Sentinel event program
Annual report 2006–07
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Foreword

The State Government 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 an 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 fifth annual public report of the sentinel event program and it presents information on the 82 sentinel events reported within Victorian public health services during 2006–07.

Hon Daniel Andrews MP
Minister of Health
Acknowledgements

The Department of Human Services thanks Victoria’s public health services, hospitals and participating private facilities 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 learning environment within Victoria’s health care system, and through this awareness decrease the rate of serious adverse events.

It is believed that the frequency of sentinel events is likely to be reduced by examining the settings in which they occur, and identifying system changes required that may reduce the likelihood of similar occurrences in the future.

This approach focuses on the organisation of health care, rather than the assignment of individual blame, and is therefore likely to promote a serious approach to error reduction at all hospital levels and is in keeping with the principles of accountability.

All information received by the department is de-identified to preserve the privacy of patients, practitioners and organisations involved. The department 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 2006–07, the department was notified of 97 sentinel events and 80 were analysed. Fifteen 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. Two reports were not available for analysis at the time of writing this report.

The overall number of events reported is less than previous years. It is believed to be due to the effectiveness of the department’s Clinical Risk Management (CRM) education program undertaken since 2005. The development and subsequent rollout of the Root Cause Analysis (RCA) education program has provided staff with a better understanding of clinical risk management and the reporting requirements. Trends have been consistent over all reporting periods, and there has been no significant shift in reported events.

Sentinel events reported under the ‘other catastrophic events’ category remain the major reporting category in 2006–07, with 45 per cent of all events reported in that category.

During 2006–07, a total of 305 contributing factors were identified.

Analysis of data shows that ‘procedures and guidelines’ and ‘communication’ continue to be the most commonly occurring system factors for 2006–07.

Included in this report is a one page patient safety checklist for health services to use as a quick guide to assess issues identified from the program locally, this is strengthening the learning organisation concept and way forward for the program.

Snapshot of the Victorian health system

The Victorian health system is a complex and busy environment.

In the 2006–07 reporting period, the Victorian Government dedicated an estimated $9,061 million to health care, employed around 66,460 EFT (equivalent full time) staff, managed approximately 1.3 million admissions to public health facilities, and performed more than 254,000 surgical procedures.

1 Department of Human Services
2 Workforce Survey data, Service and Workforce Planning, Department Human Services
3 2006–07 Public Hospital VAED (consolidated file: 19 September 2007)
4 2006–07 Public Hospital VAED (consolidated file: 19 September 2007)
Health service patient safety checklist

This checklist can be used by health services to ensure strategies are in place for minimising the risk of sentinel events occurring.

<table>
<thead>
<tr>
<th>Issue</th>
<th>Strategies</th>
<th>Yes</th>
<th>WIP*</th>
<th>N/A</th>
<th>No</th>
</tr>
</thead>
<tbody>
<tr>
<td>Procedures involving the wrong patient or body part</td>
<td>• Organisational correct patient/correct site policy in place</td>
<td></td>
<td></td>
<td></td>
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</tr>
<tr>
<td></td>
<td>• Correct patient/correct site education program is in place across the organisation</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>• Tools and framework exist to support the implementation and monitoring of correct patient/correct site</td>
<td></td>
<td></td>
<td></td>
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</tr>
<tr>
<td>Patient Identification</td>
<td>• Patient identification policy in place across all clinical interface points of the health service</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>• Unique patient identifier (medical record number) keystone of patient identification process</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>• Interpreter service is available to support culturally and linguistically diverse (CALD) patient identification</td>
<td></td>
<td></td>
<td></td>
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</tr>
<tr>
<td>Medication safety</td>
<td>• National inpatient medication chart (NIMC) is implemented across the health service</td>
<td></td>
<td></td>
<td></td>
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<tr>
<td></td>
<td>• Health service has a generic prescribing culture</td>
<td></td>
<td></td>
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<tr>
<td></td>
<td>• Appropriate resource materials, including decision support tools for medication management, available to staff in the clinical setting</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Management of mental health patients with significant self-harm risks</td>
<td>• Mental health self-harm risk assessment tool is implemented across the health service</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>• Education program in place to support the application of self harm risk assessment across the health care continuum (acute and community teams)</td>
<td></td>
<td></td>
<td></td>
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</tr>
<tr>
<td></td>
<td>• Day leave policy reflects needs of mental health patient and family/carer</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Falls minimisation</td>
<td>• Health service endorsed <em>Falls minimisation strategy</em> in place across all clinical services</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>• Standardised Falls Risk Assessment Tool (FRAT) forms part of the medical record</td>
<td></td>
<td></td>
<td></td>
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</tr>
<tr>
<td></td>
<td>• Compliance auditing of FRAT and applied falls minimisation strategies completed (as a minimum) bi-annually across health service</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Communication</td>
<td>• Clear and concise information relative to patients clinical condition and ongoing management plan form part of clinical handover</td>
<td></td>
<td></td>
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</tr>
<tr>
<td></td>
<td>• Medical records include a current patient management plan</td>
<td></td>
<td></td>
<td></td>
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</tr>
<tr>
<td></td>
<td>• Consumers and carers are included in the planning and evaluation of their care</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Credentialing and scope of practice</td>
<td>• Credentialing and scope of practice policy for senior medical staff is implemented across the health service</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>• Policy includes the introduction of new clinical services, procedures and interventions</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>• Tools exist to support the implementation and monitoring of credentialing and scope of practice framework</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Medical emergency team (MET) response</td>
<td>• Medical emergency response criteria exist to assist clinical staff to access a rapid emergency assessment of a patients clinical condition</td>
<td></td>
<td></td>
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</tr>
</tbody>
</table>

*WIP – Work in progress
The Victorian sentinel event program was developed from work undertaken by the Joint Commission on Accreditation of Healthcare Organisations in the United States. The 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 aims to reduce the likelihood of sentinel events reoccurring by examining the environment in which they occur. The focus is on the process and system issues within organisations 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 back to the wider health care community through:

- the *Risk Watch* newsletter
- alerts for significant events
- sentinel event annual report (this document)
- recommendations to individual health services and the sector.
Building a robust foundation to support patient safety across the Victorian health care sector

Sentinel event notification process

It is a requirement of Victorian policy and funding guidelines for all public health services to report to the department any sentinel event that meets the criteria outlined. The health service must notify the department within three days of the event being reported within their service. Patients, family members, carers, health service employees and the media can also inform the department of a sentinel event.

From the date of notification the health service involved has two calendar months to undertake an investigation into the event and to prepare a root cause analysis (RCA). The report identifies causal and contributing factors, and a risk-reduction action plan to prevent future occurrence.

The department reviews both the analysis and risk-reduction plan to determine:

- thoroughness and credibility, and to ensure the appropriateness of the risk-reduction strategies and timelines (see appendix 3)
- if the identified causal and contributing factors are relevant to other health care providers in Victoria.

The department submits the RCA to relevant expert bodies for review and comment (see appendix 1). The Clinical Risk Management Reference Group subcommittee undertake the final review before providing feedback to the health service.

Those recommendations, or issues identified, that may be relevant to the wider health care community are communicated through the Risk Watch newsletter, which is sent to all health services and includes de-identified case studies.

Alerts or letters to health services are published if the issue is considered urgent.

Root cause analysis

The root cause of an event is that point at which action could have been taken to reduce or prevent the likelihood of the event occurring.

RCA is an investigative process that is used to identify factors that cause adverse events. It enables answers to be found to the questions posed by high-risk, high-impact events – notably, what happened, why it occurred, and what can be done to prevent it from happening again.

The focus is on identifying the system or process issues that contributed to an event without assigning individual blame.
Risk-reduction action plan

How organisations intend to reduce the risk of similar events recurring based on the findings of the RCA form the strategies 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

Health services are expected to review their sentinel events and associated RCA and risk-reduction plans (RRAP) at a local level through the board quality committee.

It is expected that each RCA will be reviewed at six- and 12-month intervals to ensure 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, and through this committee to each health service board as part of their clinical governance responsibility.

