 2008)
a. 50% of undergraduates trained in medication safety risk awareness
b. 50% of new staff trained in medication safety risk awareness
c. 50% of medical, nursing and pharmacy students trained on safe prescribing, administration and dispensing practices
6. Work practices from med chart incorporated into CIS
7. 100% of districts having medication safety on D&T and/or QUM committees
8. 100% of high risk medication incidents referred to QHMSIG for prioritisation and addressing
9. One FMEA undertaken per year (for key initiatives impacting on medication safety)

Basis for comparison

1 All sites minimum of once a year
2. As negotiated with QH incident management.
3& 4. Pre-post audit of implementation - 50% improvement in prescribing audit criteria over 24 month period for all hospitals introducing system changes
50% improvement in administration audit criteria over 12 month period for all hospitals introducing system changes
Reduction in harm and improved patient outcomes (eg chemotherapy related adverse events, INRs >5, re-exposure of patients to drugs to which they have a known allergy, reduce wrong patient errors)
Audit of training

Strategies

How are we going to achieve it?

Strategies

Strategy	Who	When	Key partners	Resources
Build and support mechanism to obtain state-wide consensus on medication initiatives	State wide workshops QHMSIG QHMMS Board	Quarterly	Health Service Districts, Zones, Pharmaceutical Advisory Services, Central Pharmacy, Other PSC Units	6 FTEs in total
Strategic research by use of undergraduate and post graduate students	SMPU	Ongoing	As above plus universities	As above
Undergraduate lecturing and course re-design	SMPU	2005	As above	As above
Introduction of medication safety on the agenda for district D&T and/or QUM committees Use of local medication safety and patient safety officers	SMPU Local PSO and Med Safety Staff	2005	Directors of Pharmacy, D&T committees	As above

Strategy	Who	When	Key partners	Resources
Training module	Skills Centre Heaps Training	2005	SDC, Universities, Medial Education officers	As above
Involvement in and alignment with national agendas	Director SMPU	2005	ACSQHC, Medication Safety Taskforce, National Prescribing Service, APAC	1 FTE

PROJECT AREA 2 – MEDICATION CONTINUUM

Objective 2

To improve the flow of medication related information between health care providers as patients travel between points of care, and thereby decrease harm associated with dis-continuity of medication use.

Key performance indicator/s

- frequency of detailed medication history taken;
- frequency with which a medication plan is in place;
- frequency of review of medications during the stay;
- adherence to local prescribing guidelines;
- frequency of discharge counselling and information provision to patient;
- frequency of medication liaison with primary health carers
- changes in patient health outcomes (to be finalised, but including health status measurement, satisfaction with services, comprehension of medication information and treatment compliance and regimen adherence)

Basis for comparison

Audit of current service delivery

Strategies

How are we going to achieve it?

Strategies

Strategy	Who	When	Key partners	Resources
Development of policy for QH endorsement of new APAC QUM Continuum guidelines Development and endorsement of minimum data sets & standards for QUM continuum guidelines Work with QH districts to facilitate the introduction of new APAC QUM Continuum guidelines	SMPU and GPAC	2005	HSD, Zones, General Practice, Divisions, Rural and Remote Practitioners, APAC	5 FTEs
Updating of QH Medication Management Guidelines to support implementation	As above	2005	As above	

Strategy	Who	When	Key partners	Resources
Endorsement of minimum data standards for medication related information transfer on admission and discharge Ttraining, competency assessment for undertaking activities associated with continuum (eg medication history taking, pharmaceutical review, discharge medication liaison) Liaison with Health Connect	As above	2005	As above plus Health Connect	
E-PALMS implementation e-PALMS implementation business interface and work practices	INET and SMPU	Subject to funding	As above	
Facilitate districts in the implementation of APAC guidelines (prior to and following development of ePALMS) Work practice design	SMPU and HSD	2005	HSD	
Identification of workforce implications	SMPU	2005	HSD	
Work practice modelling and analysis for medication continuum	SMPU	2005	HSD and GPAC	
Undertake pilot with Bayside GPs / Nambour for the implementation of the APAC continuum guidelines	SMPU	2005	Bayside Div of GP and SCHSD	
Provision of staff awareness and education sessions via utilisation of the QRMSA services and QH Skills Centre	QRMSA	2005	HSD	
Provision of consumer information	HSD	2005	SMPU	

PROJECT AREA 3 - PHARMACEUTICAL REVIEW

Objective 3

To develop and implement pharmaceutical review and clinical pharmacy services by Jan 2007, to ensure that 100% of QH patients' medications are reviewed during their stay, in line with the Health Ministers joint communique,

Key performance indicator/s

Pharmaceutical review being undertaken in line with minimum acceptable standards. Performance indicators and practice standards developed and endorsed state-wide

In rural and remote areas, or those with workforce shortages, alternative models of service provision for pharmaceutical review, using Telehealth technology and appropriate use of support personnel.

