System-level patient safety risks: Response co-ordination and communication

Summary This Policy Directive details the NSW Health co-ordinated system-level response to a broad range of patient safety risks. Dependent on the nature of the risk, NSW Health assigns a Lead Agency who is supported by the Co-ordinating Agency.

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Distributed to Ministry of Health, Public Health System, NSW Ambulance Service

Audience All NSW Health staff (including contractors, sub-contractors and volunteers)

Secretary, NSW Health

NSW Health

Policy Directive

System-level patient safety risks: Response co-ordination and communication

Policy Statement

NSW Health coordinates a system-level response to an emerging risk to patient safety, in order to mitigate the risk and associated healthcare system impacts.

Summary of Policy Requirements

Risks to patient safety have the potential to significantly impact individuals and can impact the delivery of healthcare services. In high to extreme risk scenarios a co-ordinated systemwide response is required to ensure timely communication and effective risk mitigation or control.

This Policy Directive details the NSW Health co-ordinated system-level response to a broad range of patient safety risks. Dependent on the nature of the risk, NSW Health assigns a Lead Agency who is supported by the Co-ordinating Agency.

Local Health Districts, Specialty Health Networks, Statewide Health Services, and pillars of NSW Health are required to ensure relevant planning and clinical staff are familiar with this Policy Directive. Also making local preparations necessary to guarantee adherence to the roles and responsibilities described, in the event of a high or extreme level risk to patient safety.

The roles and responsibilities of all agencies involved in a systemwide response are outlined in this Policy Directive. It includes direction on key response actions such as risk assessment, escalation, risk mitigation and control, communication, surveillance, and de-escalation.

Revision History

Version	Approved By	Amendment Notes
PD2024_016 May-2024	Deputy Secretary, Population and Public Health & Chief Health Officer	Merger of NSW Health Policy Directives: • *Coordination of responses to urgent system-level medicine or medical device issues* (PD2019_019), and • *Safety Alert Broadcast System Policy Directive* (PD2013_009).
PD2019_019 May-2019	Deputy Secretary, Population and Public Health	First publication.
PD2013_009 May-2013	Director General	Changes in Policy reflect transfer of SAB function from MOH to CEC and replaces PD2006_102.
PD2006_102 November-2006	Director General	New policy.

Contents

1. Background

Risk management in healthcare requires a complex set of clinical and administrative systems, processes, procedures, and reporting structures which should be designed and operationalised to detect, monitor, assess, mitigate, and prevent risks to patients and system performance.

Although most patient safety risks can be managed locally, some will require co-ordination at a system-level. Multiple agencies are responsible for escalating identified risks and the coordination of a response relies on collaboration between agencies resulting in communication to the system.

Responses to risks impacting NSW Health Services will be coordinated by the Clinical Excellence Commission (CEC). Any risks that have a broader impact are led by the relevant Ministry of Health (the Ministry) branch or division.

1.1. About this document

This Policy Directive describes timely, effective, systematic, and coordinated system-level responses to risks to patient safety and system performance. These risks include those relating to:

- medicines
- medical devices
- biologicals
- infection prevention and control
- clinical practice
- public health issues with a potential or actual impact on the health system:
    - communicable diseases
    - acute environmental threats
    - foodborne risks
    - alcohol and other drugs.

1.2. Key definitions

Biological	A substance that comprises, contains, or is derived from human cells or tissues; or comprises or contains live animal cells, tissues or organs; and is represented in any way to be, or is likely to be, for therapeutic use.
Co-ordinating Agency	The CEC coordinates communication regarding system-wide patient safety risks.

Designated contact	Individuals nominated by NSW Health Services to be the point of contact and responsible for coordinating a response, if required, for risks to patients' safety and system performance.
Lead Agency	Agency responsible for leading the response, including initial risk assessment, establishing a management team, overall decision making and developing communication to be distributed. CEC leads responses for: ▪ medicines ▪ medical devices ▪ biologicals ▪ infection prevention and control ▪ clinical practice. Relevant Ministry branch or division leads responses for: ▪ communicable diseases ▪ acute environmental threats ▪ foodborne risks ▪ alcohol and other drugs ▪ mental health.
Management Team	A group of members from NSW agencies convened by the Lead Agency for a system level response with the purpose of reviewing, risk assessing and making recommendations for risk management. Medication Shortage Assessment and Management (MSAM) is an alternative name for a Management Team related to medication shortages.
Medical Device	Any instrument, apparatus, appliance, material, or other article intended by the manufacturer to be used for one or more of the following purposes: • diagnosis, prevention, monitoring, treatment, or alleviation of disease • compensation for an injury or disability • investigation, replacement, or modification of the anatomy or of a physiological process and, • control of conception.

Medicine	Therapeutic goods (other than biologicals) that are represented to achieve, or are likely to achieve, their principal intended action by pharmacological, chemical, immunological, or metabolic means in or on the body of a human; and any other therapeutic goods declared by the Secretary, for the purpose of the definition of therapeutic device, not to be therapeutic devices. For the purposes of this Policy Directive radiopharmaceuticals (as defined by the TGA) are considered medicines.
NSW Health Services	A local health district (LHD), specialty health network (SHN), statewide health service (SHS), shared service, pillar statutory health corporation or affiliated health organisation.
Risk	The effect of uncertainty on objectives, noting that effect is a deviation from the expected and may be positive and/or negative.
Safety Broadcast	A NSW Health patient safety communique with three levels aligned to the level of risk: information, notice and alert. A systematic approach to the development, distribution, prioritisation and management of patient safety information.
Sponsor	Company or individual approved by the TGA to legally sell or supply a therapeutic good in Australia, such as medicines, medical devices, biologicals, and other therapeutic goods.
System-level response	A risk that is unable to be managed locally and requires state-wide co-ordination and communication.
Therapeutic Goods Administration (TGA)	Australia's regulatory authority for the supply, import, export, manufacturing, and advertising of therapeutic goods.

1.3. Legal and legislative framework

This Policy Directive is to be read in conjunction with the following NSW Health policy documents and other related publications.