Health services are encouraged to escalate the identified risks articulated in the RRAPs to their organisational risk registers to ensure the governance endorsed treatment plans are monitored effectively over time.
Themes emerging from the program in 2006–07

Patient identification

Events involving mishaps with patient identification continue to be a strong theme emerging from statewide reporting.

While the volume of reported events remains constant compared with previous years, the nature of the events has changed. Of the 20 ‘wrong patient’ or ‘wrong site’ events reported in 2006–07, none have resulted in serious harm. Only one case reported involved a patient experiencing a wrong side surgical procedure. The patient did not require corrective surgery as the surgery had been planned to take place in the near future, not at the time the event occurred.

As shown in table 1, there were no incident severity rating 1 events related to procedure involving the wrong patient or body part during 2006-07.

Table 1: Sentinel events related to procedure involving the wrong patient or body part, 2006–07

<table>
<thead>
<tr>
<th>Event</th>
<th>Number of cases</th>
<th>ISR 1</th>
<th>ISR 2</th>
<th>ISR 3</th>
<th>ISR 4</th>
</tr>
</thead>
<tbody>
<tr>
<td>Surgery</td>
<td>9</td>
<td>0</td>
<td>6</td>
<td>3</td>
<td>0</td>
</tr>
<tr>
<td>Radiology</td>
<td>9</td>
<td>0</td>
<td>2</td>
<td>7</td>
<td>0</td>
</tr>
<tr>
<td>Other</td>
<td>2</td>
<td>0</td>
<td>2</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Total</td>
<td>20</td>
<td>0</td>
<td>10</td>
<td>10</td>
<td>0</td>
</tr>
</tbody>
</table>

ISR 1 – Severe (including death)
ISR 2 – Moderate
ISR 3 – Mild
ISR 4 – No harm (near miss)

Note: ISR = incident severity rating

The majority of events reported in this grouping have taken place in diagnostic and therapeutic radiological procedures, as demonstrated in the following case study.
Case study
A patient presented for an X-ray and medical consultation in private consulting rooms adjacent to a public hospital. The consulting rooms’ workflow practice is for X-rays to be taken in order for them to be ready for viewing by the doctors during the patient’s consultation.

On the day of the event there were a number of request slips for X-rays waiting to be processed. A number of additional request slips waiting to be processed for billing were also sitting on the same bench.

The day was particularly busy, and staff rang to request additional assistance. To increase the likelihood of having the patient X-rays for both doctors processed on time, a decision was made to X-ray the less complex ‘Patient A’, prior to the more complex ‘Patient B’.

Patient A was called into the X-ray room but the complete process of patient identification was not undertaken. The staff member referred to Patient B’s request form that was on the bench.

The X-ray process was interrupted when the doctor came and asked for the patient. At this point the staff member rechecked the patient’s X-ray request. The error was then noticed and the correct series of X-rays was taken.

Rating = ISR 2

How did the health service address the issues identified?
• A structured system to manage investigation request forms was introduced.
• A memorandum was circulated to all staff on the principles of ensuring patient identification is verified before investigations are commenced.
• A review of clerical support for peak workflow periods was undertaken to ensure appropriate practice measures are completed in a safe and efficient manner.

What are some actions other health services have undertaken when a similar event was identified in their health service?
• Introduced a correct side/site policy.
• Operative sight marking introduced.
• Correct side/site concepts implemented – ‘time out’ in radiology and nuclear medicine settings.
• Anaesthetic ‘time out’ prior to the introduction of regional anaesthesia implemented.
• Nomination of ‘team leader’ in multidiscipline correct side/site confirmation (‘time out’).
• Compliance auditing of correct side/site documentation included in health services clinical audit program.
• Inclusion of principles of patient identification and correct side/site confirmation in staff orientation and education programs for all disciplines.
• Communication workshops to encourage staff to speak up if they perceive something is not as it should be.
- Mandated use of patient’s numerical ‘unique identifier’ on all investigation request forms and patient transport dockets.
- Standardised process for confirmation of patient identification introduced.

What activities are being undertaken at a state level to address these patient safety issues?

The Victorian Surgical Consultative Council (VSCC) in association with Royal Australasian College Surgeons (RACS) released new correct side/correct site guidelines in April 2007. These guidelines combined three previous guidelines into one document (Australian Commission for Safety and Quality in Health Care (the commission), RACS and VSCC). The guidelines were made available to all VSCC members, posted on the VSCC website (www.health.vic.gov.au/vscc/) and were circulated to acute, rural and regional health services.

Numerous articles have been included in the Risk Watch newsletter presenting a selection of case studies from different care settings outlining examples of wrong patient/wrong procedure incidents, and near-miss events. Each case study included the strategies implemented to minimise similar events from recurring in the future.

What is happening at the national level?

Patient identification has been adopted as one of the nine priority program areas of the commission in its five-year work plan from 2006–07 to 2010–11.

Victoria is participating in a commission-led inter-jurisdictional working party focusing on patient identification. It is envisaged this program will focus on key safety mechanisms including exploring the feasibility of national standardised patient identification bands, reviewing the implementation of the correct site protocol, and exploring looking at the way information from root cause analyses of patient misidentification incidents can be used to improve patient safety related to these types of events.

Assessment of patients and management of mental health clients

In 2006–07 more than 60,293 people received care from specialist mental health services and there were approximately 19,989 admissions to public hospitals for mental illness.

Mental health patients are vulnerable to a number of potential risks. Often these risks are a direct result of their mental illness manifesting in particular behaviour patterns such as self-harm, aggression and violence. Others relate to security and wellbeing as a direct consequence of their prescribed treatment.

Statistically, the 11 cases of suicide reported through the sentinel event program is slightly higher than last year. Historically the sentinel event program has not experienced a strong mental health reporting pattern. The 2006–07 reporting is by no means a comprehensive overview of the significant patient safety events in the mental health setting. However, the inclusion of such compelling events provides a snapshot of significant events health services have reviewed using the RCA.
methodology. By monitoring these events statewide, recommendations will be made to health services that will inform policy and foster improvements in clinical case management of psychiatric patients in the acute health setting.

### Table 2: Sentinel events related to suicide and other mental health issues, 2006–07

<table>
<thead>
<tr>
<th>Event</th>
<th>Number of cases</th>
<th>ISR 1</th>
<th>ISR 2</th>
<th>ISR 3</th>
<th>ISR 4</th>
</tr>
</thead>
<tbody>
<tr>
<td>Suicide</td>
<td>11</td>
<td>11</td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Other mental health management</td>
<td>6</td>
<td>5</td>
<td>1</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Total</td>
<td>17</td>
<td>16</td>
<td>1</td>
<td>0</td>
<td>0</td>
</tr>
</tbody>
</table>

**Case study**

A patient with a history of mental health issues contacted the hospital triage service in the evening in a state of increasing distress. Following assessment the patient was recommended for admission as an involuntary patient.

The patient was considered to be at high risk and needed to be monitored with quarter-hourly observations during the day and hourly observations at night. Throughout the day shift the patient became upset, confessing to having tried to self-harm that morning. Asking for permission to leave (the ward), the patient talked about experiencing significant thoughts of self-harm and suicide, close monitoring was continued.

Some time later the patient was observed sitting by the exit door. Staff persuaded the patient to move away from the door. Staff requested a move to the high dependency unit (HDU), however the patient refused. To have enforced this request, physical restraint and handling would have been required. The patient was asked what might be of help at that time and stated that ‘medication might help’.

Whilst the staff member went to prepare the medication, the patient took the opportunity to push past people entering the unit and escaped the ward through the exit door.

Security, police and the patient’s next of kin were called, and the crisis assessment and treatment team (CATT) were contacted. Shortly after, the police contacted the ward stating the patient had been found deceased.

Rating = ISR 1
How did the health service address the issues identified?

• A system of review that encourages independent second opinion was developed to support staff in inpatient units and/or the community managing long-term patients with severe recurrent deliberate self-harm and or borderline personality disorder.

• Documentation of risk-reduction plans for all patients where the risk of absconding is high was prescribed.

• Risk assessment and documentation training was incorporated in the health service education program.

