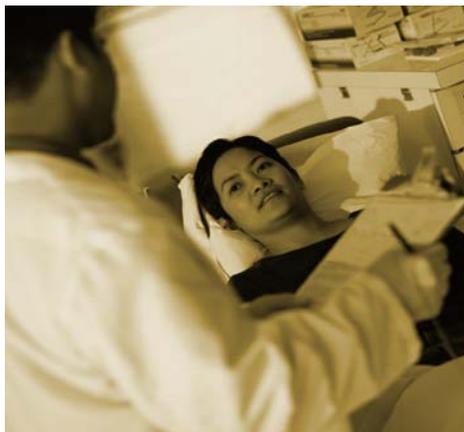


National quality improvement programme review: Incident Management

Martin Hefford, Dr George Downward

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Final draft



About LECG

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Executive Summary

LECG was commissioned by the interim Health Quality and Safety Commission Board to undertake a rapid review of the New Zealand Incident Management Programme - one of four major quality initiatives sponsored by the Quality Improvement Committee. Our review process involved interviews with a selection of key informants and examination of relevant documents.

Waikato District Health Board was contracted in late 2007 to deliver the incident management programme within a budget of \$1,150,000 over two years. The key deliverables were to develop a draft national policy for managing and reporting healthcare incidents, to deliver a training programme for those who would be operationalising the policy, and to develop the specifications for a national incident reporting system.

The project delivered all contracted outputs as per the Crown Funding Agreement – with only minor slippage in one deliverable: the final information management report which was delayed by a few weeks. Based on the documentation reviewed, and interviews with stakeholders, we conclude that best practice project management techniques were used in establishing and delivering the workstream.

The project delivered considerable progress on a very tight schedule. However, it has not yet not achieved the overall project goal: to achieve a nationally consistent approach to incident management across all health and disability services in NZ. The working draft national incident management policy requires reviewing and finalising; incident management needs to be extended from DHB owned services to the wider health and disability sector; and decisions are required on what central agency functions the HQSC will undertake, and what information systems are required to support those functions.

In order to progress best practice incident management, we recommend that the Health Quality and Safety Commission:

- a) **agree** to resource the roles outlined in the working draft national incident management policy for a ‘national central agency’ including to:
 - i) receive reportable event briefs and root cause analysis reports on serious (i.e. SAC 1 and 2) incidents from health and disability service providers;
 - ii) provide quality assurance advice back to submitters on the reports and on the actions taken;
 - iii) analyse aggregate data on healthcare incidents from a variety of sources, including health and disability service providers, ACC, the Coroner, professional (i.e. craft based) data sources, the Director of Mental Health, and the Health and Disability Commissioner;
 - iv) identify sector hazards and develop alerts and advisory statements as required;
 - v) identify strategies for improvement nationally – including facilitating collaborative shared learning between services / providers on common problems

- (e.g. falls prevention);
- vi) facilitate the provision of external independent expertise in clinical incident investigation;
- vii) issue national reports describing the major incidents and actions taken.
- b) **agree** to work with the DHB Quality and Risk Managers, and other sector stakeholders, to develop and maintain a set of online resources and training programmes to support better incident management and incident reporting, both in DHBs and in other parts of the health system;
- c) **agree** not to invest in a national incident management information system as specified in the Incident Management Project, but rather to invest in a version that contains the minimum features required to support the central agency functions, being a web enabled data base that:
 - i) facilitates easy entry of incident briefs and reports by health and disability service providers;
 - ii) enables uploading of lower severity incidents in aggregate form from multiple sources;
 - iii) supports easy querying and analysis, including by remote parties (eg DHB quality and risk managers); and
 - iv) does not replace individual DHB level incident management information systems;
- d) **agree** to promulgate expectations for:
 - i) DHB incident management information systems functionality; and
 - ii) Incident severity classification systems and incident taxonomies to be applied by all health and disability service providers;
- e) **agree** to resource a review of the working draft national incident management policy with a view to, either:
 - i) finalizing it for use by DHB health and hospital services, in which case the review should be conducted with the DHB quality and risk managers; or
 - ii) finalizing it as a health and disability sector wide policy, in which case the review should be conducted with a steering group representative of the wider sector;
- f) **agree** that if option e(i) is chosen, then a review of the policy should be undertaken within two years to extend it to the wider sector;
- g) **agree** to consult with primary care sector interest groups to assess the usefulness or otherwise of a simple online 3rd party incident reporting system (such as that currently maintained by bpac^{nz}) in supporting incident reporting and management in primary care; and
- h) **decline** to support the development of a separate medication error incident reporting system, unless a convincing business case can be made.

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1 Introduction

1.1 Purpose

LECG was contracted by the Health Quality and Safety Commission to review the Incident Management and Reporting Programme – a workstream funded via the now disbanded Quality Improvement Committee (QIC).

We were asked to report on:

- the current range of activities;
- the state of progress against the original programme objectives;
- options for next steps;
- options for collaboration of national initiatives or programmes; and
- recommended governance and management arrangements to ensure that the Board can be assured that progress is made in priority areas.

In addition, as part of the context for the review, we were asked to consider and advise on:

- the approach for finalising the current draft national policy for management of reportable events that takes into account emerging developments in aged care and primary care settings for all health care providers; and
- the proposed approach for establishing a new framework for a national central repository taking into account emerging developments in aged care and primary care settings, and national systems for ongoing improvement and learning.

Dr George Downward agreed to work with LECG on the review.

This report presents our draft findings and recommendations for feedback.

1.2 Review process

We reviewed a series of documents, including the Crown Funding Agreement, programme reports, the QIC business case, project scope, workshop reviews and correspondence. We also interviewed a selection of key informants. A list of those interviewed, and of key documents is attached as Appendix 1 to this report.

The reader should note that although efforts were made to ‘triangulate’ sources of data, we have relied on comments made and have had limited opportunity to verify the accuracy of statements.