Table 1A: Related NSW Health Policy Documents

Document Number	Document Title
PD2020_047	*Incident Management*
PD2019_023	*NSW Health Incident Co-ordination Framework*
PD2018_013	*Work Health and Safety: Better Practice Procedures*
PD2024_005	*Early Response to High Consequence Infectious Diseases*
PD2022_023	*Enterprise-wide Risk Management*
PD2022_032	*Medication Handling*
PD2024_006	*High-Risk Medicines Management*
PD2023_025	*Infection Prevention and Control in Healthcare Settings*

Table 1B: Other Related Publications

Author	Document Title
Aust Govt	*Therapeutic Goods Act 1989*
Aust Govt	*Uniform Recall Procedure for Therapeutic Goods*
Aust Govt	*Competition and Consumer Act 2010*
Aust Govt	*Radiation Safety Act 1999 – s.45*
National Blood Authority	*National Blood Supply Contingency Plan*
NSW Govt	*Protection from Harmful Radiation Regulation 2013*
NSW Govt	*Work Health and Safety Act 2011*
NSW Govt	*Work Health and Safety Regulation 2017*
NSW Govt	*Health Administration Act 1982*
NSW Govt	*Code of Practice: Managing risks of plant in the workplace 2022*
NSW Govt	*Food Act 2003*
NSW Govt	*Food Regulation 2015*
NSW Govt	*Public Health Act 2010*

2. Key Components

2.1. Adopting a principle-based approach

The following guiding principles underpin this Policy Directive for responding to risks to patient safety and system performance.

Table 2. Guiding principles

Principle	Description
Effective leadership	We designate a leadership team for critical decision making.
Responsive	We respond rapidly and effectively.
Objective	We assess risk according to the NSW Health Enterprise Risk matrix to determine appropriate action.
System driven	We have clinical and administrative systems in place to drive timely responses.
Standardised processes and procedures	We approach our work with standardised processes and procedures for efficiency and effectiveness.
Prioritisation of action	We address identified problems and prioritise actions according to the available resources and the level of the risk.
Reporting structures	We have a clear upward and downward reporting structure that ensures relevant agencies are informed.
Communication	We have defined options for communicating risk and mitigation strategies to the system.
Collaboration	We have a culture of trust and mutual respect to ensure cross-agency teamwork.

2.2. Key accountabilities

All NSW Health staff contribute to responses to address risks to patient safety and system performance. The following individuals and bodies have specific responsibilities to ensure the effective responses to risks to patient safety and system performance.

2.2.1. Ministry of Health

The NSW Ministry of Health provides centralised and coordinated oversight of the performance of Health Services and develops a common set of safety metrics that report meaningful safety and quality outcomes. During a system-level response, one or more of the following branches or divisions may be involved depending on the nature of the risk and communication required.

Population and Public Health Division

Responsibilities for units within the Population and Public Health Division include:

- Health Protection NSW leads responses to:
    - food-related risks
    - acute population level environmental threats

  - communicable diseases
  - immunisation.
- Centre for Alcohol and other Drugs (CAOD) leads responses to:
  - harm from alcohol or other drugs.
- Office of the Chief Health Officer (OCHO)
  - assists in the assessment of risk and potential responses for large scale (population level) incidents
  - works with the National Blood Authority on issues of blood and blood product supply, as well as with the Organ and Tissue Donation Authority around organ transplantation.

System Sustainability and Performance Division

Responsibilities for units within System Management Branch (SMB) of the System Sustainability and Performance Division include:

- State Preparedness & Response Unit (SPRU)
  - supports the CEC to access incident and emergency management systems and expertise to effectively manage risks to the health system.
- Patient Safety First Unit (PSFU)
  - oversight of critical patient safety incidents and potential state-wide clinical risks.

The System Sustainability and Performance Division is responsible for:

- escalation to the Executive Director, System Management Branch, Deputy Secretary, SSP, State Health Services Functional Area Coordinator and/or Chief Health Officer (CHO) for risks that may have broader system wide or population health implications.
- point of contact for System Information and Analytics to obtain data and analytics to inform risk assessment and mitigation strategies for broader system wide or population health risks.

Health System Strategy and Patient Experience Division

Responsibilities for branches of the Health System Strategy and Patient Experience Division:

- Mental Health Branch and the Chief Psychiatrist
  - point of contact for responses related to mental health.

People, Culture and Governance Division

Responsibilities for services within the People, Culture and Governance Division:

- Strategic Communications and Engagement (Digital Communications)
  - publication of Safety Broadcasts
  - point of contact for media holding statements

- liaison with media outlets during responses through the on-call media department of the Lead Agency.

- Legal & Regulatory Services
  - point of contact for licensed private health care facilities
  - review of any actual or potential legal and regulatory matters arising from the response.

2.2.2. Clinical Excellence Commission

The role of the CEC is to lead, support and promote improved safety and quality in clinical care across NSW Health through consultation and collaboration with clinicians, health consumers, other pillars and the Ministry.

The CEC is the nominated TGA Recall Coordinator for NSW. The TGA relies on state and territory coordinators to maintain a system for providing recall information within each jurisdiction. The CEC is responsible for distributing recall actions issued by the TGA to local health districts, specialty health networks and statewide health services, such as NSW Ambulance and NSW Health Pathology. The CEC relies on contacts in Health Services to ensure recall actions and responses relating to medicines, medical devices, infection prevention and control, and clinical practices notifications are managed locally.

As the Coordinating Agency, the CEC is responsible for coordinating communication regarding system-wide risks. The CEC Executive On-call is available for out-of-hours notifications and facilitates urgent communication to the health system if required.

The CEC is the Lead Agency for responses relating to medicines, medical devices, infection prevention and control, and clinical practice.

2.2.3. HealthShare NSW

The role of HealthShare NSW (HSNSW) is to support NSW Health to deliver clinical care and help drive system-wide improvements. HSNSW contributes to the care of public hospital patients through transport, linen, food and environmental services, and patients at home through assistive technology and services. HSNSW is responsible for mitigating risks in these services.