• Inclusion of environmental checks in staff shift duties to ensure appropriate safety measures are appropriately maintained.

What are some actions other health services have undertaken when a similar event was identified in their health service?

• Revision of policies specific to the granting of day leave were completed by a number of health services to ensure patient risk assessments are completed prior to the leave being granted.

• Mechanisms on gauging feedback from family and carers following a patient’s return from day leave have been revised to ensure the patient’s risk factors have been managed effectively in the community.

• Documentation practices have been reviewed to assist staff to communicate potential risk issues across the health care team.

• Broader understanding of patient risk factors have been encouraged through the inclusion of risk assessment education for hospital staff not working in a psychiatric setting, such as emergency department or aged care facility staff.

• Revision of patient observation practices have been undertaken by a number of health services to ensure current processes are reflective of best practice.

• Individual assessment of suicide risk is to be undertaken for all admitted patients, particularly those who have attempted suicide or who have self-harmed in the past or expressed suicidal thought processes.

What activities are being undertaken at a state level to address these patient safety issues?

Three key themes have emerged through the 11 events reported in 2006–07:

• the importance of coordination of care when managing a mental health patient who is medically unwell, or is being cared for in a medical unit

• ensuring that standard behavioural risk assessments are completed and well communicated amongst all staff prior to consideration and approval of leave

• management of psychiatric patient day leave.
The Clinical Risk Management Reference Committee (see appendix 1) approached the Office of the Chief Psychiatrist and the department’s Mental Health Branch for assistance in coordinating a statewide project designed to address these issues, and to develop appropriate coordination of standardised statewide behavioural assessment guidelines.

The Mental Health Branch has welcomed this approach and has begun scoping a potential project for development in 2008. Updates will be made available through the Mental Health Branch and in Risk Watch newsletter.

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

<table>
<thead>
<tr>
<th>Event</th>
<th>Number of cases</th>
<th>ISR 1</th>
<th>ISR 2</th>
<th>ISR 3</th>
<th>ISR 4</th>
</tr>
</thead>
<tbody>
<tr>
<td>Retained instrument or other material after surgery requiring re-operation or further surgical procedure</td>
<td>8</td>
<td>0</td>
<td>8</td>
<td>0</td>
<td>0</td>
</tr>
</tbody>
</table>

As shown in table 3, only eight cases were reported through the program relating to retained instruments whereby the patient was required to return to theatre to have the instrument (or material) removed at a later date. It is encouraging to see such low numbers in comparison with the level of surgical activity undertaken across the Victorian public health setting.

**Table 3: Sentinel events related to retained material after surgery requiring further surgical procedure, 2006–07**

Case study

The event relates to a patient who underwent elective heart surgery. Following surgery, the patient was transferred to the intensive care unit (ICU), which is standard practice following this procedure. The preliminary instrument and consumables count in the operating room failed to locate one (1) raytec (gauze) swab.

An extensive search of the operating area and surrounds was performed. The surgeon was informed of the missing gauze swab. Intra-operative screening (X-ray) was undertaken; however, the gauze swab was not located. Given this, it was ‘presumed’ the gauze swab would be located amongst the surgical drapes at the end of the operation. The gauze swab remained unaccounted for at the final instrument and consumable count after the operation was completed and the surgical drapes were removed. The surgical team were immediately informed of the incorrect count.
A chest X-ray was ordered and taken some hours afterwards while the patient remained in ICU. The surgeon reviewed the X-ray, locating the gauze swab in the thoracic cavity. The patient’s family were advised of the adverse event by the treating surgeon. The patient was returned to theatre for removal of the retained product that day. The surgical team suspect the gauze swab was obscured by the sternal retractor during the intraoperative imaging. Rating = ISR 2

**How did the health service address the issues identified?**

- Revised the theatre policy and procedures to ensure, where possible, all radio-opaque objects, such as retractors, are removed to allow for adequate intra-operative screening to occur.
- Where a missing item is not located during intra-operative screening, and multiple checks of theatre area after the operation are complete, an additional radiological examination is initiated prior to the patient leaving the theatre complex.
- The surgeon must be made aware that an item is still missing on completion of the surgical procedure and advised of the outcome of the X-ray taken prior to the patient leaving the operating theatre.
- The X-ray request form must specifically state that the film is required to locate a foreign body (retained instrument/material).
- The X-ray report is to make specific comment of the presence or absence of the foreign body (retained instrument/material).

**What are some of the actions other health services have undertaken when a similar event was identified in their health service?**

- Consumable items to be included in instrument count documentation record reviewed.
- Instrument count competencies developed for operating room staff.
- Documentation of communication escalation process for theatre staff where count discrepancies are identified following a surgeon’s departure from the operating suite.
- Instrument and consumable count policies reviewed to ensure they reflect the Australian College of Operating Room Nurses (ACORN) ‘Counting of Accountable Items Used During Surgery’ standard.

**What activities are being undertaken at a state level to address these patient safety issues?**

The VSCC is actively involved in reviewing sentinel events through their role as a consultative council (see appendix 1). The council recently contacted all directors of surgical services in Victoria requesting their health service policies reflect the ACORN ‘Counting of Accountable Items Used During Surgery’ standard, and recommended that their theatres implement and adhere to the current standard.
Patient falls

Falls are a common problem for older people and people in high-falls-risk populations in hospitals and residential care settings. The magnitude of the problem, the range of consequences that impact negatively on independence, function, and quality life, and the costs associated with management of falls, reflect the high priority that needs be given to this problem.

Table 4: Sentinel events related to falls, 2006–07

<table>
<thead>
<tr>
<th>Event</th>
<th>Number of cases</th>
<th>ISR 1</th>
<th>ISR2</th>
<th>ISR3</th>
<th>ISR4</th>
</tr>
</thead>
<tbody>
<tr>
<td>Complication of inpatient fall</td>
<td>5</td>
<td>5</td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
</tbody>
</table>

Case study

An elderly patient with a history of diabetes, chronic respiratory disease and renal arterial stenosis was admitted with shortness of breath, unsteady gait and a two-day history of increasing confusion.

The patient was diagnosed with an exacerbation of chronic obstructive airways disease (COAD). The patient was assessed by physiotherapy, and was noted to be unsteady at times, requiring assistance to re-balance. Early the following morning, the patient became agitated, and began climbing out of bed without waiting for nursing staff. Medical review indicated the patient was experiencing a complex combination of clinical issues including exacerbation of COAD, congestive cardiac failure, chronic renal failure and an impaired cognition secondary to hypoxia.

The patient was commenced on clopidogrel to reduce the risk of stroke or heart attack in light of complex comorbidities. The patient’s condition deteriorated over the next 24 hours, becoming confused, aggressive and incontinent. The following morning, while walking to the toilet without waiting for nursing assistance, the patient fell.

The patient sustained a mild head injury with no loss of consciousness, but was noted to be limping. The patient was placed in a chair with a seat belt as a safety mechanism to minimise the risk of falling again. A short time later the patient was found on the floor having undone the safety mechanism (seat belt). Following medical review a brain scan was ordered, which indicated a large subdural haematoma.

Rating = ISR 1

How did the health service address the issues identified?

- A review of the falls risk assessment tool (FRAT) and the education needs of staff was undertaken to identify opportunities for improvement.
- Implementation of a comprehensive multidisciplinary education program on the assessment and management of falls risk, including reference to:
  - prevention and management of confusion/delirium
  - falls strategies
  - medication management.
Health service’s medication safety committee in collaboration with the falls steering committee and medicine program were charged with implementing a communication strategy regarding:

- patients prescribed clopidogrel be considered at high risk of serious injury from falls irrespective of the presence of other potential falls risk factors
- alternative blood anticoagulation therapies to be considered for patients who are identified to be a high falls risk.

What are some of the actions other health services have undertaken when a similar event was identified in their health service?

- Establish and implement a system that ensures patients admitted for investigation of falls or with past history of falls are highest priority for high observation areas.
- Establish and implement a system where staff are accountable for implementation of falls prevention strategies at the beginning and end of each rostered shift.
- Minimisation of environmental risks in the patient care setting.
- Environmental falls hazard audits included ward activities schedule.

