

Sentinel event program

Annual report 2005-06

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Published by Rural and Regional Health and Aged Care Service Division, Victorian Government Department of Human Services, Melbourne, Victoria, Australia.

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Also published on www.health.vic.gov.au/clinrisk

Authorised by the State Government of Victoria, 50 Lonsdale Street, Melbourne.

Printed by ego, 31–37 Howleys Rd, Notting Hill VIC 3168.

November 2006

(RCC_061006)

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Foreword

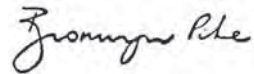
*1 Department of Human Services
2002, Clinical risk management
strategy 2001-2002, Melbourne.*

The Department of Human Services, through its Clinical Risk Management Strategy¹, is committed to ensuring high-quality, safe health care within Victorian hospitals.

A key element of this strategy is the sentinel event program. The program focuses on identifying breakdowns in the complex systems and processes, connected to even the simplest health intervention, that have a severe adverse impact on patient outcomes. By critically analysing such events, health services are able to develop strategies to reduce or eliminate the risk of reoccurrence.

The program draws its strength from a direct result of collaboration between the department, health services, clinicians and consumers who strive to improve the safety and quality of health care in Victoria.

This is the fourth annual public report of the sentinel event program and it presents information on the 91 sentinel events reported within Victorian public health services.



**Hon Bronwyn Pike MP
Minister for Health**

Acknowledgements

The Department of Human Services thanks the public health services for their ongoing contribution to the sentinel event program. The department also acknowledges the Clinical Risk Management Reference Group, the consultative councils and expert advisory groups that work closely with the department to provide recommendations to health services on system issues (see Appendix 1).

The department also acknowledges the patients and their carers who have experienced adverse patient outcomes.

Summary

The Victorian sentinel event program endeavours to create a safe environment within Victoria's health care system by decreasing the incidence of serious adverse events. To do this, the program acts to establish a secure environment in which organisations and individuals are encouraged to self-report system and process errors, and analyse the underlying cause of those errors. All information received by the Department of Human Services (the department) is de-identified to preserve the privacy of patients, practitioners and organisations involved.

The department then disseminates the lessons from these events, and the strategies by which the risk of their reoccurrence could be reduced or eliminated, throughout the health care sector.

In 2005–06, the department was notified of 103 sentinel events and 91 were analysed. Nine events were withdrawn because these resulted from known complications of the patient's condition or required procedure, and others were withdrawn because no system or process issues could be identified. Three reports were not available for analysis at the time of writing this report.

The overall number of events reported has decreased since 2004–05, and this is believed to be due to the effectiveness of an intensive education program undertaken in 2005. The development and subsequent rollout of the root cause analysis (RCA) education program has provided staff with a better understanding of the sentinel event program and its reporting requirements.

Sentinel events being reported under the 'other catastrophic events' category continue to be the major reporting category in 2005–06, with 54 per cent listed in that category.

During 2005–06, a total of 337 contributing factors were identified, and two new categories – 'patient behaviour' and 'course of disease' – were included in 2005–06 to better reflect findings.

The major trends arising from this analysis show that 'procedures and guidelines' and 'communication' continue to be the most commonly occurring system factors for 2005–06.

The following recommendations for 2006–07 resulted from a review of the 2005–06 sentinel events:

- 1 To maintain and develop the root cause analysis education program to ensure:
 - 1.1 further development of the education module package by the pilot and rollout of module 4 aimed at clinical incident response and review
 - 1.2 all health services have access to the education program, and that the program is available to new staff as required
 - 1.3 further development of the peer support group program with the aim of establishing an environment of ongoing support and education
 - 1.4 there is an established core group of experienced RCA facilitators who will be available to provide advice and support to those undertaking RCAs for the first time and/or those participating in complex RCAs
 - 1.5 a team of educators and peer group facilitators is established to ensure the ongoing sustainability of the root cause analysis education program.

- 2 To continue to develop a clinical governance policy in line with the Auditor-General's audit recommendations.
- 3 To review and clarify sentinel event definitions and categories through liaison between the department and expert bodies, thus ensuring consistency in interpretation and the integrity of sentinel event program data.
- 4 To review current national and international practices related to RCA and legal/privilege issues and develop a Victorian model.
- 5 To support the development of the incident information system (IIS) project as a means of identifying potential precursors of sentinel events.
- 6 To strengthen links with the private health sector and encourage its active participation in the sentinel event program.

Background

2 Department of Human Services 2000, Improving patient safety in Victorian hospitals 2000, Melbourne.

3 Joint Commission on Accreditation of Healthcare Organisations 1998, Sentinel events: evaluating cause and planning improvement, 2nd edition.

4 Department of Human Services 2006, Risk Watch, Melbourne, available at: www.health.vic.gov.au/clinrisk

In September 2000, a report titled *Improving patient safety in Victorian hospitals*² was published that drew on results from work undertaken by the Joint Commission on Accreditation of Healthcare Organisations³ in the United States. It was also the catalyst for the implementation of the Clinical Risk Management Strategy by the Victorian Department of Human Services in 2001–02.

An integral part of the Clinical Risk Management Strategy is the sentinel event program. This program aims to identify serious events that occur within health services that:

- are relatively infrequent
- are clear-cut events that occur independently of a patient's condition
- commonly reflect deficiencies in hospital systems and processes
- actually or potentially result in unnecessary outcomes for patients.

The program's intention is to reduce the likelihood of identified sentinel events reoccurring by examining the environment in which they occur. This requires a system-wide approach where the organisation and processes of health care delivery are scrutinised rather than the individual. To do this, the program works to create a safe environment for reporting that ensures organisational and individual confidentiality.

Reportable sentinel events

Reportable sentinel events include:

- procedures involving the wrong patient or body part
- suicide in an inpatient unit
- retained instruments or other material after surgery requiring re-operation or further surgical procedure
- haemolytic blood transfusion reaction resulting from ABO incompatibility
- medication error leading to the death of a patient
- maternal death or serious morbidity associated with labour or delivery
- infant discharge to wrong family
- intravascular gas embolism resulting in death or neurological damage
- other catastrophic event.

Communication strategies

The sentinel event program shares the lessons learnt with the wider health care community through:

- *Risk Watch*⁴, a monthly newsletter
- alerts for significant events
- sentinel event annual report
- recommendations to individual health services and the sector.

Education

The department supports education and training in clinical risk management through its root cause analysis (RCA) education program, and continues to build on work started in 2004–05 to provide a standardised statewide approach.

The RCA program was developed in modules to match organisational responsibilities and the needs of different user groups (see Appendix 2).

Modules 1 and 2, which provide the general background and organisational requirements to support an RCA program, are now available on CD-Rom. These have been sent to all health services for use in local education and training programs. The material can be customised to enable services to insert their own policy and procedures, and organisational structures such as committees that support risk management.

Further work in 2005–06 has seen the development of Module 4: Incident response and review. The majority of incidents will not be sentinel events and for many smaller organisations, the frequency of occurrence of a sentinel event will be very low. However, processes need to be in place in all health services to ensure rapid identification and action when an incident occurs. Module 4 will provide health services with an incident response process for appropriate action at the time of the incident, a methodology for review and an incident analysis report.

This module will be piloted in late 2006 and developed as a train-the-trainer package that is expected to be rolled out to all health services by early 2007.

A number of private health providers are actively participating in the sentinel event program, and the department provides education at no cost to those organisations.

There has been strong interest from other states in the RCA program, and the department has shared the intellectual property related to the Victorian program with ACT Health (Canberra) and Tasmania.

Objectives of the 2005–06 sentinel event program annual report

The objectives of the 2005–06 sentinel event program annual report are to:

- collate sentinel event notification data from Victorian public health services and participating private health care providers for the period 1 July 2005 to 30 June 2006
- provide a summary of issues identified, including causes and contributing factors, through the analysis of reported sentinel events
- provide case study information of actions taken to prevent/reduce future recurrence
- identify trends and avoidable factors and, where possible, make recommendations for improving health care delivery in Victoria
- assist all health care providers in efforts to improve the quality and safety of patient care
- increase the general knowledge and awareness of sentinel events, their causes and prevention strategies
- inform on initiatives undertaken and improvements being developed for the sentinel event program.

Sentinel event reporting

Sentinel event notification process

5 Victorian Government
Department of Human Services
2004, *Public hospitals and mental
health services policy and funding
guidelines 2004–05*, Melbourne
Victoria, available at:
www.health.vic.gov.au/pfg2004/

6 Victorian Government
Department of Human
Services 2005, *Root cause
analysis education modules*,
Melbourne, Victoria.

The *Victorian public hospitals and mental health services policy and funding guidelines 2004–2005*⁵ require that all public health services must report any sentinel event that meets the criteria outlined to the department. Notification from a health service must occur within three days of the event being identified within the health service. Patients, family members, carers, health service employees and the media can also inform the department of a sentinel event.

Once a notification has been made regarding a sentinel event, the health service involved has two calendar months to undertake an investigation into the event and to prepare a root cause analysis. This report will identify causal and contributing factors (see Appendix 3), and provide a comprehensive risk-reduction action plan.

The department reviews the root cause analysis and associated risk-reduction plan to ascertain:

- if the report is thorough and credible, and to ensure the appropriateness of the risk-reduction strategies and timelines (see Appendix 4)
- whether any of the identified causal and contributing factors are relevant to other health care providers in Victoria.

As appropriate, the department will submit the root cause analysis and risk-reduction action plan to relevant expert bodies for review and comment (see Appendix 1). Then the Clinical Risk Management Reference Group and subcommittee undertake the final review before feedback is provided to the health service.

Recommendations that are found to be relevant to the wider health care community are published in the monthly newsletter, *Risk Watch*, which is sent to all health services and includes de-identified case studies with relevant risk-reduction actions.

Root cause analysis

The root cause of a sentinel event is the earliest point at which action could have been taken to reduce or prevent the likelihood of the event occurring. Root cause analysis is an investigation methodology that is used to identify all factors that have contributed to an adverse patient outcome. It is a structured and objective process that enables health services to ask ‘why’ and ‘how’ an event occurred. The focus is on identifying the system or process issues that contributed to an event without assigning individual blame.