HSNSW leads statewide procurement and supply chain management for medicines, devices, and consumables, as well as providing payroll and human resources support.

HSNSW are responsible for identifying and/or validating the number of users of the affected products within the public system. HSNSW supports responses to system-wide risks by sourcing suitable alternative products, negotiating with sponsors in alignment with the NSW Health procurement strategy and contract management.

2.2.4. Agency for Clinical Innovation

The Agency for Clinical Innovation (ACI) is the pillar for clinical innovation in NSW. ACI's clinical streams, networks, and taskforces (see Appendix 5.1) bring patients, clinicians, and

managers together to support the design and implementation of innovation in healthcare. The ACI supports the coordination of system-level responses by engaging clinicians with subject matter expertise to participate in Management Teams.

2.2.5. NSW Health Services

NSW Health Services are responsible for mitigating risks within their facilities. Formal communication about urgent issues will be via existing line management (such as Chief Executives (CEs), Directors of Clinical Governance (DCGs), and designated contact persons.

The DCGs will be the contact point for notifications/responses during business hours. The Health Service Executive On-call will be the contact point for out-of-hours notifications/responses. In certain circumstances the Management Team may liaise with subject matter experts, such as Clinical Product Managers, Biomedical Engineers, infection prevention and control leads, or clinicians identified through CEC/ACI networks to better understand clinical impacts and system vulnerability.

2.2.5.1 Chief Executive

The CEs, of NSW Health Services are responsible for ensuring an efficient and effective local process is in place for receipt, distribution, implementation of and response to notifications, recall actions and other urgent notifications, with delegation to the Executive On-call out-of-hours.

In addition, the CE ensures:

- a system is in place to escalate emerging issues to the CEC and notify the TGA as appropriate
- there are designated contacts within the health service that will receive and lead responses with the DCG specific to:
    - Public health communications relating to infectious diseases, acute environmental threats, food, and alcohol and other drugs
    - Medicines communications to receive and respond to medicine risks (can be a generic/rotating position)
    - Medical device communications to receive and respond to medical devices risks (can be a generic/rotating position)
    - Infection prevention and control risks to receive and respond to communication relating to infection risks.
- CEC is notified of role changes impacting CEC Recalls Distribution Lists as these include the DCG and other contacts via CEC-Recalls@health.nsw.gov.au
- all records relating to the response are maintained for governance
- governance of the system that is reported to the Board.

2.2.5.2 Director of Clinical Governance

The DCG is responsible in business hours for the implementation of action(s) from communications. They are also responsible for directing and managing requests from the

CEC for information on the risk and its mitigation. This includes having a documented approach for the implementation of this Policy Directive and tracking compliance to actions specified in communications related to risks to patient safety and system performance.

2.2.5.3 Executive On Call

The Executive On-call is responsible out-of-hours for the implementation of action(s) from communications. They are also responsible for directing and managing requests from the CEC for information on the risk and its mitigation. This includes having a documented approach for the tracking compliance to actions specified in communications related to risks to patient safety and system performance.

2.2.5.4 Designated contact(s)

Each NSW Health Service has a documented internal process that ensures the designated contact communicates local actions to their DCG, executive and affected staff. Designated contacts are responsible for coordinating and implementing the actions for the response locally.

The designated contact ensures that arrangements are in place during business hours and out-of-hours, alternate arrangements are in place, to regularly monitor and report the NSW Health Service's actions.

2.2.5.5 Managers/Decision makers

Managers and decision makers at all levels are accountable for managing patient safety risks within the scope of their role. Patient safety risks that are beyond a manager's or a decision maker's scope or delegation must be escalated to a higher level of management for review.

Responsibilities also include supporting the implementation of the service's response to Safety Broadcasts, escalation of risk and implementing risk mitigation.

2.3.5.6 Clinicians and Health Care Workers

Clinicians and health care workers are responsible for the implementation of actions, providing information as requested and reporting related incidents in the Incident Management System (ims+).

3. Framework for Responding to Safety Risks

A system-level response is considered when standard NSW Health business processes may not adequately address the broader risks and magnitude of impacts regarding:

- Critical patient safety
- Health system service delivery.

A system-level response allows for:

- Broader cross-NSW Health, national and international visibility to inform risk management.

- Coordination of key pillar and agency resources and expertise to support rapid and effective responses (such as system-wide negotiation with suppliers).
- State-wide supplementary guidance to mitigate risks (such as advice on alternative products, clinical considerations in the choice of a substitute, clinical prioritisation for access and additional safeguards required for the use of the substitute product).
- Economies of scale to avoid duplication of effort.

Responses to system-level risks in NSW are managed within a framework with 6 elements:

1. Systems for incoming notifications to identify potential risks.
2. Objective risk assessment to determine the level of risk.
3. Consistent application of criteria to determine required system-level response.
4. Management of risks through actions informed by subject matter experts.
5. Multiple modes for system-wide communication of risk and mitigation strategies.
6. System-wide surveillance to ensure the risks have been mitigated or controlled.

See Appendix 5.2 for system-level response workflow.

3.1. Element 1: Systems for incoming notifications to identify potential risks

Incoming notifications about actual or potential risks can come from a variety of sources including the:

- Therapeutic Goods Administration (TGA)
- ims+
- NSW Health Services
- other jurisdictions
- Serious Incident Review Subcommittees of the Clinical Risk Advisory Group
- Reportable Incident Briefs, and
- Public Health Rapid Emergency, Disease, and Syndromic Surveillance (PHREDSS).

Notifiers are aligned to the category of risk and notifier, Lead Agency and core Management Team Members are detailed in Appendix 5.3.

3.2. Element 2: Objective risk assessment to determine the level of risk

Risk assessment provides a structure to collect and organise information, inform decision making and support a proportional response to incidents.

The Lead Agency must comprehensively assess the risk as early as possible. Risk assessment is a dynamic process that incorporates changes in circumstances and new information.