What activities are being undertaken at a state level to address these patient safety issues?

The Victorian Quality Council (VQC) conducted an evaluation project on the effectiveness of the ‘Minimising the risk of falls and falls injuries: Guidelines for acute, sub-acute and residential care settings’ initiative in two health services for a 12-month period between September 2005 August 2006.

The project findings were encouraging, with a demonstrated reduction in falls per 1,000 bed days in the majority of the wards and increased compliance with the falls minimisation strategy of the two project sites. It is important to acknowledge the limited numbers involved in the project and the short period of time over which monitoring occurred.

Falls minimisation programs are important in improving patient safety, and should not be viewed in isolation from other factors impacting on patient care. The success of the falls minimisation programs relates in part to supporting policies and resources such as equipment, management of restraints, management of the confused patient and manual handling.

Ideally falls minimisation becomes an integral component of a clinician’s role, routinely scanning the patient area prior to leaving, checking environmental factors such as the position of the gait aid or call bell will indicate that a shift in thinking has occurred.

Further information on the evaluation project is available via www.health.vic.gov.au/qualitycouncil/activities/falls.htm
Good catch

A near miss is defined as an incident that did not cause harm. Table 5 illustrates that during 2006–07, there were three of these ‘good catch’ incidents reported to the sentinel event program.

Table 5: Sentinel events related to near misses, 2006–07

<table>
<thead>
<tr>
<th>Event</th>
<th>Number of cases</th>
<th>ISR 1</th>
<th>ISR 2</th>
<th>ISR 3</th>
<th>ISR 4</th>
</tr>
</thead>
<tbody>
<tr>
<td>Good catch/near miss</td>
<td>3</td>
<td>0</td>
<td>0</td>
<td>2</td>
<td>1</td>
</tr>
</tbody>
</table>

Case study

A patient was admitted to an emergency department of a tertiary hospital with significant traumatic injuries following a motor vehicle accident. The patient received immediate medical treatment within emergency and was transferred to theatre for time critical surgical management. During resuscitative efforts the patient was mistakenly transfused with two units of red cells that had been cross matched and issued for a different patient in an adjacent operating theatre.

The blood issued was A-negative and compatible with the recipient’s type of A-positive (thereby negating the risk of ABO incompatibility).

Rating = ISR 4

How did the health service address the issues identified?

- Education on best transfusion practice was included in the operating suite education program, including the verification of patient identification prior to the administration of blood and blood products.
- Review of transportation, delivery and reception of blood and blood products within the operating suite was undertaken to identify the most efficient and effective process.
- Review of patient identification processes in the arrival and reception of time-critical patients in the emergency setting was undertaken to ensure patient safety is addressed at each handover process.

What are some of the actions other health services have undertaken when a similar event was identified in their health service?

- Clinical guidelines for the prescription, transfusion and transportation of blood and blood products are based on the National Health and Medical Research Council (NH&MRC), Australian Red Cross Blood Service (ARCBS) and Australasian Society of Blood Transfusion (ASBT) guidelines.
- Guidelines for administration of blood and blood products are periodically revised and made accessible to staff in the clinical setting in multiple modalities.
- Education programs focussed on safe transfusion practice.
- Development of escalation processes to support staff in questioning prescription orders that are ambiguous or not reflective of guidelines.
What activities are being undertaken at a state level to address these patient safety issues?

The Better Safer Transfusion Program (BeST) is a Victorian State Government program for improving the quality of hospital transfusion care to patients.

The aims are to:

- promote best practice for in patient blood management, including implementation of strategies that minimise the need for blood product use and those that help ensure safe and appropriate transfusion practices
- derive recommendations for improvements for better, safer transfusion practice from the monitoring of serious transfusion incidents (including adverse events and near misses) during blood and blood product utilisation in Victoria, and to disseminate these to Victorian hospitals and health services
- share knowledge and promote collaboration with relevant stakeholder groups locally, nationally and internationally for the achievement of better and safer transfusion practice.
What are we doing to make health care safer in Victoria?

A series of recommendations were made in the 2005–06 sentinel event report to improve the safety of health care in Victoria. The scorecard below reports on the progress of these recommendations.

Patient safety scorecard

<table>
<thead>
<tr>
<th>Issue</th>
<th>Activity</th>
<th>Progress</th>
</tr>
</thead>
</table>
| To maintain and develop the Root Cause Analysis (RCA) education program | • 236 staff completed Module 3 RCA facilitator workshops  
• Module 4 – In-depth Clinical Case Review developed to provide standardised tools and resources for clinical incident review. A total of 144 metropolitan, rural and regional health care staff attended the workshops  
• State, territory and international interest expressed in RCA training program | Achieved |
| Continue to develop a clinical governance policy in line with the Auditor-General’s recommendations | • Revision of CRM Reference Group strategic plan to determine key priority areas for 2007–10  
• Development of thematic register of key trends identified from analysis sentinel event reports  
• Thematic register will act as an enabler of clinical governance initiatives and practice change at a statewide level  
• Appointment of external consultancy to review current clinical governance practice and way forward. Planned completion in early 2008. | Work in progress |
| Review and clarify sentinel event definitions and categories through liaison between the department and expert bodies | • Expansion of sentinel event program to include either ‘near miss’ events or incidents that are considered a ‘good catch’ where serious harm was prevented from reaching the individual patient. Further clarify definitions as listed to ensure full capture. | Achieved |
| Review current national and international practices related to RCA and legal/privacy issues and develop a Victorian model | • The department has recently undertaken work with the Policy and Instruments Development and Review Branch to assess the requirements related to pursuing legislative protection for the RCA process | Achieved |
| Support development of Incident Information System (IIS) project as a means of identifying potential precursors of sentinel events | • IIS Project team under the guidance of the Project Board and Project Advisory Group have worked extensively to determine an incident classification methodology and reporting process that will be used across all public health services for recording incident data  
• Consultation with specialist working parties with expert representative working groups has helped define a statewide incident data set, including production of a comprehensive data dictionary | Achieved |
| Strengthen links with private health sector and encourage its active participation in the sentinel event program | • A number of private hospital have participated in the RCA education program in 2006–07 | Work in progress |

Achieved  
Work in progress  
Not commenced
Educating the health care sector

The department continues to support education and training in CRM through its RCA education program, and continues to build on work started in 2004–05 to provide a standardised statewide approach (see appendix 2).

There has been strong interest in the Victorian RCA program from other jurisdictions and the department has shared the program with ACT Health (Canberra) and Tasmania through releasing the intellectual property. On the international front, Victoria welcomed its first overseas attendee (Indonesia) at a 2007 workshop, and expressions of interest have been received from New Zealand. The program was also presented at a meeting of the International Society of Quality in Health Care.

Modules 1 and 2 of the program have been rolled out and are available on the sentinel events website. Module 3 is ongoing and is presented as an intensive two-day workshop aimed at up-skilling clinicians, quality and risk managers who will act as RCA facilitators in their health services. Since commencement in 2005, 285 staff have undertaken the two-day workshop. The module has been well received by the health sector to the point that a waiting list of potential candidates is maintained by department staff.

RCA Module 3 – Feedback

What part of the course did you find useful?
‘Fantastic workshop, every part of the curriculum is beneficial and I am sure I will use all tools and tips provided’

‘The variety of tools referred to and then utilising them throughout the exercise very beneficial’

What part(s) of the course did you find least useful?
‘None’

Would you recommend this course to others?
‘Absolutely!’

Periodic meetings are conducted throughout the year with RCA Module 3 graduates (known as peer support meetings). The meetings provide an opportunity for RCA facilitators to share their experiences, learn from others dealing with similar challenges and receive updates from department staff on CRM initiatives in the planning and implementation stage.

The majority of incidents occurring in health services are not ‘sentinel’ by definition and, in many smaller organisations, will rarely occur. Lower severity incidents that comprise the bulk of all adverse outcomes in health services may often be precursors for more serious adverse events. There needs to be a process in place to ensure that lower severity events are examined to reduce and minimise risk where possible.