1.3 The QIC business case

The QIC business case clearly set out the task for the lead DHB, Waikato:

“The incident management project is recommended to include the following.

- 1. Review and redevelop current national policy and guidelines that relate to incident management (including reportable events) and appropriate responses (including the open disclosure of adverse events)*
- 2. Provide a comprehensive education programme for health and disability providers on incident management. The education programme will focus on the investigation and management of serious and sentinel events for the purpose of identifying system improvements, reducing future patient risk, informing open disclosure of the results to patients and/or their families and developing the confidence and communication techniques required for effective open disclosure.*
- 3. Scope the business and technical requirements for a nationally co-ordinated incident information management system.”*

QIC business case 2007

An incident is defined for the purposes of the QIC business case as:

“an event or circumstance which could have resulted, or did result, in unintended or unnecessary harm to a person, and/or a complaint, loss or damage”

The definition derives from the Australian Council on Safety and Quality in Health Care standards. An ‘incident’ is a wider concept than an ‘adverse event’ – which is usually defined as an unintended injury caused by healthcare management rather than the underlying process of disease.

The case for incident management and reporting systems is based on logic, on comparisons with exemplar organisations such as the Veterans Health Administration, and on comparisons with very safe industries such as the aviation industry. There is, as yet, little in the way of empirical evidence in the peer reviewed literature to indicate the efficacy of reporting systems as a mechanism to improve patient safety.

However, there is good evidence that a substantial minority of individuals receiving healthcare services suffer some form of treatment related harm. For instance, a study by Davis et al of 6,579 NZ public hospital admissions found that 12.9% had an adverse event (unintended treatment related injury) and 15% of these resulted in permanent disability or death¹. About one third of events were considered preventable.

¹ Davis et al, Adverse events in New Zealand hospitals I: occurrence and impact. NZMJ, vol 115 Dec, 2002.

The World Health Organisation (WHO) Draft Guidelines for Adverse Event Reporting and Learnings Systems sets out the case for national reporting systems, in that it enables a country to take a systems level view of the opportunities to improve patient safety – see extract in the text box below.

Extract from WHO Draft Guidelines for Adverse Event Reporting and Learning Systems, 2005

Why should individuals or health-care organizations report adverse events and errors?

Health-care organizations or individuals benefit from reporting incidents if they receive back useful information gained by generalizing and analysing similar cases from other institutions. Consider the following case: in an intensive care unit at a hospital, the oxygen tubing is inadvertently connected to an intravenous line and causes an air embolism. Investigation reveals that the tubing connectors are similar, the oxygen tubing had been left disconnected from a prior respiratory treatment, and the lights in the unit were dim. The hospital's response might include implementing a new policy requiring that all tubing be labelled, a weak and cumbersome solution.

If the event and the results of the analysis are not reported to an external authority, the lessons learned are trapped within the walls of that hospital. The opportunity to generalize the problem is lost and the opportunity to develop more powerful and generalizable solutions is missed.

In contrast, if the event is reported and the findings from the investigation are entered into a database, the event can be aggregated with similar incidents to elucidate common underlying causes. A variety of solutions could emerge, ranging from nursing practice standards, to label and trace all tubing, to a requirement for medical device manufacturers to develop incompatible connectors for all medical tubing.

Seddon and Merry pointed out in the issue of the NZMJ that released Davis et al's findings that:

“‘safety’ is only one (albeit important) dimension of healthcare quality. Others, such as ‘effectiveness’, may in fact improve patient outcomes more than an excessive focus on reducing adverse events. Effective or appropriate care means avoiding overuse (providing ineffective care, in which the benefits are outweighed by the risks) and underuse (not providing effective care). Underuse is a particular problem in New Zealand as evidenced by the rationing of the provision of effective treatments such as coronary artery bypass surgery. ‘Access’, encompassing acceptability, timeliness, affordability, and equity is another important dimension of quality; it is not much use having safe care if patients are unable to access it. ‘Patient-focused’ care is increasingly seen as a defining dimension of quality, and involving patients in decisions is likely to improve their safety.”²

² Seddon, M & Merry, A, How safe are our hospitals?, NZMJ, vol 115 Dec 2002.

2 Progress against deliverables

In this section we review the programme achievements against the requirements in the Crown Funding Agreement.

2.1 The incident management project aims and objectives

Early in 2008, Waikato DHB was contracted, via a Crown Funding Agreement (CFA) variation, to deliver the incident management project. The key deliverables were to develop a draft national policy for managing and reporting healthcare incidents, to deliver a training programme for those who would be operationalising the policy and to develop the specifications for a national incident reporting system.

The project goal was to achieve a nationally consistent approach to incident management across all health and disability services in NZ, in order to:

1. reduce harm caused to patients, their families and to clinicians;
2. develop a culture and environment within which incidents could be identified, reported, investigated and acted upon to prevent recurrence and fear and defensiveness would be reduced;
3. implement (eventually) an information system that would support the culture and assist providers in the above process.

It was expected that the project would result in:

- identification of as many incidents in the health and disability sector as possible;
- prioritisation of incidents using a common tool;
- notification of all incidents to the right person (people) for action;
- review and investigation of incidents to identify causes and to develop mitigation strategies;
- classification of incidents using a common hierarchy and taxonomy;
- action, both local and national, to prevent recurrence;
- truthful and open disclosure of adverse events;
- support for patients, families and staff involved in incidents and adverse events;
- the establishment of a sustainable, consistent, ongoing programme for the management of all incidents across the entire health and disability sector.

The CFA allocated \$1,150,000 over two years for this workstream.

2.2 Project Management and Governance

Waikato DHB contracted with Communio (a consultancy group) to project manage the work and to deliver the core content. Communio established a steering group to oversee the programme, a training Faculty and an IS reference group to advise on the information system specifications. They also encouraged each DHB to set up a reference group to progress establishment.

