

PATIENT SAFETY: FROM LEARNING TO ACTION *II*



**SECOND QUEENSLAND HEALTH REPORT ON
CLINICAL INCIDENTS IN THE QUEENSLAND
PUBLIC HEALTH SYSTEM 2006/7**

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“It was never in my mind to sue. All I wanted was for them to admit that there was something wrong and that they were going to fix it”

Words of a Queensland Health patient during open disclosure for a serious adverse event.

ACKNOWLEDGEMENTS

The Patient Safety Centre would like to thank all the organisations and individuals who made this report possible. This includes:

- Staff who have reported incidents
- Patients and consumer groups who have shared their experiences of the healthcare system
- Queensland Health patient safety officers, clinicians and others who have worked hard to promote patient safety within their health services
- Healthcare leaders who have committed time and energy to patient safety improvement
- Staff of the Patient Safety Centre, Area Clinical Governance Units and other key divisions and units within Queensland Health, for their dedication to improvement
- Other partners and collaborators including the Australian Commission for Safety and Quality in Healthcare and the United States Veterans Health Administration National Center for Patient Safety.

FOREWORD

On an average day in Queensland Health:

24286 people receive clinical care through outpatient visits, (excluding emergency department visits)

3906 people receive emergency care through emergency departments

7884 people receive admitted care in public hospitals

113 babies are born and

450 callers are given qualified and supportive advice on health concerns through the health hotline, 13HEALTH (13 43 25 84).

Queenslanders enjoy very good health by world standards. We are justly proud of our healthcare system, which provides universal access to all residents, regardless of where they live.

The vast majority of care delivered in Queensland Health hospitals and health services is safe and effective. However, despite well trained and well intentioned staff, occasionally things do go wrong. When this happens, particularly when the consequence is severe and unexpected, this causes major distress for patients, families and staff. Publicity around these events can also lead to the community losing trust in their health system.

Queensland Health recognises that patients have a right to the safest possible healthcare and is committed to this goal.

The first step in addressing a problem is acknowledging that it exists. Queensland Health is working hard to develop a culture that actively encourages staff to report clinical incidents, and sees these as an opportunity to learn about and fix problems, rather than ignoring them. Sharing information in an honest and transparent way is fundamental to improving patient safety and building trust in both the community and our staff.

This report builds on the First Queensland Health Report on Clinical Incidents and Sentinel Events *Patient Safety: From Learning to Action* (2007). Queensland Health is working hard to implement patient safety improvements.

Safe organisations report more. A safe organisation has a culture where staff feel able to report, and the reports in turn help the organisation learn, and become even safer. The first sign of an improved culture is an increase in reports, and in Queensland Health, we have seen a 30% increase in clinical incident reports compared to the previous year. Most of these incidents are 'near misses' and this demonstrates that staff are more willing to raise concerns.

Significant work is occurring across the state to address the well-known patient safety issues in *medications, falls, pressure ulcers, infection, suicide prevention and procedural complications*. Other examples of patient safety improvement include the *Alert Doctors Strategy* (addressing fatigue), Clinician Performance Support Service (previously known as *Safe Doctors: Fair System Project*) (managing concerns about the performance of a clinician) and *Open Disclosure Program* (addressing needs of patient/family after an adverse event).

We continue to identify new issues from analysis of clinical incident data. Three issues have emerged that are receiving attention both in Queensland and nationally by the Australian Commission for Safety and Quality in Healthcare. These are: *patient mis-identification, clinical handover and the recognition and management of deteriorating patients*. These are the subject of pilot projects to examine solutions that can be applied across the state.

Whether you are a member of the Queensland community, or a staff member of Queensland Health, I hope this report achieves its goal of raising awareness of patient safety. Improved patient safety can only be achieved with the combined efforts of all that work in, manage and use the Queensland public health system.

Stephen Robertson
Minister for Health

EXECUTIVE SUMMARY

This report is for all Queenslanders, but in particular, for the staff of Queensland Health and for members of the community who are interested in what Queensland Health is doing to improve patient safety. It is also for anyone who wants to share in and benefit from the things that we have learned as we have introduced a comprehensive patient safety system into Queensland Health.

The Queensland Health Patient Safety System – What is it and why is it needed?

Clinical incidents (adverse events and near misses) occur in every health system in the world. Sometimes, patients are harmed. Queensland has recognised this reality, and has responded by the development of the Queensland Health Patient Safety System. The goal of this system is to minimise preventable patient harm.

Every time an incident occurs, we seek to learn from it and find ways in which to prevent its recurrence. It is only by having a system that allows us to recognise, report, analyse and learn from incidents, that we can improve and ultimately reduce preventable harm.

The Patient Safety System is made up of policies, processes and supporting tools that ensure we constantly learn from and prevent clinical incidents. More important, however, are the organisational culture and the people who make such systems work. Queensland Health's Patient Safety System could achieve nothing without the vigilance and responsiveness of Queensland Health staff.

What does this report tell us about patient safety in Queensland Health in 2006/7?

The most striking feature of the data in this report is that we have been successful in capturing reports of more clinical incidents than ever before, with 46,990 clinical incidents reported using our computerised reporting system - PRIME CI. This represents an overall increase of 30% compared with the previous year. This does not mean an increase in patient harm (77% of reported incidents were associated with minimal or no harm to patients); rather it demonstrates the successful implementation of policies, systems and cultural reform that encourage staff to identify and report problems.

This increase is spread relatively evenly across all primary incident types, with falls (10,931) and medication incidents (7,483) continuing to be the most commonly reported.

Seventy-seven percent of reported incidents were not associated with patient harm. Sometimes known as '*near misses*' these incidents involve circumstances where patient harm could have occurred but for chance or the timely intervention of systems or staff. Twenty-three percent of reported incidents did result in patient harm, but some types of reported clinical incidents are far more likely to cause harm. Forty-nine percent of pressure ulcers and 39% of falls result in patient harm of some kind. Falls are the commonest reported cause of patient harm, with 3,945 falls reported as resulting in patient harm during the 2006/2007 financial year. Pressure ulcers and medication events ranked second and third respectively. This data provides clear evidence that these continue to be high risk areas, deserving of continued prevention effort.

We have also collected data about factors that have contributed to clinical incidents. This information is categorised into patient, task, staff, team, environmental and organisational factors, because each of these categories requires different types of interventions for preventive actions.

How is this information being used to improve patient safety for Queenslanders?

Merely collecting data about clinical incidents would be pointless without analysing what went wrong and learning from the incident. Significant effort goes into analysing *what* has occurred, *why* it has occurred, and *what* can be done to prevent recurrence. Quantitative and qualitative data is available from PRIME CI, and extremely rich qualitative information flows out of Root Cause Analyses of SAC1 events.

De-identified data is shared both internally and externally to further support patient safety improvement.

In high priority areas, some of the initiatives of 2006/2007 were as follows:

Falls

- A statewide clinician-led Falls Injury Prevention Collaborative was established in March 2006 to lead initiatives to reduce fall-related injuries.

Pressure Ulcer Prevention

- Complete replacement of old style vinyl mattresses with pressure reduction mattresses.

Medication Safety

- Standardised hospital drug chart
- Electronic discharge medication summary system
- Targeted interventions for high-risk drugs such as insulin, opiates, warfarin, heparin and intravenous fluids.

Behaviour and Aggression

Behaviour and aggression in healthcare facilities can result in harm to patients and also to staff. Queensland Health has taken action in the following ways:

- Queensland Health Occupational Health Safety Management System – Occupational Violence Prevention and Management Implementation Standard¹
- Development of an Occupational Violence Risk Assessment Tool to facilitate violence management plans²
- De-escalation training for staff and introduction of violence management plans³
- Improved design of buildings⁴
- In –depth analysis of qualitative incident data to inform future strategies.

¹ http://qheps.health.qld.gov.au/safety/safety_topics/standards/ohsms_2_1_21.pdf

² http://qheps.health.qld.gov.au/safety/safety_topics/wpd/ohsms_2_59_1_38.doc

³ http://qheps.health.qld.gov.au/safety/occup_violence/training_manual.htm

⁴ <http://www.healthfacilityguidelines.com.au/guidelines.htm>

Mental Health Patient Safety and Suicide Prevention

- Standardised processes and tools for mental health assessment
- Ligation Risk Audits for Inpatient Units
- Safer models of care for mental health clients requiring emergency care accessing emergency departments
- Increased integration of mental health services and alcohol, tobacco and other drugs (ATODS)
- Developing an information system that assists mental health and emergency department staff to timely and accurate patient information.

Infection Surveillance and Prevention

- Hand hygiene program⁵
- Infection control management plans for all hospitals⁶
- I-CARE Program to prevent blood stream infections⁷
- Infection surveillance through eICAT system – providing guidance and support to Queensland Health facilities in developing standardised surveillance and analysis methods that allow timely recognition and intervention of infection problems⁸
- Staff Protect – protecting staff and patients through immunisation
- Sharps Safety Program⁹.

Ensuring Intended Surgery and Procedures

- Annual observation audits of compliance
- Projects to expand the protocol into dental and radiology practice
- Policy review to address usability and compliance issues.

Other key initiatives that have continued or commenced during the 2006/2007 financial year include

- The Open Disclosure Program, which is improving communication with patients and their families when serious incidents occur
- The Informed Consent Program which is developing and evaluating a standardised suite of consent forms and patient information sheets.
- The Coronial Management Program, which has provided a central resource for coronial liaison, data collection and compliance management
- The Clinician Performance Support Service, which provides performance assessment and support for senior doctors where there are concerns about their professional performance.
- The Alert Doctors Strategy, which has developed and piloted innovative approaches to fatigue risk management.
- Blood Transfusion Safety – the QiiT Project which will implement a robust haemovigilance system in Queensland.

What does the future hold?

Looking forward, areas for future work have been identified. These include increased work in the domains of Clinical Handover, Patient Identification, the recognition and treatment of the deteriorating patient, and a number of e-Health initiatives. The Patient Safety Centre and other state-wide units continue to take a national leadership role in patient safety improvement in conjunction with the Australian Commission for Safety and Quality in Healthcare. Open Disclosure is a recent example where Queensland is leading the way and contributing to ground

⁵ http://www.health.qld.gov.au/chrisp/hand_hygiene/alcohol_HH.asp

⁶ http://www.health.qld.gov.au/chrisp/icmp_pha/default.asp

⁷ <http://www.health.qld.gov.au/chrisp/icare/about.asp>

⁸ http://www.health.qld.gov.au/chrisp/surveillance/about_surv.asp

⁹ <http://qheps.health.qld.gov.au/safety/communications/spotlight.htm>

“Hand Hygiene is the most effective and least expensive measure in the prevention of healthcare-associated infections”

breaking research into the benefits of disclosure for patients, their families and staff, after an adverse event.

We now have the framework for ongoing development and continuous improvement. In coming years we will continue to apply lessons already learned, we will build on those lessons by continuing to report, analyse and apply our findings, and in so doing, we have the capacity to identify emerging risks at the earliest opportunity. We will never completely eliminate clinical incidents, but the learning and actions that flow from a robust patient safety system give us hope of achieving our goal of minimising preventable patient harm.

SECTION 1

QUEENSLAND HEALTH PATIENT SAFETY SYSTEM

Section 1 provides an overview of how Queensland Health uses information from clinical incidents to improve patient safety.

A) WHAT IS A CLINICAL INCIDENT?

A “clinical incident”¹⁰ is any event or circumstance which has actually or could potentially, lead to unintended and/or unnecessary mental or physical harm to a patient.

B) WHY IS A SYSTEM NEEDED TO MANAGE PATIENT SAFETY IN QUEENSLAND HEALTH?

Queensland Health is a large complex organisation, employing more than 60,000 staff and treating almost 8000 hospital inpatients and almost 30,000 outpatients¹¹ every day. Most patients have excellent outcomes from their healthcare. However, despite the best intentions of our staff, things sometimes do not go as planned. Without a well-defined system to identify and manage these adverse events, there would be little chance of improving patient safety.

C) WHAT IS THE GOAL OF THE PATIENT SAFETY SYSTEM?

The goal of the Queensland Health Patient Safety System is to minimise preventable patient harm.

D) WHAT IS MEANT BY A PATIENT SAFETY SYSTEM?

The Queensland Health Patient Safety System is defined by the people, processes and supporting systems that enable Queensland Health to learn about and prevent *clinical incidents*. The 2006 *Queensland Health Clinical Incident Management Implementation Standard*¹² (the *Standard*) outlines how this is achieved in Queensland Health. This is now also supported by a regulatory framework for analysis of serious adverse events under Section 4B of the Health Services Act Queensland¹³.

Figure 1 summarises the key components of the Queensland Health Patient Safety System. Action is required at all points on this system in order for improvements in patient safety to occur.

“The goal of the Patient Safety System is to **minimise patient harm caused by healthcare**”

“This is achieved through **learning** from near misses and adverse events and taking **corrective actions** to improve the system”

¹⁰ Clinical incidents comprise *adverse events* (patient harm occurs) and *near misses* (patient harm avoided due to chance or through a timely intervention).

¹¹ Includes outpatient and emergency department presentations

¹² <http://www.health.qld.gov.au/patientsafety/im/webpages/IncidentMan.asp> reviewed and updated July 1st 2008.