The risk assessment should consider:

- predicted duration of the issue
- number of people or patients (or key groups), and the vulnerability of the population likely to be affected
- potential impact on affected groups
- potential impact on broader service delivery
- ease of mitigation
- function/usage of the medicine or medical device
- availability, efficacy, and suitability of alternatives
- clinically relevant characteristics.

The Lead Agency conducts the risk assessment using a 4-tier risk rating system. Emerging risks must be risk assessed with a risk assessment tool. A standardised risk assessment tool is in the Toolkit available from the CEC and aligns with the NSW Enterprise Risk Management System (ERMS). The NSW Health Risk Management Framework (see NSW Health Policy Directive *Enterprise-wide Risk Management* [PD2022_023]) has been developed to help describe potential system impacts and ensure NSW public health services are responsive to risks.

3.3. Element 3: Consistent application of criteria to determine required statewide response

3.3.1. Notification of risk to the Ministry of Health

Risks that have been rated as high or extreme are escalated by the Lead Agency to the Ministry of Health (Ministry), who escalates to the relevant Deputy Secretary and/or Chief Health Officer.

All other risks that are likely to have extensive operational implications, attract media attention, or pose a reputational risk are notified to the Ministry irrespective of the risk rating.

3.3.2. Early notification of risk to the system

The CEC will escalate risks that have been rated as extreme and high to the NSW Health Service CEs and DCGs as soon as possible via Short Message Service (SMS) and email while system-wide communication is under development.

3.4. Element 4: Management of risks through actions informed by subject matter experts

Interagency communication is important, and processes will vary depending on the risk. The Lead Agency needs to identify/nominate a senior decision maker (such as the Chief Health Officer or CEC Chief Executive) and manage the risk through actions informed by subject matter experts.

If required a media spokesperson should be appointed. If media attention is expected, a media holding statement should be prepared. The Lead Agency will liaise with their media team in addition to the Co-ordinating Agency if this is required. There is implicit agreement between agencies that while a media holding statement may be required it should not slow the finalisation and publication of a Safety Broadcast due to the potential to delay important clinical information. It is appropriate for a Safety Broadcast to be published with the brief noting that a media holding statement is being prepared and will follow.

De-escalation is to be considered when the risk has been mitigated or controlled based on serial risk assessment by the Lead Agency with input from the subject matter experts. The de-escalation should also be via a senior decision maker to ensure clear communication and avoid duplication (refer to section 3.6.).

3.4.1. The Lead Agency

Risks localised to the NSW Health system (for example not extending to the general public) will be led by the CEC. Any risks that have a broader effect than NSW Health facilities are led by the relevant Ministry branch or division.

Determining the Lead Agency

The nature of the risk will determine the Lead Agency. Refer to Appendix 5.3 for suggested Lead Agency decision making. The Lead Agency will be nominated by the Chief Health Officer or the CEC Chief Executive. Public health issues will usually be led by the relevant unit or branch of the Ministry.

Medicines, medical devices, infection prevention and control and clinical practice issues will generally be led by the relevant CEC team.

Responsibilities of the Lead Agency:

- Initial and ongoing risk assessments.
- Convene a Management Team.
- Consult and collaborate with relevant stakeholders on the development and dissemination of risk mitigation strategies.
- Determine the most appropriate way to communicate the risk and risk mitigation strategies.
- Notify the Co-ordinating Agency (CEC) if a Safety Broadcast is being developed.
- Submit a draft Safety Broadcast, Request to Publish form and relevant background information to the Co-ordinating Agency.
- Follow up with NSW Health Services who have not responded that the Safety Broadcast has been received and actioned, based on Co-ordinating Agency advice.
- Establish mechanisms to evaluate risk mitigation strategies.
- Review Safety Broadcasts prior to the review date to determine if they require updating or archiving.
- Escalate high/extreme risks to Deputy Secretary/Secretary.

- Determine when the risk has been addressed/mitigated to decommission the Management Team.

Convening the Management Team

The Lead Agency will convene a Management Team and members will be selected from relevant agencies/NSW Health Services (see Appendix 5.3) to ensure input from subject matter experts. Subject matter experts include:

- Clinical – relevant Ministry chief advisors, CEC/Agency for Clinical Innovation (ACI) Networks, expert panels, public health leadership or NSW Health Service representatives
- Procurement – HSNSW, Health Service Clinical Product Managers
- Technical – Health Service Biomedical Engineers
- Legal – Legal & Regulatory Services Branch.

Developing the risk mitigation strategies

The Management Team will develop risk mitigation strategies with input from members. Risk mitigation (action plans) must address risks directly associated with the issue, as well as those which may arise, and the proposed response including change in practice or alternative products. Actions need to be proportionate and factor in the specific characteristics of the issue. Action plans should be guided by the NSW Health Policy Directive *Enterprise-wide Risk Management* (PD2022_023).

Unintended consequences should be considered and mitigated where possible.

3.4.2. The Co-ordinating Agency

The CEC is the Co-ordinating Agency for the dissemination of communication unless the Chief Health Officer or the CEC Chief Executive nominate an alternative.

Responsibilities of the Co-ordinating Agency:

- Act as NSW TGA Recalls Co-ordinator.
- Maintain a Safety Broadcast Register.
- Support Lead Agencies with publication of Safety Broadcasts including:
    - Providing a Toolkit with Safety Broadcast template, reference number, instructions, and request for background information.
    - Quality checking of the draft Safety Broadcast.
    - Facilitating approval process for the publication of the Safety Broadcast.
- Distribute Safety Broadcasts to DCG and CE.
- Send SMS and email to NSW Health Service Executive On-call when a Safety Alert is being published out-of-hours.
- Collate responses and provide to Lead Agency for follow-up of outstanding NSW Health Services.

- Co-ordinate periodic reviews of out-of-date Safety Broadcasts in collaboration with the Lead Agency.

3.5. Element 5: Multiple modes for system-wide communication of risk and mitigation strategies

Structured and consistent communication is a key part of any risk mitigation strategy. The Lead Agency provides consolidated information to the relevant stakeholders as soon as practicable, unless the risk is re-assessed as low, and the Lead Agency considers that the risk can be managed locally.

