VICTORIA

Victorian
Auditor-General

Patient Safety in Public Hospitals

Ordered to be printed

VICTORIAN
GOVERNMENT PRINTER
May 2008

PP No 100, Session 2006-08

ISBN 1 921060 68 9

VAGO

Victorian Auditor-General's Office

Auditing in the Public Interest

The Hon. Robert Smith MLC
President
Legislative Council
Parliament House
Melbourne

The Hon. Jenny Lindell MP
Speaker
Legislative Assembly
Parliament House
Melbourne

Dear Presiding Officers

Under the provisions of section 16AB of the *Audit Act 1994*, I transmit my performance report on *Patient Safety in Public Hospitals.*

Yours faithfully

DDR PEARSON
Auditor-General

28 May 2008

Foreword

The safety of patients is paramount to the confidence Victorians have in their public health system. While overall, we enjoy relatively high standards of healthcare, clinical incidents can and do happen. These are incidents occurring in a health setting that have either harmed or might have harmed a patient. A small proportion of clinical incidents are serious and have adverse consequences for patients, their families and medical staff. Accurately assessing the number of clinical incidents in Victorian hospitals is also difficult however studies estimate that they are associated with around 10 per cent of hospital admissions. Studies also suggest that up to 50 per cent of these clinical incidents are avoidable and the consequential costs to the Victorian health system have been put at more than $500 million annually.

The DHS has made considerable progress in developing a statewide patient safety system since the 2004 audit report however a concerted and focused effort is urgently required to reduce the number and severity of clinical incidents. There is duplication at all levels of the current system, and roles and responsibilities remain unclear. A statewide patient safety system which facilitates continuous improvement now needs to be in place.

It is also disappointing to note the slow progress in the development of a clinical governance policy and integrated incident system (IIS). The IIS promises a whole of system perspective on patient safety and this will be an important input into planning and improvement. While caution is required for any major investment, DHS needs to commit to a course of action and follow it through. The timeframe for the delivery of this project, 2010, is too long.

DDR PEARSON
Auditor-General

28 May 2008

Contents

1 Executive summary

1.1 Introduction

The risk that patients are harmed while receiving healthcare can never be mitigated entirely. Nevertheless, estimates suggest approximately 50 per cent of care-related injuries are avoidable, and the challenge for health services is to ensure their patient safety systems minimise the risk of harm.

Health services take a ‘systems’ approach to preventing incidents, acknowledging that while human error is unavoidable, the conditions that people work under can be controlled. Rather than blaming individuals, the ‘systems’ approach attempts to identify the underlying causes of incidents, and establish mechanisms to prevent them from recurring.

Clinical incidents are incidents that occur in a health setting that could have resulted, or did result, in the harm of a patient. In Victoria, the Department of Human Services (DHS) categorises clinical incidents according to the degree of harm, or potential harm, they cause. They range from near misses (incidents avoided through hospital strategies) to serious incidents.

Clinical incidents can have serious health and quality of life consequences for patients. At worst, they can result in death, and they can also have significant financial implications for health services, with costs estimated at around $511 million annually in Victoria.

The precise number of clinical incidents that occur in Victorian hospitals is difficult to estimate. Not all clinical incidents are recorded, and there are no data collection systems to aggregate their number and type. Several studies estimate that clinical incidents are associated with around 10 per cent of hospital admissions. In 2006-07, Victoria’s public health services admitted 1.35 million patients. This means that around 135 000 patients may have experienced a clinical incident—a proportion of which may have been serious. A concerted and systemic effort is warranted to reduce this number.

1.2 Findings

1.2.1 Patient safety governance

The audit looked at five health services. All had developed organisation-wide risk management frameworks, which included clinical risk. These frameworks outlined a consistent approach to treating and reporting of clinical risk. However, at the statewide level, there has until very recently been no overall quality and safety framework to guide and prioritise patient safety activity.

The relevant agencies had clearly documented descriptions of their own responsibilities, but there were instances where these responsibilities overlapped. This created uncertainty within the system. Overlap and duplication was most evident in the roles and responsibilities of the Victorian Quality Council (VQC) and the Statewide Quality Branch (SQB). These agencies provide the majority of expert guidance and advice on quality and safety issues, and the overlap and duplication between these agencies has obscured leadership in the patient safety system. With unclear leadership, driving change and improvement will be harder.

Coordination arrangements for patient safety are not clear. DHS advised that it was taking steps to improve coordination through the development of SQB's new statewide role and responsibilities.

An effective patient safety regime requires collaboration and the sharing of knowledge among agencies. Numerous collaborative relationships exist in the patient safety arena. These provide a useful foundation for agencies to increase the sharing of ideas and contribute to sector-wide patient safety planning.

1.2.2 Patient safety performance

In Victoria there is no incident monitoring system that collates patient safety data across the state. Victoria is the only jurisdiction in Australia that does not have a statewide system to monitor the patient safety system's performance.

While some statewide data are collected, such as sentinel events, infection rates and pressure ulcers—these represent only a proportion of the available patient safety data. Consequently, DHS is unable to measure the safety performance of the system as a whole. The Minister for Finance's response to VAGO's 2005 audit recommendations informed Parliament that DHS would address many of the issues raised through its clinical governance policy.

DHS had engaged a contractor to consult with stakeholders on the clinical governance policy, at the time of the audit fieldwork. A draft clinical governance policy has since been developed that should address many of the issues identified in 2005.

The reviews of SQB and VQC, along with the action taken to date to develop a new clinical governance framework and a statewide incident reporting system, are important initial steps to improve patient safety. More significant change and innovation is required to bring about the improvements necessary to reduce Victoria's high number of patients who experience harm while in the hospital setting.

In the meantime, accountability for patient safety in Victoria will continue to be weak, effectively masking an unacceptably high level of incidents behind data gaps and inadequate reporting. The way forward in patient safety requires a step-change in how agencies work together to design and implement safety systems and manage the health system as a whole.

1.3 Recommendations

Statewide governance

DHS should implement, as a priority, the recommendations from its 2007 review of the Quality and Safety Branch **(Recommendation 3.1)**.

RESPONSE provided by Secretary, Department of Human Services

The department is implementing the recommendations from its 2007 review.

Improvements in patient safety governance

DHS should implement, as a priority, the outstanding recommendations from the previous performance audit, as outlined in the Minister for Finance's report to Parliament. In particular, DHS should advise health services of appropriate clinical incident definitions **(Recommendation 3.2)**.

RESPONSE provided by Secretary, Department of Human Services

The recommendations made in 2005 resulted in two large scale projects being developed, these being the Review of clinical governance in Victorian public health services, with the objective to develop a statewide framework to ensure clinical governance is supported, and the Incident information system project, to establish a statewide reporting capacity for all incident data.

The clinical governance framework project has delivered a draft framework and way forward for Victoria which is currently being reviewed by quality and safety groups and the department.

Both these projects will address the recommendations made in 2005 and are being progressed as a matter of priority.

Statewide performance monitoring

DHS should implement the incident information system or a similar system with statewide reporting and analysis capability as a priority **(Recommendation 4.1)**.

RESPONSE provided by Secretary, Department of Human Services

The Incident Information System (IIS) development commenced in early 2006 and is a significant project.

To date the following outcomes have been achieved through the IIS project.

- *A clear set of definitions relating to clinical incident management.*
- *Establishment of a standardised incident severity rating (ISR) methodology.*
- *Development of a standardised incident classification model based on World Health Organisation's International Classification for Patient Safety (WHO IC4PS).*
- *Development of an incident data set that formally defines the clinical incident information to be collected and the associated data collection methodology.*

The development of a comprehensive taxonomy and data dictionary is reaching completion. It is now a matter of software development by others; implementation of data streams for hospitals to the department, VMIA, the Health Services Commissioner and Worksafe; implementing the necessary data storage; and developing the benchmarks and feedback reports to all stakeholders. The scope of the project has been altered over time in response to requests from hospitals to ensure the approach is reflective of a whole suite of incident management, not just clinical incidents. An appropriate business case will be finished in 2008. Training within hospitals will be a key to the success of the project.

Internal accountability

DHS should establish a performance measurement framework to enhance internal accountability for patient safety **(Recommendation 4.2)**.

RESPONSE by Secretary, Department of Human Services

The department is developing a program measures framework to underpin measures associated with the Statement of Priorities (SoP). This framework will monitor performance against the measures while identifying measures for inclusion in subsequent SoP iterations.

A new set of performance indicators associated with Australian Health Care Agreements include a number (to be finalised) of quality indicators that are currently in development. The department is contributing to the development of this list of indicators.

The department funds and participates in a number of external registry projects aimed at measuring quality of care. These focus on high risk/high cost clinical areas such as cardiac surgery and intensive care. The data from each registry is subject to review with feedback mechanisms in place. Many of these will be further developed through the clinical governance framework.

RESPONSE provided by Secretary, Department of Human Services

Extracts from the Secretary's response relevant to the recommendations have been included in the text above. The full text of the Secretary's response has been reproduced at Appendix D, page 43.

RESPONSE provided by the Chief Executive Officer of the Victorian Managed Insurance Authority (VMIA)

A response provided by the Chief Executive Office of the VMIA, which does not refer specifically to the recommendations is included at Appendix E, page 51.

RESPONSE provided by Acting Secretary, Department of Justice

The Department of Justice welcomes the report and, through the State Coroner's Office, will continue to collaborate with the Department of Human Services to improve patient safety.

2 Background

2.1 Patient safety

The provision of healthcare is complex, and the risk that patients may be harmed while in the care of health services can never be mitigated entirely. The challenge is to ensure that the patient safety system minimises the risk of harm.

An important contribution to patient safety is a strong commitment to clinical governance and clinical risk management by government and health services. Together, they must ensure that they have established clinical governance systems to monitor, support, evaluate and continuously improve patient safety. In health services, patient safety should receive, at the very least, the same level of attention as financial and corporate issues.