¹³ <http://www.health.qld.gov.au/patientsafety/documents/leg3.pdf> and <http://www.health.qld.gov.au/patientsafety/documents/leg2.pdf>

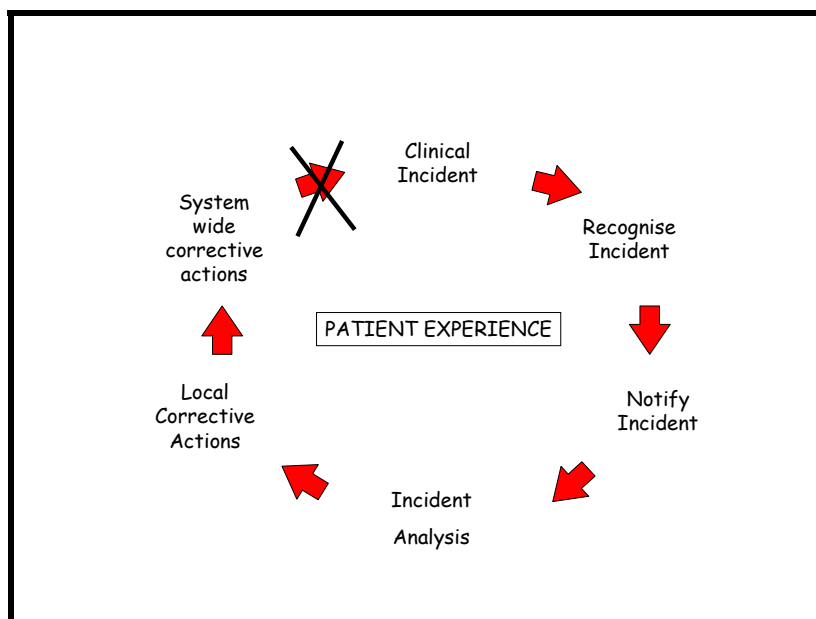


Figure 1: Components of the *Queensland Health Patient Safety System*

E) COMPONENTS OF THE QUEENSLAND HEALTH PATIENT SAFETY SYSTEM

Recognise Incident: It is essential that staff can recognise potential and actual incidents and engage in behaviours that minimise patient safety risks. Queensland Health's approach includes:

- Patient Safety Centre established to provide leadership and support for patient safety improvement in Queensland Health.
- Over 9000 Queensland Health staff trained in Human Error and Patient Safety (HEAPS)¹⁴ aimed at promoting safety behaviours.
- Patient Safety Officers are available in every Health Service District and participate in staff orientation in Patient Safety and in-service training.
- A range of training resources have been developed by the Patient Safety Centre and other specialist content providers, to provide information for staff.
- Raised awareness through *Patient Safety Matters*¹⁵ newsletters, *Alerts* and *Advisories* and forums on patient safety.
- Undergraduate medical training programs in patient safety.

Notify Incident: When a staff member becomes aware that a near miss or adverse event has occurred, it is essential that staff know what to do. Taking immediate action to minimise any further patient harm and reporting the incident to their line manager are essential actions for staff. Queensland Health's approach includes:

- Electronic reporting system on every networked Queensland Health desktop computer. (PRIME¹⁶ – web-based Clinical Incident Management Information System).
- A web portal for all types of incidents and complaints is accessible as an icon on every desktop in Queensland Health.

“Staff can report clinical incidents on any computer desktop across the length and breadth of Queensland Health”

¹⁴ <http://www.health.qld.gov.au/patientsafety/heaps/webpages/default.asp>

¹⁵ <http://www.health.qld.gov.au/patientsafety/webpages/pscmatters.asp>

¹⁶ <http://www.health.qld.gov.au/patientsafety/im/webpages/prime.asp>

This makes it easier for staff to find the right information on how to raise issues, and makes it easy for staff to report.

- Patient Safety Officers¹⁷ work in every Health Service District and are available by telephone or in person if staff prefer not to use computerised reporting.

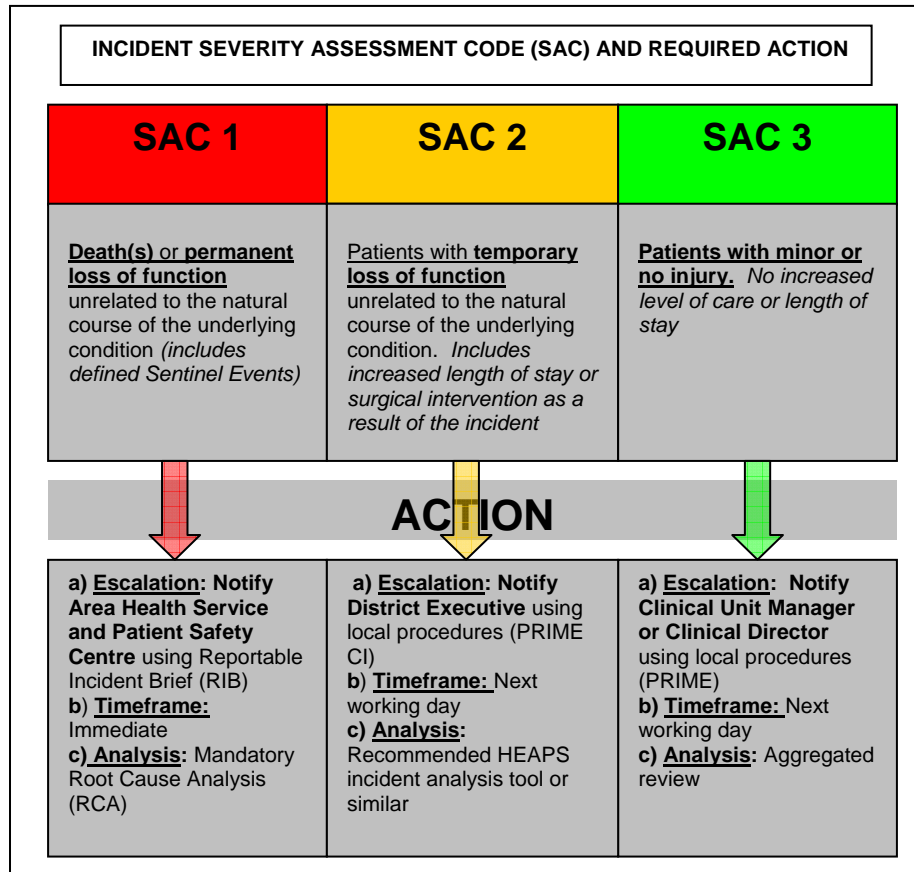


Figure 2: Summary of Clinical Incident Management Implementation Standard 2006

¹⁷ Patient Safety Officers are trained in human factors engineering and systems analysis. They provide support to clinicians and managers in Root Cause Analysis, patient safety training and safety audits.

Incident analysis: When an incident occurs, the response is prioritised based on the consequences of the incident. Corrective actions depend upon effective analysis of the incident. A systems approach is used to analyse incidents, in line with best practice in other high-hazard industries. This involves finding out *what happened, why it happened* and *what can be done to prevent similar incidents* in the future. Queensland Health does not take disciplinary action against staff involved in a clinical incident unless there is evidence of a “blameworthy” act¹⁸. Figure 2 summarises the key requirements of the *Standard*. Queensland Health’s approach includes:

- Standardised methodology, tools and training for Root Cause Analysis¹⁹
- One day Root Cause Analysis (RCA) training delivered to over 2000 staff
- Human Error and Patient Safety (HEAPS) incident analysis tool²⁰
- 41 Patient Safety Officers to teach and support incident analysis techniques²¹
- RCA legislation to promote ‘just’ culture (2008)
- Quality Management System for RCA and analysis of RCAs.

Local system changes: Constant improvement at a local level is essential for patient safety. Once incident analysis has occurred, recommendations on corrective actions are considered by local management. The level of management involvement is dependent on the consequences of the incident(s) and is outlined in the *Standard* (eg. Incidents with a minor consequence are managed at a clinical unit level; incidents with more serious consequence require the involvement of senior management). For Severity Assessment Code 1 events, corrective actions are monitored and reported by the Area Clinical Governance Units. Queensland Health’s approach includes:

- The incident management system (PRIME CI) is used by clinicians, managers and district patient safety committees at a local level. To manage and monitor incidents and corrective actions
- Regular reporting and monitoring of SAC1 corrective actions *accepted, rejected, delayed or completed*, takes place at district, area and state levels (implemented late 2007)
- Training in clinical practice improvement methods is provided Patient Safety Officers, Quality Units, and e-learning packages
- The Clinical Practice Improvement Centre²² provides leadership and support for clinical practice improvement.

System-wide changes: Queensland Health now has the ability to analyse incidents at Area and State level through the use of PRIME CI data and the Patient Safety Officer networks. This provides a *window* into the healthcare system as a whole. When incident analysis reveals a serious system-wide risk, a state-wide solution is necessary. Section 3 of this report presents key state-wide safety initiatives. Queensland Health’s approach includes:

- Funding for units to lead and support state-wide patient safety improvement initiatives: eg. Patient Safety Centre, Safe Medication

“A Root Cause Analysis (RCA) uses a team to find out **what happened, why it happened, and what can be done to prevent it happening again**”

“Every RCA recommendation is considered by management. Monitoring of recommendations **accepted, rejected, delayed or completed, promotes action**”

¹⁸ “Blameworthy Acts” are defined in part 4B of the Health Services Act and include intentionally unsafe acts, deliberate patient abuse, and conduct that constitutes a criminal offence.

¹⁹ A Root Cause Analysis is a systematic process whereby factors that contributed to an incident are identified.

²⁰ <http://www.health.qld.gov.au/patientsafety/webpages/forms.asp>

²¹ <http://www.health.qld.gov.au/patientsafety/im/webpages/IncidentMan.asp>

²² <http://www.health.qld.gov.au/cpic>

Practice Unit, Skills Development Centre, Clinical Practice Improvement Centre

- Programs addressing high risk patient safety risks
- The Queensland Health Patient Safety and Quality Board²³ providing oversight of state-wide initiatives.

After an adverse event, patients expect that we will...

- ...say "sorry"
- provide information on what happened
- take steps to correct problems
- support them on the road to recovery

Patient Experience: Patients expect that we will keep them safe; they trust us. They also understand that we are not perfect and mistakes can happen. Whether preventable or not, when outcomes of healthcare are not as expected, patients deserve honesty, empathy and support. Too often in the past, patients and their families have not only had to face the harm, but also a healthcare system that provided no information or support in the aftermath of an adverse event. Some patients pursue lengthy and costly litigation to obtain answers. Many more do not, and struggle with the grief of their injury and loss of trust in the healthcare system. Queensland Health's approach to improving care of patients and families after an adverse event includes:

- Formal Open Disclosure²⁴ for all SAC 1 (see page 14 for definition) events supported by *Open Disclosure Consultants*²⁵
- Training in Open Disclosure and empathic communication skills for clinicians and medical students
- Improved management of patient complaints through implementation of the *Complaints Management Implementation Standard*
- Consumer involvement²⁶ in the planning and implementation of patient safety initiatives
- Evaluation of the Queensland Health Informed Consent Program²⁷ to determine the extent to which it assists patients in making healthcare decisions.

"The value of incident reporting is not in **how many or how few**....it is in understanding and learning about the root causes of incidents from the narrative."

"Safe organisations report more incidents because they actively seek out and address problems"

F) MEASURING PATIENT SAFETY

Measuring patient safety is not simple. No single measure can provide assurance that patients are as safe as possible. For example, merely measuring the adverse event rates of a hospital does not provide an understanding of *why* incidents occur. Without an *understanding* of why incidents occur, it is not possible to design and implement solutions. Furthermore, if a well designed safety strategy is not *actually* implemented by hospitals and staff, improved patient safety will definitely not result. Finally, even if the hospital has the lowest *statistical* rate of adverse events, if patients don't *feel* safe and *trust* the staff and the hospital, can the hospital really be considered safe?

²³ <http://www.health.qld.gov.au/quality/psqb/default.asp>

²⁴ <http://www.health.qld.gov.au/patientsafety/od/webpages/odres.asp>

²⁵ *Open Disclosure Consultants* are senior clinicians, specially trained in empathic communication skills, to assist treating clinicians in providing support to patients and families after a serious adverse event.

²⁶ Consumer representatives are members of the Queensland Health Patient Safety and Quality Board, Patient Safety Centre Advisory Committee, and various safety improvement program committees.

²⁷ <http://www.health.qld.gov.au/informedconsent/default.asp>

A Patient Safety Measurement Framework, therefore must include all elements of measurement; **learning**; **action**; **performance** and **patient experience**. (See Table 1).

Measurement Source	What this measure is best for -	What this measure <u>can't</u> do -	Current status in Queensland Health
Incident reporting Incident analysis Claims data	LEARNING (Understanding <i>why</i> incidents occur)	Determine safety performance (<i>reported incidents ≠ actual incidents</i>)	Robust system in place for reporting and learning from clinical incidents at district, area and state
Compliance audits of patient safety initiatives and recommendations	ACTION (Determination of whether <i>corrective action</i> has been taken)	Determine whether the action has led to improved safety (implementing a strategy does not guarantee improved safety)	Systems in place for tracking compliance with RCA corrective actions
Coding of in-hospital patient charts Chart audits for in-hospital acquired patient injury	PERFORMANCE (Determination of adverse event or <i>injury rates</i>)	Determine the underlying cause for the incidents (merely knowing incident rates does not contribute to improved safety)	Well developed system for monitoring rates of key indicators linked to follow up action
Patient surveys Complaints and compliments	PATIENT EXPERIENCE (understanding whether patients <i>feel safe</i> and trust healthcare staff and healthcare system)	Determine technical safety performance (feeling safe is important, but does not necessarily equate to low rates of harm)	Regular surveys of patient satisfaction. Complaints system PRIME CF implemented during 2008
Staff surveys	STAFF EXPERIENCE (understanding organisational patient safety culture)	Determine safety performance	Workplace culture surveys conducted regularly. Patient safety culture survey conducted 2006 and repeat 2009

Table 1: Measuring Patient Safety – Strengths and Weaknesses of Methods.

G) HEALTH QUALITY AND COMPLAINTS COMMISSION²⁸

The Health Quality and Complaints Commission (HQCC) is an independent body dedicated to improving the quality and safety of health services in Queensland.