2.3 Progress against the CFA milestones

Table 1 below shows progress against the original CFA milestones.

Table 1: Incident management planned versus actual progress		
Date	Planned progress (per CFA)	Actual progress
by 30 June 2008	<p>Develop for sign off, a scoping document for the Project</p> <p>Develop the National Policy, by delivering the following milestones by the due dates:</p> <ul style="list-style-type: none"> • Committee terms of reference developed by 31 March 2008; • Summary of research completed by 31 March 2008; • Discussion paper on recommended policy components completed by 14 April 2008; • Draft policy for consultation to be completed by 25 April 2008; • Final draft of policy available for implementation by 27 April 2008 <p>Develop and provide the Education and Training Programme, by delivering the following milestones by the due dates:</p> <ul style="list-style-type: none"> • Training Programme plan to be completed by 9 May 2008; • Draft curriculum to be developed by 27 June 2008. 	<p>Completed.</p> <p>All requirements completed on time.</p>

Table 1: Incident management planned versus actual progress

Date	Planned progress (per CFA)	Actual progress
By 30 June 2009	<ul style="list-style-type: none"> • Detailed programme curriculum to be developed by 25 July 2008; • Training materials (paper) by 26 September 2008; • Delivery of the training programme in all DHBs complete by 15 August 2009; • Final report on Education programme by 15 August 2009; • Sustainability plan by 15 August 2009. <p>Develop the Incident Information Management System, by delivering the following milestones by the due dates:</p> <ul style="list-style-type: none"> • Incident Information Management System identification plan developed by 1 July 2008; • Stakeholder consultation report; • Report on DHB systems and capacity complete by 27 February 2009; • Draft Report on Specifications for consultation by 30 April 2009; • Final report on Specifications completed 30 June 2009; • Final report on recommended system/way forward by 30 June 2009. 	<p>All education and training deliverables supplied on time. 1,709 people attended a ½ day incident management training workshop; 1,127 attended a full 2/1/2 day training. Evaluations were collected and were overwhelmingly positive.</p> <p>All Information management components delivered on time except the final report on specifications and final report on way forward, which were delivered 15 August 2009 rather than 30 June 2009.</p>

In summary, the milestones have all been delivered as per the CFA – with only minor slippage in one deliverable: the final information management report which was delayed by a few weeks. Based on the documentation reviewed, and interviews with stakeholders, we conclude that Communio used best practice project management techniques in establishing and delivering the workstream. The project delivered considerable progress on a very tight schedule.

The project also delivered a communications package including a website with useful resources and project documents, six newsletters to stakeholders, a consumer forum, a brochure, a sector consultation process, and a set of DHB onsite visits.

2.4 Stakeholder views on project process

The Communio management of the project was universally described as excellent, and the quality of documentation was considered very good. Only two substantive issues were identified by stakeholders in relation to the project process. The first was that a number of stakeholders felt (rightly or wrongly) that the Communio approach involved a wholesale importation of the New South Wales model, without sufficient customisation for a New Zealand context. The second was that insufficient customisation of the policy and associated processes was undertaken to reflect the requirements of mental health services in NZ. This second more substantive issue is discussed in section three.

3 Issues for HQSC consideration, and next steps

3.1 Summary

This section outlines the issues that the HQSC might wish to consider in deciding on the next steps to take, and our views on what some of those steps should be. In summary, the key decisions relate to:

1. finalising the draft national incident management policy;
2. extending the incident management system to cover the rest of the health and disability sector;
3. putting in place the required central agency functions; and
4. resourcing ongoing training and support for incident management

The issues are interrelated, requiring a comprehensive approach in order to achieve a cohesive and effective system.

3.2 The draft national incident management policy

3.2.1 The working draft policy

The National Policy for the Management of Healthcare Incidents version dated 25 September 2008 remains a 'working draft'. It has not been reviewed or finalised since the project ended. The working draft is appended to this report.

Key aspects of the policy include a requirement for: open disclosure of adverse events; classification of all incidents using a severity assessment code (SAC) 1 – 4; investigation of all SAC 1 incidents; reporting to the National Central Agency of all SAC 1 and 2 incidents. Each healthcare provider is expected to have a local policy that is consistent with the national policy.

The DHB Quality and Risk Managers group indicated that DHBs are generally abiding by the draft policy, although it has no formal status within the DHB Operating Policy Framework.

The group, and other stakeholders, identified a number of issues with the policy, including the following:

- the policy, at 47 pages, is too long, and the policy elements need separating from the guidance and process elements (for instance by creating a 2 - 3 page policy supported by more in-depth guidance documents);
- the SAC criteria are variably and inconsistently applied for a number of reasons, including:

- different interpretations of the use of the ‘likelihood of re-occurrence’
- lack of a national moderation and feedback process
- requirement for more specific guidance on the ratings for particular types of incidents
- the usefulness or otherwise of the potential (vs. actual) consequence in deriving ratings;
- the interface with mental health incident reporting and events – noting the general view that there should be one policy for all services;
- the need for a common nomenclature & taxonomy in recording incidents;
- the appropriateness of the policy including corporate incidents as well as clinical incidents;
- the policy is oriented to DHB specialty health and hospital services and would not be suitable as currently written for other parts of the health and disability sector (primary care, aged residential care, etc.)

Nonetheless, the general view is that there is considerable benefit to having a single national policy and that this working draft is a significant advance on previous practice. Some DHBs have used the incident reporting and investigation process as a lever to build a culture of quality and safety in their workforce, and to drive a systems approach to safety.

3.2.2 Mental Health Interface

The Director of Mental Health, Dr David Chaplow, informed us that prior to the development of the national (working draft) incident management policy his office had a very effective national process in place, whereby each DHB reported significant events to his office on a timely basis and received feedback on the incident and subsequent investigation. The data are entered into a national database and are released each year with the Director of Mental Health’s annual report.