The level of risk dictates the mode and frequency of communication to the system. Communication could be via an email from the Lead or Co-ordinating Agency:

- Ministry communicates with:
    - Public health facilities
    - Licensed private health facilities
    - Primary care, when relevant.
- CEC communicates with:
    - Designated contact via the Critical Response Register
    - Executive On-call via Teams Channel
    - Clinical Networks via ACI.

A Safety Broadcast can also be authored by the Lead Agency and published by the Co-ordinating Agency on the intranet and internet. As the development and publication of a Safety Broadcast may take some time, the Co-ordinating Agency should consider other options for messaging in addition to the early notification to the system via an SMS and email of the pending Safety Broadcast.

The Co-ordinating Agency should also utilise other modes of communication to ensure Safety Broadcasts are reserved for risks that are new or emerging and cannot be sufficiently addressed by the other modes of communication.

3.5.1. Safety Huddle

In complex situations, urgent teleconferences can be convened with NSW Health Services Executives. During business hours, the DCGs are the first point of contact. Communicable diseases, environmental threats, food, and alcohol and another drugs, may also require contact with the Directors of Public Health. For urgent after-hours communication, a briefing will be with the NSW Health Service Executive On-call.

In rapidly evolving high-risk or extreme issues, the Lead Agency can also consider issuing an early notification prior to a safety huddle. In addition, regular situation reports or huddles to facilitate consistent, efficient, and timely updates to all key stakeholders may be appropriate. The Lead Agency will determine whether a brief to the Secretary of Health is required during the response and will provide ongoing reporting via updated briefs.

3.5.2. Clinical Excellence Commission Critical Response Register

The CEC maintains a Critical Response Register on a platform known as the Quality Audit Reporting System (QARS) within ReACT which automatically uploads and registers incoming TGA notices.

QARS ReACT also has the capability for manually entering additional risks into the register. The application stores email addresses in distribution lists and has the capacity to send out emails to individuals, groups (device, medicines, biological), NSW Health Services, or the system.

The CEC maintains the currency of the distribution lists to ensure that all outgoing emails reach the intended contact person(s) or CE and DCG. Any risk to the system can be communicated from this application providing the user has the appropriate user role. The CEC has centralised permission-control based on the user's role/location/group.

3.5.3. Clinical Execellence Commission Executive On-call Teams Channel

The CEC maintains an Executive On-call Teams Channel as a platform to communicate with NSW Health Services out of business hours. The application stores mobile phone numbers and email addresses enabling SMS and emails to CEC and NSW Health Services CEs and DCGs.

The CEC maintains the currency of the Executive On-call Teams Channel to ensure in the event an out-of-hours communication is required all outgoing SMS and emails will reach the intended contact person(s). Any risk to the system can be communicated from this application providing the user has access to the Executive On-call Teams Channel.

3.5.4. Specialty networks and groups

Depending on the nature of the issue, the Lead Agency or Management Team can supplement communication with the system through relevant CEC/ACI networks and groups (such as pharmacy, clinical specialties, public health and general practice).

3.5.5. Licensed private health facilities

The Ministry's Legal and Regulatory Services Branch communicates with licensed private health facilities. The Office of the Chief Health Officer can provide support for bulk SMS communication to licensed private health facilities.

Licensed private health facilities are required to ensure that processes are in place to respond to recall notices received from the TGA.

In addition, private health facilities are encouraged to routinely check the TGA's online searchable database for relevant notices and subscribe to TGA email updates.

3.5.6. Safety Broadcasts

Safety Broadcasts provide a systematic approach to the distribution of safety information to the NSW Health system. It includes a mechanism to ensure any required/recommended actions for the management of risks are undertaken by NSW Health Services.

There are 3 levels of broadcasts which correspond to the level of risk identified and actions required/recommended by NSW Health Services (see Table 3A).

Criteria for publishing a Safety Broadcast

All criteria need to be met for the publication of a Safety Broadcast:

1. New or emerging patient safety risk.
2. Broad impact – affecting multiple sites.
3. Need for rapid, statewide communication to address a patient safety risk.
4. The risk is not addressed in existing NSW Health policy directives, guidelines, or information bulletins or despite being addressed, clinical incidents or near-misses continue to occur.

In addition, a Safety Broadcast can be published for any safety risk deemed appropriate by the CEC Chief Executive, Chief Health Officer or a Deputy Secretary, including public health risks.

Out of scope

- Updates to practice that require extensive change management.
- Public health risks not impacting or not expected to impact NSW Health Facilities.
- Patient safety risks which are setting specific, and messaging can be targeted via their networks, such as general practice or emergency care.
- Corporate notifications relating to:
    - equipment – other than medical devices
    - power supply
    - information technology – except risks directly related to patient care e.g. risk associated with the use or functionality of the electronic Medical Record system (eMR).

Developing a Safety Broadcast

The level of risk dictates the mode of communication to the system. The Lead Agency will confirm that the risk meets the criteria for a Safety Broadcast publication. The Lead Agency will liaise with the relevant stakeholders to develop the Safety Broadcast, which may include consultation with:

- clinical and subject matter experts
- Management Team members
- other NSW Health staff.

Issues to be considered during development of a Broadcast include:

- What are the potential implications for patients or consumers of NSW Health Services?

- Have the relevant stakeholders been consulted?
- Are the proposed actions achievable and practical?
- Have the potential legal, industrial or workforce implications been addressed?

The Lead Agency is responsible for drafting the document and navigating consultation until the final draft is approved.

Format

The Co-ordinating Agency will provide the Lead Agency with a toolkit with the appropriate Safety Broadcast template. The content of each broadcast type requires a tailored approach to ensure clear and concise communication of information. Instructions are embedded in the templates to ensure consistent formatting.

Distribution

The CEC distributes all Safety Broadcasts via email to CEs and DCGs. Where feasible, the Co-Ordinating Agency will send an early advice email to advise the DCGs of an impending Safety Alert, particularly on Fridays.