The HQCC has endorsed seven Standards²⁹ to be implemented by health service providers from July 1, 2007.

The Standards are based on national guidelines with a strong evidence base, and cover specific issues such as surgical safety, hand hygiene, complaints management and the providers' duty to improve the quality of health services.

Queensland Health is working with the HQCC to ensure appropriate implementation of the Standards and prevent an additional burden on districts through duplication of effort with pre-existing Queensland Health patient safety improvement strategies.

Reporting against the Standards did not commence until July 1, 2007, and is therefore not addressed further in this Report.

²⁸ <http://www.hqcc.qld.gov.au/home/default.asp>

²⁹ <http://www.hqcc.qld.gov.au/home/inner.asp?pageID=267&snav=0>

SECTION 1: KEY MESSAGES

- ✓ Patient Safety Centre established to provide leadership and support for patient safety improvement in Queensland Health.
- ✓ Queensland Health has a robust *Patient Safety System* that ensures that we can learn about potential problems, and take corrective actions to continually improve patient safety.
- ✓ All Queensland Health staff can report incidents through the web-based PRIME CI system, on any networked Queensland Health computer.
- ✓ 41 Patient Safety Officers across the state support patient safety improvement at the local level.
- ✓ Standardised format for incident reporting, escalation, analysis and tracking of corrective actions. Accountabilities are clearly defined.
- ✓ Over 9000 staff trained in Human Error and Patient Safety (HEAPS) which is driving culture change.
- ✓ A legislative framework to support Root Cause Analysis of serious (SAC1) incidents was passed by the Queensland Parliament in April 2007.
- ✓ Queensland Health is developing a patient safety measurement framework with five dimensions. Each dimension provides unique information, and **all** are required for patient safety.

Learning	<i>Understanding why incidents occur</i>
Action	<i>Monitoring corrective actions implemented</i>
Performance	<i>Measuring how much harm</i>
Patient Experience	<i>Measuring how safe patients feel</i>
Staff Experience	<i>Measuring staff attitudes and safety behaviours</i>

SECTION 2

SUMMARY DATA – REPORTED CLINICAL INCIDENTS 2006/7

Section 2 presents data from clinical incidents reported by Queensland Health hospitals and Health Service Districts, during the period July 1, 2006 to June 30, 2007.

SOURCES OF REPORTED CLINICAL INCIDENT DATA

Data presented in Section 2 is from two key data-sets held by the Queensland Health Patient Safety Centre:

- State-wide clinical incident information system (PRIME CI)³⁰
- Root Cause Analysis reports³¹ for Severity Assessment Code 1 (SAC1) events reported to the Patient Safety Centre.

HOW TO INTERPRET THESE DATA?

Reported incident data provides information on the *causation* of incidents, and cannot be used to determine *safety performance* (See Table 1).

The following notes of caution should be applied in the interpretation of this data:

- The purpose of incident reporting is to understand why incidents occur and identify corrective actions. It is not designed to be used to compare the quality of clinical care and can't be used for that purpose.
- The number of incidents reported in PRIME CI is unlikely to reflect the actual number of incidents occurring in Queensland Health. International evidence suggests that incidents are significantly under-reported.
- High numbers of incident reports does not equate to poor safety performance. Safe organisations will often report more as they encourage staff to report in order to learn about and fix potential problems.
- It should be noted that the trigger for reporting clinical incidents is based on an *unexpected outcome of care* rather than *human error*. **Many incidents do not have human error as a cause.**
- Research has shown that approximately 50% of adverse events (harm) are not considered preventable.

PART 1 – SENTINEL EVENT AND SAC1 DATA

A) NATIONAL SENTINEL EVENTS (PUBLIC SECTOR) REPORTED DURING 2006/7

The National Sentinel Event List (Table 2) defines eight event categories and was developed by the Australian Council for Safety and Quality in Healthcare. Each state is required to collect data on sentinel events reported under each category, and submit it to the Australian Commission for Safety and Quality in Healthcare³². This data is aggregated and published in a National Sentinel Event Report³³.

³⁰ <http://www.health.qld.gov.au/patientsafety/im/webpages/prime.asp>

³¹ <http://www.health.qld.gov.au/patientsafety/im/webpages/finalreport.asp>

³² <http://www.safetyandquality.org>

³³ <http://www.aihw.gov.au/publications/index.cfm/title/10353>

There are some inconsistencies in the current National Sentinel Event definitions. Sentinel Event (2), (4), (6) and (7) definitions link incident type with consequence; whereas Sentinel Events (1), (3), (5) and (8) refer to incident type only. This issue has the potential to cause misinterpretation of the data:

For example, during 2006/7 year, there has been a considerable increase in reporting of Sentinel Event 1, *Procedures involving the wrong patient or body part* cases (2005/6 – 6 cases; 2006/7 – 33 cases). This represents increased awareness and reporting rather than an increase in serious patient harm; 29 out of the 33 reported cases were associated with minor or no harm (e.g. x-ray performed on the wrong patient).

Table 2 summarises events reported to the Patient Safety Centre during 2006/7, which were consistent with the current National Sentinel Event List.

National Sentinel Event Number (SE #)		Number of reports	Severity Assessment Code (SAC) ³⁴		
			SAC 1	SAC 2	SAC 3
SE 1	Procedures involving the wrong patient or body part	33	4	9	20
SE 2	Suicide of a patient in an inpatient unit ³⁵	2	2	N/A	N/A
SE 3	Retained instruments or other material after surgery, requiring re-operation or further surgical procedure	3	3	-	-
SE 4	Intravascular gas embolism resulting in death or neurological damage	-	-	-	-
SE 5	Haemolytic blood transfusion reaction resulting from ABO incompatibility	1	-	1	-
SE 6	Medication error resulting in death of a patient reasonably believed to be due to incorrect administration of drugs	6	6	N/A	N/A
SE 7	Maternal death or serious morbidity associated with labour or delivery (excluding neonates and babies)	4	4	N/A	N/A
SE 8	Infant discharged to the wrong family	-	-	-	-
TOTALS		49	19	10	20

Table 2: National Sentinel Event reporting (public sector) 2006/7.

This increased reporting of near miss events is extremely encouraging and demonstrates a culture which is focussed on learning about problems before they cause serious harm.

³⁴ Severity Assessment Code is a measure of the harm associated with the incident:

SAC 1 – death or permanent loss of function

SAC 2 – temporary loss of function

SAC 3 – minor or no injury (including near miss)

³⁵ Suspected suicide reports (Only the coroner can determine suicide as cause of death) under Coroners Act 2003.

B) SUPPLEMENTARY REPORTABLE EVENTS (SAC 1) IN QUEENSLAND (PUBLIC SECTOR)

Severity Assessment Code 1 (SAC 1) Events reported during 2006/7 (excludes National Sentinel Events in Table 2)			
SAC 1 Category	SAC 1 Sub-Category	Definition <i>Death or permanent loss of function...</i>	Number of reports
Falls	N/A	...associated with fall whilst in care	10
Pressure Ulcer	N/A	...associated with hospital acquired pressure ulcer	1
Perinatal	N/A	...of an infant during labour. Includes stillbirth.	12
General Clinical Management ³⁶	Diagnosis	...associated with delayed or missed diagnosis.	8
	Investigations	...associated with investigations that were delayed, not ordered or actioned.	1
	Treatment	...associated with treatment that was delayed or inadequate.	6
	Complications	...associated with undesired outcomes of appropriate treatment.	24
	Observations	...associated with observations not performed, or significance not recognised.	2
	Transfer of care	...associated with delayed or inadequate planning of transfer of care.	5
	Inter-hospital retrieval/transfer	...associated with inadequate stabilisation	5
Mental Health Related Events ³⁷	Mental Health inpatient	Death from natural causes	5
		Suspected suicide of mental health inpatient whilst on approved leave	5
		Suspected suicide of mental health patient after absconding from inpatient care	6
		Death associated with physical restraint during in-patient mental health care.	2
	Community Mental Health	Suspected suicide of a mental health client receiving care in the community.	14
	Emergency Department related	Suspected suicide of any patient within 24 hours of attendance at an emergency department.	2
TOTAL			108

Table 3: Queensland SAC 1 Events (public sector) reported during 2006/7.

Table 3 provides a summary of all SAC 1 Events reported to the Queensland Health Patient Safety Centre during the 2006/7. During the 2006/7 financial year, Queensland Health policy for reporting adverse events exceeded the national requirements. In addition to the National Sentinel Event list, the *Standard*³⁸ required reporting of all SAC 1 events. These categories are not used by all states and represent a commitment towards a more robust and transparent approach by Queensland Health to understand and address patient safety risks.

³⁶ Categories adapted from Clinical Excellence Commission and accessed at: http://www.cec.health.nsw.gov.au/pdf/07_01to06_incident_management.pdf

³⁷ These deaths reported under the generic SAC 1 definition: "Death or permanent loss of function unrelated to the natural course of the underlying condition".

³⁸ The 2006 Queensland Health Clinical Incident Management Implementation Standard is superseded by 2008 Queensland Health Clinical Incident Management Implementation Standard available at: <http://www.health.qld.gov.au/patientsafety/documents/cimist.pdf>

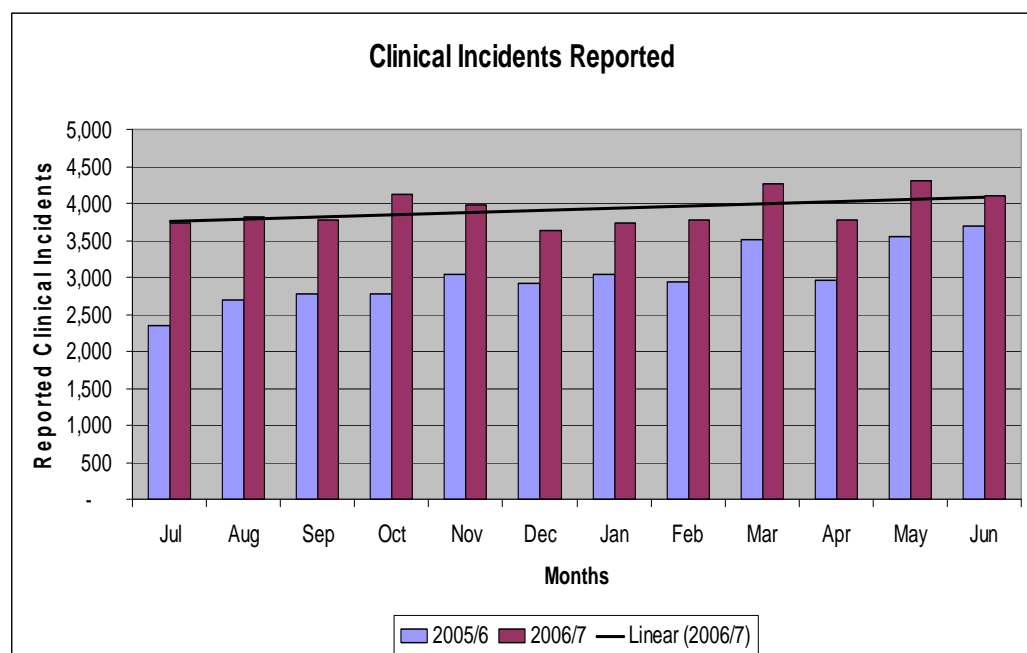
PART 2 – CLINICAL INCIDENTS REPORTED INTO PRIME SYSTEM

A) QUEENSLAND HEALTH CLINICAL INCIDENT INFORMATION SYSTEM (PRIME CI)

PRIME CI is a web-based, electronic incident management system that allows for incident reporting and management actions on any networked computer within Queensland Health.

B) INCREASED CLINICAL INCIDENT REPORTING BY STAFF INTO PRIME CI

Reporting of clinical incidents during 2006/7 has grown by 30% compared with the 2005/6 fiscal year³⁹. *Graph 1* shows the numbers of clinical incidents reported into PRIME CI month by month, for 2005/6 and 2006/7. The high proportion (77%) of incidents reported that **did not** cause patient harm, is evidence of an improved safety culture in Queensland Health. Organisations that have a healthy reporting culture are known to be safer⁴⁰.



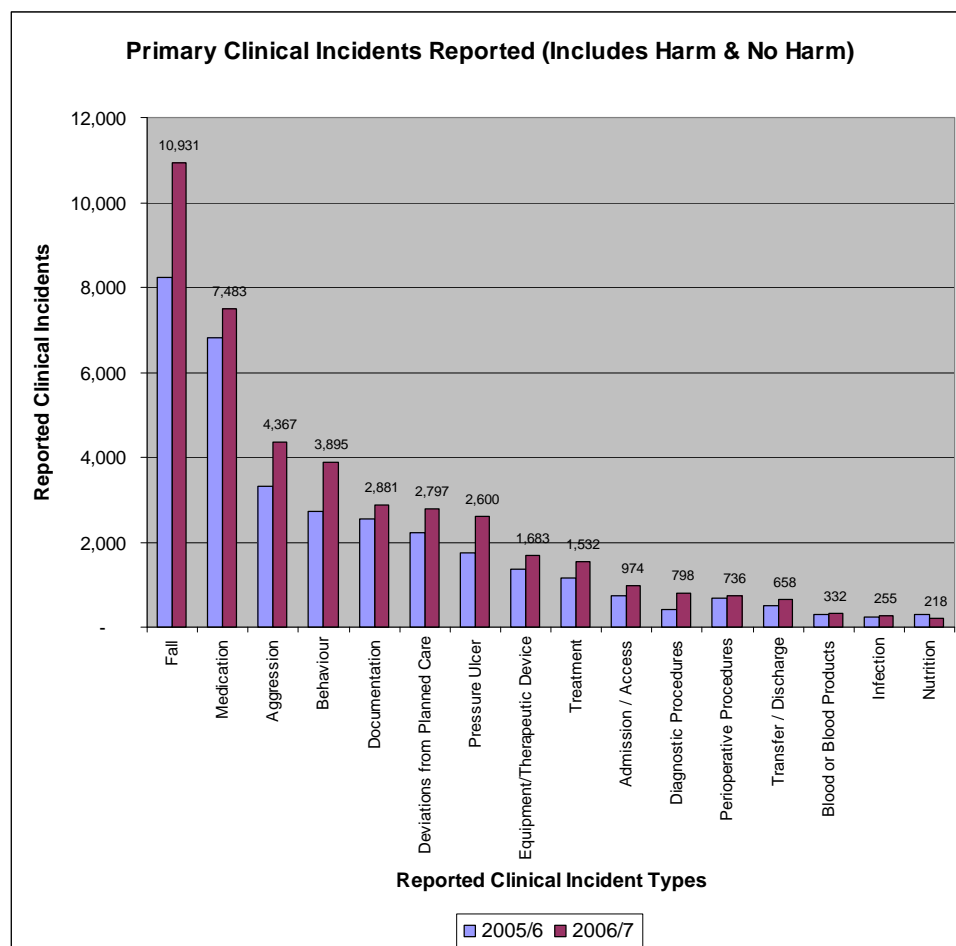
Graph 1: Clinical incidents reported into PRIME CI 2005/6 and 2006/7.