The introduction of the national policy disrupted this system by introducing the severity assessment code (SAC) rating system in place of previous reporting criteria. The SAC criteria do not take account of:

- Reports of deaths required under section 132 of the Mental Health Compulsory Assessment and Treatment Act
- Reports required in relation to Special Patients (e.g. absent without leave incidents)
- Reports of incidents that may attract media attention and that are required to ensure ‘no surprises’ for the Minister

Further, the timeframes set out in the draft policy for reporting (7 days) do not meet the Director of Mental Health expectations – usually same day alert of a serious incident. The information needed in the reportable event brief also differs for Mental Health. The

mental health brief requires, for instance, the NHI of the patient involved, whereas the generic reportable event form does not. Finally, the importance of prompt informed feedback to the sector was stressed – noting that while the draft national policy has that as an expectation, it has not been a feature of the current arrangements from a mental health perspective.

The differences between the draft national policy and the expectations of the Director of Mental Health have created considerable tensions. DHB mental health services will often get contradictory advice - from their corporate quality and risk service that something does not need to be reported - and from the Director of Mental Health that it does. In addition, investigations of incidents have at times been undertaken by generically trained quality staff not familiar with mental health services, resulting in reports that are weak or that miss the point. Overall, Dr Chaplow reported that the national policy had resulted in a reduction in the quality and timeliness of reporting to his office.

The Office of the Director of Mental Health has maintained a national database of mental health incidents, supported by a parallel (partially informal) process of reporting by mental health teams to the Director of Mental Health. However, in the past year they have not released their serious incident information in order to avoid causing confusion between their (much larger) list of incidents, and the incident list released through the national process.

The Mental Health database and processes support the group's external reporting obligations to the UN and interface with the Coroner, whereas the overall central repository may not require the same functionality.

The Director of Mental Health expressed support for a brief, values-based, single national incident management and reporting policy, provided it facilitated discharge of his statutory accountabilities, rather than impeding them as the current one does.

An option would be to clearly articulate the types of incidents that need to be reported to the Director of Mental Health, and to have them reported directly to his office (as is the current informal process), with regular sharing of information from the office database to a central repository.

3.2.3 ACC Interface

A person may qualify for treatment injury if they are injured as a result of treatment by a health professional. The ACC treatment injury centre receives some 8,000 new claims per year, of which around 5,000 are approved. One might expect the treatment injury database to be a rich source of information on the causes of adverse events, and ACC have indicated that they are willing to share data with the Commission where appropriate. However, interpretation of ACC statistics should be undertaken with care; the legal definitions applied mean that events that are known complications of a disease or treatment can trigger a treatment claim, even though they would not normally be considered adverse events by a healthcare provider.

ACC currently reports a ‘serious & sentinel’ subset of the incidents they collate to a section of the Ministry of Health – a different section to that which receives DHB reports. The Ministry compiles these, and may request comments from individual providers on the cases, but currently has no process or resources to analyse the incidents or to report back learnings to the sector.

3.2.4 HDC interface

Discussions with the Office of the Health & Disability Commissioner indicated that they are keen to have a strong and collaborative relationship with the HQSC. The HDC indicated their support for:

- consistent incident management and reporting across NZ (including the private sector, GPs and age residential care sector);
- open disclosure being a fundamental building block of a national policy on incident management;
- more work on the collation and analysis of reports and feeding back of shared learnings arising from these; and
- information sharing with the HQSC where this will lead to system improvements.

3.2.5 Legislative protection

Advice obtained through the national project is that there is no legislative protection for individuals reporting incidents or providing input to root cause analysis reviews. This means that reports can potentially be obtained under the Official Information Act – although the controlled annual release process has mitigated this risk substantially, as the ombudsman has previously ruled that DHBs can withhold details that may identify healthcare providers or patients.

Some specialty groups (e.g. anaesthetists) report through to an independent third party system rather than through DHB systems, in part because of concerns about lack of confidentiality and lack of protection from prosecution or other action under the DHB system.

Whether broader statutory protections would be useful is a matter that the HQSC may wish to consider over time, but it is outside the scope of this review.

3.2.6 Mandatory reporting

A few key informants raised the issue of mandatory reporting of serious and sentinel incidents. Currently most reporting is voluntary, although some reporting is required under various Acts of Parliament. Section 31 of the Health and Disability Service (Safety) Act requires the following:

“A person certified to provide health care services of any kind must promptly give the Director-General written notice of—

- (a) any incident or situation (for example, a fire, flood, or failure of equipment or facilities) that has put at risk, may have put at risk, puts at risk, or may be putting at risk the health or safety of people for whom the person was or is providing the services; and
- (b) any investigation commenced by a constable into any aspect of the services, their provision, or any premises in which they were provided; and
- (c) any death of a person to whom the person was providing the services, or occurring in any premises in which they were provided, that is required to be reported to a coroner under the Coroners Act 2006.”

On the face of it, ‘any incident or situation that puts at risk the health of people’ implies a wide scope of required reporting, since certified providers include all aged residential care homes, hospitals and many NGO services. However, actual reporting under this act has been generally constrained to actual fires, floods, police investigations, and referrals to the Coroner. Compliance is unknown but underreporting is suspected. The information reported is used by HealthCert in assessing the risk of an individual provider and may be taken into account in decisions on renewal of certification – i.e. the data are used for regulation and audit rather than quality improvement purposes.

The issue of whether serious reporting should be mandatory is outside the scope of this review, but our instinct is that if the purpose is quality improvement then reporting should generally be voluntary.

3.2.7 Reviewing and finalising the policy

The Quality and Risk Managers group have offered to review and finalise the draft policy, in conjunction with the Commission.