2.1.1 Clinical risk management

Clinical risk management (CRM) refers to how health services manage the risks associated with patients and patient care. It focuses on how health services implement their commitment to patient safety and incorporates the collection, analysis and reporting of patient safety information to identify and respond to risks. It outlines the roles and responsibilities of those involved and provides guidance on appropriate responses.

A central feature of CRM is incident reporting, which includes documenting actual and potential incidents, and the actions taken by health service staff to redress them. Incident reporting systems facilitate the collation of data to identify patient safety risks and monitoring performance over time.

2.1.2 Clinical incidents

Clinical incidents are incidents occurring in a health setting that could have, or did, result in harm to a patient. In Victoria, the DHS categorises clinical incidents according to the degree of harm, or potential harm, they cause.

Near misses

A near miss is an incident that has been avoided through patient safety strategies, but can also draw attention to risks of future events. Near misses are the most common type of clinical incident.

Adverse event

An adverse event is an incident that resulted in harm to a person receiving healthcare. Adverse events are less common than near misses and include incidents, such as medication errors, patient falls and equipment failures.

Sentinel event

A sentinel event is the most serious type of clinical incident. It is a relatively infrequent, clear-cut event, and occurs independently of a patient's condition. Importantly, the occurrence of a sentinel event commonly reflects hospital system and process deficiencies. Examples of sentinel events include procedures involving the wrong patient or body part, retained instruments after surgery and death from a medication error.

Causes and impacts of clinical incidents

Clinical incidents can occur when gaps in systems and processes allow errors. Health services take a 'systems' approach to preventing incidents, acknowledging that while human error is unavoidable, the conditions under which people work can be controlled. Rather than blaming individuals, the 'systems' approach attempts to identify underlying causes of incidents and put in place barriers to prevent them from recurring. This approach requires a culture of openness and transparency. It encourages clinicians to admit errors, an investigation into the events leading to the error, and the development and documentation of responses.

Clinical incidents can have serious health and quality of life consequences for patients. The consequences can be temporary, but in some instances they can result in death. Clinical incidents also have financial consequences. A recent Victorian study found that where patients experienced a clinical incident, their length of stay in hospital increased from 2.5 days to 12.6 days, while the cost of their stay increased from around $2 000 to $14 000. The study estimated the total cost to Victoria's health system annually was $511 million[1].

[1] Ehsani J, Jackson T, Duckett S *The incidence and cost of adverse events in Victorian hospitals* 2003–04 *MJA* 2006; 184: 551–555.

Frequency of clinical incidents

The number of clinical incidents that occur in Victorian hospitals is difficult to estimate. Not all clinical incidents are recorded and data collection systems to aggregate the number and type of clinical incidents are not in place. While counting clinical incidents is important, this alone is not indicative of the level of safety of a health service, or the health system. Increases in reported incidents may indicate that safety is deteriorating; it may also indicate that reporting cultures and processes are improving.

Despite these difficulties, several studies have estimated that clinical incidents may be associated with around 10 per cent of hospital admissions. In 2006–07, Victoria's public health services admitted 1.35 million patients. This means that around 135 000 public patients may have experienced a clinical incident. During this period, 97 sentinel events, which include deaths, were recorded. It is not possible to accurately compare Victoria's performance with that of other State health systems due to differences in clinical incident definitions.

2.1.3 The patient safety system

In Victoria, patient safety management occurs within a complex health system, with many interdependent and interacting agencies. No agency is solely responsible for patient safety, and there are at least three levels in the system: the health service, State and national. Figure 2A highlights the patient safety system and the key bodies within it.

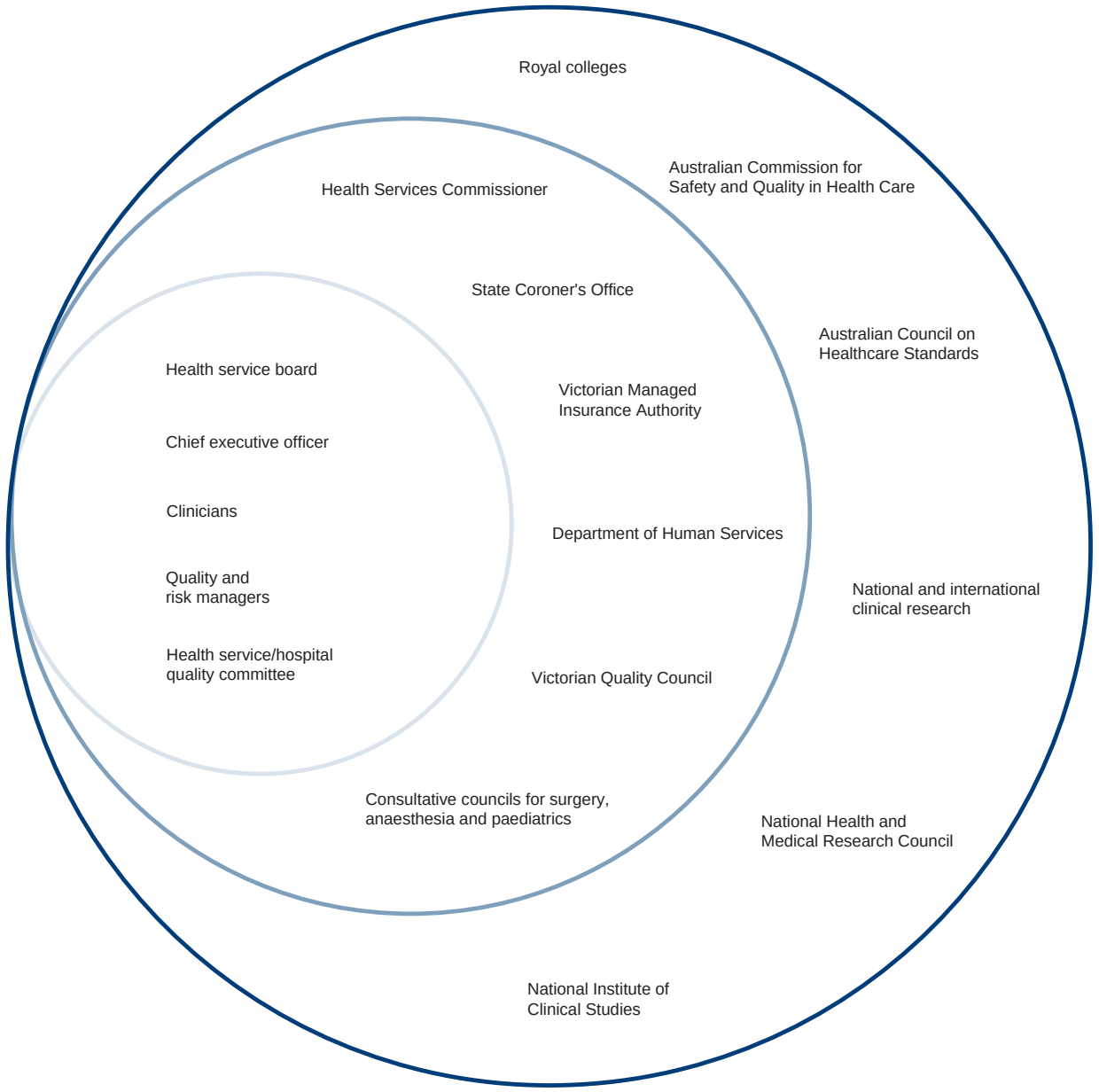
In health services, responsibility for patient safety ultimately lies with the board and the chief executive officer. Quality committees and quality and risk managers also perform a key role, acting as a conduit between clinical staff and senior management, and the monitoring and reporting of clinical incidents. Clinicians (medical and nursing staff) perform a crucial role in the patient safety system—while treating patients, they are also responsible for preventing and reporting clinical incidents.

At the State level, a range of agencies contribute to the patient safety system, including:

- DHS is responsible for statewide policy and planning, funding, and performance monitoring
- VQC is responsible for project work, including clinical governance guidance
- the Victorian Managed Insurance Authority (VMIA) is responsible for risk management advice
- Consultative councils, the State Coroner's Office (SCO) and the Health Services Commissioner are each responsible for investigating incidents and complaints.

Nationally, agencies such as the Australian Commission on Safety and Quality in Health Care (ACSQHC) perform a strategic policy role, while the Australian Council on Healthcare Standards (ACHS) accredits health services, and in Victoria is the primary accreditor. The focus of the accreditation process is quality and patient safety.

Figure 2A
The patient safety system



Source: Victorian Auditor-General's Office.

2.1.4 Patient safety policy context

At the highest level, Victoria's commitment to improve the safety and quality of its health services is directed by *Growing Victoria Together*—the government's social, economic and environmental policy. It notes the government's priority is to provide high-quality health services. The government's policy is implemented through DHS's departmental plan and clinical risk management strategy, and the VQC's safety and quality improvement framework.

Departmental plan

The departmental plan articulates the government's priorities in its area of responsibility. In relation to patient safety, objective 3 outlines the actions DHS will take during 2007-08 to improve human service safety and quality. Particular actions include:

- developing a clinical performance management plan that identifies both outstanding and concerning clinical practice and targets responses to achieve the greatest benefit
- improved public information on the quality and outcomes of healthcare
- setting and maintaining appropriate standards for health professionals.

Clinical risk management strategy

DHS's clinical risk management strategy was developed in 2001. It aims to reduce the rate and severity of clinical incidents and promote the use of a systems approach to manage clinical risk. All health services are required to:

- implement incident reporting systems
- participate in sentinel event reporting
- develop processes for analysis and response to clinical incidents
- educate staff
- conduct medical record audit for adverse events.