Module 4 was developed to 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 was provided as a train-the-trainer program to all Victorian health services in 2007.
The VQC introduced an online education package to assist health services in educating staff on quality and safety principles. The aim of the education is to:

- provide standardised information about safety and quality in health care
- increase awareness of safety and quality principles
- increase knowledge of personal roles and responsibilities in relation to safety and quality
- assist in identifying systems that promote safety and quality.

In 2007 the VQC worked with six health services across rural, regional and metropolitan sites to evaluate the effectiveness of the package prior to implementing the resource at a statewide level. An overview of the Introduction to Quality and Safety Principles project is available on the VQC website at: www.health.vic.gov.au/qualitycouncil. The online resource is included in the department’s RCA education pre-reading material.

Open disclosure

Patients expect to be fully informed about the care they receive, particularly when things don’t go according to plan. Open disclosure (OD) is the name given to the process of communicating with patients and their families when things have gone wrong.

In 2002 the Australian Council for the Safety and Quality in Health Care (now the Australian Commission on Safety and Quality in Health Care) developed the National standard on open disclosure. The Australian Health Ministers’ Conference endorsed the standard in July 2003.

Although various strategies have been used to implement OD in the past, the standard outlines clear and consistent processes including:

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

While initial concern has been expressed about the legal implications of OD, there is consensus that the principle of disclosing adverse events openly is sound and considered best practice. The council and department provided funding to 12 Victorian public health care facilities to pilot the implementation of the OD standard within their organisations. These included both metropolitan and rural and regional sites to ensure a good cross-section of health services.
Key findings from the evaluation of the OD pilot include:

- open disclosure is not a new concept; many clinicians incorporate this into their current practice, though there was no consistent way of managing this process
- there was no standardised approach to the disclosure process within all pilot sites involved
- education and training were key elements to successful implementation
- where there was a strong culture of quality and safety reporting this process was more readily adopted
- documentation of discussions with the patient/family was overall poor and this raised medico-legal concerns regarding the content of discussions and where these were documented
- some patients and their families did not wish to engage in this process.

Implementation of the recommendations arising out of the evaluation will assist in the smooth implementation of open disclosure within all Victorian health services. Education and training are key elements of a successful implementation process, and work will need to be undertaken to ensure there is a consistent, sustainable, and standard education model available.

Making medication administration safer

The Victorian Medicines Advisory Committee (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.

The Victorian Quality Use of Medicines Network (VQUMN) is a moderated email discussion group for members actively involved in developing and implementing medication safety initiatives. Membership has increased to more than 210, Australia wide. Membership comprises pharmacists (56 per cent), nurses (12 per cent) medical staff (10 per cent) health management (12 per cent) and others (10 per cent). The number of topics discussed increased from 11 in 2004 to 21 in 2007.

National Inpatient Medication Chart (NIMC)

The NIMC was implemented in more than 100 Victorian regional, rural and metropolitan health services by February 2007. VMAC has developed terms of reference for version control that were endorsed by the NIMC Oversight Committee. VMAC has also developed terms of reference for establishing a national committee to review safe prescribing and administration of insulin, which has also been endorsed by the NIMC Oversight Committee.

High-Risk Medication Working Party

The High-Risk Medication Working Party (a VMAC subcommittee) is working on strategies to minimise risks associated with high-risk medicines. Alerts and advisories for insulin, heparin and right route administration are currently being developed.

Further information about VMAC and this subcommittee is available from: www.health.vic.gov.au/vmac
Transfusion safety

The Better Safer Transfusion (BeST) program, commencing in July 2004, 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.

In 2006–07 the Serious Transfusion Incident Reporting (STIR) system was successfully piloted in nine health services and then subsequently rolled out statewide. Two audits were released: Blood management in elective orthopaedic surgery: 2005–06 hospital data and Clinical audit of fresh frozen plasma use in Victoria and Tasmanian hospitals: 2005–06. The incident and audit data are important elements for an effective haemovigilance program for Victorians.

Both audit reports showed that there remain major opportunities to improve transfusion practice. For example, avoiding unwarranted fresh frozen plasma (FFP) transfusion in bleeding patients or those undergoing invasive interventions when there are no significant coagulation abnormalities (the Clinical audit of fresh frozen plasma use in Victoria and Tasmanian hospitals: 2005–06) and that there are a number of patients undergoing elective orthopaedic surgery that were anaemic pre-operatively, who would benefit from blood management (Blood management in elective orthopaedic surgery: 2005–06 hospital data).

Both reports have been forwarded to hospitals and professional bodies for review and action. For example, the FFP report was followed with subsequent correspondence recommending several actions that health services can take to monitor, evaluate and influence use of FFP within their organisation, including self-auditing (tools were provided) and review at the hospital transfusion committee or equivalent clinical governance group. A second follow-up audit is planned for 2008.

The BeST program has an ongoing program of audits intended to provide data on current practice and areas for improvement. In 2007, the audits included a clinical audit of platelet use and a repeat of the 2005–06 audit of transfusion protocols and administration practice.

Transfusion Interest Group Forum

The discussion forum aims to provide an avenue for transfusion practitioners to privately discuss current issues and clinical views in transfusion to inform and support transfusion practice improvements.

BeST have collated a number of transfusion tools and made them available on their website. These tools have been provided by various organisations and project groups for the purpose of sharing knowledge of transfusion practice improvement strategies.

Documents providing transfusion information to consumers have been developed and can also be found on the consumer information page via www.health.vic.gov.au/best/
Principles of safe, effective communication

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 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 VQC has surveyed health services across Victoria about clinical handover process. Shift-to-shift handover and inter-hospital transfer were identified as two significant areas of concern. A set of standardised clinical handover tools was developed based on the outcome of a clinical handover workshop with health services representatives. A pilot project is currently underway in four health services trialling the tools for shift-to-shift medical handover. The project is due to complete in December 2007.

A second project has commenced to address issues related to inter-hospital patient transfer. Feedback will be sourced from the health sector relating to current status of hospital approaches to clinical handover processes and documentation relating to inter-hospital transfer. The information will underpin discussions at a future workshop with health services and consumer representatives to determine a minimum data set necessary for high-quality and safe inter-hospital patient transfer.

Addressing seclusion and restraint practice

The department identified seclusion practices as one of two key mental health strategic priorities in its 2007 policy and funding guidelines. Data collected by the Victorian Office of the Chief Psychiatrist indicates that seclusion practices affect significant numbers of people and can be a source of distress for consumers, families, visitors and staff in mental health services.

The VQC and Chief Psychiatrist’s Quality Assurance Committee (QAC) have formed a partnership project called Creating Safety: Addressing Seclusion and Restraint Practice in response to these identified issues. The project aims to strengthen and support safety in adult acute mental health inpatient units and to minimise the use of seclusion both in frequency and duration.

The project has been planned in two concurrent phases to facilitate a change in practice across the state.

1. The first stream is the development and implementation of a training and education curriculum to promote clinical best practice. The education curriculum has been finalised and 22 metropolitan and regional workshops have been scheduled for November and December 2007.

2. The second component of the project is supporting Victorian acute mental health inpatient units to promote seclusion best practice in adult acute mental health inpatient units. Six sites have been selected to participate in the project following an expression of interest process. External change facilitators are supporting each site to develop, implement and evaluate strategies to minimise the use of seclusion wherever possible.
The evaluation of the project’s implementation will assist in sharing the lessons and strategies for reducing seclusion and restraint in all Victorian acute mental health inpatient units.

**Incident Information System**

The Incident Information System (IIS) Project was commissioned in 2006 and expanded in 2007 to fulfil four main objectives:

1. To develop a statewide, standard methodology for the way incident information is reported within public health services.
2. To implement a mechanism that will enable statewide aggregation, analysis and trending of multilevel clinical incident data.
3. To establish appropriate mechanisms for the department and in-scope health services to evaluate the clinical incident data, identify trends and share relevant information such that quality improvements can be targeted toward problematic areas.
4. To work collaboratively with the Health Service Commissioner, WorkSafe Victoria and the Victorian Managed Insurance Authority (VMIA) to whom health services must submit incident data, with the aim of streamlining reporting processes to these organisations.