We agree that a review is required (indeed such a review is recommended in the incident management project Close Out Report), and suggest that the DHB Quality and Risk Managers would be a suitable group to oversee such a review (with project management support), if the policy is intended to continue to focus on DHB specialist health and hospital services. If, however, the opportunity is taken to move directly to developing a health and disability sector-wide single overarching policy, then the review would need to be driven by a broader sector governance group, incorporating representatives from primary care, aged residential care, disability services, NGOs, and pharmacies. That is, the governance of the review, and the timeframe and resources required, will vary according to the scope of the review. A review focused on DHB health and hospital services could be convened and completed quickly with relatively little investment. A review aimed at extending the policy to the wider sector would take longer, require more resources, and need to involve the wider health and disability sector.

3.3 Extending the incident management framework to cover the whole of the health and disability sector

3.3.1 Context

Incident reporting and management is emergent outside the DHB owned portion of the health and disability sector. However, there is little doubt that as many, or more adverse events occur in primary care settings, aged residential care homes, private hospitals, and NGO mental health and disability services, as occur in DHB owned hospital services.

3.3.2 Primary care settings

Nearly all primary care practices in NZ are contracted through PHOs and hence have a level of management support available to them. Some development of incident reporting and management has occurred in recent years, and a number of the relevant developments are briefly described below.

bpac^{nz} open reporting system

bpac^{nz} have developed a bespoke, open access, web-based incident reporting system for primary care providers. The system is anonymous and moderated by bpac staff to avoid misuse. Anyone can look at and comment on the reported events. This is a link to the incident reporting website: <http://www.bpac.org.nz/safety/home.aspx>.

bpac^{nz} indicated that they are intending to add further functionality, including a local 'print function' to allow practices to demonstrate that they are meeting the accreditation standards relating to incident management. The service is currently unfunded – although it is also very low cost.

The major bpac^{nz} incident system innovation is that anyone can review and comment on any or all of the reported incidents – thus creating a shared learning approach and avoiding the common 'black hole' issue with national reporting systems: that incident reports go in, but value added analysis and feedback seldom come out. However, the bpac^{nz} information system covers reporting only – it does not include investigation of the root causes of an incident or management recommendations. Nor does it currently have the ability to add a report analysing the root causes of an incident. It is solely an anonymous, confidential reporting system that is not linked to local PHO and MSO action. However, over time, analysis of the incidents reported could be useful in highlighting systemic safety issues and enabling PHOs, practices or DHBs to take action.

PHO specific systems

A number of PHOs or their management services providers have begun instituting a formal approach to recording investigating and reporting back on incidents.

For instance Pinnacle run an incident reporting service for their 90+ GP practices. Their system is based on paper reports and a spreadsheet rather than being web enabled. It includes investigation and report back on lessons learnt.

Cornerstone accreditation

The Cornerstone accreditation programme run by the Royal NZ College of GPs includes a requirement that practices have an incident documentation and review policy. By mid 20011 it is anticipated that 2/3rds of NZ practices will be accredited under this programme; hence having, at least on paper, an incident management policy.

DHB specific initiatives

Some DHBs have taken specific initiatives to extend incident management into their contracted external providers. For instance, Waikato DHB has established a pharmacy incident reporting system. Some have also run combined investigations with primary care services to uncover the root causes of specific incidents that span the hospital and primary care services. Such initiatives tend to be driven by local advocates and reliant on local relationships.

Role of PHOs and DHBs

The draft policy requires a root cause analysis be undertaken of all SAC 1 incidents, and some investigation of SAC 2 incidents. A typical primary care centre or pharmacy will not have the capability to conduct such a review. Hence, an issue to be considered in rolling the policy out wider, is the role of DHBs and PHOs in conducting such reviews for primary care providers. Some are already undertaking such reviews. Other will need training and support if we expect them to take on this role.

NZ Pharmaco-vigilance centre medication error reporting pilot

The medication error reporting system is a pilot project contracted to the NZ Pharmaco-vigilance centre (Otago University) through the MoH Medsafe business unit. It involves developing a web based reporting system for medication errors and is a separate initiative to the Centre for Adverse Reactions to Medications (CARM).

A question for the Commission (and the wider sector) to consider is whether the added value of another agency with a web-enabled reporting system focused solely on medication errors is a worthwhile investment, given that the BPAC system, and the DHB reporting systems, already allow separate identification of medication errors. The advantage might be more sophisticated classification and better targeting of communication campaigns. The downside is the degree of duplication, and the recognition that GPs, in particular, will not wish to have two incident reporting portals on their desktops.

We do not see a compelling business case for a separate reporting system for medication errors, given that these can be differentiated in current reporting systems anyway. Hence we consider that it would be better to avoid having a duplicate reporting system solely for medication errors.

3.3.3 Aged residential care, private hospitals and disability sector

Residential care facilities and private surgical hospitals are required to be certified under the Health and Disability Sector Standards. Standard 2.4 'Adverse Event Reporting' requires that all adverse events are recorded by the service and reported to the consumer in an open manner. The standard is complied with in varying ways, private hospitals

may have sophisticated reporting and investigation systems, while small rest homes may simply have a paper file documenting incidents.

NGOs providing care to those with a disability or to mental health consumers may or may not be required to be certified, depending on their size and the nature of the service they provide. However, past experience shows that marginalised groups receiving residential care can be subject to unsafe practices or may be more likely to have adverse event occur when they use hospital services.

3.3.4 How and when to extend the national policy?

It is clear that the policy needs to be extended across the wider health and disability sector. The issues are mainly around phasing: (should we finalise the policy for DHB health and hospital services first, then extend to the rest of the sector?), training and resourcing.

Our instinct is that it would be possible to develop a short overarching policy statement that sets out an expectation that all health and disability sector organisations will:

- openly disclose adverse events (in line with the Health and Disability Commissioner’s statement on open disclosure)
- document and classify all incidents using a common simple classification and coding system (e.g. the SAC system) provided centrally;
- investigate all level 1 incidents;
- report to the National Central Agency all SAC 1 and 2 incidents (or equivalent if the coding system changes).

