Department of Health

health

Victorian health incident management policy

State Government Victoria

Victorian health incident management policy

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Foreword

The Department of Health (the department) is committed to improving the quality and safety of Victorian health services.

Review of incidents and near-miss events is an important part of this, particularly those events associated with serious morbidity or mortality. In-depth investigation of these events identifies breakdowns in the often complex health systems in place, and allows health services to identify risk and develop ways to reduce or eliminate the risk of reoccurrence.

The *Victorian health incident management policy* is a comprehensive guideline for health services and agencies which incorporates a standardised framework for the collection and management of clinical (patient) incidents.

The Victorian health incident management system (VHIMS) is a mechanism to elevate the principles of a safety culture to the state level. It also introduces the concept of standardisation of reporting and terminology in relation to incident management.

Historically, the department requested health services to submit clinical incident data under specific program areas for review, such as the Sentinel Event Program and the Radiation Safety Program. The department has now broadened health service and agency reporting obligations to all clinical (patient) incidents including near-miss events.

Working collaboratively across the department with health services, agencies, clinicians and consumers has resulted in a strong culture of local reporting when things go wrong. A good safety culture encourages reporting; only when we are aware of something not working can we act to change it.

The department looks forward to working with the health sector to implement the *Victorian health incident management policy* to help ensure Victoria continues to provide a high quality health service for all Victorians.

Fran Thorn
Secretary, Department of Health

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Introduction

The *Victorian health incident management policy* (the policy) is intended to guide health services to establish and support a structured incident management review process that is consistent with best practice and reflective of their clinical governance policy and overarching framework.

It is widely recognised that incidents can occur while providing health care, and that some of these can have serious consequences for patients/clients/residents, the health service, employees/contractors/agency staff/students/volunteers and the public.

The department's role is to provide guidance and support for health services to ensure they are proactive in their management of incidents and understand that valuable lessons can be learnt from both actual incidents and near-miss events.

The *Victorian health incident management policy* is consistent with the proposed Australian Commission on Safety and Quality in Health Care (ACSQHC) national quality and safety standards due for release in 2011. Standards act as both a quality assurance and quality improvement mechanism.

Policy scope

All Victorian publicly funded health services and agencies that provide health services on behalf of the department are subject to the *Victorian health incident management policy*. In scope services include:

- public health services and all services under their governance structure
- registered community health services
- Ambulance Victoria
- Royal District Nursing Service
- Ballarat District Nursing and Healthcare
- bush nursing centres (public funded)
- Forensicare (Thomas Embling Hospital)
- incorporated residential aged care services (public funded).

This policy excludes private health services and non government organisations.

Policy purpose

The purpose of the policy is to:

1. provide governance that clearly outlines individual/health service and department responsibilities in incident management
2. ensure consistency in the approach to incident management across Victorian publicly funded health services
3. provide a system that facilitates the identification, reporting, reviewing, monitoring and evaluation of all incidents in a timely and effective manner
4. ensure those involved in, or affected by, incidents receive appropriate assistance and support
5. ensure organisational learning from incidents, including near-miss events and system failures, to mitigate future risk
6. increase awareness of reporting requirements and related legislation.

Policy principles

The principles of the policy are:

1. Obligation to act – There are clearly defined roles and responsibilities in the incident management process that are acknowledged and understood by the key stakeholders.
2. Just culture – Incidents are reported and acknowledged without fear of blame or retribution and individuals are treated fairly in an open and honest manner.
3. Prioritisation of action – Actions to assist in the investigation (review) of incidents are prioritised by the health service (organisation) in order to facilitate timely and effective reviews of high impact incidents.
4. Emphasis on learning – The policy is focused towards learning from incidents in order to create a patient safety learning culture across Victorian publicly funded health services.