Safety and quality improvement framework

VQC's safety and quality improvement framework is a guide that provides health services with a strategic overview of the principles and practices they need to establish robust quality and safety practices, including:

- leadership and accountability for the safety and quality of healthcare
- principles for managing the safety and quality of health services
- organisational focus for quality activities and reporting
- cultural requirements of quality and safety improvement.

The *Health Services Act 1988* also demonstrates the government's commitment to improve the quality and safety of healthcare at the local (health service) level. The Act requires that:

- health service boards ensure there are systems in place to manage risk and monitor the quality of services provided
- health services address quality problems in a timely manner
- health services strive to continuously improve the quality of services.

2.1.5 Funding for patient safety

The Victorian government funds DHS and VQC to manage elements of patient safety, including planning and the development of resources. DHS in turn funds health services for each episode of care—a portion of which is used for the maintenance and improvement of service quality, including patient safety.

This funding is not tied to quality initiatives or services. While required to meet quality and safety reporting requirements and performance measures, health services have discretion over how they use these funds. Based on advice from DHS, estimated 2007-08 quality funding for:

- health services was $44.6 million—representing 1.4 per cent of total funding for inpatient and outpatient services, and an increase of $11.6 million, or 35.1 per cent since 2003–04
- the SQB of DHS was $22 million—an increase of $4 million, or 22.2 per cent since 2003–04
- VQC was $3.2 million—an increase of around $0.2 million, or 6.6 per cent since 2003–04.

Additional program and project funding is available from DHS and VQC for patient safety initiatives.

2.2 Audit objective and method

The objective of the audit was to examine the patient safety arrangements in Victoria's public hospitals. We examined how well DHS worked with a selection of agencies within the patient safety system (the VMIA; SCO; and selected health services) to manage patient safety. The focus of this audit was at the health service and State levels of the patient safety system.

The audit also examined whether DHS and health services had addressed recommendations made in VAGO's 2005 patient safety performance audit. Our office did not audit the VQC because this agency was being independently reviewed at the time of our audit.

Our office audited the same five health services that we audited in 2005. We did not identify these health services at that time, and have maintained anonymity in this audit. We also sent a short questionnaire to 86 health services, which focused on patient safety systems, training and incident reporting. The survey was structured to allow comparisons with VAGO's 2005 patient safety questionnaire.

The audit was performed in accordance with the Australian Auditing Standards applicable to performance audits, and included tests and procedures sufficient to allow audit conclusions to be reached. The total cost was $202 000. This cost includes staff time, overheads and printing. Further information on the conduct of the audit is detailed in Appendix A of this report.

3 Governance in the patient safety system

At a glance

Background

In complex environments, such as the patient safety system, agencies need to work together in a coordinated manner to avoid overlapping and duplicating effort and creating gaps in the system—all of which can cloud accountability. Working together effectively depends on well-designed governance arrangements, including clear roles, responsibilities and accountabilities; leadership and coordination to improve patient safety; meaningful consultation and collaboration; managing system-specific risks; and having a robust performance monitoring framework.

Key findings

- After considerable delay, a draft clinical governance policy has been developed to guide and prioritise effort in the patient safety system. Health services have individually developed and documented their patient safety systems through local clinical risk management strategies.
- There is overlap and duplication in the roles and responsibilities of agencies, creating uncertainty within the patient safety system.
- A large number of collaborative relationships exist, with many either formal or in the process of being formalised.

Key recommendations

DHS should:

- implement, as a priority, the recommendations from its 2007 review of the then Quality and Safety Branch **(Recommendation 3.1)**
- implement, as a priority, the outstanding recommendations from the previous performance audit, as outlined in the Minister for Finance's report to Parliament. In particular, DHS should advise health services of appropriate clinical incident definitions **(Recommendation 3.2)**.

3.1 Introduction

In complex environments, such as the patient safety system, agencies need to work together in a coordinated manner to avoid overlapping and duplicating effort and creating gaps in the system, all of which can cloud accountability.

Effectively working together depends on:

- well-designed governance arrangements, including clear roles, responsibilities and accountabilities
- leadership and coordination improve patient safety
- meaningful consultation and collaboration
- managing system-specific risks
- a robust performance monitoring framework.

In assessing the adequacy of the governance arrangements in the patient safety system, we expected that the patient safety system, and the governance arrangements underpinning it, were documented and understood at both the statewide and health service level. We also expected that the role and responsibilities of the various agencies within the system were clear, that meaningful consultation and collaboration occurred between the agencies, and the risks of working in the patient safety system were managed.

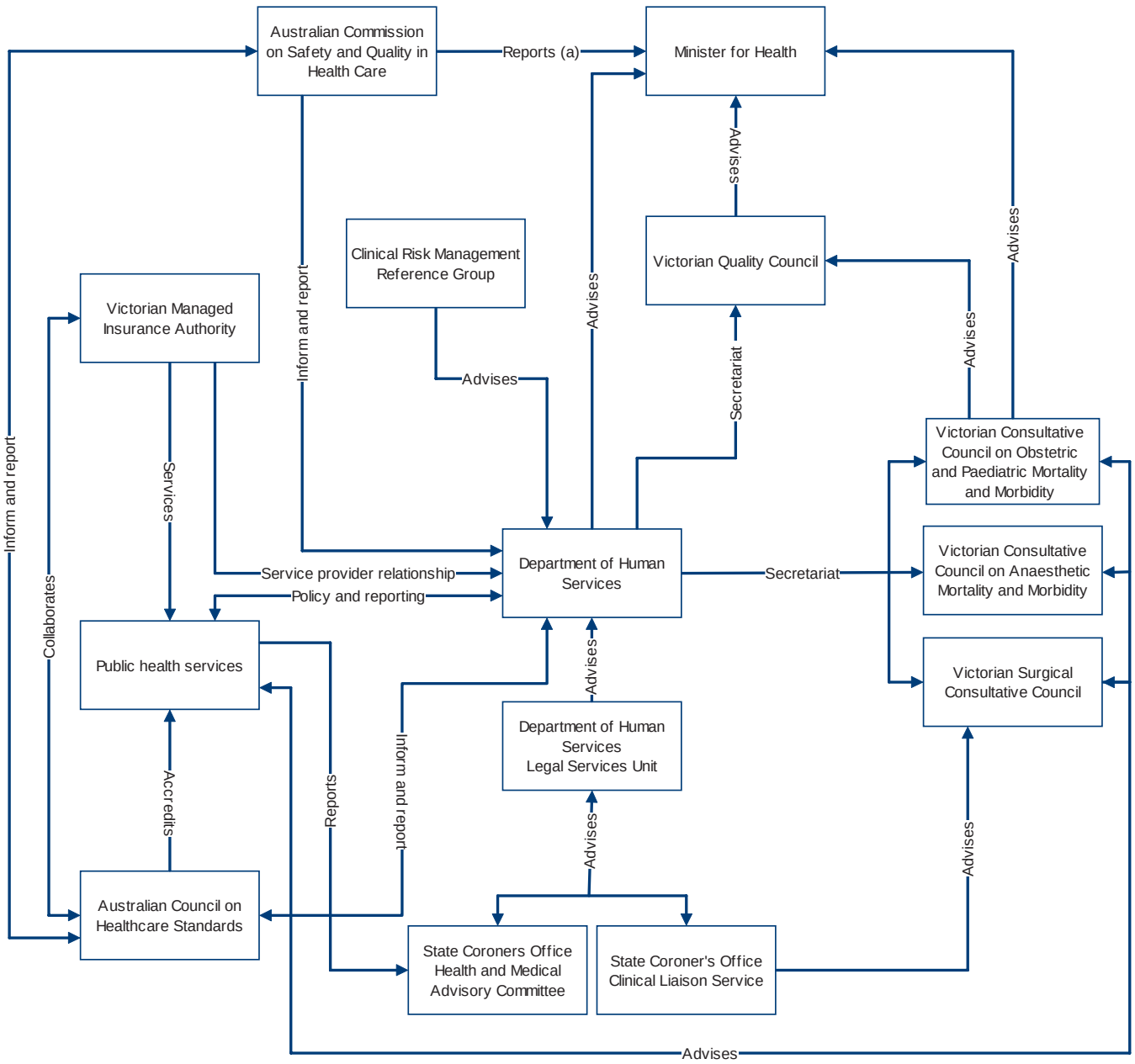
3.2 Governance arrangements

In Victoria, DHS sits at the centre of the patient safety system. While the boards of health services have legislative responsibility for local quality and safety systems, DHS has formal and informal relationships with the majority of other agencies, including:

- funding health services and guiding their patient safety effort
- with the Victorian Managed Insurance Authority (VMIA) for the provision of risk management services
- secretariat support to the VQC and Ministerial consultative councils, including obstetric and paediatric mortality and morbidity, anaesthetic mortality and morbidity, and surgical
- an advisory relationship on quality and safety with the Minister for Health.

Figure 3A shows the key agencies involved in the patient safety system at the health service, State and national levels.

Figure 3A
The Victorian patient safety system



Note

(a): The Australian Commission on Safety and Quality in Health Care reports to all Health ministers. This Figure demonstrates the relationships in the Victorian context.

Source: Victorian Auditor-General's Office.

3.3 Documented governance arrangements

Documenting the patient safety system, including the governance arrangements, is an important part of managing the system. The documentation should describe how the system works to improve patient safety, including how the different agencies relate at all levels of the system.

3.3.1 Statewide governance

Clinical Risk Management strategy

The Clinical Risk Management (CRM) strategy is the primary document for patient safety in Victoria's public hospitals. Released in 2001, it aims to reduce the rate and severity of clinical incidents, while encouraging a systems approach to investigating causal factors. Key components of the CRM strategy include the mandatory establishment of CRM programs in health services, and statewide reporting of sentinel events to DHS.