Risk-reduction action plan

Strategies are developed to reduce the risk of similar events recurring based on the findings of the root cause analysis. These strategies are presented in the risk-reduction action plan and should include:

- who is accountable for minimising future risk (executive level)
- what action is to be taken to reduce or prevent the likelihood of recurrence
- who is responsible for the action to be implemented
- timelines for completion
- how the change will be measured and outcomes evaluated.

Health service clinical governance

Individual organisations are expected to review their sentinel events and associated root cause analysis and risk-reduction plans at a local level at the board quality committee.

It is also expected that each event and subsequent actions taken will be reviewed at six- and 12-month intervals to ascertain if the correct issues were identified, and to monitor the effectiveness of the actions implemented. Such reviews and their findings should be regularly reported to the board quality committee.

Progress summary of recommendations from the 2004–05 sentinel event annual report

The 2004–05 sentinel event annual report made a number of recommendations to support and strengthen the program. The following is a progress summary of those recommendations.

That the 'ensuring correct patient, correct site, correct procedure' be applied to all areas within health services where patients receive treatment or undergo procedures, including radiology, pathology, outpatient services, radiotherapy and day procedure areas.

A letter was forwarded to all Victorian health services on 28 October 2005 requesting that:

As a result of the analysis, the department is now seeking your further cooperation in extending the implementation of the protocol to include all areas of health services where procedures occur.

All health services have advised that they have, or are working toward, extending this protocol to include all areas where procedures occur.

That health services work toward standardising emergency response codes by applying the Australian Standard (AS 3745-2002).

Work is currently being undertaken to ensure all emergency codes within health services comply with the current Australian standard. In 2005–06, a letter was sent to all health services requesting a listing of codes used. It was found that some areas did not comply with the standard, and local services had developed internal emergency response codes.

Further work needs to be undertaken to ensure there is compliance to the Australian standard to provide consistent and standard emergency response codes within all Victorian health services.

That the department continue to support and develop the sentinel event education program.

More than 700 health service staff (including executive, medical, nursing and consumer liaison staff) have participated in the education programs offered by the sentinel event program. An evaluation of the delivery of the education is undertaken at the completion of each session. To date, results show 98 per cent of participants have indicated that they had a clearer understanding of the root cause analysis process as a result of the education.

In 2006–07, the department will undertake a more detailed evaluation of the education program.

The department will continue to provide education on module 3 (RCA facilitation) to ensure all health services have participated in the department's RCA education program, and the program is offered to new staff.

Module 4 has been approved and is in the pilot phase. It is expected to be rolled out across the state in early 2007.

That there is standardisation of root cause analysis reporting.

As part of the education program, a standard RCA reporting tool was developed. The positive impact of the education program and this reporting tool has been reflected in the high-quality reports received, and the variety of system and process issues identified through root cause analysis.

That a peer group support program is developed.

Building on the 2004–05 RCA education program, the department developed peer support group meetings. These meetings provide RCA facilitators with the opportunity to discuss issues and share their experiences in using the tools, and with an opportunity to review case studies from other areas. Feedback to date indicates these meetings are of significant value to staff who undertake RCA work within their health service. The role of the meetings is being expanded to provide an ongoing educational element to maintain and develop RCA skills.

That Dental Health Services Victoria and private health services be included.

Dental Health Services Victoria and a number of private health services were invited to participate in the sentinel event program during 2004–05. There have also been a number of enquiries from other private health providers in the program, and work will continue to ensure all health services have the opportunity to participate in the sentinel event program.

That the department progress the development of statewide incident collection.

The department has recently established a project to explore ways that incident reporting practices can be standardised across Victorian health services so incident information can be collated for statewide review and trending. Research has shown that while it is important to capture very serious events, it is also important to capture and target quality improvement initiatives to lower severity incidents that may often be precursors for serious adverse events.

The department captures severity 1 rated incidents and near misses reported by health services in accordance with the sentinel event program; however, currently there is no mechanism to collate and analyse lower level incident data across health services. This is due to the variation in the way incidents are defined and severity is assessed from one health service to another.

Collecting standardised, statewide data is beneficial because it provides:

- a more comprehensive set of data for the analysis of causal factors, trending and identification of preventive strategies
- an opportunity for lessons learnt to be shared across organisations
- an ability for health services to compare their data with other similar organisational types.

The project requires the completion of several stages to identify opportunities to collect consistent, meaningful incident information that meets departmental and health service needs. Formal advice and decision-making forums have been established.

Ongoing project updates will be provided via *Risk Watch* and the IIS website that is currently in development.

Program and communication strategies update

Open disclosure

7 Australian Council for Safety and Quality in Health Care 2003, Open disclosure: a national standard for open communication in public and private hospitals following an adverse event in health care, Commonwealth of Australia.

*Open disclosure: a national standard for open communication in public and private hospitals following an adverse event in health care*⁷ was launched in July 2003 as an initiative of the Australian Council for Safety and Quality in Health Care (now the Australian Commission for Safety and Quality in Health Care) to promote a clear and consistent approach by Australian hospitals to open communication, especially when things go wrong.

Victoria is part of a national rollout of a pilot project (see Appendix 5), and work continues to ensure a best model approach is used for statewide implementation.

Education and organisational support packages have been provided to all 12 pilot sites, and further information to assist in implementing the standard is available at: www.safetyandquality.org/

The commission has identified open disclosure as a key priority, and the national evaluation report is now expected in July 2007.

Victorian Medicines Advisory Committee

The Victorian Medicines Advisory Group (VMAC) is an expert advisory group that advises the department on the application of the National Medicines Policy and the National Strategy for the Quality Use of Medicines. Two key areas have been identified as priority: the national medication chart and high-risk medications.

National Inpatient Medication Chart

The Australian Commission on Safety and Quality in Health Care has endorsed 'version E' as the official version of the National Inpatient Medication Chart (NIMC) for implementation nationally.

The VMAC working party is facilitating the implementation of the NIMC across Victoria. To date, most metropolitan teaching hospitals and over half of the regional and rural health services have implemented, or stated a commitment to implement, the NIMC by January 2007. The intention is to have one standard inpatient medication chart in use across the state.

VMAC High-Risk Medication Working Party

The High-Risk Medication Working Party aims to promote the safe use of medication that has a heightened risk of causing significant or catastrophic harm when used in error. The drugs and classes that will be the key focus areas for this working party are:

P - potassium

I - insulin

N - narcotics

C - chemotherapy

H - heparin

Further information about VMAC is available from: www.health.vic.gov.au/vmac

Safer Systems Saving Lives

Safer Systems Saving Lives (SSSL) is a national project managed by the department. It is aimed at improving patient care and preventing avoidable deaths by developing and implementing interventions that are evidence-based and known to prevent harm to patients if systematically applied across an organisation (see Appendix 6).

Better, Safer Transfusions program

The Better Safer Transfusion (BeST) program commenced in July 2004 and it has developed initiatives to improve transfusion practice within Victorian and Tasmanian Health Services by:

- auditing protocols and practice for blood administration
- educating hospital staff on the key messages of transfusion
- informing patients of the risks and benefits associated with a transfusion
- auditing the appropriateness of a transfusion of red cells and fresh frozen plasma in many diverse clinical areas across Victorian public and private health care facilities.

The Serious Transfusion Incident Reporting Program (STIR) program is being piloted in 2006 and it aims to capture data on serious adverse events, including near miss and close call incidents associated with transfusion. By monitoring these adverse events statewide, recommendations will be made to health services that will inform policy and improvements in transfusion practice, and reduce transfusion risks for patients. Further information on this program is available at: www.health.vic.gov.au/best.

Clinical handover

Clinical handover is a recognised issue in maintaining patient safety. Evidence for this can be found in sentinel event program annual reports, outcomes of health service inquiries, coroner's recommendations and the international literature. However, although the importance of good clinical handover has been recognised, there is limited research to guide the development of best practice standards.

The Victorian Quality Council (VQC) has undertaken a series of activities to address the issue of improving patient safety through clinical handover:

- A literature review was undertaken to identify the current understanding of patient safety issues related to clinical handover and potential system improvements.
- A clinical handover information sheet, outlining generic concepts, was developed and circulated to health services.
- A survey of Victorian health services demonstrated that shift-to-shift handover, acute to community, and inter-hospital transfers were the handover situations that caused the greatest concern.

Health services have approached these problems in varying ways and a workshop will be held in November 2006 to share the different approaches.

Further work will be undertaken to develop a standardised clinical handover format that will then be available for use by health services. This will be developed further throughout 2007.

Project updates will be available on the VQC website at:
www.health.vic.gov.au/qualitycouncil

Falls

An evaluation of the *Minimising the risk of falls and fall-related injuries* pack was completed in two health services recently. The Victorian Quality Council is reviewing the results of the evaluation and plans to continue to work in this area to reduce the harm from patient/consumer falls.

Project updates will be available on the VQC website at:
www.health.vic.gov.au/qualitycouncil

Creating safety: addressing seclusion and restraint practice

The *National safety priorities in mental health: a national plan for reducing harm*, endorsed by the Australian Health Ministers' Advisory Council in October 2005, has identified seclusion and restraint practices as one of the four national safety priorities in mental health.

The Victorian Quality Council (VQC) and the Chief Psychiatrist's Quality Assurance Committee (QAC) have formed a partnership to embark on a quality improvement initiative aimed at enhancing safety in inpatient environments, and to significantly reduce the use of seclusion and restraint within Victoria's area mental health services.

To support this safety priority, the VQC and the QAC commenced a joint project in October 2006. It will be aimed at creating safety in mental health inpatient units and reducing seclusion and restraint through a systematic approach that includes the provision of statewide training. The project's main objectives are to:

- identify contributing factors and establish strategies to mediate the need for seclusion and restraint
- promote consistency in standards of clinical best practice by providing a contemporary practice guideline, training curricula and a program for managing acutely disturbed behaviour and seclusion and restraint
- reduce, wherever possible, the frequency and duration of the use of seclusion and restraint.