Policy drivers

The following policies underpin and support the department's approach to incident management:

- *Australian Charter of Healthcare Rights in Victoria*
- *Victorian clinical governance policy framework*
- Australian Commission on Safety and Quality in Health Care
  National Open Disclosure Standard

The department is committed to developing a culture which is capable of creating and maintaining a sustainable, high quality care environment that:

1. promotes an open and positive approach to incident management
2. recognises that most incidents occur because of problems with systems rather than individuals
3. emphasises continuous improvement
4. facilitates the safety of health care recipients, staff and others.

Incident management principles

The following concepts and frameworks provide the context for the department's approach to incident management.

Just culture

The department is committed to supporting a 'just culture'[1] approach to incident investigation that fosters a systems approach, consumer-centred care, continuous improvement and innovation in delivery of clinical care. It is now a generally agreed principle (although not always evident in practice) that it is unproductive to single-out individuals when adverse events occur.

1 extract from Agency for Healthcare Research and Quality (AHRQ) USA glossary of patient safety terms: 'Just culture principles outline a culture in which frontline personnel feel comfortable disclosing errors—including their own—while maintaining professional accountability. A just culture also recognizes many individual or "active" errors represent predictable interactions between human operators and the systems in which they work. A just culture does not tolerate conscious disregard of clear risks to patients or gross misconduct (for example, falsifying a record, performing professional duties while intoxicated).'

This can:

- serve only to create an environment of fear and distrust in which the reporting of an incident or adverse event is unlikely to occur
- obscure the real understanding or root cause of the incident that must be addressed if a reoccurrence of the incident is to be prevented
- disregard the implication of organisational and system issues that contribute to adverse events, for example a culture of taking short cuts, failure to comply with hospital procedures, stress created through unplanned staffing crises, inexperience and the complexity of patient care.

Open disclosure

Open disclosure refers to the process of open communication with patients and their families following an adverse event.[2]

2 An adverse event for the purposes of this document is defined as any unplanned event resulting in, or having the potential to result in, injury to a patient or an unintended outcome. It isn't necessary that any harm actually occurred, or that there was a mistake or error.

Health service and agency requirements

Data requirements

All in-scope health services and agencies are to provide a de-identified data extract of all clinical incidents monthly to the department.

De-identified data is to be sent to the department via an electronic secure data exchange process. This secure pathway allows for data encryption.

Health services and agencies require a digital certificate that enables encrypted transmission of data to the department's electronic partner gateway.

Data will be validated on arrival to the department. If the file is corrupt, not compliant with the department's data specification or contains a critical amount of validation errors, the transmission will be rejected and returned (encrypted) to the sending health service or agency for correction and re-submission.

Health services (and agencies) are required to provide data according to the timelines detailed in clause (a) and (c) below.

(a) Incident data for each month must be transmitted in time for the Victorian health incident management system (VHIMS) file consolidation on the 12th day of the following month.

(b) Corrections or amendments to incident data can be submitted in the data transmission of the following month(s).

(c) Final cut off for amendments is 1 September of the new financial year, for example, amendments to 2010-2011 data must be completed and transmitted to the department by 1 September 2011.

(d) It will be the health service's responsibility to ensure the incident data submitted to the department meets the VHIMS data set specification and validation rules.

Department program incident notifications

Incident notifications relevant to the following program areas are to be sent as a single incident transmission via the electronic partner gateway. This will enable health services and agencies to meet the program, time-based and statutory reporting requirements.