The policy could be supported by online and paper based guidance documents and other resources. Processes might differ somewhat in the different sectors, but it will be important to have a common simple severity classification system and taxonomy for incidents to ensure that information for different sources can be usefully combined to provide an aggregate view.

If the HQSC Commission decide to do a single review aiming at extending the policy to cover the whole sector, then a broadly inclusive steering group for the review would be appropriate, including: people representative of the DHB sector (senior management, Quality and Risk managers, and clinicians), the primary care sector (GPs, MSOs, pharmacists) the aged care sector, the director of mental health, Heath cert and NGOs.

A policy review should also be able to deal with the level of duplicate reporting that occurs currently – in particular in relation to ACC reporting and mental health reporting, where there is a degree of waste associated with duplicate reporting and double entry.

Once finalised, it would be appropriate to include compliance with the policy within the DHB Operating Policy Framework, and, eventually within the Health and Disability Sector Standards, or similar sector wide document.

3.4 Central agency functions / repository for incidents / Information management system

3.4.1 Current processes are unsatisfactory

The draft policy requires that all DHBs send a brief description of any SAC 1 or SAC 2 incidents to the “national central agency” within 5 working days. About half the DHBs currently send brief reports to the Ministry of Health, where they are entered into a spreadsheet. The policy also requires that a summary of all SAC 1 event root cause analysis reports are sent to the “central agency” within 70 calendar days. DHBs are similarly inconsistent in whether they send these RCAs to the Ministry of Health in a timely manner. Those reports that are received are filed and not generally further analysed by the MOH except in the months before the time of the annual public release.

More than one stakeholder described the current arrangements as like a ‘black hole’ where reports go in, but information does not come out.

The World Health Organisation set out the characteristics of successful incident reporting systems in 2005. Their suggested characteristics are reproduced below.

Non-punitive	Reporters are free from fear of retaliation against themselves or punishment of others as a result of reporting.
Confidential	The identities of the patient, reporter, and institution are never revealed.
Independent	The reporting system is independent of any authority with power to punish the reporter or the organization.
Expert analysis	Reports are evaluated by experts who understand the clinical circumstances and are trained to recognize underlying systems causes.
Timely	Reports are analysed promptly and recommendations are rapidly disseminated to those who need to know, especially when serious hazards are identified.
Systems-oriented	Recommendations focus on changes in systems, processes, or products, rather than being targeted at individual performance.
Responsive	The agency that receives reports is capable of disseminating recommendations. Participating organizations commit to implementing recommendations whenever possible.

Source: WHO Draft Guidelines for Adverse Event Reporting and Learning Systems, 2005

Clearly current arrangements do not meet a number of these standards. In particular, current central processes are not timely, expert, systems oriented, or responsive. The deficits result in part from a lack of clarity of central agency roles and responsibilities, and in part by lack of resources, including information systems to support the central agency roles.

3.4.2 Proposed information system

The information specifications developed by the national incident management project are comprehensive. They describe a national system that allows for:

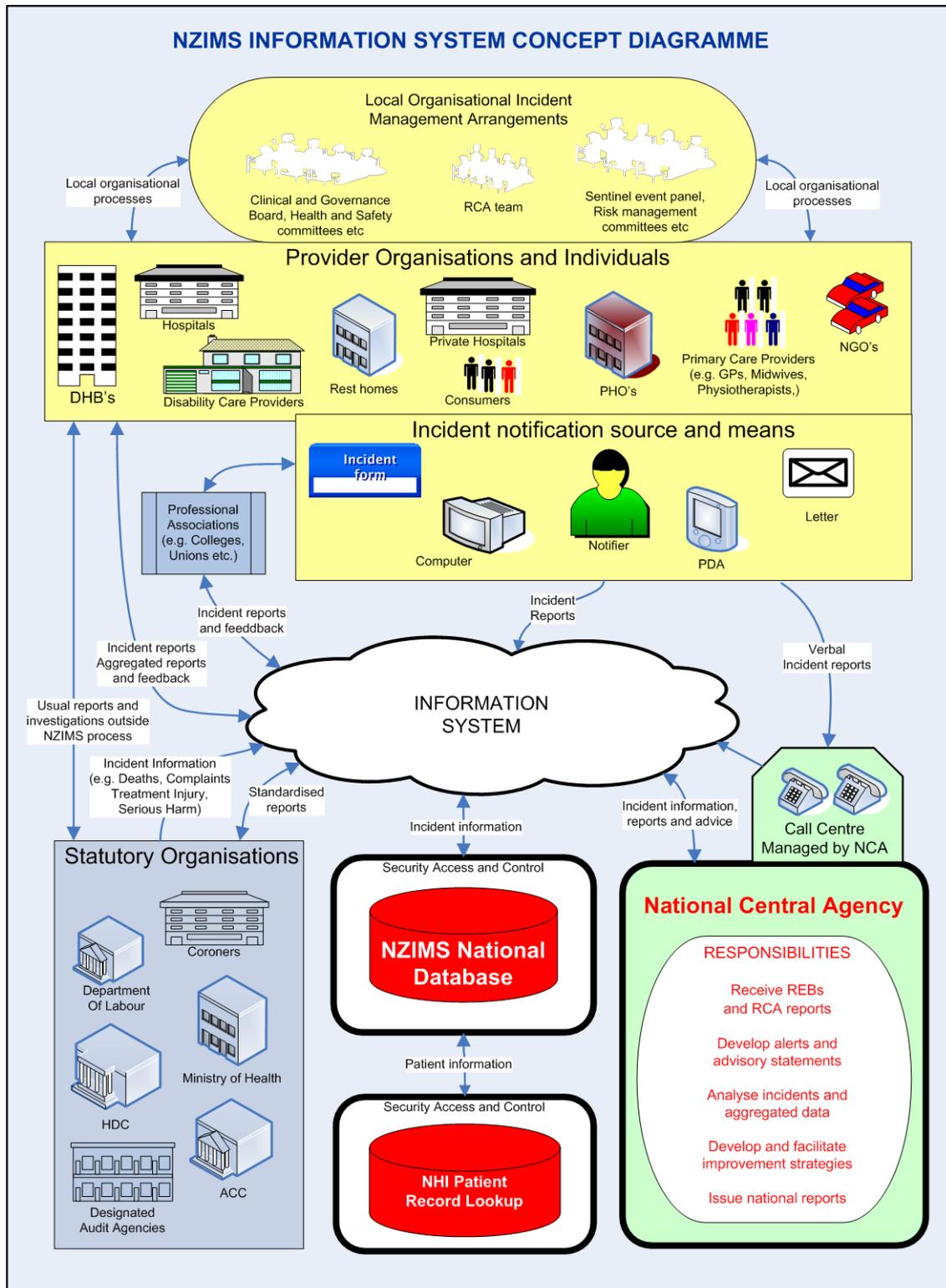
- transition of all DHBs from current local systems to the new national incident information system;
- electronic transfer of data via a national minimum dataset specification from non-DHB providers (and professional organisations) that want to maintain their own local incident management information system;
- a web-based reporting system that clinicians working in providers that do not have their own system can use;
- the option of anonymous or identified reporting; and
- a staffed phone-in option to allow those without access to the internet to report.

