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 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
- infection prevention and control
- clinical practice
- Public Health issues with a potential or actual impact on the health system:
    - communicable diseases
    - acute environmental risks
    - foodborne risks
    - alcohol and other drugs

1.2. Key definitions

Co-ordinating Agency	The Clinical Excellence Commission coordinates communication regarding system-wide patient safety risks.
Designated contact	Nominated by Health Services as the medicine, medical device, biological and infection prevention and control leads to be the point of contact and co-ordinate a response if required
Lead Agency	Agency responsible for leading the response, including initial risk assessment, establishing management team, overall decision making and developing communication to be distributed. CEC leads responses for: ▪ clinical practice

	▪ infection prevention and control ▪ medical devices ▪ medicines ▪ biologicals ▪ communicable diseases 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 the purpose of reviewing, risk assessing and making recommendations for risk management. MSAM is an alternative name for the Management Team related to medication shortages (*MSAM = Medication Shortage and Assessment Management).*
Medical Device	A wide range of products, such as medical gloves, bandages, syringes, blood pressure monitors, and x-ray equipment. They differ from medicines as they generally have a physical or mechanical effect on the body or are used to measure (or monitor) the body and its functions.
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.
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 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 e.g., 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 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	Incident Co-ordination Framework
PD2023_008	Early Response to High Consequence Infectious Diseases
PD2022_023	Enterprise-wide Risk Management
PD2022_032	Medication Handling
PD2020_045	High Risk Medicines Management
PD2023_25	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

Author	Document Title
NSW Govt	Radiation Control Regulation 2013
NSW Govt	Work Health and Safety Act 2011
NSW Govt	Work Health and Safety Regulation 2011
NSW Govt	Health Administration Act 1982
Safe Work Aust	Model Code of Practice: Managing risks of plant in the workplace 2021
NSW Govt	Food Act 2003
NSW Govt	Food Regulation 2015

2. KEY COMPONENTS

2.1. Framework

Responses to system-level risks in NSW are managed within a framework with six domains:

1. Systems for incoming notifications to identify potential risks.
2. Objective risk assessment to stratify 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 options for system-wide communication of risk and mitigation strategies.
6. System-wide surveillance to ensure the risks have been mitigated or controlled.

See Appendix 1 for system-level response workflow.

2.2. Adopting a principle-based approach

The following guiding principles underpin this policy directive for responding to safety risks 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.

2.3. Key accountabilities

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

2.3.1. 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.

2.3.1.2 Population and Public Health Division

Within the Population and Public Health Division are:

- Health Protection NSW – involved in responses for food-related risks, and communicable diseases and vaccination.
- Centre for Alcohol and other Drugs (CAOD) – involved in responses related to alcohol or other drugs (addiction and illicit).

2.3.1.3. System Sustainability and Performance Division

- System Management Branch, 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. SPRU may escalate incidents to the Executive Director, System Management Branch, Deputy Secretary of System Sustainability and Performance (Dep Sec, SSP) and/or Chief Health Officer (CHO) for risks that may have system wide operational implications.
- System Management Branch, Patient Safety First Unit (PSFU) – has oversight of critical patient safety incidents and potential state-wide clinical risks. PSFU may escalate incidents to the Executive Director, System Management Branch, and/ or Deputy Secretary, System Sustainability and Performance (Dep Sec, SSP).

2.3.1.4. Health System Strategy and Patient Experience Division

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

2.3.1.5. People, Culture and Governance Division

- Strategic Communications and Engagement (Digital Communications) – publication of Safety Broadcasts and point of contact for media holding statements. Liaison with media outlets during responses will be through the on-call media department of the lead agency.
- Legal & Regulatory Services – point of contact for licensed private health care facilities and review of any actual or potential legal and regulatory matters arising from the response.

2.3.3. 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 NSW Ministry of Health. The CEC is the nominated TGA

Recall Coordinator for NSW. The TGA relies on state and territory designated contacts 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 (LHD), specialty health networks (SHN) and statewide health services (SHS), such as NSW Ambulance and NSW Health Pathology. The CEC relies on designated 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.