High-severity clinical adverse events (ISR 1) are currently reported to the department through the Sentinel Event Program (see appendix 2). Research has shown that whilst it is important to capture very serious events, they tend to occur relatively infrequently and may receive a disproportionate amount of finite resources available for improving patient safety.

It is envisaged the IIS project will provide a mechanism to capture and target quality improvement initiatives toward lower severity incidents that may often be precursors for serious adverse events.

Following significant local, national and international research into recommended incident severity rating methodologies, the IIS Project Advisory Group has agreed on a methodology that aligns to current recommendations made by the World Health Organisation (WHO) International Alliance for Patient Safety. WHO advise that an incident severity rating should be primarily based on a consequence (outcome) assessment, rather than a combination of consequence and likelihood, a common risk rating approach currently used throughout health services. This latter approach relies on incident reporters making an assessment of when the event may reoccur and adds an element of subjectivity to the determination of severity.

The IIS methodology involves using three key questions surrounding actual outcome and care requirements following an incident. The answers to these questions derive an ISR outcome score for users, which is stratified as follows:

- **ISR 1 – Severe (including death)**
- **ISR 2 – Moderate**
- **ISR 3 – Mild**
- **ISR 4 – No harm (near miss)**
Although the IIS methodology’s focus is on actual outcomes, it also provides ability for ‘potential severity’ to be determined. The methodology utilises the Australian Commission for Safety and Quality in Health Care definitions for ‘harm’ and ‘near miss’, the latter defined as ‘an incident that did not cause harm’. The methodology has been designed to make determining ISR as objective as possible, as well as providing Victoria with an ability to compare incident outcome data with other Australian or international jurisdictions.

The IIS methodology is currently being tested in six health services, to assist in refining and improving its functionality, and to date has been well supported by health services.

**Credentialing and scope of practice policy**

It is essential that all medical practitioners who have independent responsibility for patient care within health services in Victoria are appropriately credentialed and have their scope of clinical practice defined in accordance with their level of skill and experience, and the capability of the health service they work within.

The former Australian Council for Safety and Quality in Health Care developed a national standard to guide this important process: *Standard for credentialing and defining the scope of clinical practice*, July 2004 (the ‘national standard’).

Building on the national standard, Victoria has formulated a consistent approach for credentialing and defining scope of clinical practice to be implemented in all Victorian publicly funded health services.

The department has worked extensively with representation from health service chief executives, directors of medical services and other stakeholders to determine how a robust process for credentialing and defining the scope of clinical practice can be applied across Victoria’s rural, regional and metropolitan public health sector. The national standard (2004) does not include the level of detail required for local implementation. The consultation process undertaken by the department was extremely valuable in establishing the process required for the statewide implementation.

The Victorian policy does not apply to hospital-employed junior staff as these staff are under supervision. Nor does the policy currently apply to practitioners nominated by the patient as their private practitioner in a residential care setting within the health service.

**Alerts**

The department issues alerts to the public health sector through the chief executives of metropolitan, regional and rural health services on key patient safety issues identified from the analysis of RCA reports.

Five alerts have been initiated in 2006–07, relating to the following patient safety issues:

- medical emergency team (MET) criteria and initiation of MET emergency response
- access to emergency and life-saving drugs (organophosphates)
- emergency management of chest pain
- use of haloperidol in an acute mental health setting
- emergency management psychiatric patients.

Initial feedback from the sector indicates this initiative has been well received.
Sentinel event program 2006–07

Figure 1: Reported sentinel events, 2006–07

- Suicide in an inpatient unit: N = 11
- Retained instrument or other material after surgery requiring re-operation or further surgical procedure: N = 8
- Haemolytic blood transfusion reaction resulting from ABO incompatibility: N = 1
- Procedures involving wrong patient/body part: N = 20
- Maternal death or serious morbidity associated with labour or delivery: N = 2
- Medication error leading to the death of patient reasonably believed to be due to the incorrect administration of drugs: N = 3
- Other catastrophic event: N = 37

Number (N)

Figure 2: Comparisons between reported ‘other catastrophic events’, 2006–07

- Complication of emergency management: N = 2
- Medication error (not resulting in death): N = 3
- Other mental health management: N = 6
- A good catch/near miss: N = 3
- Misdiagnosis and subsequent management: N = 3
- Complication of inpatient fall (death or serious morbidity): N = 5
- Infection control breach: N = 2
- Complication of surgical management: N = 3
- Foetal complication of delivery: N = 2
- Other - unspecified: N = 8

Number (N)
What’s in the pipeline?

“We must learn from the success of other industries and take the appropriate action; that way, we will save more lives.”
Source – NHS Chief Medical Officer Annual Report, 2005

Patient safety indicators – focusing on the blips in the road map

Translating a set of patient safety indicators for use with the Victorian Admitted Episodes Dataset (VAED) was completed in October 2007. These 20 indicators were developed by the Agency for Healthcare Research and Quality in the United States to provide information on potential in-hospital complications and adverse events following surgery, procedures and childbirth. These translated indicators will now be improved to capitalise on the functionality available in the VAED that is not available in the equivalent United States dataset. These improvements will use the VAED’s increased coding specificity and the capacity to differentiate timing of events (pre-existing/acquired).

These indictors are planned for use as a screening tool to identify areas of concern or success. This will enable the targeting of resources and efforts to improve these areas of concern and to highlight areas of success. They will be used in concert with other data sources such as clinical databases and registries in directing attentions where required.

Clinical governance review – providing a robust framework

It has been seven years since a comprehensive review of patient quality and safety has been undertaken in Victoria. Significant issues have been identified in the current clinical risk management strategy that are impacting on the broader area of clinical governance.

Funding has been made available to the Quality and Safety Branch to enable a statewide review of clinical governance in Victoria, and a tender has been advertised seeking an appropriate vendor to undertake this work.

This review will include:

• evaluating current clinical governance strategies across all health services
• reviewing national and international literature on clinical governance
• consulting with senior clinicians, quality and risk managers, clinical governance directors (boards and executive will also be included)
• educating health services regarding the framework
• tools to assist services in the application of the framework
• developing a policy based on the framework, which will be included in the policy and funding guidelines for 2008–09
• implementing a framework and policy from 1 July 2008.

Appropriate communication strategies will be established to review and assess the work, and provide information on the progress.
Empowering health care teams to review events within the appropriate legal framework

Health services have expressed concerns about the current absence of legislated protection for the RCA process. These concerns are mainly to do with protecting deliberative discussions, peer review and staff involved in the process.

The Quality and Safety Branch have recently undertaken work with the Policy and Instruments Development and Review Branch to assess the requirements related to pursuing legislative protection for the RCA process.

There needs to be a balance between qualified privilege/legislation and the ability to disclose information to the appropriate and relevant people, such as those directly involved in the event, and protections from indiscriminate access and external legal sources.

Start clean

Infection associated with health care is one of the most common adverse outcomes in health care systems in the developed world. The patients most at risk are the very sick, the very old and very young. While not all hospital-acquired infections (HAIs) can be prevented, we can ensure that systems are in place to minimise their occurrence.

The implementation of the Victorian infection control strategy 2007–11 is a comprehensive direction for the prevention, detection and management of HAIs in the short, medium and long term. The strategy is informed by a range of sources such as:

- the VOC Hand Hygiene Project
- the VOC Hand Hygiene Sustainability Forum
- the recommendations of the Multi-Resistant Organism Consensus Conference (held in December 2005)
- the UK Clean Hands Project through the NHS’s National Patient Safety Agency.

The strategy is supported by funding to facilitate the three key components:

1. prevention, through hand hygiene, hospital cleaning and judicious use of antibiotics
2. consumer information and participation through a public clean hands campaign where alcohol hand rub is accessible to general public throughout hospitals
3. detection and management through multi-resistant organism surveillance, screening and organism identification and the development of statewide infection surveillance guidelines.
Collaboration at a national level

In July 2007, the Australian Health Ministers’ Conference (AHMC) endorsed nine priority program areas identified by the commission in their five-year work plan from 2006–07 to 2010–11. These programs stem from common themes and issues identified at both the national and jurisdictional level in relation to safety and quality issues in health care.