The evaluation of the project's implementation will assist in sharing the learning and strategies for reducing seclusion and restraint in all Victorian acute mental health inpatient units.

Project updates will be available on the VQC website at:
www.health.vic.gov.au/qualitycouncil

Sentinel event program 2005–06

In 2005–06, 103 notifications were made to the sentinel events program. Nine notifications were withdrawn after reviews were unable to identify any system or process issues, or specific events were attributed to the patient's condition and/or known complication of the procedure.

Three reports were not submitted to the department in time for inclusion in this report.

An analysis of the remaining 91 sentinel events reported in 2005–06 was conducted using a modified Joint Commission on Accreditation of Healthcare Organisations root cause analysis matrix.⁸

Table 1 indicates the number of analysed sentinel events and their categories. The number of reports received for the category 'procedure involving wrong patient or body part' remains level with the figures from 2004–05. This may be a result of ongoing development, education and awareness campaigns of the 'ensuring correct patient, correct site, and correct procedure' guidelines, and further rollout to all clinical areas where patients undergo procedures.

The number of reports for 'suicide in an inpatient unit' has risen slightly, although this may be associated with a broader interpretation of 'inpatient' beyond the physical inpatient area to include those registered as inpatient but who may be on some form of leave (such as day leave or family leave).

Two near miss events relating to 'haemolytic blood transfusion reaction resulting from ABO incompatibility' were reported, but due to the specific nature of the sentinel event categories, the events have been classified under 'other catastrophic'.

'Maternal death or serious morbidity associated with labour or delivery' showed a decrease in reports from 2004–05 but remained in line with previous years. There has been ongoing debate about the interpretation of sentinel events in this category due to the complex nature of pregnancy and associated rare complications, specifically post-partum haemorrhage resulting in hysterectomy.

The trend of the majority of sentinel events being reported under the 'other catastrophic events' category continues in 2005–06, and 54 per cent of all reported events were in this category (see Table 2).

The decrease of total events received by the department may be misleading if interpreted purely numerically. The data may reflect a greater level of understanding of the sentinel event program following an intensive education rollout in 2005–06, and this area will continue to be monitored.

In 2004–05, 329 system issues were identified and, during 2005–06, 337 system issues were identified (see Table 3).

8 Adapted from Joint Commission on Accreditation of Healthcare Organisations 2002, Sentinel event policy and procedures, available at: www.jcacho.org/accredited+organisations/health+care+network/sentinel+events/se_pp.htm

Table 1: Comparisons between reported events for 2002–03, 2003–04, 2004–05 and 2005–06

Classification of event	Frequency			
	2002–03	2003–04	2004–05	2005–06
Procedure involving the wrong patient or body part	16	14	25	25
Suicide in an inpatient unit	5	1	4	7
Retained instruments or other material after surgery requiring re-operation or further surgical procedure	9	8	5	6
Haemolytic blood transfusion reaction resulting from ABO incompatibility	0	1	1	0
Medication error leading to the death of patient reasonably believed to be due to the incorrect administration of drugs	3	4	1	2
Maternal death or serious morbidity associated with labour or delivery	4	2	9	2
Infant discharged to wrong family	0	0	0	0
Intravascular gas embolism resulting in death or neurological damage	0	0	0	0
Other catastrophic event	42	55	77	49
Total	79	85	122	91

Table 2: Comparisons between reported 'other catastrophic events'

Event	2002–03	2003–04	2004–05	2005–06
Complication of emergency management	9	11	6	4
Complication of anaesthetic management	*	6	1	0
Complication of surgical management	9	10	6	5
Foetal complication of delivery	3	0	1	2
Complication of inpatient fall (death or serious morbidity)	2	10	11	4
Complication of fall (no death or serious morbidity)	*	*	18	1
Patient absconding from inpatient unit with adverse outcome	2	1	1	2
Infection control breach	6	7	8	3
Hospital process issue	9	7	0	6
Medication error (not resulting in death)	*	*	9	7
Mis-diagnosis and subsequent management	*	*	4	3
Communication of test results	*	*	3	1
Other – Mental health management	*	*	4	3
Other – unspecified	2	3	5	8
Total	42	52	77	49

* New catastrophic event classifications used in the 2004–05 data analysis.

System factors that contributed to the occurrence of sentinel events

The tables below contain examples of factors that have contributed to the occurrence of sentinel events for the last four years of reporting (see Appendix 3).

Table 3: Factors contributing to sentinel events expressed as a percentage

Contributing factor	Percent of contributing factors			
	2002-03 Number of contributing factors = 210	2003-04 Number of contributing factors = 283	2004-05 Number of contributing factors = 291	2005-06 Number of contributing factors = 337
Procedures/guidelines	32	41	31	43
Human resources	17	17	24	14
Communication	16	17	27	20
Health information	7	9	4	2
Equipment	7	7	4	5
Physical environment	9	6	6	4
Facilities management	6	3	1	3
Patient Behaviour	*	*	*	5
Course of disease	*	*	*	3
Other	6	0	3	1
Total	100	100	100	100

*New contributing factor for 2005-06.

Table 4: Subcategories of contributing factors

Contributing factor	
Procedures/guidelines	Facilities management
Behavioural assessment	Transportation issues
Physical assessment	Intra-hospital issues
Patient observation process	
Clinical guidelines	Human resources
Patient/site identification	Staff allocation
Coordination of care	Staff training
	Staff supervision
Communication	Appraisals
Between staff	Recruitment
Between staff and patient/family	
Translation/NESB issues [#]	Patient behaviour*
	Course of disease*
Physical environment	Health information
Environment (distraction etc.)	Equipment
Security/design	Other

*New contributing factor for 2005–06.

[#]Non-English speaking background.

Common factors contributing to different types of events

A review of sentinel events reported to the department during 2005–06 has led to trends being identified. By comparing contributing factors, it is possible to establish a better understanding of the root causes of such events. A summary of the trends that emerged during 2005–06 is outlined below.

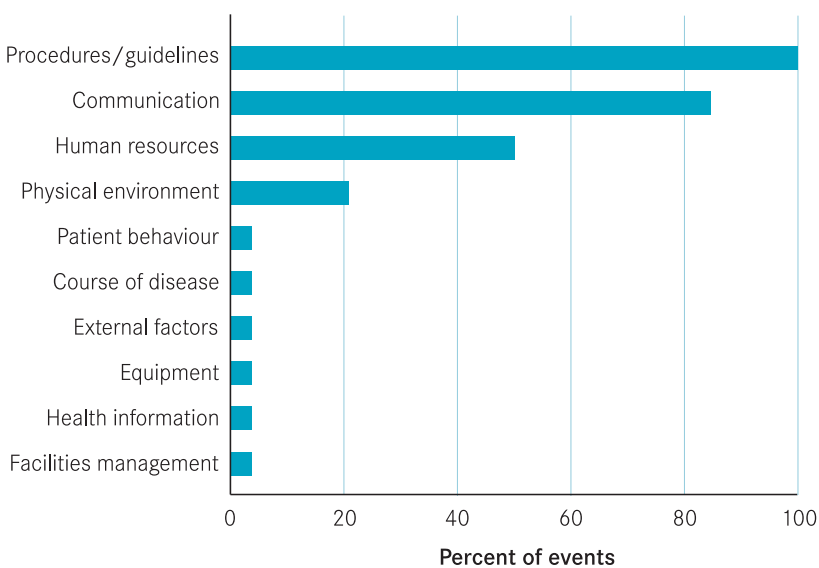
The wide range of identified contributing factors continues to reflect an ongoing improvement in root cause investigations and analysis at health service level.

Procedure involving the wrong patient or body part

In 2005–06, 25 notifications were reported in this category. In descending order of frequency, the contributing factors associated with this event included:

- procedures and guidelines (identification process, physical assessment, clinical management guidelines, patient observation, coordination of care)
- communication (between staff, between staff and patient/family)
- human resources (staff training, staff supervision)
- physical environment
- patient behaviour
- course of disease
- facilities management (inter-hospital issues)
- health information
- equipment
- external factors.

Figure 1: Root cause of procedure involving wrong patient or body part

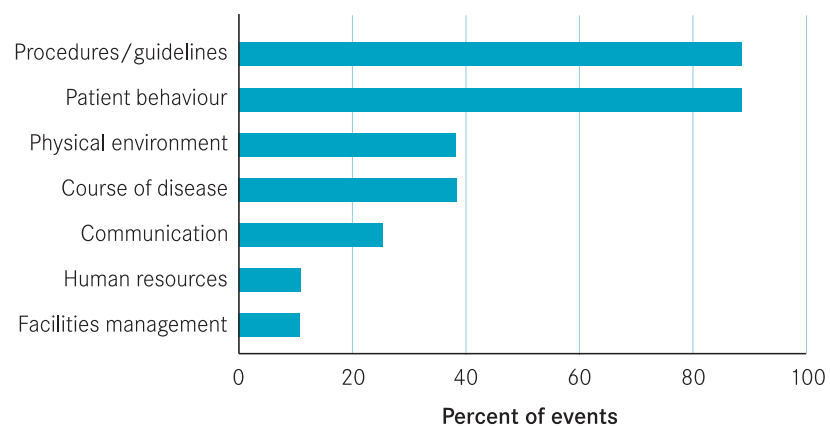


Suicide in an inpatient unit

In 2005–06, eight incidents were reported in this category. Seven reports were available for analysis and were included in this report. In descending order of frequency, the contributing factors for this event were:

- patient behaviour
- procedures and guidelines (behavioural assessment, patient observation process, clinical management guidelines, coordination of care)
- physical environment (environment, security)
- course of disease
- communication (between staff)
- human resources (staff training)
- facilities management (inter-hospital issues).