³⁹ Fraser Coast and Gympie did not implement PRIME CI until late 2007.

⁴⁰ Billings CE. Some hopes and concerns regarding medical event reporting systems: lessons from the NASA aviation safety reporting system (ASRS). *Arch Pathol Lab Med.* 1998;121:214–215.

C) REPORTED PRIMARY CLINICAL INCIDENT TYPES

During 2006/7, the 30% increase in reporting of clinical incidents was relatively evenly spread across all primary incident types, with falls and medication incidents, the most commonly reported.

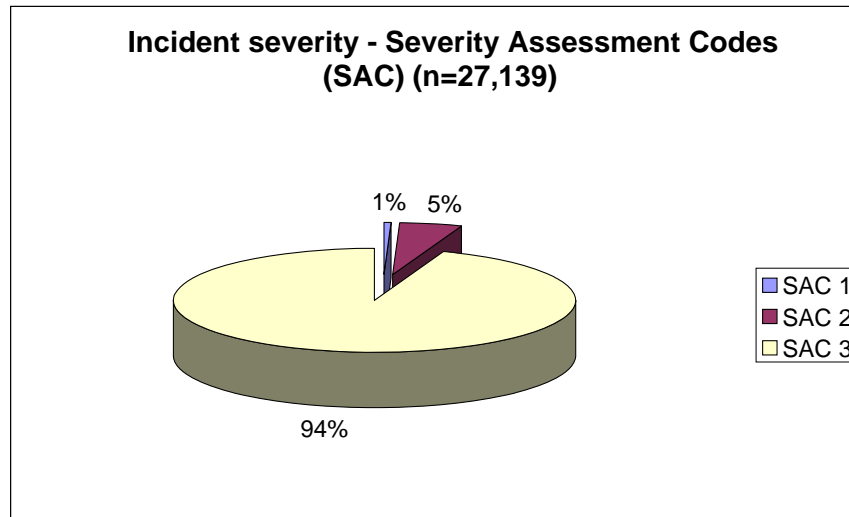


Graph 2: Primary clinical incident types reported 2005/6 and 2006/7.

D) CONSEQUENCE OF INCIDENTS – SEVERITY ASSESSMENT CODES (SAC)

From December 2006, PRIME CI changes were made to align with the clinical incident *Standard* (2006). This enabled staff reporting incidents to assign a Severity Assessment Codes or SAC. SAC is a measure of consequence as follows: SAC 1 – *death or permanent loss of function*; SAC 2 – *temporary loss of function*; SAC 3 – *minor or no injury* (unrelated to the natural course of the underlying condition).

Note: The data in Graph 3 is from January to June 2007 only, due to changes to the PRIME CI software during this period.

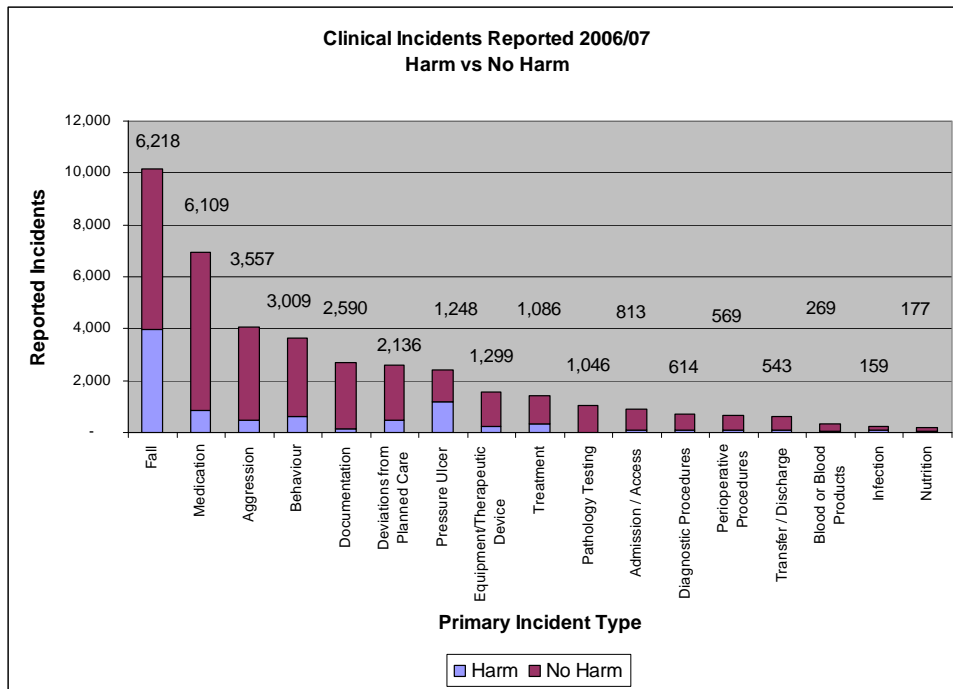


Graph 3: Incident severity - Severity Assessment Code (Jan – June 2007).

E) REPORTED *HARM* AND *NO-HARM*⁴¹ INCIDENTS BY PRIMARY INCIDENT TYPE

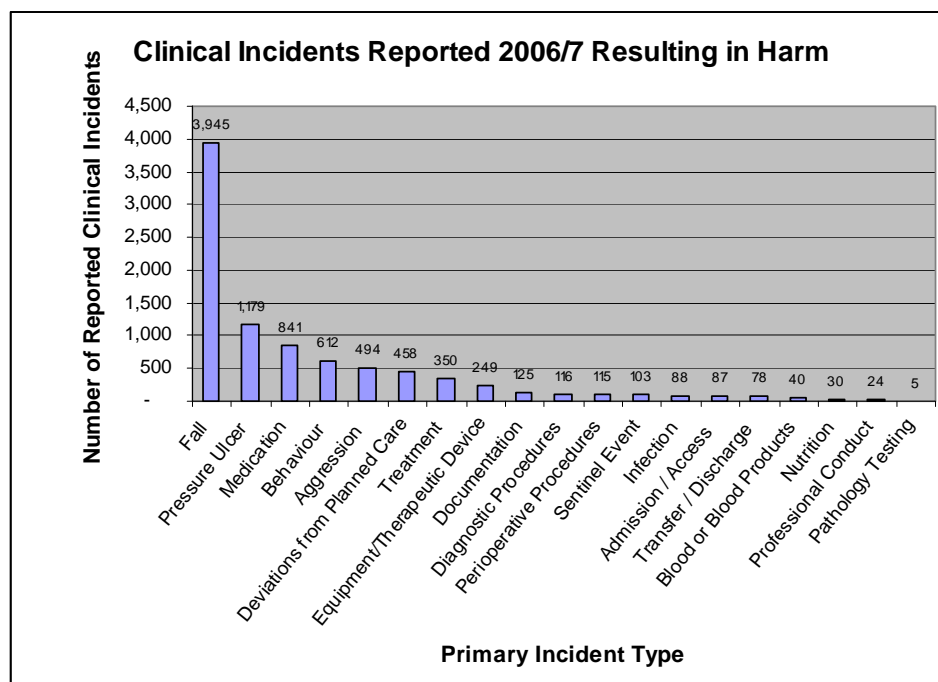
Changes in PRIME CI now enable the reporting of incidents by severity code. SAC 3 incidents are generally limited to *near miss* incidents or incidents with very minor consequence. These have been grouped as *no-harm* incidents. SAC 1 and SAC 2 events have been combined, and represented as *harm* incidents.

⁴¹ *No-Harm* pressure ulcers involve erythema only (Stage 1)

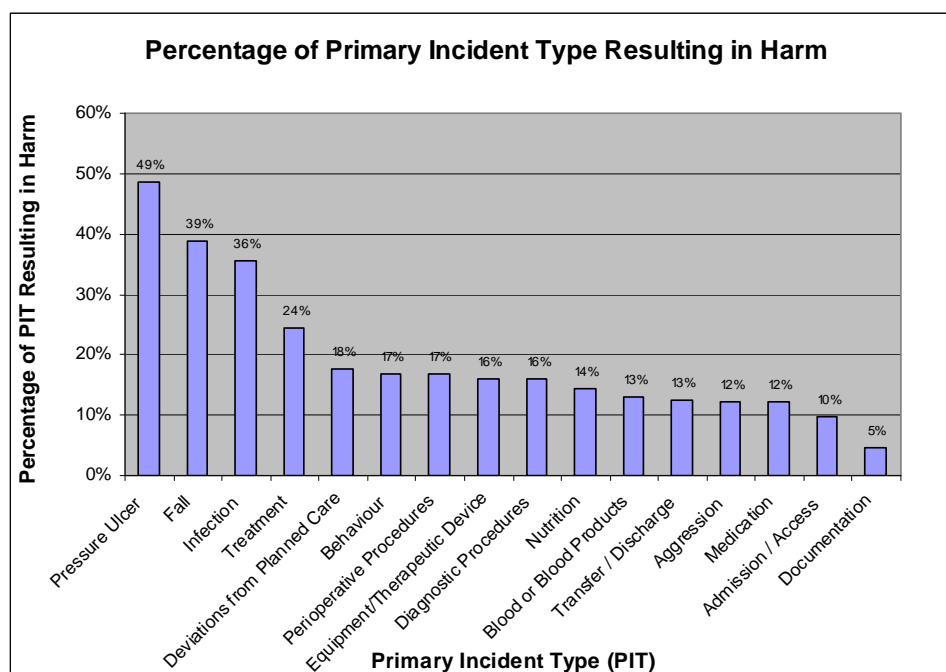


Graph 4: Harm versus no-harm incidents reported 2006/7.

When no-harm incidents are excluded, falls injury remains by far the most commonly reported event. This is followed by pressure ulcers, medication events and behaviour and aggression incidents.



Graph 5: Harm incidents reported 2006/7



Graph 6: Percentage of reported primary incident types that result in harm.

For each primary incident type, the percentage of reported incidents that result in harm varies significantly. For example, almost 50% of falls and pressure ulcer incidents reported result in patient harm; however, only around 10% of medication incidents reported resulted in patient harm.

E) INCIDENT CONTRIBUTING FACTORS REPORTED IN PRIME CI

Factors contributing to clinical incidents are recorded by staff by entering data into PRIME CI. These fields are not mandatory, and multiple entries may be made for a single incident. Managers may also add or amend these data after incident analysis has been undertaken.

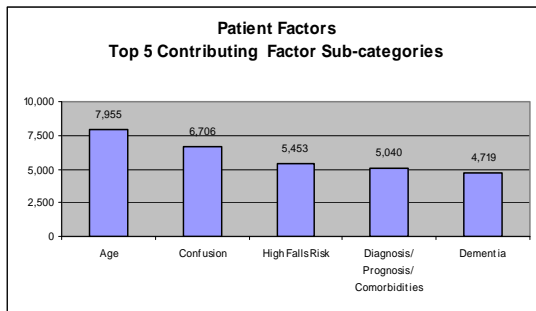
The taxonomy used for categorisation is based on human factors and accident causation theories of Professor James Reason⁴², and includes the categories listed in Table 4.

Contributing Factor Categories	Subcategories
Patient Factors	a) age; b) confusion; c) high falls-risk; d) diagnosis/prognosis/comorbidities; e) dementia
Task Factors	a) routine; b) time constraints; c) simple; d) complex; e) emergency
Staff/Practitioner Factors	a) distraction or inattention; b) communication – care/treatment; c) instructions not followed or mis-interpreted; d) knowledge/skills issues; e) workload issues
Team Factors	a) irregular team; b) team culture/morale; c) lack of defined roles; d) authority gradients
Environment/Equipment Factors	a) equipment-fault; b) environment-physical layout; c) equipment-inappropriate; d) equipment-design; e) environment-access/isolation
Organisational Factors	a) staffing patterns-organisation requirement; b) organisational culture issues; c) lack of access to appropriate information; d) staffing patterns-trainees/casuals/locums; e) administrative support issues

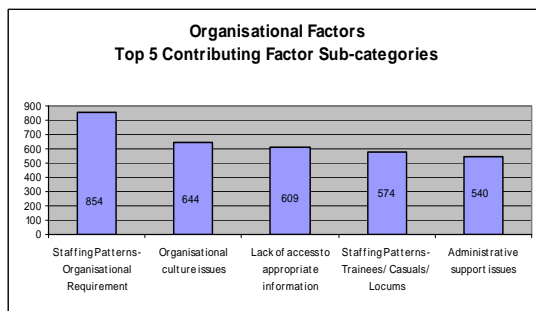
Table 4: Clinical incident contributing factor categories.