The requirements under the CRM strategy have changed since it was first released. DHS uses the annual policy and funding guidelines to advise health services of changes, although health services were not always informed of the changes, and DHS did not always insist that its CRM requirements were met. For example:

- the CRM strategy initially required health services to provide a CRM program report, which was divided into two parts. Part 1 was due annually and outlined the key elements of the CRM program, while Part 2 was due biannually and included program outcomes. This requirement stopped in 2003 without health services being notified of the change
- the policy and funding guidelines for 2004–05 required health services to submit patient safety risk management plans. DHS did not provide details of this requirement to health services.

While there have been regular updates and changes, there is no consolidated version of the CRM strategy that clearly articulates changes and the current requirements. The advice to health services, published on DHS's website, is that 2004–05 policy and funding guidelines contain the current CRM requirements. This advice is outdated.

The CRM strategy has a limited scope, with a heavy focus on sentinel events. This has resulted in a strategy that does not apply to patient safety more broadly. While sentinel events generally cause the greatest harm, they represent only a very small number of total incidents. There is no mechanism in place for capturing and analysing lower-level incidents, which make up the majority of clinical incidents. DHS plans to address this through the development of the incident information system, discussed in Part 4 of this report.

DHS has acknowledged these limitations and, following a review of the CRM strategy, has developed a draft clinical governance framework.

Clinical governance framework

Following advice from DHS's Clinical Risk Management Reference Group (CRMRG) to SQB, DHS decided to review the CRM strategy to determine current and outdated content, evaluate progress against achievements and update the strategy to include identified CRM trends.

In April 2008, following consultation with patient safety stakeholders, DHS produced a **draft** clinical governance framework—*Enhancing clinical care: A framework for improving the governance of quality and safety of healthcare in Victoria*. It details:

- the principles underpinning the clinical governance framework
- priorities and strategic direction
- planning and resource allocation
- performance monitoring
- roles and responsibilities of key patient safety stakeholders.

DHS expects to formalise the governance framework in mid-2008.

3.3.2 Health service governance

Health services had developed and documented the patient safety system at the health service level, through local CRM strategies. All had developed organisation-wide risk management frameworks, which included clinical risk. These frameworks outlined a consistent approach to the treatment and reporting of both clinical and corporate risk.

Health services based their local CRM strategies on DHS guidance and reporting requirements, such as policy and funding guidelines and statements of priorities. However, health services advised the adequacy of their documented systems was hampered by a lack of detailed guidance from DHS on CRM and clinical governance, as well as the lack of an overarching patient safety strategy.

3.3.3 Improvements in patient safety governance

This audit examined progress against recommendations of the 2005 audit. Figures 3B and 3C describe the progress made in addressing the recommendations regarding governance.

Figure 3B
Recommendations relating to clinical risk management frameworks

In 2005, the strength of risk management frameworks in health services varied. Not all health services had rigorous and accountable risk management systems and the quality of local CRM policies and guidelines varied. Health services collected clinical incident data locally, but there was no statewide data collection and analysis of all clinical incidents. This impaired the ability to identify statewide trends and patterns, and to investigate and address the underlying issues. To improve local CRM frameworks and systems, we recommended that:

- hospitals and health services link their clinical risk management frameworks to wider organisational risk management frameworks
- DHS should develop minimum requirements for the content of hospital clinical incident policies
- hospital and health service incident reporting systems meet minimum guidelines
- DHS should develop a minimum dataset for incident reporting in hospitals and health services.

The Minister for Finance responded to VAGO's audit recommendations, on behalf of the Victorian Government, in November 2005. This response is part of the government's accountability process for the management of public resources. The Minister advised that DHS's planned development of a clinical governance policy would address these issues. This would occur in conjunction with health services' continued development of their risk management frameworks.

Health services have improved their risk management systems since 2005, adopting consistent processes for the identification, reporting and management of clinical risks. Health services use organisation-wide risk registers to document and monitor clinical risks, and report these to their board or a board sub-committee. Of the 84 health services we surveyed in 2008, 99 per cent had developed CRM frameworks, compared with 88 per cent in 2005.

DHS did not develop the clinical governance policy. As a result, most of the recommendations have not been addressed. They advised that this was due to structural changes within the Department, and because they wanted to avoid being too prescriptive, instead providing principles and measures to guide health services. DHS now plans to re-evaluate this approach through its review of clinical governance. DHS has commissioned an incident reporting system for clinical and non-clinical incidents. It will provide hospitals with a minimum dataset for incident reporting, allowing the collection and analysis of statewide incident data. DHS does not expect to implement the reporting system until 2010.

Source: Victorian Auditor-General's Office.

Figure 3C
Recommendations relating to clinical risk management practices

Our 2005 audit found that the practice in reporting and investigating clinical incidents varied across health services. Local CRM relied on individual judgment, rather than an objective approach, and health services needed to improve their evaluation of actions taken to determine whether improvements had been sustained. Local CRM practices were hampered by inconsistent clinical incident definitions and systems across health services.

We recommended that health services:

- collate clinical incidents from internal incident reporting systems and report them centrally to the board and quality committee
- conduct investigations into lower-risk incidents, and that DHS develop guidance for this process
- implement standard risk rating methodologies for clinical incidents
- develop strategies to ensure that responses to clinical incidents are reviewed and their effectiveness is evaluated.

We also recommended that DHS should ensure that health services and hospitals adopt consistent clinical incident definitions.

The Minister for Finance reported to Parliament in November 2005 that DHS would address these issues through the development of its clinical governance policy, and would advise health services on accepted definitions.

Since 2005, there has been significant progress in implementing formal risk rating methodologies and processes. All health services have adopted a consistent risk rating methodology, and use risk ratings to prioritise clinical risks in their risk register. Varying progress has been made by health services in ensuring clinical incidents are reported, investigated and evaluated. Health services demonstrated effective strategies to monitor and evaluate their responses to clinical incidents; however, documentation of interventions was inconsistent.

DHS has adopted the clinical incident definitions developed by the Australian Commission on Safety and Quality in Health Care, but has yet to advise health services on the appropriate definitions to use.

Our statewide survey showed that inconsistent definitions were still used by health services. Statewide there were 27 sentinel event definitions, 37 definitions of adverse event and 53 definitions of near misses. The development of the IIS should provide for consistent definitions, although this is not due for completion until 2010.

Source: Victorian Auditor-General's Office.

3.4 Roles and responsibilities within the patient safety system

In any system, working together effectively requires all stakeholders having a clear understanding of each others roles and responsibilities. This helps to minimise the risk of overlap or duplicated effort and clarifies accountabilities.

Each agency had clearly documented descriptions of their own responsibilities. However, in some instances, there was overlap and duplication in the role and responsibilities of agencies, creating uncertainty within the patient safety system.

3.4.1 Overlap and duplication

Overlap and duplication was most evident in the role and responsibilities of both VQC and SQB. Together, these agencies provide the majority of expert guidance and advice to health services and other agencies on quality and safety issues. Figure 3D highlights their respective roles as they were in late 2007, and shows the similarities in responsibilities.

Figure 3D
Role and responsibilities of VQC and SQB, 2007

Statewide Quality Branch	Victorian Quality Council
Implement innovative strategies to ensure high quality and safe healthcare.	Advise the Minister for Health and the Department of Human Services on the actions that should be taken to improve safety and quality of care in Victoria.
Developing a standardised approach to managing adverse events.	Collaborate with stakeholders and other quality related bodies in fostering quality improvement in Victoria's health services.
Establishing mechanisms that allow consumers in health services to contribute to departmental policy development and advise government on priority issues.	Advise on the most effective ways to involve consumers in healthcare provision and the improvement of healthcare safety and quality.
Develop and maintain systems to monitor and evaluate safe patient care.	Analyse issues and information about systemic safety and quality issues and provide advice on strategies for system improvement.
Contribute to the management and progress of the priorities of key Victorian clinical Councils.	Review the effectiveness of actions taken to respond to quality issues identified by expert bodies and health service quality committees and recommend best practice approaches for dissemination.
	Work with the Australian Commission on Safety and Quality in Health Care to develop and implement a coherent national strategy for improved safety and quality in healthcare.
	Provide advice on matters relevant to the quality of health services in Victoria as requested from time to time by the Minister for Health, or by stakeholders.

Source: Victorian Auditor-General's Office.

Agencies in the patient safety system, and particularly health services, were unclear about how the roles and responsibilities of these two agencies differed, and whether the SQB or VQC was the appropriate agency to seek advice from regarding quality and safety issues. Agencies considered VQC to be the safety and quality expert, which was contrary to SQB's view of its own role.

A review of SQB, conducted by an independent consultant for DHS in 2007, highlighted the need for clarity regarding the roles and responsibilities of the VQC and DHS. The report noted that cooperation between the two entities was largely relationship based, and recommended the development of a strategic framework articulating the respective roles and relationships between divisions, branches and units of DHS and the VQC and other relevant bodies.

During the conduct of this audit SQB changed its roles and responsibilities to reflect the recommendations of its internal review. The new responsibilities involve:

- patient safety and quality advice to the Minister for Health and DHS executive
- statewide policy development and planning
- resource allocation and monitoring performance.

DHS was unable to provide further detail regarding these responsibilities. DHS is also considering changes to the responsibilities of VQC following a recent evaluation. One of the recommendations from the VQC evaluation was to develop new terms of reference to reflect contemporary issues and practice in patient safety and quality. The final evaluation report was submitted to DHS in November 2007 and the Minister for Health in December 2007. DHS advised that they will consider the report's recommendations in 2008.