Figure 2: Root cause of inpatient suicide

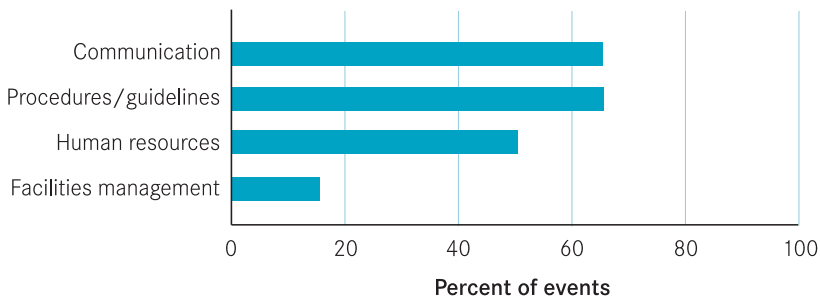


Retained instruments or other material after surgery requiring re-operation or further surgical procedure

In 2005–06, six events were reported in this category. In descending order of frequency, the contributing factors reported included:

- procedures and guidelines (clinical management guidelines)
- communication (between staff)
- human resources (staff training, staff supervision)
- facilities management (inter-hospital issues).

Figure 3: Root cause of retained instruments



Intravascular gas embolism resulting in death or neurological damage

No sentinel events were reported in this category during 2005–06.

Haemolytic blood transfusion reaction resulting from ABO incompatibility

No sentinel events were reported in this category during 2005–06.

Medication error leading to the death of a patient reasonably believed to be due to incorrect administration of drugs

In 2005–06, two events were reported in this category. In descending order of frequency, the contributing factors reported included:

- communication (between staff)
- procedures and guidelines (clinical management guidelines, coordination of care)
- human resources (staff supervision).

Maternal death or serious morbidity associated with labour or delivery

In 2005–06, five events were reported in this category. After review, three were withdrawn as the events were determined to be the result of rare complications of pregnancy and childbirth. In descending order of frequency, the contributing factors for the remaining two events reported included:

- course of disease
- procedures and guidelines (patient observation, clinical management guidelines, coordination of care)
- human resources (staff allocation, staff training)
- communication (between staff).

Infant discharged to wrong family

No events were reported in this category during 2005–06.

Other catastrophic event categories

In 2005–06, 54 events were reported in this category. After review, five notifications were withdrawn as no process or system issue was identified, and the individual events were considered to be associated with the patient's health condition.

Complication of emergency/resuscitation management

In 2005–06, four notifications were reported in this category. In descending order of frequency, the contributing factors reported included:

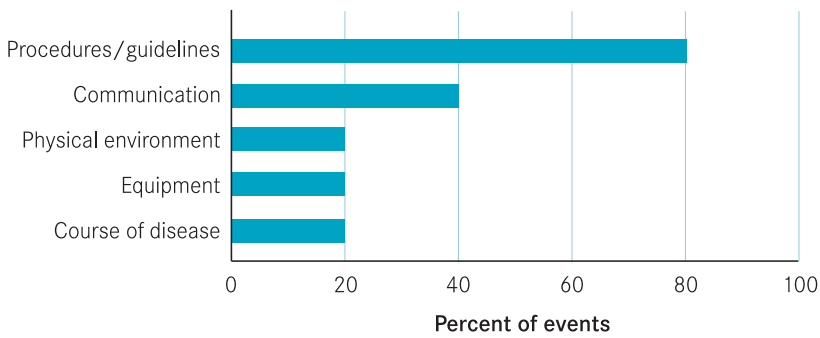
- procedures and management (physical assessment, clinical management guidelines, identification process, coordination of care)
- human resources (staff training)
- communication (between staff).

Complication of surgery

In 2005–06, five notifications were reported in this category. The contributing factors in descending order of frequency reported included:

- procedures and management (physical assessment, patient observation, clinical management guidelines, identification process, coordination of care)
- communication (between staff)
- course of disease
- equipment
- physical environment.

Figure 4: Root cause of complication of surgery



Complication of anaesthetic management

No events were reported in this category during 2005–06.

Foetal complication of delivery

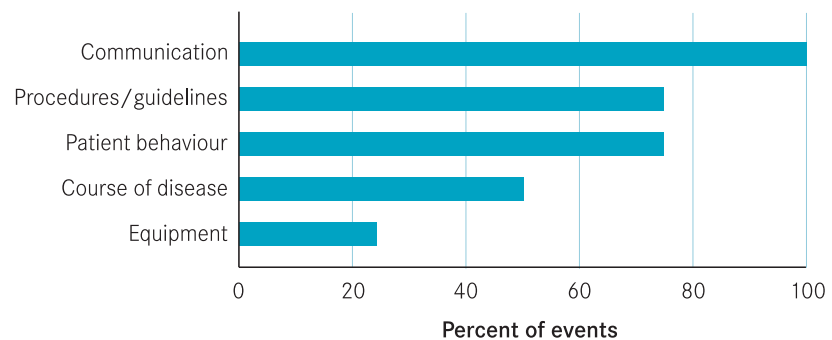
In 2005–06, two events were reported in this category. In descending order of frequency, the contributing factors reported included:

- procedures and guidelines (physical assessment, clinical management guidelines)
- course of disease
- facilities management (inter-hospital issues)
- human resources (staff training)
- communication (between staff).

Complication of inpatient fall resulting in death or serious morbidity

In 2005–06, five events were reported in this category. One report was not available for analysis at the time of writing this report. In descending order of frequency, the contributing factors for the remaining four events reported included:

- communication (between staff, between staff and patients/family's, translation/NESB)
- procedures and guidelines (patient observation, clinical management guidelines, coordination of care)
- patient behaviour
- course of disease
- equipment.

Figure 5: Root cause of inpatient fall resulting in death

Patient absconding from inpatient unit with adverse outcome

In 2005–06, two notifications were reported in this category. In descending order of frequency, the contributing factors reported included:

- procedures and guidelines (behavioural assessment, patient observation, coordination of care)
- patient behaviour
- physical environment (security)
- human resources (staff allocation).

Infection control breach

In 2005–06, three notifications were reported in this category. In descending order of frequency, the contributing factors reported included:

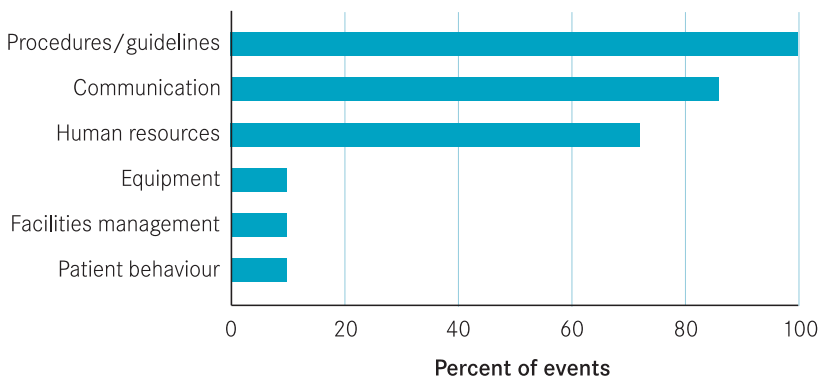
- human resources (staff allocation, staff training)
- procedures and guidelines (clinical management guidelines)
- facilities management (inter-hospital issues)
- communication (between staff)
- physical environment.

Medication error not resulting in death/near miss

In 2005–06, seven events were reported in this category. In descending order of frequency, the contributing factors reported included:

- procedures and guidelines (physical assessment, patient observation, clinical management guidelines, coordination of care)
- communication (between staff, between staff and patients/families)
- human resources (staff allocation, staff training, recruitment)
- facilities management (inter-hospital issues)
- equipment
- patient behaviour.

Figure 6: Root cause of medication error not resulting in death/near miss



Misdiagnosis and subsequent treatment

In 2005–06, three events were reported in this category. In descending order of frequency, the contributing factors reported included:

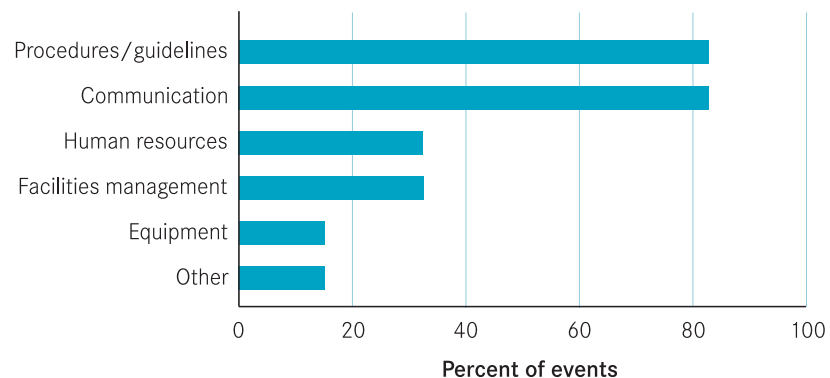
- procedures and guidelines (physical assessment, patient observation, clinical management guidelines, coordination of care)
- faculties management (transportation, inter-hospital issues)
- human resources (staff allocation, staff supervision)
- communication (between staff).

Hospital process issues

In 2005–06, six events were reported in this category. In descending order of frequency, the contributing factors reported included:

- procedures and guidelines (physical assessment, patient observation, identification process, clinical management guidelines)
- communication (between staff, between staff and patient and families, translation/NESB)
- human resources (staff allocation, staff training)
- faculties management (inter-hospital issues)
- equipment
- other.

Figure 7: Root cause of hospital process issues



Communication of test results – delay or error in reporting

In 2005–06, one notification was reported in this category. The contributing factors reported included:

- procedures and guidelines (physical assessment, patient observation, clinical management guidelines)
- communication (between staff).

Other catastrophic – mental health

In 2005–06, three notifications were reported in this category. In descending order of frequency, the contributing factors reported included:

- procedures and guidelines (physical assessment, patient observation, clinical management guidelines, coordination of care)
- communication (between staff, between staff and patients and families)
- physical environment
- course of disease
- patient behaviour.

Other catastrophic – other

In 2005–06, eight events were reported in this category. However, because events in this category occur in isolation, no trends could be identified.