⁴² Reason J. Human error: models and management. *BMJ* 2000; 320: 768-70 available at <http://bmj.bmjournals.com/cgi/reprint/320/7237/768.pdf>

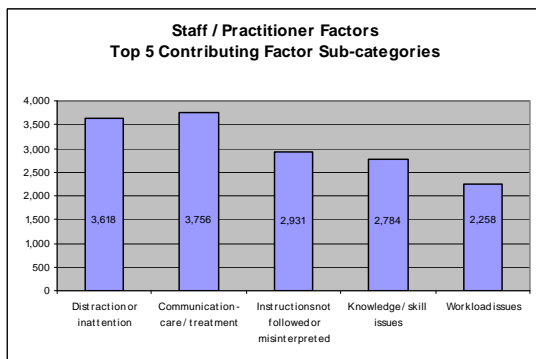
Graphs 7 to 12 represent the contributing factors reported for the clinical incidents reported during the 2006/7 year. (Number of clinical incidents = 46,990; number of contributing factors = 82,703)



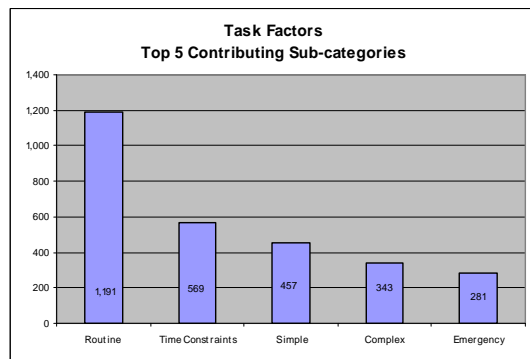
Graph 7: Patient Factors



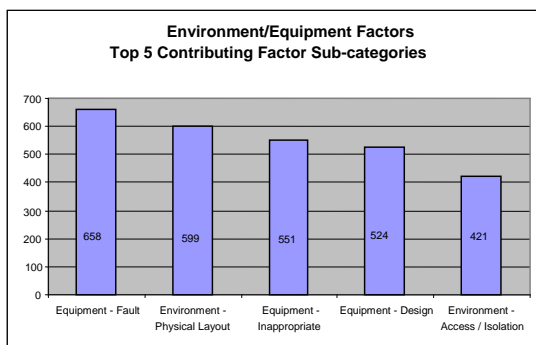
Graph 8: Organisational Factors



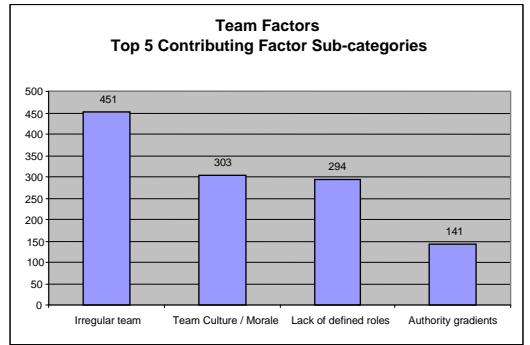
Graph 9: Staff/Practitioner Factors



Graph 10: Task Factors



Graph 11: Environment/Equipment Factors



Graph 12: Team Factors

SECTION 2: KEY MESSAGES

- ✓ During 2006/7, the following events were reported to the Patient Safety Centre:
 - 49 Sentinel Events (national definitions); (19 x SAC1; 10 x SAC2; 20 x SAC3)
 - 108 *Supplementary* Reportable Events (Queensland Health SAC1 definitions).
- ✓ 46,990 clinical incidents were reported using the PRIME CI system. This represents a 30% increase in reported incidents compared with 2005/6.
- ✓ 77% of the reported clinical incidents did not lead to patient harm; 23% of incidents were associated with patient harm.
- ✓ The high proportion (77%) of incidents reported that did not cause patient harm is evidence of an improved safety culture in Queensland Health. **Organisations that have a healthy reporting culture are known to be safer.**
- ✓ The most commonly reported adverse events (incidents which caused patient harm) were *falls injury* (3,945); *pressure ulcer* (1,179); *medication event* (841); and *aggression/behaviour* events (612/494).
- ✓ The ratio of 'harm' to 'no harm' incident reports varies by primary incident type. Approximately 1 out of every 2 incident reports of *falls* and *pressure ulcers*; 1 out of every 4 *treatment-related* incident reports; and 1 in every 10 *medication incident* reports, were associated with patient harm.
- ✓ The commonest reported contributing factors for clinical incidents are *patient factors* and *staff/practitioner* factors. Older, confused patients with complex problems and high falls risk are most at risk of adverse events.
- ✓ Australian data suggests that up to 50% of adverse events are preventable^a, 70-80% have a component of human error^b, and the error is twice as likely to be one of omission (52%) than commission (27%)^a.

^a) Wilson, R, Runciman WB, Gibberd RW, et al. The Quality in Australian Health Care Study. *Med J Aust* 1995;163:458-471.

^b) Runciman WB, Webb RK, Lee R, Holland R. System failure: An analysis of 2000 incident reports. *Anaesth Intensive Care* 1993;21:529-542.

SECTION 3

FROM LEARNING TO ACTION – ACTIONS TO IMPROVE PATIENT SAFETY IN QUEENSLAND HEALTH 2006/7

Section 3 provides a snapshot of state-wide patient safety improvement initiatives in the Queensland public health system, during 2006/7. It is not possible to include all information in this report; readers are encouraged to follow relevant links for detailed information on safety improvement programs.

A) HOW DOES QUEENSLAND HEALTH USE CLINICAL INCIDENT DATA FOR LEARNING?

Because the numbers of incidents *reported* do not accurately reflect the *actual* number of incidents occurring, these data can't be used to measure safety performance. However, analysis of clinical incidents provides a rich source of information on *what* incidents occur, *why* they occur and *what* can be done to prevent recurrence.

The Queensland Health Patient Safety Centre collects incident data from all Queensland Health services through the PRIME CI database and Root Cause Analysis (RCA) reports. These data are coded, aggregated, analysed, de-identified and provided to various district, area, state and national agencies responsible for leading patient safety improvement.

The Queensland Health Patient Safety and Quality Board is the peak public sector governance body for patient safety. Queensland Health also works in partnership with the Australian Commission for Safety and Quality in Healthcare, in using these data to develop patient safety initiatives. In addition, key service groups, professional groups and state-wide committees increasingly use these data to inform clinical improvement activities. Examples of Queensland public sector groups using these data include: Area Clinical Governance Units, Safe Medication Practice Unit⁴³, Blood Management Program⁴⁴, Falls⁴⁵ and Pressure Ulcer⁴⁶ Collaboratives and state-wide Mental Health Network⁴⁷.

Lessons learnt are shared in several other ways including:

- Bi-monthly *Patient Safety Matters* Newsletter⁴⁸
- Alerts and Advisories
- Training programs include case studies: eg. RCA & Open Disclosure
- Publications and reports⁴⁹.
- Presentations and Grand Rounds

“Queensland Health Patient Safety and Quality Board brings consumers and key staff together to oversee improvements in patients safety and quality”



⁴³ <http://qheps.health.qld.gov.au/qhmms>

⁴⁴ <http://qheps.health.qld.gov.au/qbmp/home.htm>

⁴⁵ <http://www.health.qld.gov.au/patientsafety/falls/webpages/fip.asp>

⁴⁶ <http://www.health.qld.gov.au/patientsafety/pupp/webpages/qpupc.asp>

⁴⁷ <http://www.health.qld.gov.au/patientsafety/mh/webpages/mhhome.asp>

⁴⁸ <http://www.health.qld.gov.au/patientsafety/webpages/pscmatters.asp>

⁴⁹ *Patient Safety: From Learning to Action* Report 2007 available at: <http://qheps.health.qld.gov.au/psc/documents/Patient%20Safety%20Report.pdf>

B) PATIENT SAFETY PROGRAMS IN HIGH RISK AREAS

Queensland Health has programs focussed on known high risk areas of patient safety. Such programs have a long-term focus of building capacity and skills in our workforce and introducing sustainable system changes to improve patient safety.

FALLS INJURY PREVENTION

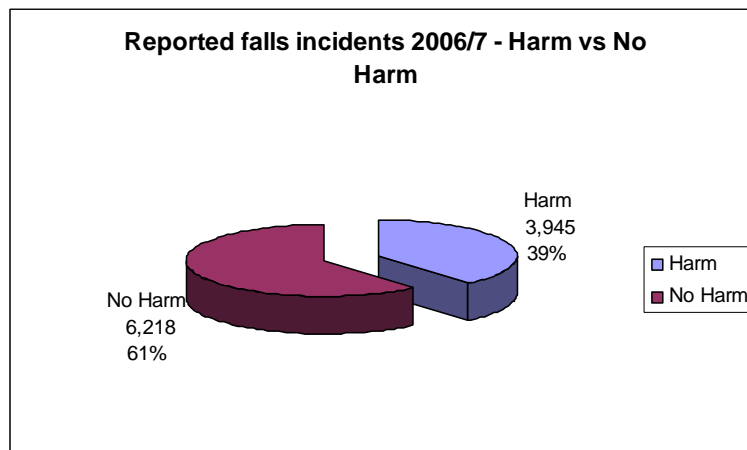


Falls are the single biggest reason for admission to hospital and presentation to an emergency department in people over the age of 65 years⁵⁰. Along with cognitive impairment and incontinence, falls are one of the major factors in precipitating admission to residential aged care facilities⁵¹.

Older people entering hospital are particularly at risk of falls. The impact of illness, unfamiliar environment, medications, mobility, hearing and visual problems, all contribute to this risk. Implementation of targeted prevention strategies can produce a reduction in falls injury in acute hospitals and residential aged care facilities⁵².

Incident notifications - Falls

In the period July 1, 2006 to June 30, 2007, 10,931 falls incidents were reported into PRIME CI. Graph 13 shows falls incidents with and without harm.



Graph 13: Falls incidents – Harm vs No-Harm 2006/7.

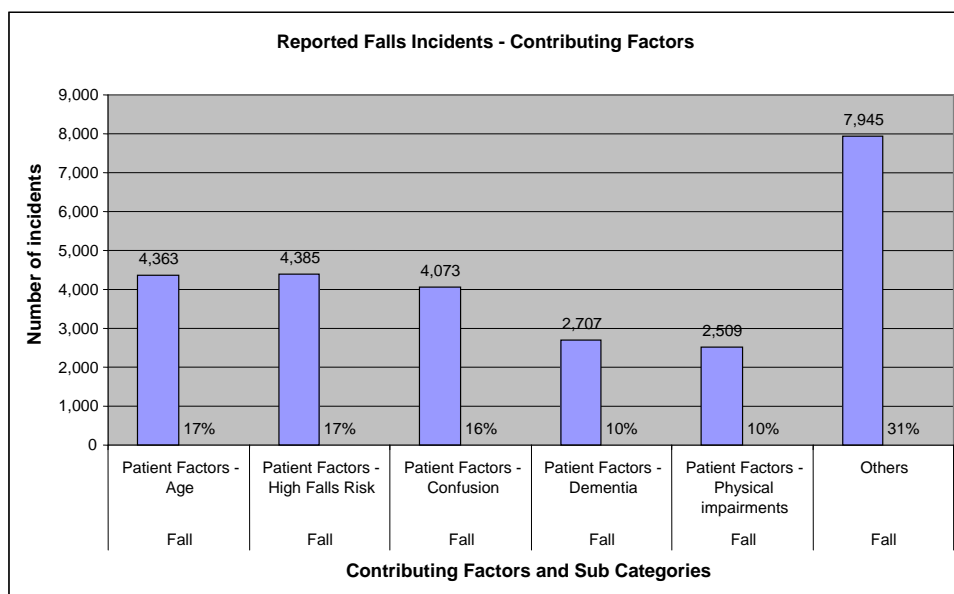
⁵⁰ Davies A, Kenny R. Falls presenting to accident and emergency. *Age and Aging* 2000;25:362-6.

⁵¹ Rubenstein L, Josephson K, Ostewial D. Falls and fall prevention in the nursing home. *Clinics in Geriatric Medicine* 1996; 12(4): 881-902.

⁵² Healey F, Monro A, Cockram A, Adams V, Heseltine D. Using targeted risk factor reduction to prevent falls in older patients: a randomised controlled trial. *Age and Aging* 2004; 33: 290-95.

Contributing factors - Falls

During this reporting period, the top five contributing factors identified by staff reporting falls incidents are all patient factors. These are illustrated in Graph 14.



Graph 14: Falls primary incident type – Top 5 Contributing Factors.

Queensland Health Action - Falls

A statewide clinician-led cross-continuum Falls Injury Prevention Collaborative was established in March 2006 to lead statewide evidence-based initiatives to reduce falls injuries⁵³. This involves a partnership between public and private hospitals, residential aged care organisations, health promotion and community providers. Activities include:

- Baseline snapshot surveys across Health Service Districts (2005)
- Working with Health Service Districts, Patient Safety Officers and delegates to plan strategies for support and sustainability of Falls Injury Prevention Programs
- Implementing the ACSQHC *Preventing Falls and Harm From Falls in Older People (2005)*⁵⁴ throughout Health Service Districts
- Partnerships with Health Promotion, Community, Aged Care and private facilities have been established to share information, develop standardised initiatives and provide a consistent message to staff, patients and carers.