- 100% of patients receiving pharmaceutical review
- All clinical pharmacists achieving minimum standards of pharmaceutical review

Basis for comparison

Audit

Competency skills assessment (OSCI)

Strategies

Strategy	Who	When	Key partners	Resources

Strategy	Who	When	Key partners	Resources
Develop standards for pharmaceutical review in line with national Health Minister's Joint Communiqué. Development of policy on: 1. implementation of pharmaceutical review. 2. prioritisation of service provision 3. remote supervision of medication services (including technicians roles and use of tele-pharmacy, indigenous QUM, Community Mental health	SMPU	2005	PAS, HSD	6 FTEs
Involvement in national working party on medication management	Director SMPU	2005	APAC	1 FTE
Training, competency, credentialing (using UK NHS and Australian PSA/PGA frameworks)	SMPU	2005	UQ, SDC, HSD	6 FTEs
Clinical pharmacy training : Credentialing and Competency. Pharmacy skills training in non-clinical domains	SMPU	2005		
Facilitation of pharmaceutical review service implementation in QH districts	SMPU	2006	HSD	
Identification of workforce implications of Health Ministers' Joint Communiqué	SMPU	2005		
Tele-pharmacy	SMPU	2006	Telehealth Unit	
Use of pharmacy support personnel work practice alignment with priorities and Remote supervision	SMPU	2005	PAS, Workforce Branch	
Clinical pharmacy service standards	SMPU	2005	Workforce Training, Innovation Branch	
Define and implement Clinical Pharmacy Intervention reporting and analysis (In consultation with Integrated Risk Management)				
Prescribing rights (nurse and pharmacist)				

PROJECT AREA 4 – ELECTRONIC MEDICATION MANAGEMENT STRATEGY

Objective 4	*Key performance indicator/s*	*Basis for comparison*
To develop a strategy for the ongoing implementation of IM/ICT initiatives to enhance electronic medication management. The strategy will provide strong business leadership and direction and be in line with QH published goals and associated outcome indicators and facilitate medication management services.	Endorsed QH strategy for Electronic Medicines Management	Board endorsement by 30 June 2006

Strategies

Initiative	Who	When	Key partners	Resources
Work with IM/ICT strategy group within Information Directorate to develop strategy for pharmacy business	SMPU	2005-6	Information Directorate, Innovation Branch (I&WRD)	1 FTE
Work with Centre for IT Innovation (QUT) to develop strategy	SMPU	2005	QUT	As above
Undertake analysis of best practice in e-medicines management internationally	SMPU	2005	As per 1	

Further information?

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Copies of the plan are available from:
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Abbreviations

Acronyms

ACSQHC	Australian Council for Safety and Quality In HealthCare
ADE	Adverse Drug Event
ADEP	Adverse Drug Event Project
AMDS	Automated Drug Distribution System
APAC	Australian Pharmaceutical Advisory Council
CE	Continuing Education
CIU	Clinical Informatics Unit
CRE	Centre for Research Excellence
D&T Committee	Drug and Therapeutics Committee
DM	District Manager
E-PALMS	Electronic Patient Associated Liaison Medication System
EPDS	Electronic Prescribing Decision Support
FMEA	Failure Modes Effects Analysis
FTE	Full Time Equivalent
GPAC	General Practice Advisory Council
HPAC	Hospital Pharmacy Advisory Committee
HSD	Health Services District
I&WRD	Innovation and Workforce Reform Directorate
IM/ICT	Information Management / Information Communication Technology
INR	International Normalized Ratio
IRM	Integrated Risk Management
KCl	Potassium Chloride
KPI	Key Performance Indicator
LAN	Local Area Network
MAPSU	Medications and Pharmacy Services Unit (previously Pharmaceutical Advisory Services)
NSH	National Health Service
OSCE	Objective Structured Competency Evaluation
PAC	Pre Admission Clinic
PALMS	Princess Alexandra Liaison Medication System
PAM	Program Area Manager
PGA	Pharmacy Guild of Australia
PSA	Pharmaceutical Society of Australia
PAS	Pharmaceutical Advisory Service (now MAPSU)
PBS	Pharmaceutical Benefits Scheme
PSC	Patient Safety Centre
QC	Quality Council
QH	Queensland Health
QHMSIG	Queensland Health Medication Safety Implementation Group
QHMMS	Queensland Health Medication Management Service
QHDAC	Queensland Health Drug Advisory Committee
QHPIMS	Queensland Health Pharmacy Information Management System
QIEP	Quality Improvement & Enhancement Program
QIS	Quality Information Systems
QRMSA	Queensland Rural Medical Support Agency
QSU	Quality Strategy Unit
QSUM	Quality Summation Report
QUM	Quality Use of Medicines
QUMI	Quality Use of Medicines Initiatives
RARE	Rural and Remote Email
RBWH	Royal Brisbane and Women's Hospital
SDC	Skills Development Centre
SHPA	Society of Hospital Pharmacists of Australia
SMPU	Safe Medication Practice Unit