Recommended strategies for 2006–07

- 1 To maintain and develop the root cause analysis education program to ensure:
 - 1.1 further development of the education module package by the pilot and rollout of module 4 aimed at clinical incident response and review
 - 1.2 all health services have access to the education program, and that the program is available to new staff as required
 - 1.3 further development of the peer support group program with the aim of establishing an environment of ongoing support and education
 - 1.4 there is an established core group of experienced RCA facilitators who will be available to provide advice and support to those undertaking RCAs for the first time and/or those participating in complex RCAs
 - 1.5 a team of educators and peer group facilitators is established to ensure the ongoing sustainability of the root cause analysis education program.
- 2 To continue to develop a clinical governance policy in line with the Auditor-General's audit recommendations.
- 3 To review and clarify sentinel event definitions and categories through liaison between the department and expert bodies, thus ensuring consistency in interpretation and the integrity of sentinel event program data.
- 4 To review current national and international practices related to RCA and legal/privilege issues and develop a Victorian model.
- 5 To support the development of the incident information system (IIS) project as a means of identifying potential precursors of sentinel events.
- 6 To strengthen links with the private health sector and encourage its active participation in the sentinel event program.

Risk-reduction strategies – case studies

Retained instrument or other material after surgery requiring re-operation or further surgical procedure

Description of the event

A patient was transferred to an intensive care unit after surgery where a central venous catheter (CVC) was inserted for monitoring. A chest X-ray confirmed the position of the CVC. The patient improved and was discharged but later re-presented with chest pain. Investigations revealed that the guide wire had been inadvertently left in place from the CVC insertion. Further surgery was required to remove the guide wire.

Contributing factors

Procedures and guidelines: a standardised insertion method was not available within the health service and there were no mandatory requirements for the completion of a request slip or reporting on chest X-rays post-CVC insertion to check for presence of a guide wire.

Human resources: there was a lack of a formalised education and a credentialling process for the insertion procedure for junior medical staff.

Communication: communication between staff was lacking during the insertion procedure and assisting nursing staff did not realise that the guide wire had not been removed.

Risk-reduction strategies

The following risk-reduction strategies were considered and implemented:

- Guidelines to be developed to ensure a comprehensive monitoring line insertion protocol, methodology and worksheet system.
- A formalised protocol to be developed to address the minimum clinical information required when requesting and reporting X-rays in this situation.
- Documentation to include the removal of the guide wire in the current nursing CVC insertion protocol.

System factors

The sentinel events program received a number of notifications during 2005–06 involving retained guide wires. The Clinical Risk Management Reference Group reviewed the RCAs and found common systems factors included:

- education and credentialling of staff
- standardisation of method of insertion procedure
- standardisation of minimum information requested and reported for radiological investigations
- nursing guidelines.

The Safer Systems Saving Lives project (SSSL) makes a number of recommendations regarding the management of CVC's including reference to the training and experience of the person inserting CVC lines (appendix 6).

Medication error leading to the death of patient reasonably believed to be due to incorrect administration of drugs

Description of the event

A patient was administered a dose of sedation larger than that ordered and was found deceased a short time later. The patient had a history of respiratory and cardiac illness.

Contributing factors

Human resources: the nurse administering the drug was relatively new to the environment, was unfamiliar with the drug and the drug chart, and was not being supervised.

Communication: additions to the drug register had been added in hand-drawn columns, and it was hard to distinguish that two strengths of the particular drug were available.

There was a delay in contacting medical staff when the medication error was first identified and thus orders were not obtained for specific observations.

Risk-reduction strategies

The following risk-reduction strategies were considered and implemented:

- Education and competency assessments to be arranged for new nursing staff to reinforce the drug checking protocol, particularly checking patient identification against the written drug order and the label drug strength on the packaging.
- Education to be conducted with all nursing staff to reinforce the need for timely reporting and documentation of clinical errors.
- Review of the drug charts and drug register be undertaken to ensure appropriateness and ease of use.

System factors

Medication errors occur in 5 to 20 per cent of drug administrations in Australian hospitals. Although the majority of events are not serious, the risk is still present. On 23 April 2004, the Australian Health Ministers Joint Communiqué stated:

To reduce the harm to patients from medication errors, by June 2006, all public hospitals will be using a common medication chart. This means that the same chart will be used wherever a doctor or nurse works and wherever the patient is within a hospital.

The Victorian Medicines Advisory Committee's National Inpatient Medication Chart (NIMC) working party is facilitating the implementation of the NIMC across Victoria. To date, most metropolitan teaching hospitals and more than half of the regional and rural health services have either implemented, or stated a commitment to implement, the NIMC by January 2007.

Haemolytic blood transfusion reaction resulting from ABO incompatibility

Description of the event

As noted in the sentinel event annual report for 2005–06, no sentinel events were reported under this particular category; however, a small number of near-miss events were reported. The reporting and analysis of a near miss/close call is of considerable value as it reflects not only systems and process errors, but also the system safety nets that can prevent an event from occurring or escalating. This, in turn, provides important learning opportunities and re-enforcement of the need to continually evaluate the way in which systems and processes work within the health care setting.

As reported in 2005–06, a near-miss event involved two patients in the same unit and with similar surnames who both required blood transfusions on the same day. A sample was taken from patient A and sent for processing, but it was mislabelled as a sample from patient B. When the blood arrived for transfusion, another nurse queried where the blood for patient A was and, in consultation with the pathology unit, did double checks on the patient samples and the error was identified.

Contributing factors

Procedures and guidelines: a member of staff did not follow correct procedure in labelling the blood specimen immediately at the bedside. Instead, they returned to the centralised desk, thus increasing the likelihood of using the wrong patient labels.

Communication: despite the fact that two patients in the same unit had similar names, few warning labels were visible on the patients' charts and histories to alert staff.

Risk-reduction strategies

The following risk-reduction strategies were considered and implemented:

- Informal blood collection practices be identified and eliminated.
- An awareness campaign be conducted for all relevant staff on the contents of the organisational policy on verification of patient identification, and the guidelines on blood specimen collection.

System factors

Haemovigilance for the BeST program is defined as:

a system of surveillance and alarm, which encompasses all steps of the transfusion process, from blood collection to the follow-up of recipients.⁹

The Serious Transfusion Incident Reporting Program (STIR) is a BeST haemovigilance initiative that was commenced as a pilot program in 2006. This program aims to capture data on serious adverse events and near misses associated with transfusion. By monitoring these adverse events statewide, recommendations will be made to health services that will inform policy and improvements in clinical transfusion practice, and reduce exposure to transfusion risks for patients.

More information is available at: www.health.vic.gov.au/best

9 Debeir, J, Noel, L, Aullen, J, Frette, C, Sari, F, Mai, MP & Cosson, A 1999, Vox Sanguinis, vol. 77, no. 2, pp. 77–81, The French haemovigilance system.

Misdiagnosis and subsequent treatment

Description of the event

A patient presented with neck pain and arm discomfort. An MRI scan was required for a definitive diagnosis but it was delayed for prolonged period due to a miscommunication regarding the availability of the scanner, and the appropriate process for requesting the procedure. Consequently, treatment was delayed as a result of conflicting interpretations of the symptoms. This resulted in permanent spinal damage to the patient.

Contributing factors

Procedures and guidelines: clear guidelines for the management of patients with possible spinal injury were not available.

Communication: only a few staff were aware of new radiology services offered at the hospital due to a breakdown of communication pathways. In addition, there was confusion as to the correct approval process for accessing radiological investigations.

Facilities management: there was a lack of understanding of a service agreement between hospitals that guarantees bed availability for certain high-risk patients; thus, an attempt to transfer the patient to another facility for scanning was unsuccessful.

Human resources: the medical consultant delegated the patient management to a less experienced doctor who had limited practice in dealing with diagnostic conflicts.

Risk-reduction strategies

The following risk-reduction strategies were considered and implemented:

- A review and revision be undertaken of the respective processes for communicating major changes in access to radiology investigations and the appropriate approval processes.
- All medical staff to be informed of the appropriate channels for help and support in managing clinical disputes.
- All medical staff to be informed of agreements established with external agencies regarding the transfer of patients requiring specialist facilities.

System factors

Over recent years, a small but significant number of sentinel events concerning the management of cervical spine injuries have occurred. As a result, in 2002–03 the State Trauma Committee (STC) was asked to develop an appropriate protocol for managing suspected cervical spine injuries. The STC endorsed a final cervical spine acute care guideline for paediatrics under 16 years and adults in February 2006, and the introduction of the guideline is planned for the latter half of 2006 (see Appendix 7).

Procedures involving the wrong patient or body part

Description of the event

A patient with generalised seizures was brought into the emergency department. The patient was sedated for a CT scan but, because of airway difficulties, the patient was placed in the CT scanner feet first. Normal procedure dictates that patients are placed in a CT scanner head first. The scan showed a right-sided subdural bleed requiring surgery. The patient was stabilised and then transferred to another hospital. Surgery commenced but no blood was found. The surgeon contacted the CT radiographer who confirmed that the CT scan was labelled the wrong way around as a result of the unusual positioning. After discussion with senior consultants, the surgery proceeded on the correct side without complication.

Contributing factors

Procedures and guidelines: the radiographer did not adhere to the protocol of changing all fields when a patient is placed in an unconventional position for a CT brain scan.

Communication: medical staff did not consult with radiology and/or read the accompanying report when doubts were raised about the labelling of the scan.

Human resources: a senior radiographer was not present at the time of the scan.

Risk-reduction strategies

The following risk-reduction strategies were considered and implemented:

- The radiology protocol be reviewed to ensure external skin markers are placed for all scans where there is unconventional positioning of the patient.
- Escalation procedures be reviewed/developed to ensure junior staff are able to contact senior staff in the event that additional support is required.
- Where decisions regarding site or side of surgery are dependent on radiological or other investigation results, scans and accompanying reports must be read prior to commencement of surgery. If in doubt, contact must be made with the radiology department and consultant.

System factors

Procedures involving the wrong patient, the wrong site and/or wrong side continue to dominate the sentinel event notifications. In response to this ongoing trend, the Clinical Risk Management Reference Group maintains its recommendation to implement the *Ensuring correct patient, correct site, correct procedure* (as developed by the Australian Council for Safety and Quality in Health Care (now the Australian Commission for Safety and Quality in Health Care), and that all health services expand the guideline to include all areas where patients receive treatment or undergo procedures such as radiology, pathology, outpatient departments, radiotherapy and day procedure areas.