2006-2007 Priorities & Objectives of the Collaborative are:

- To improve incident reporting indicators for falls and to modify the reports available to clinicians (PRIME CI)
- To improve education/training/awareness programs for both clinicians and consumers
- To implement service development initiatives including:
 - (i) Specialist Falls Prevention Resource Officers.
 - (ii) Falls Clinics (community or outpatient).
 - (iii) Cross continuum approaches where appropriate statewide (including primary prevention programs).
- Research regarding best practice – eg non-slip socks, low low beds.



⁵³ <http://www.health.qld.gov.au/patientsafety/falls/webpages/fipc.asp>

⁵⁴ <http://www.health.qld.gov.au/patientsafety/falls/webpages/fipres.asp>

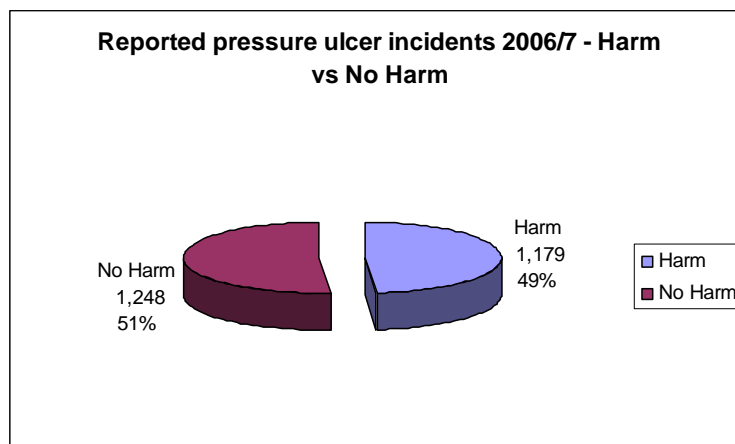
PRESSURE ULCER PREVENTION



Pressure ulcers are a common cause of preventable patient harm, in hospitals, residential aged care facilities and in the community.

Estimates of pressure ulcer prevalence range from 14.8%⁵⁵ to 37%⁵⁶. The human and financial impact of pressure ulcers is significant. In 1997, the estimated cost of managing pressure ulcers in Australia was \$350 million per annum⁵⁷. A Cochrane review⁵⁸ on pressure ulcer relieving surfaces demonstrated that the only surface that consistently outperformed the traditional hospital mattress in reducing the incidence of pressure ulcers was a high specification foam mattress.

Incident notifications - Pressure Ulcers



Graph 15: Pressure ulcer incidents – Harm vs No Harm 2006/7⁵⁹

In the period July 1, 2006 to June 30, 2007, 2,427 pressure ulcer incidents were reported into PRIME CI. Graph 15 shows pressure ulcer incidents with and without harm.

⁵⁵ Amlung S, Miller W, Bosley L. The 1999 national pressure ulcer prevalence survey: a benchmarking approach. *Adv Skin Wound Care* 2001; 14:297-302

⁵⁶ Prentice J, Stacey MC, Lewin JEK. An Australian model for conducting pressure ulcer prevention surveys. *Primary Intention* 2003;11(2):87-109.

⁵⁷ Woolridge M. Address at the launch of the Australian Medical Sheepskin. Melbourne: StVincent's Hospital; 1997 2nd July.

⁵⁸ Cullum N, Deeks J, Sheldon T, et al. Beds, mattresses and cushions for pressure sore prevention and treatment (Cochrane Methodology Review). The Cochrane Library, Issue 4, 2003. Chichester UK: John Wiley.

⁵⁹ These data do not separate pressure ulcers present on admission to hospital from those arising during admission. Reports of "No Harm" pressure ulcers generally refer to Stage 1 injury with erythema of skin.

Queensland Health Action - Pressure Ulcers

A multidisciplinary collaborative steering committee⁶⁰ representing the private, public and community sectors meets regularly to discuss and drive key directions for the *Pressure Ulcer Prevention Program*. The annual targets of the collaborative currently include:

- Updating the *Queensland Health Pressure Ulcer Prevention and Management Guidelines (2004)*⁶¹ to include additional guidelines for pressure ulcer prevention in care of:
 - Patients with morbid obesity
 - Paediatric patients
 - Spinal patients
 - Patients in the community setting
- Development of patient information materials
- Funding replacement of all non pressure-reducing "vinyl" mattresses with pressure reduction mattresses (completed in 2007)
- Improve pressure ulcer reporting and indicators across the health care continuum
- Provide education and training tools across the health care continuum
- Providing support to the Pressure Ulcer Prevention Collaborative members- a group of clinicians across Queensland.

Prevention better than cure:

"During 2006/7, all non-compliant vinyl mattresses were replaced with pressure reduction mattresses which will lead to less harm from pressure ulcers"

MEDICATION ADVERSE EVENT PREVENTION



CaSS | Medication Services Queensland

A CLINICAL AND STATEWIDE SERVICE

Every year in Australia, almost 200 million prescriptions are dispensed. In any two week period, medication has been taken by 70% of the overall population and greater than 90% of the elderly⁶². Research in Queensland⁶³ found the error rate for prescriptions in a major hospital to be 2.4%; with *wrong dose* 1.0%; *missing dose* 0.6% and *missing frequency* 0.4%.

Incident notifications - Medication Adverse Events

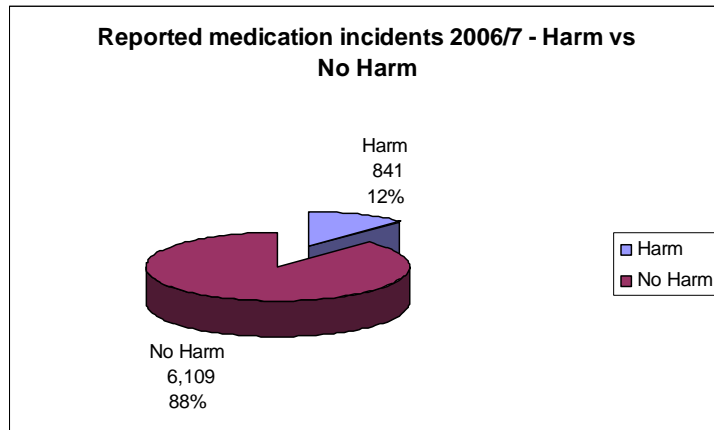
In the period July 1, 2006 to June 30, 2007, 6,950 medication incidents were reported into PRIME CI. Graph 16 shows medication incidents with and without harm.

⁶⁰ <http://www.health.qld.gov.au/patientsafety/pupp/webpages/qpupc.asp>

⁶¹ http://www.health.qld.gov.au/quality/Publication/pressure_mgt2004.pdf

⁶² Australian Bureau of Statistics (ABS) 1995 National Health Survey Use of Medications Australia. Catalogue No 4377.0. Canberra: ABS, 1999. *cited in* Runciman WB, Roughead EE, Semple S, Adams RJ. Adverse drug events and medication errors in Australia. *International Journal for Quality in Health Care* 2003; 15: i49-i59

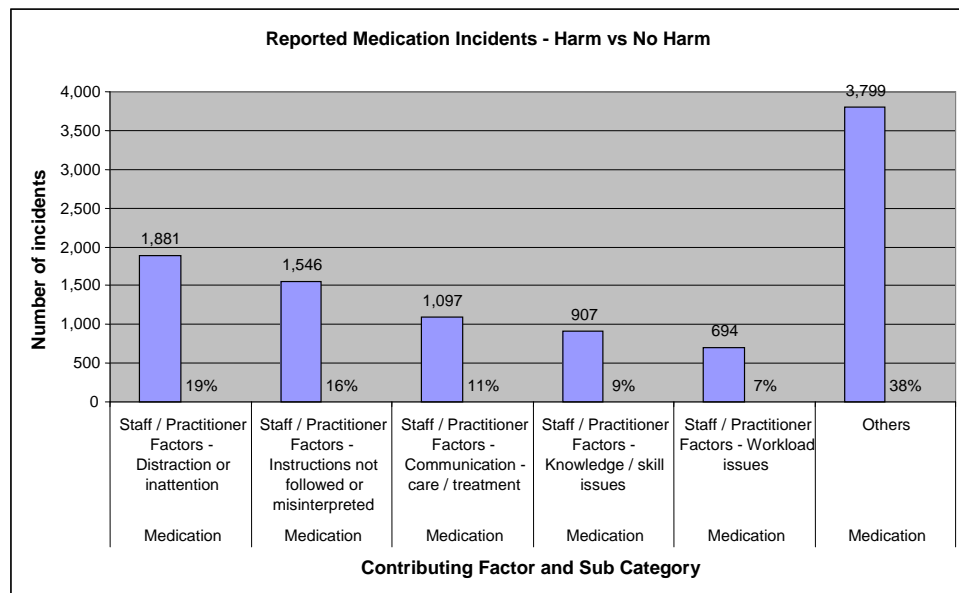
⁶³ Coombes ID, Pillans PI, Storie WJ, Radford JM. Quality of medication ordering at a large teaching hospital. *Aust J Hosp Pharm* 2001;31:102-106.



Graph 16: Medication incidents – Harm vs No Harm 2006/7.

Contributing factors - Medication Adverse Events

During this reporting period, the top five contributing factors identified by staff reporting medication incidents are staff/practitioner factors. These are illustrated in Graph 17.



Graph 17: Medication primary incident type – Top 5 Contributing Factors 2006/7.

Queensland Health Action - Medication Adverse Events

The Queensland Health Safe Medication Practice Unit (SMPU)⁶⁴ in partnership with the Health Service Districts, have been leaders in improving medication safety.

SMPU has a comprehensive range of programs aimed at improving patient safety through reducing medication adverse events. Key activities include:

- Introduction of safer systems for the use of drugs commonly associated with adverse events: insulin (for diabetes); opiates (for use in pain)

⁶⁴ <http://www.health.qld.gov.au/qhcss>

control); warfarin and heparin (blood thinning drugs) and; intravenous fluids

- Introduction of a standardised hospital drug chart in all Queensland Health facilities. This has now been taken up nationally
- Implementation of an electronic discharge medication system that provides a printed record, especially designed for patients, at discharge
- Processes to ensure that 100% of hospital in-patients have a medication review during admission; utilising tele-pharmacy for rural and remote patients
- Collection and reporting of data on improved outcomes from medication safety initiatives
- Developing a strategy for Queensland Health electronic medication management. *The use of electronic systems to support decision making in prescribing and administering medications has been shown to improve patient safety.*

Standardise for safety

“All Queensland Health hospitals now use a standard medication order sheet. This minimises the risk of medication mistakes and improves patient safety”

BEHAVIOUR AND AGGRESSION

Safety for ALL



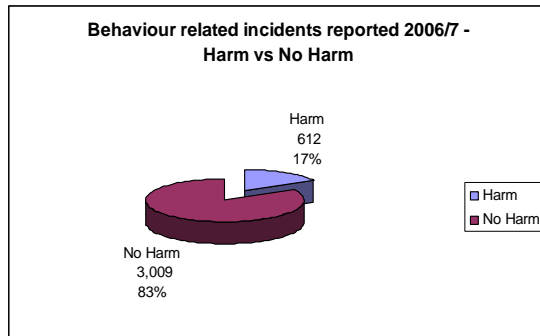
Aggression and physical violence in hospitals and health services is a significant issue in Australia and worldwide. In an Australian study of incident reports⁶⁵, 9% of all reported incidents involved physical violence or violent verbal exchange. The study found the following key facts about these incident reports:

- The commonest locations of these reported incidents is:
 - emergency departments; and
 - mental health units.
- Contributing factors:
 - Patient-related – mental health related (40%); dementia (15%); confusion (9%); alcohol or drug intoxication (6%)
 - Staff-related – “insufficient staff”; “communication problems”; “inexperienced staff”
 - System-related – “security problems”.
- Outcomes:
 - Change of treatment (40%)
 - Restraint team called (16%)
 - Police or security called (15%)
 - Staff injury (5%).

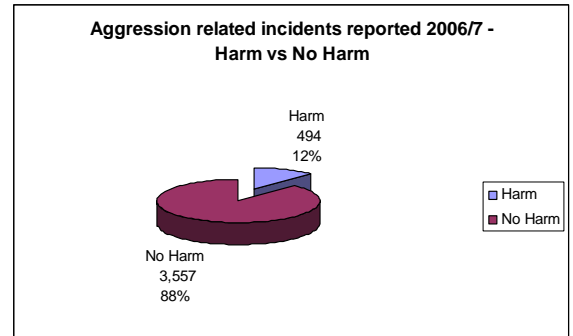
Incident notifications - Behaviour and Aggression incidents

Incident reports with a primary incident type of ‘Behaviour’ (n= 3,621) ‘Aggression’ (n= 4,051) are the 4th and 5th most commonly reported clinical incident in PRIME CI during 2006/7.

⁶⁵ Beneveniste KA, Hibbert PD, Runciman WB. Violence in health care: the contribution of the Australian Patient Safety Foundation to incident monitoring and analysis. *MJA* 2005; 183 (7): 348-351.



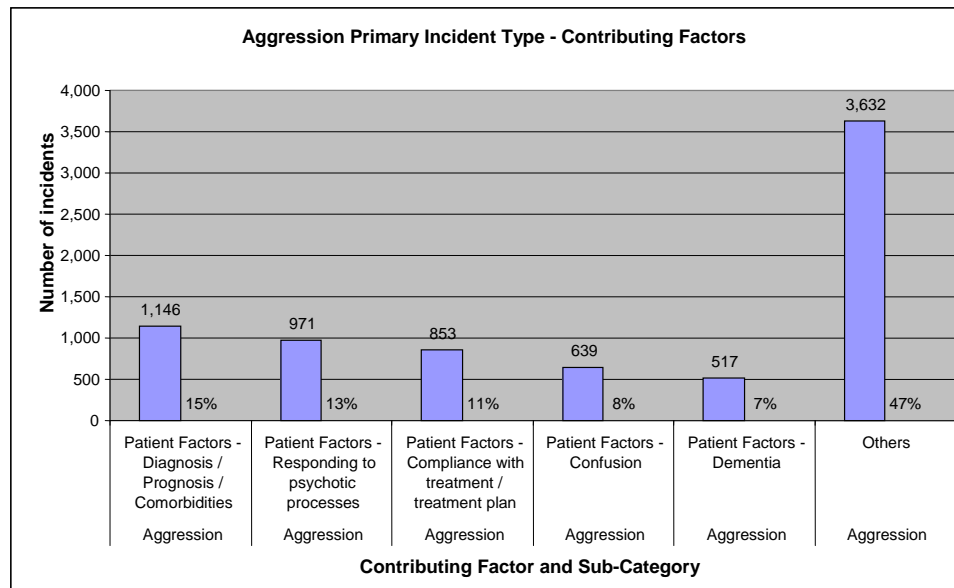
Graph 18: Behaviour-related incidents 2006/7 – Harm vs No Harm.