Table 1: Department of Health notification timeframes for specific program areas

Department program	Notification time frame	Notification process
Sentinel Event Program; Quality, Safety and Patient Experience Branch (QSPE)	Notification is required within three working days of event occurring, or being identified.	Incident to be transmitted to the department via VHIMS transmission module. On receipt by the department, an automated notification email will be forwarded to the Sentinel Event Program generic email address (sentinel.events@health.vic.gov.au). A summary report will be included with the notification email.
Serious Transfusion Incident Report (STIR); QSPE	Notification is expected within three days of the incident occurrence.	Incident to be transmitted to the department via VHIMS transmission module. On receipt by the department, an automated notification email will be forwarded to the STIR generic email address (stir@health.vic.gov.au). A summary report will be included with the notification email.
Radiation Safety Program; Environmental Health; Public Health	Theft/loss/damage of/to radiation source is to be reported immediately. Other incident types to be reported within five days of the occurrence.	Incident to be transmitted to the department via VHIMS transmission module. On receipt by the department, an automated notification email will be forwarded to the radiation safety generic email address radiation.safety@health.vic.gov.au. A summary report will be included with the notification email.
Critical incidents This applies to organisations as outlined in *Appendix 1: Department of Health incident reporting instruction 2010 pg 3-4* Note: Alcohol and other drug (AOD) services under the auspices of a health service are included in this department reporting requirement.	Critical incidents classified as either Category 1 or 2 must be reported to the department. Category 1 incidents immediately and within 24 hours of incident. Category 2 incidents, as soon as possible and within two working days.	Health services and agencies are to continue to notify the department regional office of department defined critical incidents. Criteria for the notification of Category 1 and 2 incidents are summarised in the *Department of Health incident reporting instruction 2010* accessed via Funded Agency Channel www.fac.dhs.vic.gov.au The department advocates, wherever possible that critical incidents be recorded in VHIMS to ensure the health service or agency incident data repository holds a complete record of all reported incidents.

With the implementation of this policy the department will ensure the following standards are met:

1. All clinical incidents will be reported in a standardised and timely manner in accordance with supporting department guidelines and local (health service) procedures.
2. All clinical incidents shall be reported using a single specified data collection known as the VHIMS data collection.
3. Statutory and other requirements for reporting adverse events to external organisations and bodies will continue to be fulfilled by the individual health services and agencies.
4. All clinical incidents shall be subjected to a health service (or agency) based review process for the purpose of identification of action required to prevent, or reduce, the likelihood of recurrence.
5. All clinical incidents with an incident severity rating (ISR) of 1 or 2 will be subject to an in-depth investigation and review process by the health service or agency.

Incident review process

Sentinel events

Sentinel events are relatively infrequent, clear-cut events that occur independently of a patient's condition, commonly reflect hospital (or agency) system and process deficiencies; and result in unnecessary outcomes for patients.[3]

The eight national defined sentinel events[4] are:

1. procedures involving the wrong patient or body part resulting in death or major permanent loss of function
2. suicide in an inpatient unit
3. retained instruments or other material after surgery requiring re-operation or further surgical procedure
4. intravascular gas embolism resulting in death or neurological damage
5. haemolytic blood transfusion reaction resulting from ABO incompatibility
6. medication error leading to the death of patient reasonably believed to be due to incorrect administration of drugs
7. maternal death or serious morbidity associated with labour or delivery, and
8. infant discharged to wrong family.

All health services and agencies that identify an incident that reflects a national sentinel event definition are required to report the incident to the department's Sentinel Event Program:

- Notification to the department must be made within three days of the incident occurring as outlined in Table 1.
- The final de-identified root cause analysis (RCA) summary report is to be provided to the department within 60 days of notification.
- Report templates and additional information on the department's Sentinel Event Program can be accessed at: http://www.health.vic.gov.au/clinrisk/sentinel/ser.

The department's Sentinel Event Program excludes any incident that is subject to review under the state or Commonwealth criminal justice system:

- In the mental health care setting this includes murder–suicides and allegations of sexual or physical assault.
- In the aged care setting this includes allegations of sexual or physical assault.

The RCA methodology is not to be used for performance management related issues. Performance management issues should be handled by the relevant personnel in a performance management context.

National defined sentinel events may not always result in an ISR 1 rating. The degree of impact to the patient/client/resident, as a result of the incident, may be more reflective of an ISR 2 or 3 rating. Irrespective of the ISR, Victoria will continue to report nationally, as required, against these sentinel event definitions.