The program areas are:
1. patient charter of rights
2. open disclosure
3. hygiene/health associated infection
4. patient identification
5. handover
6. medication safety
7. accreditation
8. quantification and benchmarking
9. harness information technology and communication.

The department is engaged with the commission through a number of inter-jurisdictional working parties to address these key areas.

RCA education – the next phase

In order to determine the impact of the standardised RCA process on sentinel event reporting, an evaluation of the RCA education program was commenced in the later part of 2006. It is anticipated the evaluation will assist the department in reviewing the current RCA education modules. A review of the international and national education landscape in regard to CRM will assist to inform the future direction and scope of statewide CRM education for the Victorian public health care sector.
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.

<table>
<thead>
<tr>
<th>Term</th>
<th>Definition</th>
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<tbody>
<tr>
<td>adverse event</td>
<td>an unintended injury or complication that results in disability, death or prolongation of hospital stay and is caused by health care management rather than the patient’s disease</td>
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<tr>
<td>accountability</td>
<td>being held responsible</td>
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<td>ABO blood group</td>
<td>a system for classifying human blood based on the antigenic components of blood cells and their corresponding antibodies</td>
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<tr>
<td>behavioural</td>
<td>processes involved in establishing a patient’s cognitive state, particularly whether the patient is at risk of wandering, absconding or causing harm to staff</td>
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<tr>
<td>assessment</td>
<td></td>
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<tr>
<td>contributing factor</td>
<td>a factor that shaped the outcome of a situation</td>
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<tr>
<td>clinical guidelines</td>
<td>any policy, procedure or guidelines concerning the processes involved in the clinical management of patients</td>
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<tr>
<td>clinical risk</td>
<td>an approach to improving quality in health care that places special emphasis on identifying circumstances that put patients at risk of harm, and then acting to prevent or control those risks</td>
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<tr>
<td>management</td>
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<tr>
<td>clinical governance</td>
<td>a health service board’s accountability for ensuring a framework and rigorous systems are established so health care safety and quality are monitored, evaluated and continuously improved</td>
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<tr>
<td>clinical pathway</td>
<td>a treatment regime agreed on by consensus that includes all the elements of care, regardless of the effect on patient outcomes</td>
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<tr>
<td>cost</td>
<td>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</td>
</tr>
<tr>
<td>external factors</td>
<td>contributing factors that are a result of an issue external to the organisation</td>
</tr>
<tr>
<td>harm</td>
<td>death, disease, injury or harm, suffering or disability experienced by a person</td>
</tr>
<tr>
<td>hazard</td>
<td>a source of potential harm or a situation with a potential to cause loss</td>
</tr>
<tr>
<td>incident</td>
<td>an event or circumstance resulting from health care that could have, or did, lead to unintended or unnecessary harm to a person and/or a complaint, loss or damage</td>
</tr>
<tr>
<td>incident severity</td>
<td>a method to quantify the actual or potential consequences of an incident or near miss</td>
</tr>
<tr>
<td>rating (ISR)</td>
<td></td>
</tr>
<tr>
<td>likelihood</td>
<td>used as a qualitative description of probability or frequency</td>
</tr>
<tr>
<td>monitor</td>
<td>to check, supervise, observe critically or record the progress of an activity or system on a regular basis to identify change</td>
</tr>
<tr>
<td>near miss</td>
<td>an incident that did not cause harm</td>
</tr>
<tr>
<td>probability</td>
<td>the likelihood of a specific outcome</td>
</tr>
<tr>
<td>risk</td>
<td>the chance of something happening that will have an impact on objectives; it is measured in terms of consequence and likelihood</td>
</tr>
<tr>
<td>risk assessment</td>
<td>the overall process of risk analysis and risk evaluation</td>
</tr>
<tr>
<td>Term</td>
<td>Definition</td>
</tr>
<tr>
<td>------------------------------------</td>
<td>---------------------------------------------------------------------------</td>
</tr>
<tr>
<td>risk evaluation</td>
<td>the process used to determine risk-management priorities by comparing the level of risk against predetermined standards, target risk levels or other criteria</td>
</tr>
<tr>
<td>risk management</td>
<td>the culture, processes and structures that are directed to the effective management of potential opportunities and adverse effects</td>
</tr>
<tr>
<td>root cause</td>
<td>a significant factor that contributed to an incident</td>
</tr>
<tr>
<td>root cause analysis (RCA)</td>
<td>a systematic process where the factors that contributed to an incident are identified</td>
</tr>
<tr>
<td>risk-reduction action plan</td>
<td>strategies required to reduce the risk of similar adverse patient outcomes occurring in the future</td>
</tr>
<tr>
<td>safety</td>
<td>a state in which risk has been reduced to an acceptable level</td>
</tr>
<tr>
<td>sentinel event</td>
<td>a relatively infrequent, clear-cut event that occurs independently of a patient’s condition; it commonly reflects hospital system and process deficiencies, and results in unnecessary outcomes for the patient</td>
</tr>
<tr>
<td>underlying cause</td>
<td>the systems or process cause that allows for the proximate cause of an event to occur</td>
</tr>
<tr>
<td>VAED</td>
<td>Victorian Admitted Episodes Data Set</td>
</tr>
</tbody>
</table>
Appendix 1: Clinical Risk Management Reference Group, consultative councils and expert groups

The Clinical Risk Management Reference Group (CRMRG) 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 CRMRG subcommittee reviews all RCA reports to identify issues and trends from events, and provides feedback to the department.

Clinical Risk Management Reference Group 2006–07

<table>
<thead>
<tr>
<th>Name</th>
<th>Position</th>
</tr>
</thead>
<tbody>
<tr>
<td>Associate Professor Alan Wolff, Chair</td>
<td>Director of Medical Services, Wimmera Health Care Group</td>
</tr>
<tr>
<td>Dr Bill Shearer</td>
<td>Director of Critical Care Services, Southern Health</td>
</tr>
<tr>
<td>Professor Megan-Jane Johnstone</td>
<td>Department of Nursing and Midwifery, RMIT Bundoora Campus</td>
</tr>
<tr>
<td>Ms Anne Curtin</td>
<td>Health Service Executive Representative, West Gippsland Health Care</td>
</tr>
<tr>
<td>Mr Russell Jones</td>
<td>Claims Manager, Victorian Managed Insurance Authority</td>
</tr>
<tr>
<td>Ms Jo Bourke</td>
<td>Director Governance, Barwon Health</td>
</tr>
<tr>
<td>Dr Sandra Leggat</td>
<td>Senior Lecturer, School of Public Health, La Trobe University</td>
</tr>
<tr>
<td>Dr Bruce Warton</td>
<td>Director of Medical Services, Western District Health Service</td>
</tr>
<tr>
<td>Ms Bernadette Lane</td>
<td>Infection Control Practitioner (resigned May 2007)</td>
</tr>
<tr>
<td>Mr Kent Garrett</td>
<td>Director of Pharmacy, Austin Health</td>
</tr>
<tr>
<td>Dr Grant Phelps</td>
<td>Gastroenterologist and Director of Physician Training, Ballarat Health Services</td>
</tr>
<tr>
<td>Ms Margaret Way</td>
<td>Director Clinical Governance, Bayside Health</td>
</tr>
<tr>
<td>Ms Therese Carroll</td>
<td>Clinical Risk Manager, Medical Defence Association of Victoria</td>
</tr>
<tr>
<td>Dr Peter Waxman (Vale)</td>
<td>Senior Medical Advisor, General Practice, Department of Human Services</td>
</tr>
<tr>
<td>Mr Alistair Kerr</td>
<td>Consumer representative</td>
</tr>
<tr>
<td>Ms Elise Sullivan</td>
<td>Senior Nursing Advisor, Department of Human Services</td>
</tr>
<tr>
<td>Dr Peter Longmore</td>
<td>Director Medical Services, Mercy Hospital for Women (resigned December 2006)</td>
</tr>
<tr>
<td>Mr Pete Marshall</td>
<td>LAOS Project Officer, General Practice Divisions – Victoria</td>
</tr>
<tr>
<td>Ms Nicky Walker</td>
<td>Chief Nurse, Mercy Health &amp; Aged Care (from April 2007)</td>
</tr>
<tr>
<td>Ms Megan Kaims</td>
<td>Infection Control Practitioner (from May 2007)</td>
</tr>
<tr>
<td>Ms Kate Thwaites</td>
<td>Clinical Advisor to Chief Psychiatrist, Mental Health, Department of Human Services (from October 2006)</td>
</tr>
<tr>
<td>Ms Maureen Wilson</td>
<td>Manager, Victorian Quality Council, Department of Human Services</td>
</tr>
<tr>
<td>Mr Deane Wilks</td>
<td>Program Manager, Department of Human Services</td>
</tr>
<tr>
<td>Ms Susan Edmondson</td>
<td>Senior Program Advisor, Department of Human Services (on leave from March 2007)</td>
</tr>
<tr>
<td>Ms Laurene Graham</td>
<td>Project Officer, Department of Human Services</td>
</tr>
<tr>
<td>Ms Theresa Williamson</td>
<td>Senior Program Advisor, Department of Human Services (from March 2007)</td>
</tr>
</tbody>
</table>
Consultative councils 2006–07