'JGW-12'

CHRISP

Patient Safety Centre

Operational Plan 2005-2006

Overview

Our mission	*'Promoting a healthier Queensland'*
Our values	Professionalism, teamwork, performance accountability, quality and recognition
Guiding Principles	We exist to support those delivering healthcare We will evaluate our work to determine value for money We will treat others with honesty, respect and fairness We accept responsibility for our actions

Who we are

CHRISP undertakes the state-wide coordination of infection management services through surveillance of healthcare related infections, assessment of the economic impact of infections, undertaking research to determine and influence behaviours associated with infections.

What we do

CHRISP can be described as a clinical governance support unit which delivers services through the Administrative Director, Medical Director and team leaders in areas of surveillance, health economics and behavioural research.

	Patient Safety Centre				
CHRISP	Administrative Director	Medical Director	Team Leader Surveillance	Team leader Health Economics	Team Leader Behavioural Research

The Administrative Director is responsible for providing high-level advice, developing, implementing and managing CHRISP initiatives and activities aimed at preventing patient harm by improving infection control practices in strategic priority areas.

The Medical Director leads the co-ordination of the state-wide surveillance and prevention of healthcare associated infection with the provision of information regarding the impact on Queensland Health, with subsequent research into areas of enquiry.

The Team leaders manage and coordinate activity in their respective areas with outcomes being used to further enhance and support existing systems and structure, and/or stimulate the review of infection control programs, interventions, policy and practice.

This plan

This plan provides an overview of the CHRISP Work Plan for the financial year 2005-06.

Key priorities

CHRISP directly contributes to 2 of the 5 key priorities of the Innovation and Workforce Reform Directorate:

1. **Standardisation of systems and clinical practice**
2. **Developing a culture of safety**
3. Exploit the full potential of the skills development centre consistent with QH Strategic Intents
4. Systematically applying innovation through the organisation
5. Attracting, training and retaining appropriately skilled staff in appropriate numbers

The following services, organizations and professional groups contribute to CHRISP:

Staff within the Patient Safety Centre, Infectious Diseases Physicians and Microbiologists, Zones, Health Service Districts, Communicable Diseases Unit and business units within Public Health Services, Office of the Chief Health Officer, Information Directorate, Infection Control Managers and portfolio holders, Statewide Quality Coordinators, Queensland Health Pathology and Statewide Services, business units of the Innovation and Workforce Reform Directorate.

Australian Council for Safety and Quality in Healthcare, professional associations such as the Infection Control Practitioners Association, Australian Infection Control Association, Australian Society of Microbiologists and the Australian Society of Infectious Diseases.

Objectives

CHRISP has four key objectives:

1. Sustain and enhance a healthcare associated infection surveillance system. This enables Health Service Districts to continuously monitor their own performance using longitudinal data, with subsequent comparison against the statewide aggregated data set provided in the CHRISP Report.
2. To provide algorithms and resources to assist healthcare workers to determine both the cost of healthcare associated infection and cost effectiveness of prevention programs with outcomes informing local and state policy and guidelines.
3. Develop and applies Theoretical Behavioural Models, strategies and processes to improve and sustain compliance with interventions known to reduce the transmission of infection i.e. handwashing.
4. To strengthen and build upon internal and external partnerships to promote cultural/behavioural change, with focus on strategies that minimise preventable harm through the development and/or enhancement of new and/or existing systems, structures and processes to provide decision support for clinicians.