3 http://www.health.vic.gov.au/clinrisk/sentinel/ser
4 endorsed by the Australian Health Ministers Advisory Committee (AHMAC) and Health Ministers in 2009

ISR 1

With the introduction of VHIMS as a standardised statewide data set, the department will broaden the scope of their Sentinel Event Program to include ISR 1 clinical incidents from March 2011.

All ISR 1 incidents must be reviewed by health services to determine causation and opportunities for system improvement.

On identification of an ISR 1 clinical incident, the health service is to review the incident to determine whether the outcome was directly related to system or process issues.

If this initial review signifies hospital (or agency) processes contributed to the incident outcome, an RCA is to be undertaken to explore causation and indentify contributing factors, and the following notifications are to be made:

- Notification to the department's Sentinel Event Program must be made within three days of the incident occurring as outlined in Table 1.
- The final de-identified RCA summary report is to be provided to the department within 60 days of notification.

Not every ISR 1 clinical incident will require an RCA.

Where the health service (or agency) initial incident review identifies the major contributing factors to the incident outcome were related to the patient's illness or management phase of their chronic illness, then an RCA is not warranted.

These cases should still be reviewed as all incidents present an opportunity for organisational learning.

The department advocate health services using an in-depth case review methodology to determine the significant characteristics of these events, and opportunities for process and system improvement. Further information on the department's in-depth case review methodology can be accessed at: www.health.vic.gov.au/clinrisk/vhims/index.htm

Organisations are not required to submit in depth case reviews to the department's Sentinel Event Program.

ISR 2

Health services and agencies are expected to review ISR 2 incidents with in-depth case review methodology. This process enables health services to use a similar rigorous methodology to that of RCA.

This review process can be undertaken by a team of two and there is no prescribed reporting template for documenting issues identified, recommendations and mitigation strategies.

The department expects all complete ISR 2 case reviews to be submitted to the health service (or agency) clinical governance committee for consideration.

ISR 3 and 4

ISR 3 and 4 incidents will require an aggregate review over a designated time period (weekly, monthly or quarterly) as prescribed within the individual health service or agency clinical governance policy and guidelines.

Health services and agencies may elect to undertake additional review of ISR 4 incidents (near-miss events) where only by luck or chance circumstances prevented the incident from having a potentially higher outcome (either ISR 1 or 2).

Both in-depth case review and RCA methodologies can be utilised for these activities.

Open disclosure

Discussing adverse events with patients who have been affected by them is an ethical obligation of health care professionals. It is now also a legal obligation for public entities (including public health services) in Victoria.

The Victorian parliament passed legislation[5] which came into operation in July 2007 to protect human rights in Victoria and ensure that government departments and public bodies observe these rights when making decisions and developing policy.

In 2002 the Australian Council for Safety and Quality in Health Care (now the Australian Commission on Safety and Quality in Health Care) developed the National Standard on Open Disclosure. This was endorsed by the Australian Health Ministers Conference in July 2003.

The standard outlines a clear and consistent process which includes:

- an apology or expression of regret
- a factual explanation of what occurred, including actual and potential consequences
- the steps being taken to manage the event and prevent its recurrence.

The National Open Disclosure Standard published by the then Australian Council for Quality and Safety in Health Care in 2003 outlines the key principles of open disclosure:

i. **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.
ii. **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.
iii. **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.
iv. **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.
v. **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.
vi. **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 ISO 31000:2009). Outcomes of investigations are to focus on improving systems of care and will be reviewed for their effectiveness.
vii. **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 organisation's chief executive officer or governing body to ensure that these changes are implemented and their effectiveness reviewed.

5 The Victorian Charter of Human Rights and Responsibilities 2006 (Vic)

viii. **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 or territory privacy and health records legislation.