The VMIA is a statutory authority, reporting through the Department of Treasury and Finance, which provides insurance and risk management services to public health services. The VMIA has recently sought to clarify its role, in relation to clinical risk management, with a focus on factors driving medical indemnity claims. In collaboration with DHS and other key stakeholders, the VMIA is aiming to address what it perceives as a lack of integrated effort through the development of its own CRM strategy. The strategy aims to enhance VMIA's contribution to patient safety through actions including:

- establishing a leadership role in improving patient safety
- establishing a multi-year accredited clinical risk management program
- developing a uniform clinical risk management framework
- improving the quality, frequency and analysis of incident reporting
- working collaboratively with key stakeholders to promote and ensure a strategic and sustainable response to improving clinical risk management structures systems and processes across the Victorian public healthcare sector.

The VMIA's focus on leadership in patient safety, developing a patient safety framework and improving incident reporting strongly resembles the responsibilities of SQB and VQC. This has created the risk of overlap and duplication, adding to the confusion in health services.

RESPONSE provided by Chief Executive Office, Victorian Managed Insurance Authority

The VMIA is confident that potential confusion of roles and responsibilities will be avoided through our demonstrated collaborative approach with DHS. Specific examples of such collaboration, outlined in our earlier response, are also included above. (see Appendix E)

3.4.2 Leadership and coordination

Successfully working together in the patient safety system needs effective leadership to integrate and coordinate effort at the statewide level. While DHS's SQB has a clear leadership role in the patient safety system through its responsibilities as principal policy advisor on patient safety, statewide planning and policy development, the leadership and coordination arrangements were not always clear.

SQB currently leads and coordinates a range of initiatives within the patient safety system. These include coordinating:

- responses to sentinel events
- development of the planned statewide incident reporting system
- implementation of open disclosure.

However, leadership and coordination was limited, and it was unclear which agency was responsible for leading the patient safety agenda to generate system-wide improvements.

A range of issues regarding leadership were identified in the review of SQB in 2007. These included:

- a lack of strategic influence and clinical leadership, including limited visibility in the quality and safety sector
- the need to better coordinate and integrate other clinical governance strategies within DHS
- uncertainty about how quality and safety projects across DHS and health services integrated
- the need for SQB to take a greater leadership and coordination role.

Through the development of SQB's new statewide role and responsibilities, DHS is taking steps to improve its leadership and coordination. Further improvements will rely on role clarification of the other agencies, and the implementation of recommendations from the SQB review. DHS have started implementing these recommendations.

3.5 Collaboration and consultation

Collaboration and consultation provides agencies with the opportunity to discuss issues, share ideas, and contribute to the planning processes within the patient safety system. A large number of collaborative relationships exist, with many either formal or in the process of being formalised. Given the complexity of the patient safety system, we expected to see governance arrangements becoming more formal. Key collaborative relationships are described below.

Statewide Quality Branch and the Victorian Managed Insurance Authority

SQB's collaboration with VMIA has been formalised in a service level agreement. VMIA attends the DHS clinical risk management reference group bi-monthly, and meets quarterly with the SQB to discuss a range of issues, including training and projects. The meetings are minuted and action items identified. VMIA also collaborates with DHS on the incident information system (a proposed statewide incident reporting system), and the development of a risk management module. VMIA has recently appointed a manager to oversee clinical risk management. This position will work with a range of patient safety agencies to avoid duplicating effort.

Department of Human Services and the State Coroner's Office

The State Coroner's Office (SCO) and DHS are developing a memorandum of understanding to formalise their relationship. SCO engages the health sector and DHS through the Health and Medical Advisory Committee. The committee, which includes representation from SQB and medical colleges, discusses Coronial findings and was established in response to claims that recurrent systems failures within the patient safety system were not being adequately addressed. SCO informs DHS of statewide issues and recommendations for health services, which SQB subsequently communicates to health services.

Victorian Managed Insurance Authority and the Australian Council on Healthcare Standards

The Australian Council on Healthcare Standards (ACHS) accredits health services. A key element of the accreditation process is the development of integrated, organisation-wide risk management policies and systems that ensure clinical and corporate risks are identified, minimised and managed.

In 2006, VMIA also implemented a Risk Quality Framework Review to assess health service risk management frameworks and provide risk management identification and advice to the government. Consequently, VMIA and ACHS have established a collaborative relationship to coordinate quality and risk objectives and eliminate the duplication of activities in health services.

3.5.2 Gaps in collaboration

There were a number of gaps in the collaborative arrangements. SQB, through its 2007 review, identified that it has not developed effective collaborative relationships with other business areas within DHS, including those that have quality and safety responsibilities. SQB has also identified that there is limited collaboration and a lack of awareness of what these units are doing in relation to patient safety. It plans to establish a quality and liaison network of DHS representatives with patient safety responsibilities.

3.6 Managing risks

The importance of risk management has been well-documented, including most recently in VAGO's *Managing risk across the public sector* performance audit, completed in 2007. Working in a system that involves multiple levels and agencies increases the risk of confusion, duplication, gaps and overlaps.

We expected that the stakeholders involved in the patient safety system, and particularly SQB as the lead stakeholder, had considered risks in terms of working collaboratively within the patient safety system. There is no evidence that this had occurred, with a number of projects within health services originating from the VQC, SQB and VMIA. While the projects contribute to the development of patient safety strategies, there is the risk of confusion, duplicated effort and disparate practices.

RESPONSE provided by Chief Executive Officer, Victorian Managed Insurance Authority

Any VMIA initiative within the health sector has been initiated in consultation with a specific heath service, DHS or both depending on the scope.

3.7 Conclusion

Statewide, the patient safety system involves multiple agencies with varying roles, responsibilities and relationships. To enhance its effectiveness, agencies within the system need to understand not only the roles and responsibilities of each agency but their relationships and how the parts of the system work together. This is to minimise the risk of overlap and duplicated effort, and so the system works as efficiently as possible. It should also clarify who has responsibility for leading system-wide improvements in patient safety. While DHS is positioned to lead and coordinate statewide system improvements, it has not done so. Currently, it appears that VMIA, through its CRM strategy, is filling this leadership void. This is a role better performed by a health sector agency or entity, such as DHS through the SQB, or the VQC.

The absence of a documented patient safety framework that considers the broader system to guide and prioritise effort, has diminished the effectiveness and efficiency of the system. While there has been innovation and improvements in the patient safety system, to fully realise these benefits the system needs to be considered as a whole. The development of the draft clinical governance policy should help address these issues and reduce the likelihood of confusion and duplicated effort.

Collaboration is improving across the patient safety system, with defined relationships established or in the process of being established. While these relationships are currently quite specific in their purpose, such as disseminating information, they provide an ideal foundation to share ideas, discuss patient safety issues and contribute to patient safety planning. DHS needs to take the lead in establishing arrangements to gain these benefits. The recommendations from the review of the SQB offer DHS a way forward.

RESPONSE provided by Chief Executive Officer, Victorian Managed Insurance Authority

In our earlier response we emphasised that the VMIA's CRM strategy will not be acted upon independently. Our formal relationships with DHS will ensure that initiatives are mutually agreed and prioritised.

Recommendations

DHS should:

3.1 implement, as a priority, the recommendations from its 2007 review of the then Quality and Safety Branch

3.2 implement, as a priority, the outstanding recommendations from the previous performance audit, as outlined in the Minister for Finance's report to Parliament. In particular, DHS should advise health services of appropriate clinical incident definitions.

4 Monitoring performance in patient safety

At a glance

Background

Monitoring performance is an important, challenging task within the patient safety system. Counting clinical incidents does not necessarily demonstrate the level of safety, as increases in reported incidents may indicate that safety is deteriorating, or alternatively that incident reporting processes and cultures are improving.

Key findings

- Health services maintained clinical incident reporting databases to record and analyse clinical incidents. The data generated from these databases was also used to report performance.
- There was no statewide system that collated this data to monitor overall performance in patient safety. Victoria is the only Australian jurisdiction in this position.
- DHS is developing a statewide incident reporting system—the incident information system. The planned completion date for the IIS is December 2010.
- There were only limited accountability mechanisms in place, due largely to the absence of a statewide incident reporting system providing comprehensive data.

Key recommendations

DHS should:

- implement the IIS, or a similar system with statewide reporting and analysis, as a priority **(Recommendation 4.1)**
- establish a performance measurement framework to enhance internal accountability for patient safety **(Recommendation 4.2)**.

4.1 Introduction

Understanding how well the patient safety system is performing, at both state and health service level, is essential. Performance monitoring enables the identification of areas of concern, provides information on the effectiveness of actions and interventions, and an evidence base for the provision of public assurance about the safety of Victorian public hospitals.

We expected that health services would report, at board level, collated and trended data on clinical incidents and the majority of VQC recommended indicators. We also expected that patient safety would be reported at a statewide level.

4.2 Performance monitoring frameworks

4.2.1 Health service performance monitoring

The five health services audited maintained clinical incident reporting databases to record and analyse clinical incidents. The data generated from these databases was also used to report performance to the health service's board as part of their clinical governance arrangements, although the extent to which this occurred varied. For example:

- one health service reported performance against 11 recommended performance indicators, while the other four reported against as few as eight of these indicators
- one health service provided collated and trended data on all clinical incidents to their board annually only, although trended reporting was provided monthly to the board's quality committee
- one health service's performance monitoring omitted near misses, which are the most prevalent type of clinical incident
- one health service only provided information on incidents resulting in serious harm, and for specific incident types.

Not all the health services used the same system to record clinical incident data, and some health services maintained incident reporting systems specific to defined clinical areas, separate to their organisation-wide clinical incident system. At two health services, staff groups used separate incident reporting systems, with incidents reported in the alternate system not guaranteed to also be recorded in the organisation-wide database. This compromises the completeness of data within the central system.

4.2.2 Statewide performance monitoring

There is no statewide system that collates data to monitor overall performance in patient safety, notwithstanding that health services monitor patient safety performance at the local level. Victoria is the only jurisdiction in Australia that does not have a statewide system to monitor the patient safety system performance.