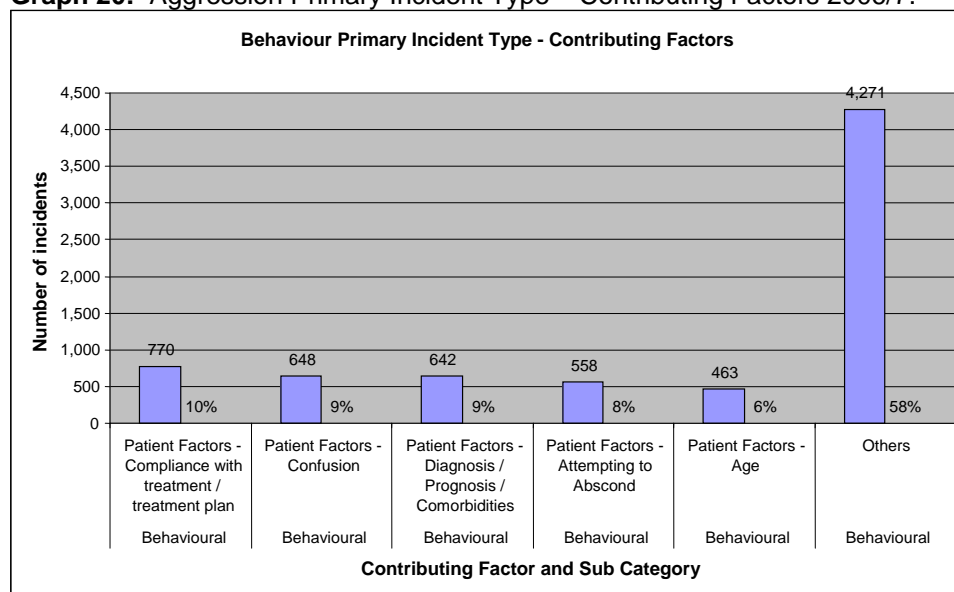
Graph 19: Aggression-related incidents 2006/7 – Harm vs No Harm.

Contributing factors - Behaviour and aggression incidents

During this reporting period, the top five contributing factors identified by staff reporting behaviour and aggression related incidents are patient factors. These are illustrated in Graphs 20 and 21.



Graph 20: Aggression Primary Incident Type – Contributing Factors 2006/7.



Graph 21: Behaviour Primary Incident Type – Contributing Factors 2006/7.

Queensland Health Action - Behaviour and aggression incidents

Behaviour and aggression incidents have previously been associated with staff safety. Preliminary review of incident data suggests that staff are reporting both staff **and** patient injury from such incidents into PRIME CI. Further analysis of this data is required to better understand the specific high risk areas and remedial actions.

Action already taken, or underway includes:

- Queensland Health Occupational Health Safety Management System – Occupational Violence Prevention and Management Implementation Standard⁶⁶
- Development of an Occupational Violence Risk Assessment Tool to facilitate violence management plans
- De-escalation training for staff and introduction of violence management plans⁶⁷
- Improved design of buildings⁶⁸
- In –depth analysis of qualitative incident data to inform future strategies.

MENTAL HEALTH PATIENT SAFETY AND SUICIDE PREVENTION



Serious mental disorders have an associated high rate of mortality through suicide despite optimal care. Rates of death by suicide of 10% of people with schizophrenia and 15% of people with bipolar affective disorder are generally accepted as existing in developed countries worldwide. It is estimated that the suicide rate for individuals with serious mental illness is 7-10 times that in the general population.

Despite these data, we are constantly exploring ways to prevent the tragedy of suicide for the individual patient, their families and the staff that care for them.

Incident notifications - Mental health patient safety and suicide prevention

Thirty-two mental health related SAC 1 events were reported to the Patient Safety Centre during the 2006/7 reporting period:

⁶⁶ http://qheps.health.qld.gov.au/safety/safety_topics/standards/ohsms_2_1_21.pdf

⁶⁷ http://qheps.health.qld.gov.au/safety/occup_violence/training_manual.htm

⁶⁸ <http://www.healthfacilityguidelines.com.au/guidelines.htm>

Mental Health Related Events ⁶⁹	Definitions	Number of reports
Mental Health inpatient	Death from natural causes	5
	Suspected suicide of mental health inpatient whilst on approved leave	5
	Suspected suicide of mental health patient after absconding from inpatient care	6
Community Mental Health	Suspected suicide of a mental health client receiving care in the community	14
Emergency Department related	Suspected suicide of any patient within 24 hours of attendance at an emergency department	2

Table 5: Mental Health Related Events.

Queensland Action - *Mental Health patient safety and suicide prevention*

In February 2004, the Director-General of Queensland Health established a committee to undertake the Queensland Review of Fatal Mental Health Sentinel Events (the Review). The task of the Review was to investigate certain deaths involving people with serious mental illness that occurred in a two year period (1 January 2002-31 December 2003), and to determine if there were systemic issues in mental health services that needed to be addressed. The committee examined 45 deaths that met the criteria for the 4 categories - inpatient suicides, unexpected deaths, homicides and police shootings. The Report and recommendations⁷⁰ formed the basis for Mental Health patient safety initiatives.

Action already taken or underway includes⁷¹:

- Standardised processes and tools for mental health clinical practices including assessments, treatment and discharge planning
- Removing potential means of suicide in mental health units
- Safer models of care for mental health clients accessing emergency departments
- Increased integration of mental health services and alcohol, tobacco and other drugs (ATODS)
- Developing an information system that assists mental health and emergency department staff to timely and accurate patient information.

Hand-hygiene facts:

Average hand washing time per 8-hour nursing shift:

Soap & water:

56 minutes (based on 7 x 60 second hand washes per hour).

Alcoholic gel:

18 minutes (based on 7 x 20 second hand washes per hour)

Voss A, Widmer AF. *Infect Control Hosp Epidemiol* 1997; 18: 205-208

INFECTION SURVEILLANCE AND PREVENTION

Clean hands are life savers



Healthcare associated infections (HAIs) pose a serious threat to all who are admitted to hospital. On average, infections complicate 7% to 10% of hospital admissions with 10% to 70% of these infections being preventable. In preventing HAIs the Centre for Healthcare Related Infection Surveillance and Prevention (CHRISP) have implemented a statewide hand hygiene program (Clean hands are life savers) aimed at improving hand hygiene compliance. The program is a systematic, multifaceted approach which focuses on changing the culture and

⁶⁹ These deaths reported under the generic SAC 1 definition: "Death or permanent loss of function unrelated to the natural course of the underlying condition".

⁷⁰ http://www.health.qld.gov.au/mental_hlth/publications/Achieving_Balance.pdf

⁷¹ http://www.health.qld.gov.au/mentalhealth/docs/balance_update7.pdf

ultimately health care workers hand hygiene behaviour. Some specific strategies include:

- Observational audits
- Alcoholic hand gel implemented at the bed side
- The establishment of teams to influence behaviour and advocate the change
- Recruitment of medical leadership.

The program to date has achieved an improvement in state wide hand hygiene compliance.

To assist facilities to comply with reporting requirements for the surgical antibiotic prophylaxis component of the HQCC surgical safety standard CHRISP, has provided guidance for the local development of surgical antibiotic prophylaxis guidelines and updated the surgical surveillance module of its data collection and analysis software.

Queensland Health HAI surveillance data are not routinely collected through incident reporting. Infection data are actively collected through a network of large to medium size hospitals who regularly contribute data to a statewide system. These data are collected, analysed and reported separately by CHRISP⁷² which is liaising with Health Community Councils regarding local release of surveillance data.

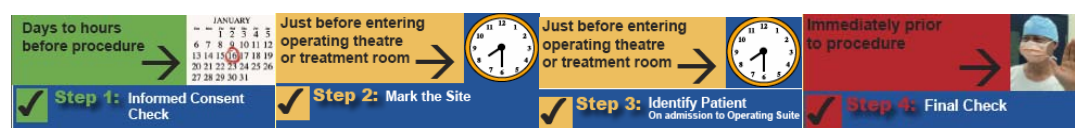
Queensland Action - Infection surveillance and prevention

Queensland Health has a comprehensive infection surveillance and prevention program. Key actions include:

- Hand hygiene program⁷³
- Infection control management plans for all hospitals⁷⁴
- I-CARE Program to prevent blood stream infections⁷⁵
- Infection surveillance through eICAT system – providing guidance and support to Queensland Health facilities in developing standardised surveillance and analysis methods that allow timely recognition and intervention of infection problems⁷⁶
- Staff Protect – protecting staff and patients through immunisation
- Sharps Safety Program⁷⁷.

“Hand Hygiene is the most effective and least expensive measure in the prevention of healthcare-associated infections”

ENSURING INTENDED SURGERY AND PROCEDURES (EIS&P)



Procedures on the wrong patient or body part are rare and totally preventable adverse events. In 2005 Queensland Health introduced a simple protocol in operating theatres to eliminate this adverse event. The protocol is a 4-Step check system⁷⁸ which includes marking the operative site with the surgeons initials and undertaking a final check just before surgery, where a ‘team check’ occurs.

⁷² <http://www.health.qld.gov.au/chrisp>

⁷³ http://www.health.qld.gov.au/chrisp/hand_hygiene/alcohol_HH.asp

⁷⁴ http://www.health.qld.gov.au/chrisp/icmp_pha/default.asp

⁷⁵ <http://www.health.qld.gov.au/chrisp/icare/about.asp>

⁷⁶ http://www.health.qld.gov.au/chrisp/surveillance/about_surv.asp

⁷⁷ <http://qhps.health.qld.gov.au/safety/communications/spotlight.htm>

⁷⁸ <http://www.health.qld.gov.au/patientsafety/eis/documents/26961.pdf>

Incident notifications - Ensuring Intended Surgery and Procedures

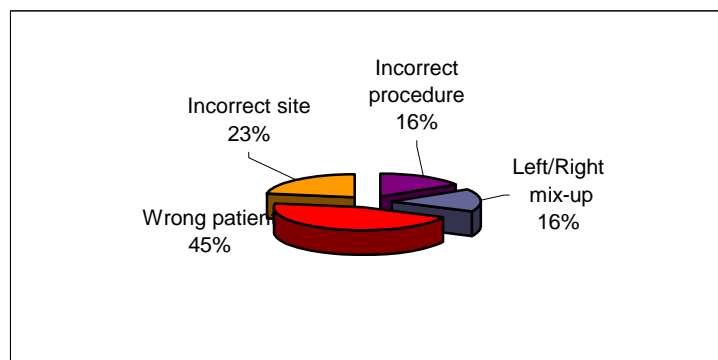
During 2006/7, there were 4 serious adverse events (death or permanent disability) due to procedures on the wrong patient or body part. There were a further 29 reports under this definition, where there was temporary or no harm. The significant increase in reports from the previous year was due to increased awareness due to the implementation of the EIS&P Program, causing the reporting of *near miss* and minor harm incidents.

National Sentinel Event Number (SE #)		Number of reports	Severity Assessment Code (SAC) ⁷⁹		
			SAC 1	SAC 2	SAC 3
SE 1	Procedures involving the wrong patient or body part	33	4	9	20

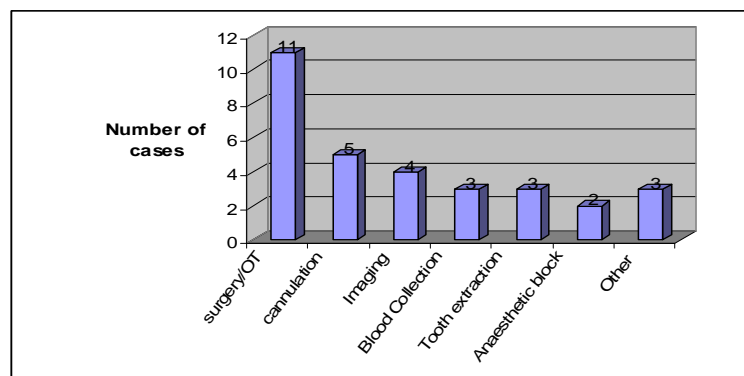
Table 6: Wrong Patient or Body Part Procedure Events.

Contributing factors - Ensuring intended surgery and procedures

Analysis of the RCA reports from these incidents has been undertaken. A summary of this analysis⁸⁰ demonstrates that almost half were 'wrong patient' events. It was also clear that this incident is also occurring outside of the operating theatre environment and includes areas such as dental, oncology, radiology, and pathology collection and testing.



Graph 22: Classification of procedures involving wrong patient or body part.



Graph 23: Procedure type causing reports of procedures involving the wrong patient or body part.