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 RCA
- the appropriateness of suggested system improvements provided in the risk-reduction action plans
- the usefulness and quality of information contained in the RCA
- 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 Committee 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
- Royal Australian and New Zealand College of Radiology
- Intensive Care Advisory Committee.
Appendix 2: The Victorian Root Cause Analysis education program

The RCA 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.

The first module is designed to introduce the RCA 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 RCA process, including appointing a RCA coordinator and RCA facilitator. The third module focuses on the investigation methodology and developing 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.

The fourth module was implemented in 2006–07. 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 RCA 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.

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 RCA investigation. (See Module 1 for level of organisational response.) If an injury can be characterised by more than one rating, apply the higher rating.
Appendix 3: Department of Human Services’ review process for root cause analyses and action plans

A root cause analysis will be considered complete if it:
• focuses primarily on organisational systems and processes, not individual clinicians
• digs deeper by asking ‘why’ repeatedly
• 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
• is thorough and credible.

To be thorough, the RCA 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 RCA 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.\(^\text{10}\)
The Department of Human Services Sentinel Event Review Process
## Appendix 4: Sentinel event program – comparison between reported events

### Table 1: Comparisons between reported events, 2002–03 to 2006–07

<table>
<thead>
<tr>
<th>Classification of event</th>
<th>Frequency</th>
</tr>
</thead>
<tbody>
<tr>
<td>Procedure involving the wrong patient or body part</td>
<td>16 14 25 25 20</td>
</tr>
<tr>
<td>Suicide in an inpatient unit</td>
<td>5 1 4 7 11</td>
</tr>
<tr>
<td>Retained instruments or other material after surgery requiring re-operation or further surgical procedure</td>
<td>9 8 5 6 8</td>
</tr>
<tr>
<td>Haemolytic blood transfusion reaction resulting from ABO incompatibility</td>
<td>0 1 1 0 1</td>
</tr>
<tr>
<td>Medication error leading to the death of patient reasonably believed to be due to the incorrect administration of drugs</td>
<td>3 4 1 2 3</td>
</tr>
<tr>
<td>Maternal death or serious morbidity associated with labour or delivery</td>
<td>4 2 9 2 2</td>
</tr>
<tr>
<td>Infant discharged to wrong family</td>
<td>0 0 0 0 0</td>
</tr>
<tr>
<td>Intravascular gas embolism resulting in death or neurological damage</td>
<td>0 0 0 0 0</td>
</tr>
<tr>
<td>Other catastrophic event</td>
<td>42 55 77 49 37</td>
</tr>
<tr>
<td>Total</td>
<td>79 85 122 91 82</td>
</tr>
</tbody>
</table>
## Appendix 5: System factors that contributed to the occurrence of sentinel events

### Table 2: Comparisons between reported ‘other catastrophic events’, 2002–03 to 2006–07

<table>
<thead>
<tr>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Complication of emergency management</td>
<td>9</td>
<td>11</td>
<td>6</td>
<td>4</td>
<td>2</td>
</tr>
<tr>
<td>Complication of anaesthetic management</td>
<td>*</td>
<td>6</td>
<td>1</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Complication of surgical management</td>
<td>9</td>
<td>10</td>
<td>6</td>
<td>5</td>
<td>3</td>
</tr>
<tr>
<td>Foetal complication of delivery</td>
<td>3</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>2</td>
</tr>
<tr>
<td>Complication of inpatient fall (death or serious morbidity)</td>
<td>2</td>
<td>10</td>
<td>11</td>
<td>4</td>
<td>5</td>
</tr>
<tr>
<td>Complication of fall (not resulting in death or serious morbidity)</td>
<td>*</td>
<td>*</td>
<td>18</td>
<td>1</td>
<td>0</td>
</tr>
<tr>
<td>Patient absconding from inpatient unit with adverse outcome</td>
<td>2</td>
<td>1</td>
<td>1</td>
<td>2</td>
<td>0</td>
</tr>
<tr>
<td>Infection control breach</td>
<td>6</td>
<td>7</td>
<td>8</td>
<td>3</td>
<td>2</td>
</tr>
<tr>
<td>Hospital process issue</td>
<td>9</td>
<td>7</td>
<td>0</td>
<td>6</td>
<td>0</td>
</tr>
<tr>
<td>Medication error (not resulting in death)</td>
<td>*</td>
<td>*</td>
<td>9</td>
<td>7</td>
<td>3</td>
</tr>
<tr>
<td>Misdiagnosis and subsequent management</td>
<td>*</td>
<td>*</td>
<td>4</td>
<td>3</td>
<td>3</td>
</tr>
<tr>
<td>Communication of test results</td>
<td>*</td>
<td>*</td>
<td>3</td>
<td>1</td>
<td>0</td>
</tr>
<tr>
<td>Other – mental health management</td>
<td>*</td>
<td>*</td>
<td>4</td>
<td>3</td>
<td>6</td>
</tr>
<tr>
<td>Other – unspecified</td>
<td>2</td>
<td>3</td>
<td>5</td>
<td>8</td>
<td>8</td>
</tr>
<tr>
<td>A good catch/near miss</td>
<td>+</td>
<td>+</td>
<td>+</td>
<td>+</td>
<td>3</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td><strong>42</strong></td>
<td><strong>52</strong></td>
<td><strong>77</strong></td>
<td><strong>49</strong></td>
<td><strong>37</strong></td>
</tr>
</tbody>
</table>

* New catastrophic event classifications used in the 2004–05 data analysis
+ New catastrophic event classifications used in the 2006–07 data analysis
The table below contains examples of factors that have contributed to the occurrence of sentinel events for the past five years of reporting.

Table 3: Factors contributing to sentinel events expressed as a percentage, 2002–03 to 2006–07

<table>
<thead>
<tr>
<th>Contributing factor</th>
<th>Percentage of contributing factor</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Number of contributing factors =</td>
</tr>
<tr>
<td>Number of contributing</td>
<td>210</td>
</tr>
<tr>
<td>factors</td>
<td></td>
</tr>
<tr>
<td>Procedures/guidelines</td>
<td>32</td>
</tr>
<tr>
<td>Human resources</td>
<td>17</td>
</tr>
<tr>
<td>Communication</td>
<td>16</td>
</tr>
<tr>
<td>Health information</td>
<td>7</td>
</tr>
<tr>
<td>Equipment</td>
<td>7</td>
</tr>
<tr>
<td>Physical environment</td>
<td>9</td>
</tr>
<tr>
<td>Facilities management</td>
<td>6</td>
</tr>
<tr>
<td>Patient behaviour*</td>
<td>–</td>
</tr>
<tr>
<td>Course of disease*</td>
<td>–</td>
</tr>
<tr>
<td>Other</td>
<td>6</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td><strong>100</strong></td>
</tr>
</tbody>
</table>

* New contributing factor for 2005–06
Table 4: Subcategories of contributing factors

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

* New contributing factor for 2005–06
* New-English speaking background