In addition to these principles, further learnings as a result of the evaluation of the national and Victorian pilot programs have been added to the standard:

Flexibility within a framework

Open disclosure processes need to be flexible but underpinned by a strong central framework that is understood by all. It is important to reduce risks associated with variations from the accepted and agreed open disclosure processes that may arise from poor communication or documentation.

Communication and information

Good and effective communication of the open disclosure process is imperative. Most health services will only implement open disclosure for serious events a few times a year at most and different clinicians are likely to be involved on each occasion. Therefore, tools such as a 'ready reference', brochures or brief guidelines are useful to assist clinicians to quickly re-familiarise themselves with the health service's open disclosure principles and processes and ensure that risks associated with the process are appreciated and managed.

Understanding of responsibilities

Clear guidelines to ensure that staff are aware of their respective roles and responsibilities in the open disclosure process is imperative to ensure that the right people give the right information at the right time.

Relationship between open disclosure, root cause analysis and other investigatory processes

Open disclosure is closely linked with the incident management process which takes place in response to an adverse event. It is also incorporated into the health service's clinical governance policy framework.

Health services will vary in their individual approaches but there are three important and interrelated components to the incident management process:

1. Inform the patient and his or her family (as appropriate) about what has occurred in a sensitive but open and honest way. This includes an apology or some expression of regret.
2. The level of investigation will vary depending on the incident severity rating. Sentinel event and equivalent ISR 1 incidents will have RCA, ISR 2 incidents will have in-depth case review and ISR 3 and 4 incidents will have local investigation and aggregate review.
3. Identify measures to address apparent weaknesses in the system and a commitment to address these.

Just culture approach to adverse event investigation

It is an accepted principle (although not always evident in practice) that blaming individuals when adverse events occur is unproductive and may have the effect of:

- serving only to create an environment of fear and distrust in which the reporting of adverse events is unlikely to occur
- obscuring the real underlying or root cause of the incident which must be addressed if a reoccurrence of the incident is to be prevented
- disregarding the implication of organisational and system issues which contribute to adverse events, for example a culture of taking short cuts, failure to comply with hospital procedures, stress created through unplanned staffing crises, inexperience and the complexity of patient care.

The open disclosure process should incorporate the principles of just culture, and the learning organisation approach and health professionals need to be consistent in their understanding of these concepts.

A patient and his or her family may want to know who was 'at fault' and may not have encountered this approach before. Initial reactions may be to interpret the just culture approach as a way of 'covering-up', 'closing ranks' or protecting individuals. The principles of just culture should be communicated sensitively to patients and supporters affected by adverse events.

The open disclosure procedure

In general, the open disclosure process should be invoked whenever a patient has suffered an adverse event.

The process should be flexible enough to respond appropriately to ISR 1 or 2 adverse events, as well as ISR 3 or 4 events. Considerations to be taken into account include:

- the patient's and family's need to, and right to know
- the clinician's duty to apply professional ethical judgement to their ways of working
- the clinical team's preparedness to discuss and analyse unexpected outcomes over and beyond the adverse event's medical–technical dimensions
- the organisation's obligations to engage staff in lifelong learning and practice improvement (under clinical governance).

Tools and resources, including an on line education package for open disclosure are available at: www.health.vic.gov.au/clinrisk/opendisc.htm.

Definitions

The following terms are referred to throughout the policy:

Adverse event	An incident that resulted in harm to a person receiving care (Australian Commission on Safety and Quality in Health Care [ACSQHC])
Clinical governance	The system by which the governing body, managers, clinicians and staff share responsibility and accountability for the quality of care, continuously improving, minimising risks, and fostering an environment of excellence in care for consumers, patients or residents[6]
Clinical (patient) incident	An event or circumstance that could have, or did, lead to unintended and/or unnecessary harm to a person receiving care.[7] Clinical incidents include adverse events, near misses and hazards in the environment that pose a clinical risk.
Incident	An event or circumstance that could have, or did lead to unintended and or unnecessary harm (ACSQHC)
Harm	Harm includes disease, suffering, impairment (disability) and death: • disease: a psychological or physiological dysfunction • suffering: experiencing anything subjectively unpleasant. This may include pain, malaise, nausea, vomiting, loss (any negative consequence, including financial) depression, agitation, alarm, fear or grief • impairment (disability): any type of impairment of body structure or function, activity limitation and/or restriction of participation in society, associated with a past or present harm
Health service	Health service collectively refers to public health services and public hospitals which are defined under *Health Services Act 1988* (Vic)
Incident severity rating (ISR)	A score of 1, 2, 3 or 4 that measures the severity of the impact caused to the person affected following an incident, ISR 1 being the highest or most severe and ISR 4 a near miss The ISR is derived from a response to three consequence-descriptor category questions related to: • degree of impact • level of care • treatment required.
Near miss	An incident that did not cause harm (ACSQHC). A near miss is also an incident that had the potential to cause harm but didn't, due to timely intervention and/or luck and/or chance.
Open disclosure	The process of open communication with patients and their families following an adverse event[8]
Sentinel event	Sentinel events are all clinical incidents with an ISR 1 where following initial review, the outcome of the patient/client/resident (harm) was directly related to the incident (and not their pre-exiting condition or disease process).

6 Department of Health (2009), *Victorian clinical governance policy framework: Enhancing clinical care* State Government of Victoria, Melbourne.
7 Department of Health (2008), *VHIMS data set specification*, State Government of Victoria, Melbourne.
8 Department of Health (2008) *Open disclosure for Victorian health services: a guide book*, State Government of Victoria, Melbourne, p.1.

Appendix 1 – Department of Health: Incident reporting instruction 2010

Extract from *Department of Health Incident reporting instruction 2010* pages 3-4.

The *Incident reporting instruction 2010* can be accessed at http://intranet.health.vic.gov.au/resources-and-tools/policies-and-standards/incident_reporting.pdf. Supporting materials and guidelines for particular program areas are available on the Funded Agency Channel www.fac.dhs.vic.gov.au.

Scope – Critical incident/Category one and two incidents

The Department of Health incident reporting instruction sets out the management and reporting requirements for incidents involving clients or staff in Department of Health-funded community service organisations (CSOs), registered community health centres and supported residential services (SRSs).

Funded organisations are required to comply with departmental incident reporting processes as part of their service agreement. Note: there is no current legislative requirement for proprietors of an SRS to report incidents directly to the department, however, regional Department of Health SRS program staff are required to report category one incidents in accordance with this instruction.

The following organisations are required to submit incident reports to the Department of Health.

3.1 Category one and two incidents

- CSOs providing psychiatric disability rehabilitation support (PDRS) services
- All providers of alcohol and other drug (AOD) services.

3.2 Category one incidents only

- CSOs providing home and community care (HACC) services
- CSOs providing aged care, carer's support programs
- registered community health centres providing community and women's health programs
- SRSs.

3.3 Services outside the scope of policy

This instruction does not apply to clients or employees in approved specialist clinical mental health services as defined by the *Mental Health Act 1986* that report via the hospital process.

This instruction does not apply to hospitals listed in Schedules 1-5 in the *Health Services Act 1988*:

- public hospitals, except those providing AOD services
- denominational hospitals
- metropolitan hospitals
- privately-operated hospitals
- metropolitan health services.

Alcohol and other drugs (AOD) services

Department-funded AOD services are obliged to report incidents involving unknown clients where the incident has a direct correlation to the nature of services that the agency is providing.

AOD services or programs managed by public health services are required to comply with the department's incident reporting instruction for category one and two incidents occurring in the department-funded service.

AOD services are required to keep a record of category one, two and three incidents, however only category one and two incident reports should be submitted to the department.

AOD services should record category three incidents on an internal register/database and on the client file.