Only Safety Alerts, requiring immediate attention and mandatory action, may be issued out-of-hours. In this instance, a SMS and email will be sent by the Co-ordinating Agency to:

- NSW Health Services Executive On-call
- Director, Regulation and Compliance Unit.

The SMS will notify recipients of an urgent Safety Alert sent to the nominated emails for that Health Service. Recipients of a SMS are required to confirm receipt by SMS or email to the Co-ordinating Agency. A follow up phone call by the Lead Agency will be undertaken to any recipient who does not confirm receipt of the SMS within one hour.

Health Service Responsibilities

All Safety Broadcasts require the following actions by NSW Health Services at a minimum:

- Distribution to all relevant clinicians, clinical departments as listed in the Safety Broadcast
- Inclusion of the Safety Broadcast in relevant handovers and safety huddles
- Escalation of any concerns to the email contact listed in the Safety Broadcast
- Reporting of any incidents associated with the system-level risk into ims+ and/or to the TGA.

For Safety Alerts, NSW Health Services must respond to the Co-ordinating Agency within 24-hours that they have received and actioned its requirements.

All actions of the Safety Broadcast should be undertaken in accordance with the recipient's roles and responsibilities, within the specified timeframe.

Publication

The Safety Broadcast is published on the NSW Health intranet, and where appropriate on the NSW Health internet, after the Request to Publish form has been submitted by the Lead Agency and approved by the CEC Chief Executive. The Ministry's Strategic Communications and Engagement (Digital) team are to upload the Safety Broadcast to:

- Intranet: https://internal.health.nsw.gov.au/quality/sabs/
- Internet: https://www.health.nsw.gov.au/sabs/Pages/default.aspx

Records management

All Safety Broadcasts have a publication and review date to indicate when the document is active, requires updating or is to be made obsolete. The review date is usually one (1) year after publication; however, the Lead Agency may assign a longer or shorter duration depending on context of the Safety Broadcast.

Table 3A. Types of broadcasts, development, distribution strategies and NSW Health Services responsibilities

Broadcast aim	Development	Distribution strategy	Health Service responsibilities
Safety Alert To alert Health Services to a high to extreme safety risk needing immediate attention and mandatory action. 	Lead Agency with relevant expertise authors the Safety Alert. Co-ordinating Agency facilitates publication, dissemination and tracking of responses.	During business hours CEC distributes the Safety Alert to: • Chief Executives • Directors of Clinical Governance • Director, Regulation and Compliance Unit. Out-of-hours CEC distributes the Safety Alert to: • LHD/SHN Executives On-call • Director, Regulation and Compliance Unit. CEC arranges with the MoH to post the Safety Alert to the intranet and/or internet. Health Services distribute Safety Alert to: • the recommended notification list • other relevant staff.	Within the designated timeframes: • Acknowledge receipt of Safety Alert to Lead Agency • Distribute to relevant staff and groups. • Conduct a local risk assessment. • Ensure completion of required action(s) within specified timeframe. • Document local response and report back to CEC on actions taken within specified timeframe. • Ensure local policies and guidelines are updated to include new information, if required.

Broadcast aim	Development	Distribution strategy	Health Service responsibilities
Safety Notice To advise Health Services about medium risks (actual or potential) requiring risk assessment at the local level. 	Lead Agency with relevant expertise authors the Safety Notice Co-ordinating Agency facilitates publication and dissemination.	CEC arranges with the MoH[1] to post the Safety Notice to the intranet and/or internet. CEC emails Chief Executives and Directors of Clinical Governance and relevant clinical groups/networks (for example, Directors of Pharmacy). Health Services distribute Safety Notice to: • the recommended notification list • other relevant staff.	• Distribute to relevant staff and groups. • Conduct a local risk assessment. • Ensure completion of required/recommended action(s). • Ensure relevant policies and procedures are in place to address the risks.
Safety Information To inform Health Services about low risks that may impact on clinical care. 	Lead Agency with relevant expertise authors the Safety Information. Co-ordinating Agency facilitates publication and dissemination.	CEC arranges with MoH to post the Safety Information to the intranet and/or internet. CEC emails the Chief Executives and Directors of Clinical Governance and relevant clinical groups/networks (for example, Directors of Pharmacy). Health Services distribute Safety Information to: • the recommended notification list • other relevant staff.	• Distribute to relevant staff and groups. • Considers implementation of recommended action(s). • Ensure relevant policies and procedures are in place to address the risks.

[1] In this table, MoH refers to the Ministry of Health.

Communication responsibilities of agencies are outlined in the Table 3B. The Safety Broadcasts are available on the NSW Health website and are also circulated to licensed private health care facilities.

Safety Broadcasts which contain information only relevant to NSW Health clinicians or material that is considered legally or commercially sensitive or inappropriate for members of the public should only be published on the NSW Health Intranet. This is indicated on the 'Request to Upload' form to the Ministry's Strategic Communications and Engagement Branch where the author specifies the sites for publication.

For matters likely to be of media interest the authors should alert their agency's media team. The holding statement will be reviewed by the Lead Agency's media team and included for approval by the agency's CE before progressing to the Ministry.

Table 3B. Agencies and responsibilities for communication

Agency	Communication responsibilities
CEC	Health Services CEs, DCGs and Executive on call * HSNSW Where relevant: • Directors of Pharmacy • Directors of Public Health Units • Relevant ACI networks via network managers/clinical directors • Infection Prevention and Control and Infectious Diseases network • Cancer Institute NSW • TGA
HealthShare NSW	Suppliers and wholesalers Clinical product managers Biomedical engineers
Office of the Chief Health Officer Ministry/Population and Public Health	Professional peak bodies Primary Health practitioners Public Health Units
Legal and Regulatory Services, Ministry	Licensed private health facilities Pharmacy networks and peak bodies (for example, Pharmacy Guild and Pharmaceutical Society of Australia)
Digital Communication, Ministry	Publication of Broadcasts to intranet and/or internet

*The CEC is the primary point of contact with Health Services. Responsibility for immediate, life-threatening risk may be shared or transition to the Ministry's Office of the Chief Health Officer.