⁷⁹ Severity Assessment Code is a measure of the harm associated with the incident:

SAC 1 – death or permanent loss of function

SAC 2 – temporary loss of function

SAC 3 – minor or no injury

⁸⁰ <http://www.health.qld.gov.au/patientsafety/eis/documents/eissaf.pdf>

Queensland Action – Ensuring Intended Surgery and Procedures

The Patient Safety Centre in partnership with the Health Services Districts and the Clinical and State-wide Support Services (CaSS) continue to implement the protocol. Key actions include:

- Annual observation audits of compliance⁸¹ (n=649 cases):
 - 82% compliance with Final Check
 - 43% compliance with Site Marking
- Projects to expand the protocol into dental and radiology practice
- Policy review to address useability and compliance issues⁸².

“Hospitals are busy and complex places. A simple “pre-flight” safety check prevents procedures on the wrong patient or body part”

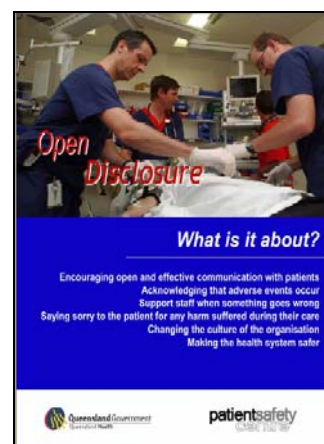
C) OTHER KEY PATIENT SAFETY INITIATIVES:

OPEN DISCLOSURE PROGRAM

The Patient Safety Centre completed the National Open Disclosure Pilot in 2006/7. Queensland managed the Pilot on behalf of the Australian Commission for Safety and Quality in Healthcare. The Final Report⁸³ and paper in the Medical Journal of Australia were released in April 2008.

Open Disclosure is the open discussion of incidents that result in harm to a patient. It includes:

- An apology
- A factual explanation of what happened
- Potential consequences
- Steps being taken to manage the event and prevent recurrence.



Queensland Action – Open Disclosure Program

Queensland Health is committed to full implementation of Open Disclosure across all health services. Actions include:

- Formal Open Disclosure required for all SAC 1 events
- Hi-fidelity training for senior clinicians to provide expert support for disclosure
- All districts will have trained clinicians by June 2008
- Medical school training pilot planned for 2008.

INFORMED CONSENT PROGRAM



Informed consent⁸⁴ is the process of providing all relevant information to a patient in order that they can make a decision about the best course of action for their own circumstances. Where procedures are involved, written consent is usually obtained. Components of *Informed Consent* may include:

⁸¹ <http://www.health.qld.gov.au/patientsafety/eis/webpages/eisaudit.asp>

⁸² <http://www.health.qld.gov.au/patientsafety/eis/webpages/eisrev.asp>

⁸³ [http://www.safetyandquality.gov.au/internet/safety/publishing_nsf/Content/3B994EFC1C9C0B22CA25741F0019FDEE/\\$File/EvaluationOf-Pilot-NOD-Std.PDF](http://www.safetyandquality.gov.au/internet/safety/publishing_nsf/Content/3B994EFC1C9C0B22CA25741F0019FDEE/$File/EvaluationOf-Pilot-NOD-Std.PDF)

⁸⁴ <http://www.health.qld.gov.au/informedconsent/beinformed.asp>

- Discussion with the health professional who is performing the procedure or treatment as an option for consideration
- Discussion with other professionals – eg general practitioner, anaesthetist, nurse or allied health professional
- Discussion with family and trusted friends
- Reading relevant literature
- Signing consent form.

Queensland Action – Informed Consent Program

Queensland Health has developed a comprehensive resource to assist professionals and patients in making decisions before surgery or other procedures⁸⁵. These resources are used in all Queensland Health facilities and also contribute to appropriate patient identification and correct site procedures. Current actions include:

- Revising and updating procedure specific consent forms and patient information
- New Anaesthetic consent forms
- External review of the program to determine its contribution to patient decision making.

CORONIAL MANAGEMENT

The coronial system has a key role in patient safety. Queensland Health reports deaths to the coroner in accordance with the Coroners Act 2003⁸⁶. Certain deaths investigated by the coroner lead to coronial inquests. Inquest reports and recommendations are made to address local or system-wide improvements.

Queensland Action – Coronial Management

The Patient Safety Centre works closely with the Office of the State Coroner. Current actions include:

- Improved compliance with Coroners Act 2003 through training, staff resources and process redesign
- Policy and legislation review
- Coordination of Queensland Health responses to Inquest recommendations
- Use of data for patient safety improvement projects.

⁸⁵ <http://www.health.qld.gov.au/informedconsent/default.asp>

⁸⁶ <http://www.courts.qld.gov.au/129.htm>

CLINICIAN PERFORMANCE AND SUPPORT SERVICE (CliPSS)

CliPSS

Managing concerns raised about the performance of a doctor is essential to ensure patient safety. It is a challenging and complex task.

In 2007, Queensland Health endorsed the *Safe Doctors: Fair System Framework*⁸⁷. This Framework provides for an assessment and remediation process for doctors that will provide prompt action to address patient safety concerns and a 'just' approach to the doctor concerned.

Queensland Action – CliPSS

The Patient Safety Centre has been working closely with the Area Clinical Governance Units, District Medical Administrators and external stakeholders, to implement this Framework. Current actions include:

- Development of the *Clinician Performance Support Service (CliPPS)*; a central component of Safe Doctors Framework to provide expert assessment and remediation of doctors where there are concerns that performance is a risk to patient safety
- Release of the QH Credentials and Scope of Clinical Practice Guidelines 2008.

ALERT DOCTORS STRATEGY

Fatigue is a fact of life for doctors. The 24/7 demands on medical staff time resulting from increased complexity of treatments, chronic disease and an aging population, have been significant. Coupled with a world-wide shortage of doctors, this has posed a significant challenge for all those in healthcare.

The effects of fatigue on performance are well documented. For example, after 14 hours of continuous work, cognitive and motor functions are equivalent to an blood alcohol concentration of 0.05 – above the legal limit for driving a motor vehicle. This has led to both staff and patient harm. Fatigue is a patient safety issue.

Queensland Action – Alert Doctors Strategy

The Alert Doctors Strategy⁸⁸ (ADS) is an initiative arising from the Medical Officers (Queensland Health) Certified Agreement (No.1) 2005. Initially targeting hours of work, it has evolved to focus on managing fatigue risk rather than simply work hours. Current actions include:

- Alert Doctors Strategy developed and piloted across QH sites
- *Focus on Fatigue* workshops to address fatigue risk
- *Fatigue Risk Management System* developed
- Innovative approaches to fatigue risk management.

Fatigue is a patient safety issue:

“Managing doctors’ fatigue will improve patient and staff safety”

⁸⁷ <http://www.health.qld.gov.au/patientsafety/webpages/safedocs.asp>

⁸⁸ http://qheps.health.qld.gov.au/mwac/content/ads/ads_overview.htm

BLOOD TRANSFUSION SAFETY – QUEENSLAND INCIDENTS IN TRANSFUSION (QiiT) PROJECT

CaSS | Queensland Blood Management Program
A CLINICAL AND STATEWIDE SERVICE



Under the terms of the *National Blood Agreement* (2003) the Queensland Government has a responsibility “to promote safe, high quality management and use of blood products, blood related products and blood related services in Australia”.

There are many definitions for *haemovigilance*. The definition given by the *Council of Europe*⁸⁹ is: “*Haemovigilance consists of the detection, gathering and analysis of information regarding untoward and unexpected effects of blood transfusion*”. It is expected that all the information provided by *haemovigilance* may contribute to improving the safety of blood transfusion by:

- Providing the medical community with a reliable source of information about untoward effects of blood transfusion
- Indicating corrective measures required to prevent the recurrence of some incidents or dysfunctions in the transfusion process
- Warning hospital and blood transfusion services about adverse events that could involve more individuals than a single recipient.

“**Queensland incidents in transfusion**” (QiiT) is the name of the haemovigilance system being developed for Queensland. Initially, QiiT will only collect information on adverse events and incidents that occur as a result of transfusions of fresh blood products.

SECTION 3: KEY MESSAGES

- ✓ Queensland Health is using the information from clinical incident reporting to learn about the underlying causes of patient harm and take action to improve safety.
- ✓ Comprehensive programs are in place focussed on reducing harm from **falls, pressure ulcers, medication events, infection, surgical procedures and mental health related injury**.
- ✓ All Queensland Health hospitals now use a standard medication chart which is reducing harm from medication adverse events.
- ✓ Patients having surgery undergo standardised pre-operative checks (similar to a pre-flight check for pilots) including marking the operation site, to prevent wrong site/side/patient surgery.
- ✓ The Queensland incidents in transfusion (QiiT) is a haemovigilance system that collects information on adverse events and incidents arising from the transfusion of fresh blood products.
- ✓ Through the Informed Consent Program, patients have access to information about their procedure that allows them to make the best decision regarding their own healthcare.
- ✓ The Clinician Performance Support Service (CliPSS) will improve patient safety by ensuring a prompt and rigorous approach to doctors with performance problems focussed on remediation.
- ✓ Open Disclosure is being implemented across Queensland Health to ensure that patients and families, affected by adverse events, receive appropriate information and support.

⁸⁹ Council of Europe: Guide on the preparation, use and quality assurance of blood components

SECTION 4

PATIENT SAFETY: THE FUTURE

Section 4 provides information on emerging areas of focus for systematic changes in 'how we do business', aimed at improving patient safety.

CLINICAL HANDOVER

Clinical Handover is defined as *"the transfer of professional responsibility and accountability for some or all aspects of care for a patient or a group of patients to another person or group on a permanent or temporary basis"*.

Deficient clinical handover is a significant contributing factor in preventable patient harm and has been implicated in 65% of sentinel events⁹⁰. The June 2008 Patient Safety Matters newsletter⁹¹ focussed on Clinical Handover, and the evidence for what works to improve it.

During 2007, Queensland Health has conducted pilots of several strategies known to improve Clinical Handover. The next step is to evaluate the pilots and determine a Queensland Health strategy for state-wide implementation.

PATIENT IDENTIFICATION

Patient mis-identification has emerged as a significant contributing factor in adverse events in medication, procedures, pathology and radiology, as described in Section 3 of this report. Whilst there are few cases of severe patient harm reported as a result of this problem, they do occur. The number of 'near miss' events or events with minor harm, is much greater and reflects a lack of awareness in staff of the potential risks of misidentification.



A 2007 Queensland Health observational study of blood administration⁹² revealed marked variation in practice for collection and administration of blood. This issue was examined further in the July 2007 edition of Patient Safety Matters⁹³. The cause of this variation and potential risk of misidentification includes:

- No clear standard operating procedure (SOP) for patient ID
- No reliable standard of training and assessment of patient ID for trainee healthcare workers
- No reliable modelling of this behaviour by senior staff in the workplace
- No reliable audit and assessment of this in the workplace
- Lack of awareness in healthcare workers, of the risks of patient misidentification
- Absence of enabling IT systems to support staff, such as bar coding of patient bracelets.

Queensland Health is currently examining potential options for state-wide implementation of patient identification solutions.

⁹⁰ Joint Commission on Accreditation of Healthcare Organisations (JCAHO) data 1995-2005.

⁹¹ <http://www.health.qld.gov.au/patientsafety/documents/junpscsm.pdf>

⁹² <http://qhps.health.qld.gov.au/qbmp/qiit.htm>

⁹³ <http://www.health.qld.gov.au/patientsafety/documents/julaug07.pdf>

RECOGNITION AND TREATMENT OF THE DETERIORATING PATIENT

There is evidence emerging from review of sentinel events that failure to recognise or respond appropriately to a deteriorating patient is a significant contributing factor to serious adverse events.

Work is occurring at national and jurisdictional levels to better understand the root causes and strategies aimed at minimising this risk. In July 2007, the UK National Institute for Health and Clinical Excellence produced a clinical guideline on this issue⁹⁴.

Factors being investigated and implemented include:

- Improved staff training and competencies in the recognition and management of early shock, including the use of simulation
- Observation charts which are designed using human factors engineering principles to trigger specific response, reducing reliance on memory and vigilance of nursing staff
- Rapid response teams specially trained to provide rapid assessment and definitive treatment for acute deterioration
- Rural models including the use of tele-health to provide specialist input to healthcare workers in rural and remote settings
- Effective clinical coordination systems to ensure rapid stabilisation, preparation, retrieval and transportation of unstable patients to definitive care.



E-HEALTH

The use of electronic systems to support clinicians in their work and address patient safety is well documented in certain areas such as medication adverse events. Such systems are in existence in many healthcare organisations internationally, and most notably in the United States. Many such systems originated from a requirement for utilisation for patient billing purposes.

Queensland Health is making a significant investment in e-Health, focussed on driving improvements in safety and quality. Evidence is emerging that such improvements are also associated with increased efficiency as well as improved effectiveness.

The six priority areas currently being addressed in the Queensland e-Health strategy⁹⁵ are:

- Discharge Summary
- Results Reporting
- Order Entry
- Electronic Clinical Notes
- State-wide Scheduling
- Medication Management.

⁹⁴ <http://www.nice.org.uk/nicemedia/pdf/CG50FullGuidance.pdf>

⁹⁵ <http://qheps.health.qld.gov.au/ehealth/home.htm>

SECTION 4: KEY MESSAGES

- ✓ Emerging evidence exists for systemic problems in the areas of *patient identification, clinical handover and recognition and management of the deteriorating patient.*
- ✓ The evidence for '*what works*' to address these risks is being explored and tested, through pilots in Queensland Health hospitals and health services.
- ✓ Queensland Health is working in partnership with other states and the Australian Commission for Safety and Quality in Health Care in progressing strategies that are suited to the challenges of delivering healthcare across a large de-centralised state.
- ✓ Queensland Health is implementing a strategy for deployment of electronic systems that make it more difficult for clinical staff to make mistakes, improve quality and efficiency, and ultimately lead to better patient outcomes.