DHS collects a range of statewide patient safety data, such as sentinel events, infection rates, pressure ulcers and cardiac surgery. However, this represents only a portion of the available patient safety data. These datasets are not linked and do not provide an overall picture of patient safety. Consequently, DHS is unable to measure the performance of the patient safety system as a whole.

DHS advised VAGO that it plans to develop a statewide incident reporting system, the IIS, by 2010, to address these limitations.

Incident information system

The proposed IIS, at an estimated cost of $12.5 million, will establish a statewide incident reporting system for use by Victoria's public health services and other patient safety agencies. The IIS should deliver five outcomes:

- a statewide, standard methodology for the way incident information is reported within the public health system
- implementation of a mechanism to enable statewide aggregation, analysis and trends in multi-level clinical (patient) incident data
- a mechanism to evaluate the clinical incident data, identify trends and share relevant information so that quality improvements can be targeted and actioned
- deliver data to the Health Services Commissioner, WorkSafe Victoria and the Victorian Managed Insurance Authority (VMIA), who receive incident data from health services
- establish a safety culture in health services in Victoria.

DHS has identified a range of benefits from the implementation of IIS, including a safer and more efficient healthcare system, with improved patient outcomes. Specific anticipated improvements include:

- improved reporting rates
- better quality data
- reductions in the number of patients with extended hospitals stays linked to clinical incidents
- fewer high-severity clinical incidents
- fewer unexpected complications.

The planning of the IIS is progressing; however, funding has not yet been confirmed, and there is no certainty that the project will proceed. In the interim, DHS advised that it is exploring how its existing databases can provide a more detailed picture of trends and patterns in clinical incidents.

Other statewide data and information systems

SQB maintains a range of patient safety-related databases, including those that collect health service data on sentinel events; cardiac and vascular surgery; pressure ulcers; and infection control. In addition, there are other datasets maintained throughout DHS for various clinical specialities, which include patient safety information.

The Victorian admitted episode dataset (VAED) is the main dataset for health service activity, from which DHS generates funding allocation. The VAED can be 'mined' for patient safety information to look at variance against expected mortality and other outcomes. DHS does not use the VAED to generate patient safety information, although it is conducting research on four different methods for applying the data to patient safety.

The VMIA also collects a range of patient safety data from health services relating to medical insurance claims. Despite receiving around 100 000 incident reports each year there are limitations in the way this data can be used to improve the patient safety system. This includes inadequate analysis of claims data and poor consolidation and use of clinical incident information. VMIA advised that through its newly developed CRM strategy it aims to improve the quality, frequency and analysis of incident reporting by:

- supporting the design, development and implementation of the IIS
- developing a VMIA incident reporting capability, including incident benchmark reporting
- working with agencies to gain access to available sources of risk information, such as performance against benchmark data
- supporting and promoting initiatives that contribute to a culture of improvement such as open disclosure and no blame.

4.3 Accountability mechanisms

In line with the Victorian Government's policy commitment to provide high-quality health services, Parliament and the public expect that health services and DHS will be held accountable for performance in relation to safety and quality.

There were only limited accountability mechanisms in place, due largely to the absence of a statewide incident reporting system providing comprehensive data. However, there are a range of internal and public mechanisms contributing to accountability.

4.3.1 Internal accountability

The key state-level performance monitoring tool is the Integrated Performance Report (IPR). DHS requires each health service to report against the IPR, which contains 22 key performance indicators.

Following VAGO's 2005 patient safety performance audit, the Minister for Finance informed Parliament that there would be greater patient safety reporting in the IPR. Clinical performance indicators that the government planned to include were:

- Australian Council Healthcare Standards accreditation status
- clinical incidents reported per 1 000 bed days
- inpatient falls that result in fractures per 1 000 bed days
- pressure ulcer prevalence rates per 1 000 bed days
- surgical site infection rates.

Only one of the proposed indicators, accreditation status, has been included in the IPR. The two other quality and safety indicators currently included in the report are cleaning standards, and submission of data to VICNISS—the infection control database. VICNISS data has been included only since 2007–08. The remaining 19 indicators relate to finance and access.

DHS acknowledged that the three quality and safety indicators do not adequately measure patient safety performance. It is developing a new internal performance reporting tool, the performance measures framework, to better monitor patient safety performance. The performance measures framework may include indicators originally planned for the IPR, such as the number of clinical incidents reported and the number of patient falls per 1 000 bed days. Responsibility for this framework sits outside SQB, and the project has not progressed far. It is still unclear what DHS will include and when it will be completed.

4.3.2 Public accountability

DHS publishes public reports that address, in some way, patient safety. These include the *Your Hospitals* and the sentinel event reports. DHS also requires health services to publish quality of care reports.

Quality of care reports

All Victorian health services are required to publish quality of care reports annually. Health services use the reports to inform the community of their quality and safety systems, processes and outcomes. Accreditation and clinical risk management outcomes are reported, and health services must identify at least four key quality and safety measures to report on, such as:

- infection control and cleaning
- medication errors
- falls monitoring and prevention
- pressure wound monitoring and prevention
- clinical indicators for dental services.

There is no requirement for health services to provide broader patient safety data, such as the total number of clinical incidents, even though health services collect and collate this information already.

DHS advised that for 2006–07, all health services met the requirements in relation to patient safety and quality.

Your Hospitals

The main public report of health system performance is the *Your Hospitals* report. This report details performance against the key performance indicators (KPIs) for health services. Of the three KPIs for quality and safety, only cleaning standards are reported against, and only a small selection of health services' results is provided. DHS advised that while only a selection of health services was included in the report, all health services met the cleaning standards KPI.

Sentinel event report

The key statewide, publicly reported patient safety performance data is for sentinel events. DHS produces an annual report that identifies the total number of sentinel events reported in that year, the types of sentinel events, specific case details and lessons learnt.

While sentinel events are the most serious clinical incidents, they represent only a very small proportion of the total estimated clinical incidents. In 2006–07, there were 97 reported sentinel events, with an estimated 135 000 clinical incidents in the same year.

4.4 Conclusions

Health services have introduced local clinical risk management strategies, which include education strategies and monitoring and reporting (local) patient safety performance at board level. This is an improvement since the 2005 audit.

Performance data are a crucial element of continuous improvement, without which the ability to improve the patient safety system is significantly diminished. There has been progress in developing a statewide performance monitoring framework. The new performance monitoring framework, currently being planned, should address the gap in statewide patient safety data. However, aside from the long timeframe for completion, the framework has not been assured funding, and recent IT implementation within DHS suggests the risks of delays are high.

DHS needs to take account of the previous lessons in IT implementation. Health services have independently purchased and/or developed incident reporting systems tailored to their individual needs. There are resource implications for changing systems, and likely stakeholder resistance to change, which may affect the take-up rate. These issues will present significant challenges for DHS.

The lack of a statewide incident reporting system has diminished the accountability for patient safety. While internal and public accountability mechanisms exist, their scope is limited. DHS has options to increase the meaningfulness of internal reporting; however, it is heavily reliant on health services adopting consistent definitions to improve the robustness and comparability of performance.

Much more also needs to be done to improve public reporting for safety and quality. While this may increase the reporting burden for health services, the community is entitled to expect comprehensive and effective accountability frameworks. The ability to provide meaningful public reports, however, will continue to be a significant risk in the absence of a statewide incident reporting system producing robust data.

Recommendations

DHS should:

4.1 implement the IIS, or a similar system with statewide reporting and analysis capability, as a priority

4.2 establish a performance measurement framework to enhance internal accountability for patient safety.

Appendix A.
Audit conduct

Audit objective

The objective of this audit was to examine whether the management of patient safety in Victoria's public hospitals and patient safety agencies was effective, efficient and economical. The audit assessed:

- how well the DHS worked with other relevant agencies and bodies to improve patient safety
- whether DHS and health services had addressed issues identified VAGO's 2005 patient safety performance audit.

Method

Audit conduct occurred in the five health services that we examined in our 2005 patient safety performance audit. This allowed the audit team to assess the health services' progress in addressing our earlier recommendations, and also to examine how this selection of health services worked with other agencies within the patient safety system. These health services (two regional and three metropolitan) were not identified in the previous performance audit, and for consistency, have not been identified in this performance audit.

We also examined how DHS's SQB, the VMIA and the SCO worked together and with health services to improve patient safety. We selected SQB so we could assess progress on the previous recommendations, and also because of its leadership role in the patient safety system. VMIA and SCO were selected because of their key roles in preventing and investigating clinical incidents.

The VQC performs an important role in safety and quality in healthcare. We did not examine VQC because, at the time of our audit, their performance was being independently examined.

Audit criteria

To assess the performance of the patient safety system, including how well agencies worked together, and the progress made since VAGO's 2005 patient safety audit, criteria were developed to ensure consistent assessments. The following criteria, reflecting better practice, were based on authoritative literature and national and international practice:

- the patient safety system was documented, available and well-understood
- roles and responsibilities of agencies within the patient safety system were clearly identified and understood
- meaningful consultation and collaboration occurred across the patient safety agencies, supported by formal protocols
- responses to patient safety issues were coordinated within a continuous improvement framework
- the performance monitoring framework was robust and captured relevant data about the effectiveness of patient safety
- risks and opportunities were identified and managed
- DHS and health services had addressed the recommendations identified VAGO's 2005 patient safety performance audit.

Detailed questionnaire

A short, detailed questionnaire was sent to 86 health services asking about safety systems, training of staff and reporting. The survey was structured to enable comparisons to be made from the results of the questionnaire that was sent to all health services as part of our 2005 performance audit, as well as to assess how well the patient safety system was developed within each hospital. All health services responded to the questionnaire.

Acknowledgments

The audit team consulted with a range of people and organisations to obtain information about the issues associated with the patient safety system. We thank the staff at the health services we visited, and all those involved in completing the survey for their input. We also thank:

- Ms Alison McMillan, Department of Human Services
- Ms Michele Gardner, State Coroner's Office
- Mr Andy Johnston, Victorian Managed Insurance Authority
- Dr Beth Wilson, Health Services Commissioner.