Reviewing Safety Broadcasts

It is the responsibility of the Lead Agency to review Safety Broadcasts at the designated review date. The review should include consultation with:

- subject matter experts
- members of Management Team

- other relevant stakeholders.

The Lead Agency should conduct an earlier review where there are changes to the risk assessment, to the required/recommended mitigating strategies, and/ or in related legislation, policy, or practice.

The Safety Broadcast can be either archived or updated.

Archiving Safety Broadcasts

Following a review, a Safety Broadcast can be made obsolete and archived if the risk has been resolved, mitigating strategies to manage the underlying risk have been implemented, or the recommended actions have been integrated into NSW Health or national policies, guidelines and/or procedures.

The Co-ordinating Agency will take timely action to:

- Rescind Safety Broadcasts through a formal approval from the CEC Chief Executive.
- Request the Ministry's Strategic Communications and Engagement Branch move the Safety Broadcast from the active document list to the archive list.
- Advise the DCGs and other relevant stakeholders (for example, Directors of Pharmacy or Infection Prevention and Control Leads) via email, information bulletins or in meetings/forums.

Updating Safety Broadcasts

A Safety Broadcast may need to be updated if new information becomes available or if the risk to patient safety or system performance is ongoing. The Lead Agency can republish with the assistance of the Co-ordinating Agency. The Safety Broadcast should include a summary of what has been updated.

3.6. Element 6: System-wide surveillance to ensure the risks have been mitigated or controlled

3.6.1. Surveillance

The Lead Agency can review information from a range of sources, including ims+, the QARS, the Health Quality Reporting System (HQRS), PHREDSS, and the Poisons Information Centre to identify any possible harm arising from a notification and to inform serial risk assessments.

Health Protection NSW can provide recommendations on additions of clinical or laboratory surveillance.

3.6.2. Debriefing

The Lead Agency may debrief with the Management Team following a coordinated response. The debrief session aims to identify what worked well, as well as areas for improvement.

3.6.3. Decommissioning the Management Team

The Lead Agency decommissions the Management Team when the risk no longer requires central coordination and can be managed locally.

4. References

Therapeutic Goods Administration, “Report a problem or side effect,” Therapeutic Goods Administration, 2021. [Online]. Available: https://www.tga.gov.au/reporting-problems. [Accessed 16 October 2023].

Australian Comission on Safety and Quality in Health Care [ACSQHC], “ISBAR revisited: Identifying and Solving BARriers to effective clinical handover in inter-hospital transfer,” Clinical Governance Hunter New England Health, 2009. [Online]. Available: https://www.safetyandquality.gov.au/publications-and-resources/resource-library/isbar-revisited-identifying-and-solving-barriers-effective-clinical-handover-inter-hospital-transfer. [Accessed 16 October 2023].

Australian Commission on Safety and Quality in Health Care [ACSQHC], National Safety and Quality Health Service Standards, 2nd Edition – Version 2, Sydney: ACSQHC, 2021.