Infection control breach

Description of the event

An orthopaedic loan set of equipment (specialised surgical equipment) was required for urgent use at hospital A after it had been used and returned by hospital B. When preparing the equipment in theatre, a piece of tissue from the previous patient was discovered. The equipment had to be returned for re-sterilisation, which meant the patient was subjected to an unnecessarily prolonged general anaesthetic.

Contributing factors

Human resources: a member of staff who was processing the equipment was unaware of routine practice of brushing equipment that had been loaned and returned, which resulted in inadequate checking and cleaning.

Communication: there was a lack of support documentation to indicate cleaning and sterilisation processes undertaken on the loan equipment at hospital B.

Equipment: the unsuitability of the ultrasonic cleaner at hospital B resulted in insufficient cleaning of the equipment.

There was a limited amount of such equipment, which was in great demand, and staff felt pressure to ensure its availability. The extensive variability in orthopaedic equipment prohibits hospitals from carrying all orthopaedic surgical items.

Risk-reduction strategies

The following risk-reduction strategies were considered and implemented:

- A process be developed to ensure hospitals receive clean, sterilised loan equipment, and clear, supportive documentation of processing requirements.
- The guidelines for the reprocessing of loan equipment be reviewed to ensure all relevant staff be educated and trained as to these changes in practice.

System factors

The Victorian Advisory Committee on Infection Control reviews all infection control related events. Various themes continue in the infection control breach events, and there is a need for organisations to ensure:

*10 AS/NZS4187: 2003
Australian and New Zealand
Standard: Cleaning, disinfecting
and sterilising reusable medical
and surgical equipment,
and maintenance
of associated environments
in health care facilities*

- education in AS4187 for sterilising and theatre staff¹⁰
- staff training in their area and job
- annual or biannual staff competencies
- sterilising checklists and documentation as per AS4187
- training for staff using flash sterilisers (when, how and why).

Glossary

The following terms are used frequently in this report. The department acknowledges that their usage varies, and that a number of definitions are used in the literature.

adverse event	an unintended injury or complication which results in disability, death or prolongation of hospital stay and is caused by health care management rather than the patient's disease
accountability	being held responsible
ABO blood group	a system for classifying human blood based on the antigenic components of blood cells and their corresponding antibodies
behavioral assessment	processes involved in establishing a patient's cognitive state, particularly whether the patient is at risk of wandering, absconding or causing harm to staff
contributing factor	a factor that shaped the outcome of a situation
clinical guidelines	any policy or procedure or guidelines surrounding the processes involved in the clinical management of patients
clinical risk management	an approach to improving quality in health care which places special emphasis on identifying circumstances that put patients at risk of harm, and then acting to prevent or control those risks
clinical governance	a health service's board's accountability for ensuring a framework and rigorous systems are established so health care safety and quality are monitored, evaluated and continuously improved
clinical pathway	a treatment regime agreed on by consensus which includes all the elements of care, regardless of the effect on patient outcomes
cost	direct and indirect activities involving a negative impact, including injury, death, increased length of stay, time loss, money loss, service disruption, and reputation, political and intangible losses
external factors	contributing factors that are a result of an issue external to the organisation
harm	death, disease, injury or harm, suffering or disability experienced by a person
hazard	a source of potential harm or a situation with a potential to cause loss
incident	an event or circumstance resulting from health care which could have or did lead to unintended or unnecessary harm to a person and or a complaint, loss or damage
incident severity rating	a method to quantify the actual or potential consequences of an incident or near miss
likelihood	used as a qualitative description of probability or frequency
monitor	to check, supervise, observe critically or record the progress of an activity or system on a regular basis in order to identify change
near miss	an incident that did not cause harm
probability	the likelihood of a specific outcome
risk	the chance of something happening that will have an impact on objectives. It is measured in terms of consequence and likelihood.
risk assessment	the overall process of risk analysis and risk evaluation
risk evaluation	the process used to determine risk management priorities by comparing the level of risk against predetermined standards, target risk levels or other criteria

risk management	the culture, processes and structures that are directed towards the effective management of potential opportunities and adverse effects
root cause	a significant factor that contributed to an incident
root cause analysis	a systematic process whereby the factors that contributed to an incident are identified
risk reduction action plan	strategies required to reduce the risk of similar adverse patient outcomes occurring in the future
safety	a state in which risk has been reduced to an acceptable level
sentinel event	a relatively infrequent, clear-cut event that occurs independently of a patient's condition, commonly reflects a hospital system and process deficiencies, and results in unnecessary outcomes for the patient
underlying cause	the systems or process cause that allows for the proximate cause of an event to occur

Appendix 1: Clinical Risk Management Reference Group, consultative councils and expert groups

The Clinical Risk Management Reference Group (CRM RG) was established to address current issues in clinical risk management throughout Victoria. The committee comprises clinicians, health professionals, quality managers, hospital board members and consumers. The committee provides advice to the sentinel event program. A CRM RG subcommittee reviews all RCA reports to identify issues and trends from events, and provides feedback to the department.

Clinical Risk Management Reference Group 2005–06

Dr Bill Shearer, Chair	Director of Critical Care Services, Southern Health
Professor Megan-Jane Johnstone	Department of Nursing and Midwifery, RMIT Bundoora Campus
Dr Alan Wolff	Director of Medical Services, Wimmera Health Care Group
Dr Heather Wellington	Consultant, Phillips Fox Lawyers
Ms Anne Curtin	Health Service Executive Representative, West Gippsland Health Care
Mr Russell Jones	Claims Manager, Victorian Managed Insurance Authority
Ms Jo Bourke	Risk Manager, Barwon Health
Dr Sandra Leggat	Senior Lecturer, School of Public Health, Latrobe University
Dr Bruce Warton	Director of Medical Services, Goulburn Valley Health, Shepparton
Ms Bernadette Lane	Infection Control Practitioner
Mr Kent Garrett	Director of Pharmacy, Austin Health
Dr Grant Phelps	Clinical Director Internal Medicine, Ballarat Health Services
Ms Margaret Way	Clinical Governance Program Manager, Austin Health
Ms Therese Carroll	Clinical Risk Manager, Medical Defence Association of Victoria
Dr Peter Waxman	Senior Medical Advisor, General Practice, Department of Human Services
Mr Alistair Kerr	Consumer representative
Ms Elise Sullivan	Senior Nursing Advisor, Department of Human Services
Dr Peter Longmore	Director Medical Services, Mercy Hospital for Women
Ms Alison McMillan	Acting Director, Quality and Safety Branch, Department of Human Services
Ms Maureen Willson	Manager, Victorian Quality Council, Department of Human Services
Mr Deane Wilks	Program Manager, Department of Human Services
Ms Susan Edmondson	Senior Program Advisor, Department of Human Services
Ms Laurene Graham	Project Officer, Department of Human Services

Consultative councils 2005–06

As part of the sentinel event program, the department forwards information provided in root cause analyses and risk-reduction action plans to relevant expert bodies so they can comment on:

- identified system issues based on information contained in the root cause analysis
- the appropriateness of suggested system improvements provided in the risk-reduction action plans
- the usefulness and quality of information contained in the root cause analyses
- recommendations that are specific to the health service, and recommendations for statewide dissemination.

The Quality and Safety Branch works closely with a range of consultative councils and other relevant clinical bodies to provide recommendations to hospitals on specific sentinel events. These include the:

- Consultative Council on Obstetric and Paediatric Mortality and Morbidity
- Victorian Surgical Consultative Council
- Victorian Consultative Council on Anaesthetic Mortality and Morbidity
- Victorian Advisory Committee on Infection Control
- Australian Red Cross Blood Service Victoria
- Chief Psychiatrist, Department of Human Services
- State Trauma Committee
- Nurse Policy Branch, Department of Human Services
- Royal Australian and New Zealand College of Radiology
- Intensive Care Advisory Committee.

Appendix 2: The Victorian root cause analysis education program

The root cause analysis education program was developed in modules to match the organisational responsibilities and needs of different user groups. The modules are:

- Module 1: Root cause analysis. What's in it for you?
- Module 2: Root cause analysis. Getting started
- Module 3: Root cause analysis. Conducting an investigation
- Module 4: Incident response and review (in development).

The first module is designed to introduce the root cause analysis process to health service staff while providing education on human factors theory. The second module is designed to assist organisations with the implementation of the root cause analysis process, including the appointment of the root cause analysis coordinator and the root cause analysis facilitator. The third module focuses on the investigation methodology and development of an action report for the executive staff that identifies root causes and makes recommendations to prevent the catastrophic adverse event recurring. A new reporting proforma was incorporated in the third module to further assist interpretation and analysis of data by the department and expert bodies.

A fourth module is in development and will be piloted in late 2006. As most incidents that occur will not be sentinel events, this module will provide health services with an incident response process for appropriate action at the time of the incident, and a process for review and analysis.

The following information is an excerpt from Module 2 of the RCA education program.

What is an incident response process?

An incident response process is a formal means of classifying the severity or consequence of an actual incident or near miss to trigger the appropriate level of management response. The staff member reporting the incident undertakes the initial assessment of the incident. The staff member responsible for safety or risk management verifies it.

Why is an incident response process necessary?

A systematic process for identifying risks begins with, and relies on, an effective incident reporting and response process. The reporting of incidents and their subsequent severity rating and investigation to determine contributing root causes enables risks to be identified and managed. Each organisation will already have an incident reporting system in place, but might not have developed a process to guide the appropriate level of organisational response to each reported incident.

In many incident reporting systems, a committee has the discretion to decide which incident requires a root cause analysis investigation. This decision-making process might be influenced by social, cultural, administrative or political issues and might not enable investigation to be undertaken in a timely manner.

Without a formal process of responding to incidents, the appropriate level of management and resource allocation might not occur, and opportunities to improve the outcomes for patients and the organisation might be lost.