The concept schematic (sourced from the project Incident Information Specification August 2009, page 14) over page provides an overview of the proposed information system.

The specified national database is expected to gather data using standardised report templates from Coroners, ACC, the HDC, Audit Agencies and profession based entities (e.g. RNCGPs, ANZCA). The policy and information system also envisage a 'National Central Agency' which would:

- receive reportable events briefs and root cause analysis reports;
- develop alerts and advisory statements;
- analyse incidents and aggregated data;
- develop and facilitate improvement strategies; and
- issue national reports.

The national central agency might or might not operate the national incident management information system.



3.4.3 What do we need in a national incident management information system?

Developing a new national minimum dataset and information system is a major undertaking. It will require significant start up capital investment, as well as ongoing operational resources. It will tie up health funds that could otherwise be used to deliver health services or be invested in change programmes to directly improve safety.

The state of Victoria is in the last stages of a well resourced project to roll out a state-wide incident management information system. Key informants we spoke to indicated that they have had a dedicated team working on it for over four years, but considered that the cost of the project was commercially sensitive. The other Australian states either already have, or are planning to implement state-wide information systems.

Currently the national repository of incidents is an incomplete spreadsheet filled out in an inconsistent manner and supported by a filing cabinet. The specification for a new information system developed through the project is for a web enabled, customisable, nationally available database supplemented by a telephonic and online help centre that would replace existing DHB information systems. The current system is unacceptable; the specified system may not be cost effective.

A question for the HQSC to consider is the balance between investing in a national incident reporting information system, versus investing in change programmes to address already known safety issues (e.g. falls, medication management, infection control, etc). The WHO also provides some advice on this issue (set text box below), recommending that it is more important to develop a response system than a reporting system.

Extract from WHO Draft Guidelines for Adverse Event Reporting and Learning Systems, 2005

'Reporting is a tool for obtaining safety information. A national reporting system, therefore, can usefully be regarded as a tool to advance public policy concerning patient safety. It should be an extension of a programme of quality improvement and error prevention. To be effective, learnings from the analysis of reports must feed into a mechanism for developing and disseminating changes in policy and practice that improve safety.

If the commitment to improvement is weak, or if there is no infrastructure to carry out implementation of changes, such as an agency charged with improving safety, a reporting system will be of little value. Stating it simply, it is more important to develop a response system than a reporting system. If there is a commitment to improvement of patient safety and some infrastructure, but resources are scant, alternative methods of identifying problem areas may be preferable.' (p53)

A further question is the appropriate balance between a centralised national information system, and local DHB or regional information systems. Many of the DHBs have

already purchased a software system to support incident reporting. Others have not been able to gain approval for the capex required, because of the expectation that a national system will be implemented.

3.4.4 A middle ground?

A middle ground between the current unsatisfactory system and investing in a new national information system would be to focus the HQSC activities on the 'National Central Agency' responsibilities described in the Close Out report. That is:

1. reviewing and analysing reportable events briefs and root cause analysis reports for the severity assessment code 1 or 2 incidents;
2. providing advice back to submitters on the reports and on the actions taken (CQI review);
3. analysing healthcare incidents and aggregated data from a variety of sources, including DHBs, ACC primary care, professional data sources, the HDC etc.;
4. developing & promulgating alerts and advisory statements;
5. developing and facilitate improvement strategies – including facilitating collaborative shared learning between services / providers on common problems (e.g. falls prevention); and
6. issuing national reports describing the major incidents and actions taken.

The HQSC could commission the minimum information system required to fulfil this function, and add enhancements as time goes on. In this way resources would be primarily invested in the shared learning and response aspects of incident management, rather than the information gathering aspects.

The functionality envisaged is a simple web portal that DHBs and other providers could use to submit their SAC 1 and 2 reportable event briefs and SAC 1 root cause analysis reports as specified in the national policy, with the ability to upload data on all their lower scoring reportable events. The portal would link to a database that could be viewed by authorized quality and risk managers and which would support sophisticated querying, analysis and report generation.

An important disadvantage of not having a national incident management information system is that the opportunity to force use of a consistent taxonomy of event and classification system is lost. This disadvantage can be ameliorated by developing and promulgating a simple, required, taxonomy and classification system as part of the national policy and training resources.