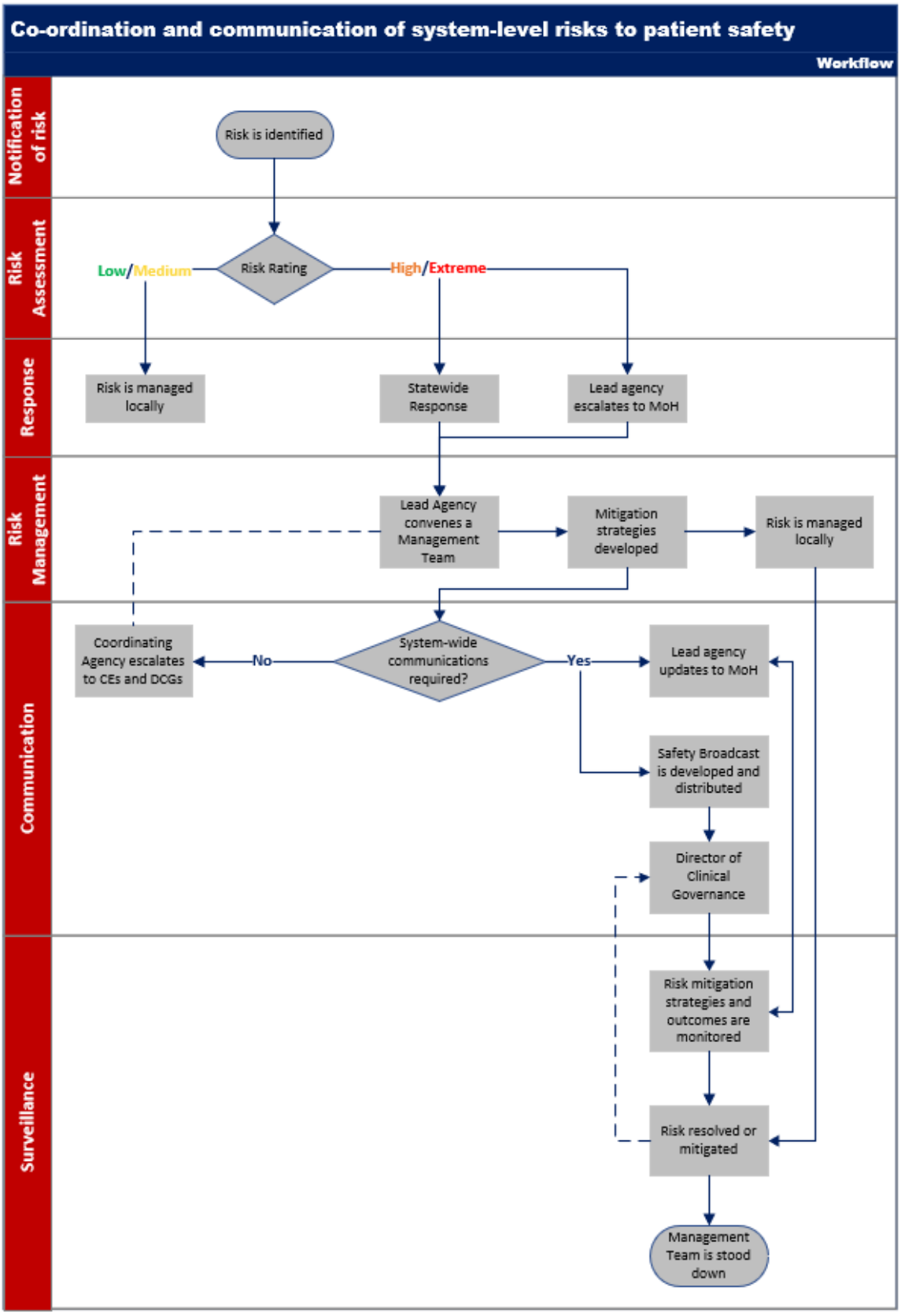
5. Appendices

5.1. Clinical Networks

ACI: aci.health.nsw.gov.au/media/documents/networks

CEC: https://www.cec.health.nsw.gov.au/

5.2. System-level Workflow



5.3. Risk Categories and system-level management

Risk Category	Notifier	Lead Agency	Core Management Team Members
Clinical practice • emerging trends in the community impacting on clinical care and patient safety • practices that mitigate patient safety risk • guidance on safe use of equipment	Health Service Other jurisdictions Serious Incident Review Subcommittee SMB, PSFU	CEC Critical Response Unit	CEC Infection Prevention and Control (IPAC) and Healthcare Associated Infections (HAI) Team CEC Adult Patient Safety Team CEC Older Persons Patient Safety Team CEC Maternity and Perinatal Patient Safety Team CEC Paediatric Patient Safety Team CEC Mental Health Patient Safety Team HSNSW Clinical Product Managers SMB, SPRU SMB, PSFU ACI-Network Managers, Chairs and members MoH[2] Chief Advisors
Infection prevention & control • outbreaks in hospitals • personal protective equipment • environmental cleaning • reprocessing of reusable medical equipment • clinical practice • infrastructure and environmental controls • National Quality and Safety Standard 3 breaches • antimicrobial resistance • novel infections and prevention and control of communicable diseases	Health Service Other jurisdictions SIR Subcommittee SMB, PSFU PHREDSS IPC Leads	CEC IPAC and HAI Team	CEC IPAC and HAI Team HSNSW Clinical Product Managers MoH Health Protection NSW
Medical devices • product defect/ contamination	TGA Health Service Other jurisdictions	CEC Critical Response Unit	HSNSW Clinical Product Managers Biomedical Engineers

[2] In this table, MoH refers to the Ministry of Health.

Risk Category	Notifier	Lead Agency	Core Management Team Members
• manufacturing disruptions • supply chain disruptions • increased product demand • regulatory issues and recalls • business decision to no longer manufacture or stock an item • reliance on single manufacturers			SMB, SPRU ACI-Network Managers, Chairs and members MoH Chief Advisors CEC IPAC and HAI Team MoH Health Protection NSW (if relevant to contaminant)
Medicine • product defect/ contamination • manufacturing disruptions • supply chain disruptions • increased product demand • regulatory issues and recalls • business decision to no longer manufacture or stock an item • reliance on single manufacturers	TGA Health Service Other jurisdictions	CEC Medication Safety and Quality Team	HSNSW MoH Pharmaceutical Services Directors of Pharmacy SMB, SPRU ACI-Network Managers, Chairs and members MoH Chief Advisors
Biologicals • product defect/ contamination • manufacturing disruptions • supply chain disruptions • increased product demand • regulatory issues and recalls • business decision to no longer manufacture or stock an item • reliance on single manufacturers	TGA Health Service Other jurisdictions National Blood Authority Lifeblood NSW	CEC Critical Response Unit	CEC Blood Watch SMB, SPRU ACI-Network Managers, Chairs and members MoH Chief Advisors MoH Health Protection NSW (if relevant to contaminant) OCHO (blood or blood product supply) Health Pathology NSW

Risk Category	Notifier	Lead Agency	Core Management Team Members
Communicable diseases • communicable disease outbreaks potentially impacting the health system • clinician alerts about presenting signs and symptoms	Health Service Other jurisdictions PHREDSS	MoH Communicable Diseases Branch/One Health Branch CEC IPAC and HAI Team (Hospital Focus)	CEC IPAC and HAI Team HSNSW MoH Health Protection NSW Clinical Product Managers SMB, SPRU
Acute environmental threats • site contamination • water contamination	Health Service Other jurisdictions Public Health Unit Environmental Protection Authority (NSW) Local Government NSW Fire and Rescue (HAZMAT) Sydney Water	MoH (dependent on nature of threat) Environmental Health Branch	HSNSW CEC IPAC and HAI Team MoH Health Protection NSW Clinical Product Managers SMB, SPRU ACI-Network Managers, Chairs and members MoH Chief Advisors
Food • food contamination • food labelling • product Recall	TGA NSW Food Authority Health Service Other jurisdictions	MoH Health Protection NSW – One Health	HSNSW MoH Health Protection NSW SMB, SPRU ACI-Network Managers, Chairs and members MoH Chief Advisors
Alcohol and other drugs • counterfeit substances • risk of harm linked to high doses	Health Service Other jurisdictions SIR Subcommittee SMB, PSFU NSW Poisons Information Service NSW Coroner	MoH Centre for Alcohol and Other Drugs	CEC Mental Health Patient Safety Team SMB, SPRU ACI-Network Managers, Chairs and members MoH Chief Advisors Standing Panel on Toxicity Risk
Mental Health • processes that support leave from mental health inpatient units • recognition and treatment of side effects from treatment • environmental risk factors impacting on patient safety	Health Service Other jurisdictions SIR Subcommittee SMB, PSFU	MoH Mental Health Branch	CEC Mental Health Patient Safety Team SMB, SPRU ACI-Network Managers, Chairs and members MoH Chief Advisors