Appendix B.

Key stakeholders in the patient safety system

Key stakeholders in patient safety

Department of Human Services

Statewide Quality Branch (SQB)

The SQB supports the continued improvement of patient care. It is the principal advisor to the Minister for Health and the DHS executive regarding the development of statewide policy, planning, resource allocation and performance monitoring in relation to safety and quality in healthcare.

SQB also undertakes projects and initiatives to achieve improved patient safety, and provides administrative (secretariat) support to the Victorian Quality Council and three consultative councils.

Clinical Risk Management Reference Group (CRMRG)

The CRMRG was established by SQB to address current issues in, and advise DHS on, clinical risk management (CRM) issues. CRMRG comprises clinicians, health professionals, quality managers, hospital board members and consumers.

Legal Services Unit

The Legal Services Unit provides strategic legal and policy advice, litigation services and legislative services. In relation to patient safety, the unit is responsible for coordinating coronial matters and disseminating information to relevant branches and units within DHS.

Victorian Quality Council (VQC)

The VQC is an expert strategic advisory group, responsible for fostering better quality health services in Victoria. It does this by working with stakeholders to develop useful resources, tools and strategies to improve health service safety and quality.

Consultative councils

Victorian Consultative Council on Anaesthetic Mortality and Morbidity

The Victorian Consultative Council on Anaesthetic Mortality and Morbidity identifies avoidable causes of morbidity or mortality related to anaesthesia, and to disseminate relevant information and practical strategies to improve the safety and quality of anaesthesia practice. The council is under the auspices of DHS and reports to the Minister for Health and the VQC, as required. SQB provides administrative support.

Victorian Surgical Consultative Council

The Victorian Surgical Consultative Council studies cases of avoidable surgical mortality and morbidity, and provides feedback to the medical community. The council reports to the Minister for Health and the VQC, and is required to respond to specific matters referred to it by the Minister for investigation and reporting.

Victorian Consultative Council on Obstetric and Paediatric Mortality and Morbidity

The Consultative Council on Obstetric and Paediatric Mortality and Morbidity is the advisory body to the Minister for Health on maternal, perinatal and paediatric deaths. It consists of a twelve member council and four committees: maternal mortality committee; stillbirth committee; neonatal mortality committee; and infant and child mortality committee. The council identifies deficiencies in standards of maternity and paediatric care and instances where practice improvements can be made or opportunities for the risk of death to be reduced.

State Coroner's office (Department of Justice)

The State Coroner of Victoria is responsible for investigating reportable deaths. In the context of patient safety, health services are required to report deaths that were unexpected or unnatural; resulted directly or indirectly from accident or injury; happened during an anaesthetic; or resulted from an anaesthetic and were not due to natural causes.

Clinical liaison service (CLS)

The CLS is a business unit under the direction of the State Coroner's Office. It undertakes detailed analysis under the direction of the coroner of individual or clusters of cases of reportable deaths that health services report to the Coroner. The work undertaken by the service informs changes to the healthcare system through Coroner's recommendations and explores whether there are possible reforms to the coronial process

Health and Medical Advisory Committee

The Health and Medical Advisory Committee was established in response to the concern that hospital deaths may be related to recurrent systems failures that were not being adequately addressed within the health system. HMAC includes representation from the SQB and from various medical colleges, who discuss coronial findings and other relevant matters.

Victorian Managed Insurance Authority (VMIA)

The VMIA is a statutory authority, reporting through the Department of Treasury and Finance, providing insurance and risk management services for public health services.

As part of its risk management services, VMIA co-funds health service initiatives to enhance their risk management systems and processes.

Australian Commission for Quality and Safety in Health Care (ACQSHC)

The ACQSHC is a national body formed to address healthcare safety and quality. It is jointly funding by federal, state and territory government to lead national efforts in promoting systemic improvements in the safety and quality of healthcare, with a particular focus on minimising the likelihood and effects of error.

As part of its role, the commission provides strategic advice to all Health Ministers on best practice thinking and recommends nationally agreed standards for safety and quality improvement.

Australian Council on Healthcare Standards (ACHS)

The ACHS accredits the majority of Victoria's health services. This involves a four-year cycles of health service self assessment, an organisation-wide survey and periodic review to ensure that standards are met. ACHS standards for evaluation, assessment and accreditation are determined by a council drawn from peak bodies in health, government and consumers.

Appendix C.

Review of the Safety and Quality Branch

Review of the Safety and Quality Branch

DHS's Safety and Quality Branch (now the Statewide Quality Branch) was reviewed in 2007 following its relocation to the Rural and Regional Health and Aged Care Services division, and the appointment of a new director.

The review provided recommendations to DHS about the strategic directions the QSB should pursue and identified organisation resources required to support them.

Main review findings

Key findings from the review included:

- there was no shared view of the prevailing departmental governance model as it applies to quality and safety
- there were few key performance indicators, with those that exist being process rather than outcome oriented
- there was a lack of clarity between the roles and the responsibilities of the branch and the VQC
- the QSB lacked profile within DHS and had not been closely engaged in contributing to the DHS strategic direction.

Recommendations

A number of recommendations were made about the QSB, including:

- it be renamed (Statewide Quality and Safety Branch)
- its overarching purpose should be the principal advisor to the Minister for Health and the DHS executive team for statewide policy development, planning, resource allocation and monitoring of performance in relation to the systematic improvement of safety and quality
- the branch's structure should be changed to reflect a higher emphasis on policy, strategy and system building.

The review also recommended the Branch's objectives for the next three to five years should include:

- ensuring that a clear strategic framework for managing safety and quality is in place, is widely communicated and understood, is implemented across DHS and the health services and is influential to Victoria's private and non-government health sector
- the strategic framework should include:
  - affirmation of the importance of safety and quality to the Victorian government and DHS
  - articulation of the respective roles and linkages between the branch and other relevant divisions, branches and units within DHS, the VQC and other relevant committees and entities and health services
  - a statewide clinical governance framework
  - a strategic plan for safety and quality, including identification of shorter-term priorities, programs and plans
  - an approach to evaluating progress
- developing and coordinating the implementation of a comprehensive data, information and knowledge management framework for safety and quality in Victoria that is consistent with national strategic directions
- determining key performance indicators to be included in the annual statement of priorities for public health services
- focusing only on projects that are statewide in nature, and which can be systematically implemented
- developing and implementing a systematic approach to engagement and communication with the branch's clinical and non-clinical key stakeholders and the sector more broadly.

Appendix D.

Department of Human Services' response

Department of Human Services

Secretary

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e1217457

9 May 2008

Mr Des Pearson
Auditor-General
Victorian Auditor-General's Office
Level 24, 35 Collins Street
MELBOURNE VIC 3000

Dear Mr Pearson,

In accordance with section 16(3) (b) of the *Audit Act 1994*, I enclose the Department of Human Services' response to your report on Patient Safety in Public Hospitals 2008.

Thank you for providing the opportunity to discuss the findings of the report. I believe the dialogue was of value to all present.

It is my understanding that the report is due to be tabled in Parliament in May 2008.

Please contact Alison McMillan, Director, Statewide Quality Branch, on (03) 9096 6900 if you require any additional information.

Yours sincerely

FRAN THORN
Secretary

Victoria
The Place To Be

Department of Human Services Response to the Victorian Auditor General's Report into Patient Safety in Public Hospitals.

Introduction

In our public hospitals, safety is the first priority of our professional clinical staff and the teams in which they work.

But hospital care, especially urgent care, can and does lead to adverse events, most of which are of a minor nature.

Adverse events need to be considered in the context of the complexity of hospital care and the often very poor state of health of the patient receiving that care.

Vigilance and innovation are forever necessary to reduce avoidable adverse events and a range of processes – for example, clinical audit or peer review – are conducted to identify potential for care improvement.

There is no known and accepted 'norm' for adverse events. Nor is the literature helpful in identifying systemic reductions in rates of adverse events. However, mortality rates for selected types of care and overall death rates from avoidable causes have declined and continue to move sharply downwards in Australia, while life expectancy continues to increase.

The picture of healthcare in Victoria however is not painted by a theoretical rate of adverse events. Victorian men and women arguably have the second highest life expectancy in the world[1]. Our life expectancy continues to increase every year, and for the first time, we can now correlate this with the world's largest fall in avoidable deaths – that is deaths prevented or delayed by intervention[2].

We also know that in Victoria, over the last six years, cardiac surgery survival in all Public Hospitals remains consistent and is as safe, or safer, than that of hospitals overseas[3]. Adult intensive care patients have a higher than expected survival rate using an internationally validated risk adjustment tool.[4]

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[1] www.aihw.gov.au/mortality/data/faqs.cfm#othercountries

[2] Nolte, E and McKee, C.M. 'Measuring The Health Of Nations: Updating An Earlier Analysis' *Health Affairs*, January/February 2008; 27(1): 58-71.

[3] ASCTS Surgeons' Comprehensive Report 2006-07

[4] Monitoring Adult Intensive Care Victorian Intensive Care Data Review Committee Annual Report 2005-06

What are Adverse Events?

An adverse event is defined as an incident in which harm resulted to a person receiving health care[5] .

A clinical incident is defined as an event or circumstance which could have resulted, or did result, in unintended or unnecessary harm to a person receiving care[6]. Information about clinical incidents is usually collected by voluntary notification by clinical staff, often as a subset of broader incident monitoring. Clinical incidents will include some, but by no means all, adverse events.

The Department of Human Services (the department) fully recognises the literature which demonstrates an adverse event rate of up to 10 per cent or even more, depending on the method used and definitions applied; and the type of care - for example, emergency, life-threatening illness care as opposed to simple elective surgery.