The HQSC could usefully set standards for DHBs purchasing incident management information systems, and may wish to facilitate joint purchasing of compliant information systems by DHBs through Health Benefits Ltd.

The HQSC may also wish to consider contracting to provide a nationally available web based confidential incident reporting system for primary care and others without a local

reporting system. This would be a low cost way of delivering easy access to a national reporting system. However, the priority should be on learning from and responding to incidents rather than just facilitating reporting.

3.5 Resources and training

The initial training programme was well received, but Quality and Risk Managers identified a requirement for ongoing training, and for resources to support implementation of the policy. The Commission may be able to reassemble the previous training Faculty and extend it to support delivery of a training programme using current DHB expertise.

DHB Quality managers have developed a draft ‘Guide book’ to support those working on incident management, and plan to request HQSC support to finalise the guide. Technical writing resources and support to convert the document to an online version would be required.

Some resources and training programmes will need to be customised for different audiences/sectors – e.g. pharmacies, general practice, age residential care, community NGOs, mental health to support role out of the policy to the wider sector.

The incident management web page developed in 2008 will need to be redeveloped and maintained. If the HQSC decides to take on the specified central agency functions then the incident management web page should become a subset of the HQSC web presence.

Patient safety is a core interest of the HQSC. We recommend that the HQSC invest in ongoing training and other resources to support incident management.

3.6 Future programme management and governance

The HQSC will need to decide which central agency activities it will undertake itself, and which it will subcontract to a 3rd party. The potential scale of activities is substantial. A consultancy proposal received by the MoH in 2009 quoted the following costs for the next stage of incident management activities:

Establish central agency functions and minimum information system	\$704,000
Support DHB incident management activities	\$206,250
Finalise national policy	\$40,500
Training programmes	\$530,000
Extend policy to non-DHB sectors	\$155,300
Total	1,636,050

The Commission should be able to reduce the cost of these activities substantially from the above estimates by working in partnership with DHBs and with other sector groups, rather than contracting the service from a consultancy. However, some considerable investment will be required.

In the context of incident management the key role for the Commission is to collate and feedback learnings. This function needs to be appropriately resourced to ensure it works well. Given the Commission's limited resource much will need to continue to be done by supporting and drawing on enthusiasts based in DHBs or in other parts of the sector.

3.7 Recommendations

We recommend that the Health Quality and Safety Commission:

- a) **agree** to resource the roles outlined in the working draft national incident management policy for a 'national central agency' including to:
 - i) receive reportable event briefs and root cause analysis reports on serious (i.e. SAC 1 and 2) incidents from health and disability service providers;
 - ii) provide quality assurance advice back to submitters on the reports and on the actions taken;
 - iii) analyse aggregate data on healthcare incidents from a variety of sources, including health and disability service providers, ACC, the Coroner, professional (i.e. craft based) data sources, the Director of Mental Health, and the Health and Disability Commissioner;
 - iv) identify sector hazards and develop alerts and advisory statements as required;
 - v) identify strategies for improvement nationally – including facilitating collaborative shared learning between services / providers on common problems (e.g. falls prevention);
 - vi) facilitate the provision of external independent expertise in clinical incident investigation;
 - vii) issue national reports describing the major incidents and actions taken.
- b) **agree** to work with the DHB Quality and Risk Managers, and other sector stakeholders, to develop and maintain a set of online resources and training programmes to support better incident management and incident reporting, both in DHBs and in other parts of the health system;
- c) **agree** not to invest in a national incident management information system as specified in the Incident Management Project, but rather to invest in a version that contains the minimum features required to support the central agency functions, being a web enabled data base that:
 - i) facilitates easy entry of incident briefs and reports by health and disability service providers;
 - ii) enables uploading of lower severity incidents in aggregate form from multiple sources;

- iii) supports easy querying and analysis, including by remote parties (eg DHB quality and risk managers); and
 - iv) does not replace individual DHB level incident management information systems;
- d) **agree** to promulgate expectations for:
 - i) DHB incident management information systems functionality; and
 - ii) Incident severity classification systems and incident taxonomies to be applied by all health and disability service providers;
- e) **agree** to resource a review of the working draft national incident management policy with a view to, either:
 - i) finalizing it for use by DHB health and hospital services, in which case the review should be conducted with the DHB quality and risk managers; or
 - ii) finalizing it as a health and disability sector wide policy, in which case it the review should be conducted with a steering group representative of the wider sector;
- f) **agree** that if option e(i) is chosen, then a review of the policy should be undertaken within two years to extend it to the wider sector;
- g) **agree** to consult with primary care sector interest groups to assess the usefulness or otherwise of a simple online 3rd party incident reporting system (such as that currently maintained by bpac^{nz}) in supporting incident reporting and management in primary care; and
- h) **decline** to support the development of a separate medication error incident reporting system, unless a convincing business case can be made.

Appendix 1: list of individuals interviewed

Dr Susan Dovey, Otago University
Dr David Chaplow, Director of Mental health
Frances Hughes, Senior Advisor, MoH
Gillian Bohm Senior Advisor, MoH
Kate Macyn tyre, Patient Safety Manager, CCDHB
Dr Murray Tilyard, CEO, BPAC
Gillian Grew, Chief Advisor Services, MoH
Rachel Taylor, Dylan Tapp, ACC Treatment Injury Unit
Julie Patterson, CEO Whanganui DHB
Nicola Sladden, Chief Legal Advisor, HDC
Neville Hablous, Project sponsor, Waikato DHB
Mary Jo Doherty, Quality Manager Waikato DHB
Maureen Robinson, Ex Comunio CEO
DHB Quality & Risk Managers (group discussion)
Hayley Lord, Quality Manager, Pinnacle Network
Dr Colin McArthur, Auckland DHB
Dean Wilkes & Theresa Williamson, Victoria Health Incident Management Project

Appendix 2: Draft National Incident Management Policy

Attached as a separate document.