Using an incident severity rating process

Developing and integrating an incident severity rating (ISR) process into the incident reporting procedures will enable the organisation's incident response expectations to be clearly defined and communicated to staff. Applying an ISR classification provides a standardised yardstick by which organisational incident review and appropriate action can be prioritised.

The severity or consequences of an incident can be divided into four categories that are consistent with an appropriate level of management response. These levels are:

ISR 1 – executive management response

ISR 2 – senior management response

ISR 3 – line management response

ISR 4 – line management response.

The following guidance on how to classify incidents is intended as a suggested starting point when determining which incidents will be the subject of a root cause analysis investigation.

This guidance is not intended to cover all possible scenarios, but to illustrate a range of typical harm-related outcomes.

For near-miss incidents, judgment will be required to determine the potential safety value (organisational and industry-wide lessons) to be gained from conducting a root cause analysis investigation. (See Module 1 for level of organisational response.) If an injury can be characterised by more than one rating, apply the higher rating.

Case examples of incident severity rating classifications

Case 1

The evening nursing staff found a dementia patient on the floor. No obvious injuries were reported. The patient was returned to bed. The fall was not communicated at handover. Later, the patient was found to be unconscious. An urgent CAT scan was ordered and a subdural haematoma was diagnosed. Despite surgery to evacuate the clot, the patient did not regain consciousness and died the following day.

ISR 1 classification: relatively infrequent, clear-cut events that occur independently of a patient's condition commonly reflect hospital system and process deficiencies, and result in or have the potential to result in, an unexpected death or a permanent disabling injury or psychological harm to a person. These include reportable sentinel events.

The incident contributed to the patient's death. It would be classified as an ISR 1 and a recommendation would be made to the appropriate executive director to commission a root cause analysis investigation. The incident would also be reported to the coroner, the insurer and the Department of Human Services.

The root cause analysis coordinator must review all ISR 1 incidents to determine if a root cause analysis investigation is indicated.

Case 2

A visitor observed a patient climb over a bed rail and fall to the floor. The patient complained of right hip pain and was unable to bear weight. A doctor saw the patient and ordered an X-ray. A fractured neck of femur was diagnosed and the patient underwent a Moore's prosthesis procedure the following day.

ISR 2 classification: events that result in a temporary loss of function (sensory, motor, physiological or intellectual) that are unrelated to the natural course of the patient's illness and differ from the expected outcome of the person's management.

The patient suffered a serious temporary injury that will require significant additional care. The incident would be classified as an ISR 2. It would be expected that this incident would be reported to a divisional director who would arrange for the case to be reviewed.

Case 3

A patient fell off a shower chair while being showered and hit his face, lip and shoulder on the grab rail as he fell. A doctor saw the patient and ordered X-rays. No fractures were noted. The patient was returned to bed where neurological observations were initiated as per policy and reported as normal.

ISR 3 classification: events that result in a person requiring increased treatment, but not hospitalisation or an increased length of stay in hospital.

The patient required medical review and additional investigations; therefore, the classification would be ISR 3. In addition to ensuring the patient's falls risk was reassessed, it would be expected the department would undertake a process of aggregate review of similar incidents.

Case 4

A patient was found on the floor after rolling off his high-low bed. He sustained a small skin tear to his left arm, which a nurse dressed.

ISR 4 classification: events that result in minor injury requiring only first aid treatment or no injury.

The patient sustained a minor injury and required only first aid attention. This incident would be classified as an ISR 4. The nurse unit manager would be expected to assess the patient's falls risk and take appropriate action as indicated.

Appendix 3: Contributing factor descriptions

Each root cause analysis identifies the contributing systems factors that impacted on the event's occurrence. The factors identified in the events for 2004–05 were reviewed and a classification system was developed. The system is adapted from the Joint Commission on Accreditation of Health Care Organisations' reporting root cause analysis template (1998), and from the New South Wales Health Institute for Clinical Excellence's *Checklist flip chart for root cause analysis* (2003).

The contributing factors included in each of the categories are outlined below.

Procedures and guidelines

This category includes all contributing factors that are a result of a procedure, policy or guideline. These are issues relating to the existence and ready accessibility of policy or guidelines, the misunderstanding or misuse of current procedures and guidelines, or failure to comply with current procedure. A common subcategory that impacts on this category involves the orientation and training of staff, and the availability of information and training for policy and guideline compliance for part-time, temporary or voluntary workers and students. Subcategories are outlined below.

Behavioural assessment

This subcategory involves any policy, procedure or guidelines concerning the processes involved in assessing a patient's behaviour. This category is most relevant when establishing a patient's suicidal or self-harm intent. This category is also relevant for the processes involved in establishing a patient's cognitive state, particularly whether the patient is at risk of wandering, absconding or causing harm to staff. This contributing factor impacts predominantly on the sentinel events of 'suicide as an inpatient'.

Physical assessment

This subcategory involves any policy, procedure or guidelines concerning technical information for assessing patient risks, mechanisms for feedback on key processes, effective interventions developed after events, and compliance with national policies.

This subcategory involves any policy, procedure or guidelines concerning the processes involved in the clinical observation of a patient. This category might include either medical, nursing or allied health procedures or guidelines. Examples of factors that might be included in this subcategory are:

- policies involving operative or postoperative clinical observation
- policies or procedures involving neurological observations post-head injury
- policies or procedures involving observation of patients at risk of self-harm or absconding.

Clinical management guidelines

This subcategory involves any policy, procedure or guidelines concerning the processes involved in the clinical management of patients. It might include either medical, nursing or allied health clinical management plans. Examples of clinical management guidelines are:

- clinical pathways for the management of stroke patients
- clinical pathways for the pre-operative management of patients for bowel surgery
- clinical management guidelines on the management of patients post-myocardial infarction.

Identification process

This subcategory involves any policy, procedure or guidelines concerning the processes involved in the identification of patients. This also includes any processes involved in identifying the correct site/side for surgery/radiology. Examples of identification process are:

- policies involving confirming a patient's identity prior to an operation
- policies involving identifying the correct side prior to surgery (for example, confirming that the knee replacement will occur on the right, not on the left)
- policies involving identifying the correct patient and site for radiotherapy.

Coordination of care

This subcategory involves any policy, procedure or guidelines concerning the processes required for coordinating a patient's care that are not specifically outlined in the above categories. The processes involved in coordinating patient care can overlap between departments, inpatient and outpatient departments, clinical and non-clinical units, administrative units, and external organisations (for example, rehabilitation organisations, general practitioners, the Royal District Nursing Service). Examples of processes involved in the coordination of patient care are:

- procedure to ensure outpatient follow-up on discharge
- procedures to ensure communication of test results
- health services' policies on infection control
- operating theatre procedures to ensure pathology specimens obtained in theatre are transported to the pathology department.

Patient behaviour

This new category for 2005–06 picks up factors that are associated with the patient's behaviour that may have contributed to the event. This includes non-compliance, refusal of treatment and risk-taking behaviours; for example, drug and/or alcohol abuse.

Course of disease

This new category for 2005–06 picks up factors associated with the patient’s course of disease that may have contributed to the event (such as dementia) and physical factors associated with the illness that may have contributed to the event.

Facilities management issues

This category includes all contributing factors that are a result of an issue with how the facility is managed. This can include environmental issues and maintenance issues, such as supply of medical gases without interruption to supply.

Transportation issues

This category includes all contributing factors that are a result of an issue with interagency or health service transportation of a patient. Such issues might relate to:

- coordination of retrieval services between health services
- referral processes
- provision of clinical escort services.

Inter-hospital issues

This category includes all contributing factors that are a result of an issue with the transfer of a patient from one health service provider to another. Such issues might relate to:

- coordination of health information between the health service and external organisations or other health services involved at time of transfer
- provision of all relevant documentation at the time of transfer
- completion of relevant information at the time of transfer.

Human resources

This category includes all contributing factors that are a result of a human resource or staffing issue, including knowledge, skills and competence. The subcategories are outlined below.

Staff allocation

Staff allocation might influence the stress and fatigue of staff that can result from change, scheduling and staffing issues and sleep deprivation. This subcategory includes all issues concerning the allocation of staff, whether medical, nursing or allied health. Predominantly the issues involve:

- medical understaffing and workload allocation
- nursing understaffing and workload allocation
- replacement, or lack, of medical and nursing staff on sick leave
- replacement of staff on leave with staff of too junior a level for the position
- sufficiency of staff on hand for the workload at the time.

Staff training

Staff training includes issues relating to routine job training, special training and continuing education, including the timing of training. Training issues might concern the application of approved procedures, correct use of equipment or appropriate safety mechanisms. This subcategory includes all issues concerning staff training and experience, whether medical, nursing or allied health. Predominantly the issues involve:

- medical and nursing training inadequacies in clinical procedures
- inexperienced staff in positions at a level greater than their experience
- training undertaken after the commencement of new work processes
- monitoring of training adequacy over time
- existence of programs to identify what training was actually needed.

Staff supervision

This subcategory includes all issues concerning staff supervision, whether medical, nursing or allied health staff. It also covers a range of levels of experience, and predominantly the issues involve a lack of supervision or inadequate supervision. Examples of the contributing factors are:

- junior medical staff supervision requirements
- new nursing graduates' supervision requirements
- supervision required for newly graduated surgical fellows in operating theatres
- supervision required for clinical nurse specialists in intensive care.

Staff appraisals

This subcategory includes all issues concerning staff appraisals of performance, whether medical, nursing or allied health staff. The issues predominantly involve a lack of appraisal or less appraisal than expected by the profession involved.

Recruitment

This subcategory includes any issue about medical, nursing or allied health recruitment.

Communication

Communication involves the flow of information and availability of information as needed. Communication is important for ensuring the correct use of equipment, and the application of policy and procedures. This category includes all contributing factors that are a result of a communication issue. The subcategories are outlined below.

Communication between staff

This subcategory involves all issues that arise from miscommunication or lack of communication that occurs between staff members. Examples of such issues are:

- miscommunication or lack of communication between junior and senior medical staff
- miscommunication or lack of communication between medical and nursing staff
- miscommunication or lack of communication between departments within the health service
- miscommunication or lack of communication between health services and external organisations.