Most adverse events result in minimal harm. As an example, vomiting following an anaesthetic administration is an adverse event, even though it is a relatively common side-effect and no-one would suggest that anaesthetics should not be given. In all of the literature which looks at seemingly comparable acute hospital care, the rate of serious adverse events which cause significant harm is around 3-4 per cent[7]. A sub-set of these will be associated with death, but in most circumstances these patients would have died without the treatment. Risks associated with life saving treatment are a standard part of discussion between doctors and their patients and the consent process. The whole system constantly focuses on reducing such risk.

Can Adverse Events be Reduced?

The Audit Report states that 50 per cent of Adverse Events could be avoided[8]. This comes from literature emanating from the USA, in reference to idealised circumstances.

In 1995, some five years after the Harvard Medical Practice study was published one of the original authors expressed disappointment that despite the enormous effort that had been devoted to preventing

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[5] Australian Council for Safety and Quality in Health Care
[6] Australian Council for Safety and Quality in Health Care (Adapted)
[7] Wilson RM, Runciman WB, Gibberd RW, et al. The Quality in Australian Health Care Study. *Med J Aust* 1995; 163: 458-471

[8] Leape LL, Brennan TA, Laird N, et al. The nature of adverse events in hospitalized patients. Results of the Harvard Medical Practice Study II. *N Engl J Med* 1991; 324: 377-384

avoidable harm, the argument that 50 per cent of harm could be avoided had not been supported in evidence.[9]

The department supports the view that the rate of adverse events can be reduced and has supported many initiatives aimed at lowering rates, for example, leading the 'safer systems, saving lives' project of 2006; a number of breakthrough collaboratives based on the Institute for Healthcare Improvement methodology including medication safety, emergency care and patient flow; initiatives such as Blood Matters and the hand hygiene project. All of these initiatives are about encouraging engagement of clinical teams in hospitals, to embrace new approaches to their own systems of care, using their own ideas and disseminating them.

Evidence of actual improvements can be demonstrated by a number of published reports:-

- A 33 per cent reduction in pressure ulcers prevalence over 3 years a as a result of surveillance, education and a mattress replacement program.[10]

- A pilot program to reduce hospital acquired infections has demonstrated a statistically significant reduction the number of patients with MRSA bacteraemia[11]

- The in-hospital death rate of major trauma patients has fallen from 15 per cent in 2001-2002 to 12 per cent in 2005-2006.[12]

Who Is Responsible For Patient Safety?

Direct responsibility for patient safety sits with the clinical treatment team, always in the context of their employer and the organiser of their work, which is the hospital. It is essential that health services have appropriate quality and safety processes in place and the report acknowledges this is so.

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[9] Brennan TA, Gawande A, Thomas E, Studdert D. Accidental deaths, saved lives, and improved quality. N Engl J Med 2005;353:1405-1409

[10] PUPPS 3--Pressure ulcer point prevalence survey Statewide report 2006 Department of Human Services, 2006.

[11] Grayson L, et al. Significant reductions in methicillin-resistant *Staphylococcus aureus* bacteremia and clinical isolates associated with a multi-site, hand hygiene culture-change program and subsequent successful State-wide roll-out. 2008 yet to be published in the MJA

[12] The Victorian State Trauma System Report July 2001 – June 2006

The department acknowledges that it has an important role in adequately resourcing care - including staff, facilities and equipment; ensuring adequate governance of hospitals - including clinical governance; working with others - for example, VMIA - to ensure adequacy of risk frameworks; working with universities and clinical colleges to ensure a well trained workforce; and ensuring that hospitals abide by appropriate regulation, for example, professional registration and facility accreditation; among other things.

What of Incident Monitoring?

We support the development of incident monitoring. Incident reporting on its own, however, cannot reveal a complete picture of what does, or could, lead to patient harm[13] and it is but one tool to reduce adverse events. We also concur with the need for consistent data definitions and have been working with the field for more than two years to develop a statewide Incident Information System including a Gateway review in 2007.

[13] O'Neil AC, Petersen LA, Cook EF, et al. Physician reporting compared with medical-record review to identify adverse medical events. *Ann Intern Med* 1993; 119: 370-376.

Recommendation 3.1

'DHS should implement, as a priority, the recommendations from its 2007 review of the (then) Quality and Safety Branch'

The department is implementing the recommendations from its 2007 review.

Recommendation 3.2

'DHS should implement, as a priority, the outstanding recommendations from the previous performance audit, as outlined in the Minister for Finance's report to Parliament. In particular, DHS should advise health services of appropriate clinical incident definitions'.

The recommendations made in 2005 resulted in two large scale projects being developed, these being the *Review of clinical governance in Victorian public health services,* with the objective to develop a statewide framework to ensure clinical governance is supported, and the *Incident information system project,* to establish a statewide reporting capacity for all incident data.

The clinical governance framework project has delivered a draft framework and way forward for Victoria which is currently being reviewed by quality and safety groups and the department.

Both these projects will address the recommendations made in 2005 and are being progressed as a matter of priority.

Recommendation 4.1

'DHS should implement the IIS or a similar system with statewide reporting and analysis capability as a priority'.

The Incident Information System (IIS) development commenced in early 2006 and is a significant project.

To date the following outcomes have been achieved through the IIS project.

1. A clear set of definitions relating to clinical incident management.
2. Establishment of a standardised incident severity rating (ISR) methodology.

5

3. Development of a standardised incident classification model based on World Health Organisation's International Classification for Patient Safety (WHO IC4PS).
4. Development of an incident data set that formally defines the clinical incident information to be collected and the associated data collection methodology.

The development of a comprehensive taxonomy and data dictionary is reaching completion. It is now a matter of software development by others; implementation of data streams for hospitals to the department, VMIA, the Health Services Commissioner and Worksafe; implementing the necessary data storage; and developing the benchmarks and feedback reports to all stakeholders. The scope of the project has been altered over time in response to requests from hospitals to ensure the approach is reflective of the whole suite of incident management, not just clinical incidents. An appropriate business case will be finished in 2008. Training within hospitals will be a key to success of the project.

Recommendation 4.2
'DHS should establish a performance measures framework to enhance internal accountability for patient safety'.

The department is developing a program measures framework to underpin measures associated with the Statement of Priorities (SoP). This framework will monitor performance against the measures while identifying measures for inclusion in subsequent SoP iterations.

A new set of performance indicators associated with Australian Health Care Agreements include a number (to be finalised) of quality indicators that are currently in development. The department is contributing to the development of this list of indicators.

The department funds and participates in a number of external registry projects aimed at measuring quality of care. These focus on high risk/high cost clinical areas such as cardiac surgery and intensive care. The data from each registry is subject to review with feedback mechanisms in place. Many of these will be further developed through the clinical governance framework.

6

Appendix E

Victorian Managed Insurance Authority response

VMIA

VICTORIAN MANAGED INSURANCE AUTHORITY
Taking care of risk

STEVE MARSHALL
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6 May 2008

Mr Des Pearson
Auditor-General
Victorian Auditor-General's Office
Level 24, 35 Collins Street
Melbourne 3000.

Dear Des,

Thank you for the opportunity to review the updated draft audit report on "Patient Safety in Public Hospitals". As the medical indemnity (MI) insurer for Victorian public hospitals we are committed to addressing the issues that are leading to MI claims, a class of claims that are predicted to account for two-thirds of the VMIA's future claims liabilities.

In developing our clinical risk management strategy we were conscious of the potential for overlap with other stakeholders. To minimise any duplication of effort we undertook a thorough environmental analysis in preparation of the strategy. The VMIA's "leadership" role in clinical risk management is clear in the following areas:

- Lessons from claims losses
- Incident reporting
- Benchmarking reporting related to incidents and claims
- Risk framework reviews with an emphasis on clinical risks
- Communication to hospitals in relation to the above

In other areas such as:

- Clinical governance
- Clinical risk management training
- Risk management in response to known causes of adverse events

we see our role as one which requires a close working relationship with Dept of Human Services (DHS) and other stakeholders.

As outlined in our earlier response to the first version of the draft report our collaborative efforts with DHS and others include:

- the department's invitation to the VMIA to apply for a position on the new term of the Victorian Quality Council;

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Victoria
The Place To Be

- VMIA membership on the Incident Information System's (IIS) Project Advisory Group. The VMIA and the department are working together to identify common data definitions to support a more thorough analysis of incident data in the long term through the IIS. In the shorter term, the VMIA is currently working with the Riskman service provider to enable incident reporting analysis on current submitted health services' incidences so that a better understanding of system issues are identified and addressed;
- VMIA membership on the department's Clinical Risk Management Reference Group;
- VMIA membership on the department's Clinical Engagement Advisory Group; and
- VMIA attendance at the department's Clinical Networks' Leaders Group.

In relation to the draft VAGO report I make the following comments:

1. Section 3.4.1 last paragraph
   The VMIA is confident that potential confusion of roles and responsibilities will be avoided through our demonstrated collaborative approach with DHS. Specific examples of such collaboration, outlined in our earlier response, are also included above.

2. Section 3.6, 2nd paragraph

   Any VMIA initiative within the health sector has been initiated in consultation with a specific health service, DHS or both depending on the scope.

3. Section 3.7, 1st paragraph

   In our earlier response we emphasised that the VMIA's CRM strategy will not be acted upon independently. Our formal relationships with DHS will ensure that initiatives are mutually agreed and prioritised.

4. Appendix B page 39

   We mentioned in our earlier response that the two practicing clinicians are no longer in our employ. We are now focussed on the development of a more strategic, client centred approach that will be implemented in July 2008.

Please do not hesitate to contact me if there are further questions or any aspect of our response that you would like to discuss. Thank you again for the opportunity to participate in the review of patient safety in Victoria.

Yours sincerely,

Steve Marshall

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VAGO

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