The key priorities for achieving those objectives are:

- Enhance the surveillance system and processes to promote the timely review of outcomes and detailed analysis of data which leads to an evaluation of interventions to reduce the risk of preventable healthcare associated infection.
- Develop tools, resources and processes that support the delivery of cost effective programs and strategies aimed at reducing preventable healthcare associated infection.
- Develop strategies and resources to support compliance with infection control protocols.
- Formalise partnerships through agreements such as a Memorandum of Understanding.

The first priority involves a business analysis of the CHRISP surveillance software *electronic Infection Control Assessment Technology* (eICAT) to be undertaken by Development Services / InfoSolutions, Information Directorate. It is anticipated the business analysis will be completed by 30 June 2005. This work will provide clear direction regarding the enhancements

(interfacing with other information technology systems to improve automation) that are required to be made. The process will enable Queensland Health to quantify and qualify the benefits of the system. Further, the information contained within the Business Case will allow the Information Service Investment Board to make an informed decision regarding ongoing investment in this capital asset and endorsement of eICAT as a standard application.

Priority 2 is underway. A proposal has been submitted to Innov8 to consider the development of Infection Control with Economic Decisions (ICED) to enable infection control personnel to calculate (and provide confidence intervals around) the:

- bed days lost to infection
- cash costs lost to infection
- overall economic cost of infection; and

Identify prevention strategies in terms of:

- the cost of the strategy
- the effectiveness of the strategy (% reduction in risk)

Estimate:

- number of infections prevented
- number of bed days saved
- cash savings
- whether the cost of the prevention strategy is offset by the savings
- which strategies are cost-effective strategies and which are dominated
- the optimum level of investment in prevention, and so the optimal infection rate

Priority 3 and 4 are in-progress with input from external collaborators such as the World Health Organisation and the Infection Control Service South Australia and the Communicable Diseases Unit, Queensland Health.

The fluid nature of the work described above and dependant variables which include the appointment of Team Leaders will require this plan to be reviewed immediately prior to the commencement of the 2005/2006 year.

Further information

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Copies of the plan are available from:
http://qheps.health.qld.gov.au/

Abbreviations

CDU	Communicable Diseases Unit
CHRISP	Centre for Healthcare Related Infection Surveillance & Prevention
eICAT	electronic Infection Control Assessment Technology
PHS	Public Health Services
PSC	Patient Safety Centre
QHPSS	Queensland Health Pathology and Scientific Services
SIU	Safety Improvement Unit
SMPU	Safe Medication Practice Unit

Work Plan

Objective1 *What are we seeking to achieve?*	*Key performance indicator/s*	*Basis for comparison*
To evaluate the service provided by CHRISP, with focus on the surveillance stream, that includes a business and systems analysis of eICAT to better meet the needs of both Health Service Districts and other business units within the Health Service Directorate	▪ The evaluation of CHRISP, with focus on the surveillance stream including eICAT will be completed by March 31 2005	Evaluation undertaken by the Information Directorate in 2004 Previous evaluations undertaken by CHRISP
	▪ Findings and recommendations of the above evaluation to be actioned by December 2005.	The CHRISP Evaluation Report
	▪ Business and systems analysis of eICAT and subsequent business case be completed by 30 June 2005 and submitted to the Information Services Investment Board at its first meeting after the above date	Evaluation survey undertaken by the Information Directorate in August 04

Initiative	Who	When	Key partners	Resources *(human/ financial)*
▪ An evaluation of the service provided by CHRISP by District Health Services	Epidemiologist in collaboration with the staff of CHRISP	Nov 2004	District Health Services including District Managers Communicable Diseases Unit Representative Participant Group	
▪ A business and systems analysis of eICAT with the subsequent business case being tabled at the Information Services Investment Board meeting for consideration	Administrative Director in consultation with CHRISP staff and the project team from Development Services / InfoSolutions Information Directorate	June 05	CHRISP participating Hospitals Representative Participant Group Information Directorate Communicable Diseases Unit	