Communication between staff and patients/family members

This subcategory involves all issues that arise from a miscommunication or lack of communication that occurs between staff members and patients/families. Such issues might involve cultural or language barriers or ‘medical or technical language’ barriers. Examples of such issues are:

- a staff member explaining a procedure in a manner the patient could not comprehend
- failure to communicate the results of a test to a patient and/or family member
- explanation to family members about a patient’s medical state.

Translation/non-English speaking background (NESB) issues

This category includes all contributing factors that are a result of an issue with the translation of health information for a patient. Such issues might include:

- not using translation services for non-English speaking patients
- using family or carers for translation rather than professional translation services.

Health information

This category includes all contributing factors that are a result of an issue a patient’s health information. Such issues might relate to:

- documentation (or lack of) in the medical record
- communication of electronic health information
- communication of health information between the health service and external organisations.

Equipment

This category includes all contributing factors that are a result of an issue with equipment. Predominantly, the issues involve faulty equipment, lack of equipment provision and incorrect use for a given purpose, but might also relate to the use and location of equipment, fire protection and disaster drills, and codes. Often, what appears to be equipment failure might relate to human factors, policy and procedure questions, and training needs. Examples are:

- the equipment design does not allow the operator to detect problems or make usage mistakes
- equipment displays and controls are not working properly
- equipment in use does not meet standards, specifications or regulations
- lack of maintenance programs to maintain equipment and lack of documentation of previous inspections
- insufficient equipment to perform work processes
- no emergency provisions and backup systems in case of equipment failure.

Physical environment

This category includes all contributing factors that are a result of an issue with the physical environment of the health service, or the general suitability of the environment to support the function it is being used for, including environmental distractions such as noise. Examples of such issues include:

- existence of environmental risk assessment programs
- design of security systems in the health services to prevent at-risk patients from absconding
- design of seclusion rooms for psychiatric patients to avoid self-harm
- design of rooms to allow observation of at-risk patients
- design of outdoor areas for ambulant patients to prevent at-risk patients from falls.

External factors

This category includes all contributing factors that are a result of an issue external to the organisation. Examples of such issues are:

- service provision from the Australian Red Cross Blood Service
- service provision from diagnostic services sourced externally
- lack of availability of beds at an external organisation for an at-risk psychiatric patient that requires the patient to be cared for in a health service not designed for such patients
- retrieval by air and/or road ambulance to another health service (which may offer higher level care).

Other factors

This category includes contributing factors that arise from issues other than those discussed in this section. An example of such factors is the impact of a busy or stressful environment.

Appendix 4: Department of Human Services' review process for root cause analyses and action plans

A root cause analysis will be considered complete if it has the following characteristics:

- The analysis focuses primarily on organisational systems and processes, not individual clinicians.
- The analysis repeatedly digs deeper by asking 'why?' repeatedly.
- The analysis identifies changes that could be made to systems and processes through redesign or development of new systems or processes that would reduce the risk of such events occurring in the future.
- The analysis is thorough and credible.

To be thorough, the root cause analysis must include:

- a determination of the human and other factors most directly associated with the sentinel event, and the processes and systems related to its occurrence
- analysis of the underlying systems and processes through a series of 'why?' questions to determine where redesign might reduce risk
- identification of risk points and their potential contributions to this type of event
- a determination of potential improvement in processes or systems that would decrease the likelihood of such events in the future, or a determination, after analysis, that no such improvement opportunities exist.

To be credible, the root cause analysis must:

- include participation by the leadership of the organisation and the individuals most closely involved in the processes and systems under review
- be internally consistent; that is, not contradict itself or leave obvious questions unanswered
- provide an explanation for all findings of 'not applicable' or 'no problem'
- include consideration of any relevant literature.

An action plan will be considered *acceptable* if it:

- identifies changes that can be implemented to reduce risk, or formulates a rationale for not undertaking such changes
- identifies (where improvement actions are planned) the role responsible for implementation, when the action will be implemented (including any pilot testing), and how the effectiveness of the actions will be evaluated.¹¹

11 Adapted from the Joint Commission on Accreditation of Health Care Organisations' sentinel events website procedures page available at: www.jcaho.org/accredited+organizations/health+care+network/sentinel+events/se_pp.htm

Appendix 5: Open disclosure standard

Victoria's rollout of the open disclosure standard commenced in February 2004. Twelve health services are part of the pilot project: the six metropolitan and six regional health services listed below.

Open disclosure pilot site participants by organisation

Metropolitan sites	Rural and regional sites
St Vincent's Health	Northeast Health, Wangaratta
Eastern Health	Wodonga Regional Health Service
Bayside Health	West Gippsland Healthcare Group
Royal Women's Hospital	Bendigo Health Care Group
Royal Children's Hospital	Barwon Health
Southern Health	Goulburn Valley Health

Steering committee

The department established a Victorian steering committee to support the rollout of the standard. All pilot sites are represented, along with the Health Services Commissioner, a consumer, the Victorian Managed Insurance Authority (Victoria's public hospital insurer), a representative from Medical Defence Association of Victoria (a private medical insurer) and various departmental representatives. The meetings are held six-weekly.

A progress report was developed to assist each health site to identify its progress and current issues, which are then discussed at each meeting. To share lessons from the pilot sites, three case studies are discussed at each meeting.

Recording the open disclosure process in the patient's medical record, and subsequent meetings with the patient and their family and the clinicians have also been discussed.

Open disclosure education

Education was undertaken with the Cognitive Institute in October 2005. The Clinical Incident Management Program workshops were designed to educate clinicians to talk directly to patients, or to help other clinicians talk to patients about things that may have gone wrong and the patient's disappointment. Four clinical champions from each site were selected to attend the workshops and take the lessons back to their services to implement.

Feedback to date has indicated that this has been extremely advantageous and the key lessons reflect the need for education about communication techniques, specifically when communicating 'bad news'.

Open disclosure policy development

All pilot sites have developed policies by incorporating open disclosure into a clinical incident management policy or by developing a separate open disclosure policy. The Victorian Managed Insurance Authority has worked through the steering committee to develop a flowchart of activity that would be undertaken when a serious adverse event occurs. Pilot sites have included the flowchart in their policies and modified it for their organisational requirements.

Funding for pilot sites

All pilot sites have received funding to support the rollout of the open disclosure standard (allocated by the Australian Council on Quality and Safety in Health Care at \$40 000 per site). Key performance indicators have been developed to ensure the pilot sites continue with their progress of the rollout.

Future of pilot project

The state steering committee sees an ongoing role in assisting in the implementation of open disclosure across the state, and to evaluate the statewide rollout of the program.

The new commission has identified open disclosure as a key priority. The National Open Disclosure Steering Committee has reconvened to map future work required to ensure this project reaches completion.

The national evaluation report is now expected in July 2007.

It is currently anticipated that Victoria will rollout open disclosure across the state in late 2006–07, with a planned and detailed education and training program.

Appendix 6: Safer Systems Saving Lives

The Safer Systems Saving Lives (SSSL) is a national collaborative project initiated by the Australian Commission on Safety and Quality in Health Care. The project is based on the Institute for Healthcare Improvement's 100K Lives project.

The project's objective is to achieve national improvement in patient health outcomes by using six specific key evidence-based interventions. Improvement is measured by participant compliance with the interventions and the outcome of consistently applying them.

The majority of the interventions involve a 'bundle' of care. Care bundles are groupings of best practice that individually improve care but, when applied together, result in substantially greater improvement.

The preventing central venous catheter associated bloodstream infections intervention (CVC bundle) seeks to apply agreed practice in the areas of:

- catheter site selection
- hand hygiene
- maximal barrier precautions
- skin antisepsis
- daily review of catheter necessity.

In addition to these key areas of practice, the CVC bundle toolkit makes recommendations about dressing CVC sites, managing CVC lines, and the experience of the person inserting CVC lines.

More information is available at: www.health.vic.gov.au/sssl/

Appendix 7: Cervical spine acute care guideline (adult and paediatric)

During 2002–03, the sentinel event program reported two separate sentinel events concerning the management of cervical spine injuries in the elderly. One hospital reported that it ‘missed a cervical spine fracture almost every year for the past three years’. Given the frequency of the events, and their significantly adverse outcomes, the Department of Human Services recommended further investigations of the issues.

The specific issues raised in the two cases focused predominantly on processes and procedures involved in clearing cervical spine injuries post-trauma. They also highlighted the added clinical complexities for consideration when managing elderly patients who may also have degenerative spine disease, and co-morbidities including anticoagulant therapy.

The Clinical Risk Management Reference Group reviewed the cases and wrote to the State Trauma Committee (STC) chair in 2003. The STC was asked to provide a statewide solution that would address the management of cervical spine injuries in the elderly post-trauma in response to the following root cause analysis outcomes:

- review of the protocol for management of suspected cervical spine injuries
- review of the protocol for management of trauma patients taking anticoagulants
- review of the removing cervical collar protocol.

In 2003, the STC recommended the Major Trauma Services Operations Group (MTSOG) devise a spinal clearance policy for statewide application. In 2004, MTSOG developed a draft adult cervical spine guideline. It was trialled statewide for six months and feedback was ascertained from online surveys and from the five Regional Critical Care Advisory Committees (RECCACs).

In February 2006, the STC endorsed the final cervical spine acute care guideline (paediatric under 16 years and adult) for distribution. Critical to the guideline’s success is statewide promotion to the wider trauma community. The MTSOG is responsible for the annual review of the guideline.

The Statewide Emergency Program (SEP) is working with the Victorian Spinal Cord Unit at the Austin Hospital to provide statewide videoconferences to introduce the guideline in late 2006. The SEP will advise hospitals and the Victorian Division of General Practice of these dates shortly.

In August 2006, the SEP distributed the guideline to health services, the Victorian Adult Emergency Retrieval and Coordination Service and the RECCACs.

The MTSOG has commenced work on a thoracolumbar acute spine care guideline and aims to finalise the guideline in December 2006.

The guideline is available on the trauma website at:
<http://www.health.vic.gov.au/trauma>