Objective 2 *What are we seeking to achieve?*	***Key performance indicator/s***	***Basis for comparison***
To provide evidence and resources that assist healthcare workers to determine both the cost of healthcare associated infection and cost effectiveness of prevention programs, with outcomes informing local and state policy and/or guidelines	Proposal to be submitted to Innov8 to obtain funding to develop Infection Control with Economic Decisions (ICED) software by 5 March 2005.	Nil
	Valid and reliable post discharge surveillance of surgical site infection methodology to be finalised by 30 June 2006 with subsequent rollout implementation and evaluation to be undertaken by June 2007.	Literature
	To produce a simulation model of multi-resistant organism (MRO) transmission in relation to patient flow to determine the effects of isolation and quarantine on the spread of MROs as well as the effects of over utilization of bed occupancy and patient movement between areas by June 2007. In order to provide guidelines to administrators on methods of maximising bed utilization while preventing cross-transmission of MROs	Nil
	The cost to Queensland Health of surgical site, blood stream, urinary tract infection will be quantified by June 2006 with the findings being presented locally, statewide, nationally and internationally for the purpose of: ▪ Assessing the impact on Queensland Health ▪ Stimulating the review of interventions and subsequent update of existing guidelines and/or policy(s)	Nil
	By 30 June 2006, the cost effectiveness of interventions to prevent intravascular catheter related blood stream infection in intensive care patients will be known.	Literature
	The costing methodology used in the studies outlined above will be made available by 30 June 2006 to enable clinicians to assess and cost local interventions	Nil

Initiative	Who	When	Key partners	Resources (human/ financial)
Evidence and resources that assist healthcare workers to determine both the cost of healthcare associated infection and cost effectiveness of prevention programs	Dr Nick Graves	June 2006	Twenty-five District Health Services Intensive care units throughout Australia Communicable Diseases Unit CHRISP Representative Participant Group Innovation Unit	

Objective 3 *What are we seeking to achieve?*	*Key performance indicator/s*	*Basis for comparison*
Provision of evidence-based (Theoretical Behavioural Models) strategies, tools and resources to improve and sustain compliance with interventions known to reduce the transmission of infection i.e. handwashing	▪ Findings to be published by June 2006 ▪ By June 2005, the findings of this study and details contained within the CHRISP Report are to be formally presented at the Statewide Forum of District Managers ▪ Findings on *Behavioural Considerations* to be presented at the meeting of the World Health Organisation (WHO) Technical Advisory Group on Handwashing with subsequent inclusion of this body of work in the WHO Guidelines on Handwashing. ▪ To evaluate the occurrence and causation of solid needlestick injuries in the Operating Theatres in Queensland Health facilities by June 2007.	Literature Previous CHRISP Report

Initiative	Who	When	Key partners	Resources (human/ financial)
The provision of evidence and the promotion of outcomes designed to improve compliance with infection control protocols, especially handwashing behaviour in health care workers	Medical Director	June 2006	Health Service Districts Infection Control Professionals World Health Organisation	

Objective4	*Key performance indicator/s*	*Basis for comparison*
To strengthen and build upon internal and external partnerships to promote cultural/behavioural change with focus on strategies that minimise preventable harm through the development and/or enhancement of new and/or existing systems, structures and processes to provide decision support for clinicians	To establish a governance structure that includes District Health Service representatives from all levels of the organisation by 30 June 2005. Project plans for initiatives 1, 2 and 3 to be developed and submitted to the CHRISP Advisory Board by 30 June 2005. Memorandum of Understanding with the Infection Control Service, South Australia to be formalised by 30 June 2005.	Infection control structures of other jurisdictions New initiatives

Initiative	Who	When	Key partners	Resources
To partner other jurisdictions, organisations and business units within Queensland Health to develop and/or enhance existing systems to improve patient and staff safety in areas of: A. Laboratory notification of incidents, incidence and/or prevalence of health care associated infections B. Establish both the local and statewide use of both oral and intravenous antibiotics using STOCCA; and develop methodology and processes to enable antibiotic utilisation to be correlated with the incidence and/or prevalence of multi-resistance organisms. C. The collaborative development of process indicators to assist small and medium sized hospitals to evaluate the administration and use of prophylactic and therapeutic antibiotics. D. Develop a tool that supports the investigation of blood stream infection using Root Cause Analysis methodology in collaboration with South Australia	Administrative Director of CHRISP Medical Director of CHRISP	A - 30 June 06 B - 30 June 07 C – 30 June 07 D - 30 June 06	Public Health Services -Medicines and Pharmacy Services Unit Patient Safety Centre (Safe Medication Practice and Safety Improvement Units) QHPSS (executive, zonal and local staff members) CDU Information Directorate Infection Control Service and infection control network of South Australia	
Provision of a full evaluation and cost benefit and/or effectiveness of retractable safety devices that seek to reduce high-risk needle stick injuries. Business Case and Cabinet Submission that supports that implementation of this initiative in District Health Services to be prepared for the consideration of the Senior Executive Director of IWR and Board of Management	Administrative Director of CHRISP Medical Director of CHRISP	30 June 06	All District Health Services CDU Purchasing and Logistics	