2.3.4. 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 cleaning 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 and private 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.

2.3.5. Agency for Clinical Innovation and Research

The Agency for Clinical Innovation (ACI) is the pillar for clinical innovation and research in NSW. ACI's clinical streams, networks and taskforces (Appendix 2) 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.

2.3.6. NSW Health Services

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

The DCGs will be the contact point for business hours notifications/responses. 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.

2.3.5.1 Chief Executive (CE)

The CE is 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
- 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 & 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
- a reporting structure for CE and Board oversight.

2.3.5.2 Director of Clinical Governance (DCG)

The DCG is responsible for the implementation of nominated 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.

2.3.5.3 Designated contact(s)

Each health service has a documented internal process that ensures the designated contact communicates local actions to their 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 the health service's actions.

2.3.5.4 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.

2.3.5.5 Clinicians and Health Care Workers

Clinicians and Health Care Workers are responsible for the implementation of directed actions, providing information as requested and reporting related incidents in ims+.

3. 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-Health, national and international visibility to inform risk management.
- Coordination of key pillar and agency resources and expertise to support rapid and effective responses (e.g., system-wide negotiation with suppliers).
- State-wide supplementary guidance to mitigate risks (e.g., 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.

3.1. Systems for incoming notifications to identify potential risks

Incoming notifications about actual or potential risks can come from a variety of sources including ims+, Health Services, other jurisdictions, Serious Incident Review Subcommittees of the Clinical Risk Advisory Group, Reportable Incident Briefs, and the Public Health Rapid Emergency, Disease, and Syndromic Surveillance (PHREDSS). Notifiers are aligned to the category of risk and are displayed in Table 3A.

Table 3A: Risk Categories and system-level management

Risk Category	Notifier	Lead Agency	Core Management Team Members
Clinical practice	Health Service Other jurisdictions SIR Subcommittee PSFU	CEC Critical Response Unit	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 SPRU PSFU ACI-Network Managers, Chairs and members MoH Chief Advisors

Risk Category	Notifier	Lead Agency	Core Management Team Members
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 PSFU PHREDSS IPC Leads	CEC Infection Protection & Control Team	CEC HAI and Infection Prevention and Control Team HSNSW Clinical Product Managers MoH Communicable Diseases Unit
Medical devices • 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 Critical Response Unit	HSNSW Clinical Product Managers Biomedical Engineers SPRU ACI-Network Managers, Chairs and members MoH Chief Advisors
Medicine • product defect/ contamination • manufacturing disruptions • supply chain disruptions • increased product demand • regulatory issues and recalls	TGA Health Service Other jurisdictions	CEC Medication Safety and Quality Team	HSNSW Directors of Pharmacy SPRU ACI-Network Managers, Chairs and members MoH Chief Advisors

Risk Category	Notifier	Lead Agency	Core Management Team Members
• business decision to no longer manufacture or stock an item • reliance on single manufacturers			
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 Red Cross Blood Bank	CEC Critical Response Unit	CEC Blood Watch SPRU ACI-Network Managers, Chairs and members MoH Chief Advisors
Communicable diseases	Health Service Other jurisdictions PHREDSS	MoH Communicable Diseases Unit CEC HAI/IPAC Team (Hospital Focus)	CEC HAI and Infection Prevention and Control Team HSNSW Clinical Product Managers SPRU
Acute environmental threats	Health Service Other jurisdictions Public Health Unit	MoH (dependent on nature of threat)	HSNSW Clinical Product Managers SPRU ACI-Network Managers, Chairs and members MoH Chief Advisors
Food • Food contamination • Food labelling	TGA NSW Food Authority Health Service Other jurisdictions	MoH Health Protection NSW	HSNSW SPRU ACI-Network Managers, Chairs and members MoH Chief Advisors
Alcohol and other drugs	Health Service Other jurisdictions SIR Subcommittee PSFU	MoH Centre for Alcohol and Other Drugs	CEC Mental Health Patient Safety Team SPRU ACI-Network Managers, Chairs and members MoH Chief Advisors
Mental Health	Health Service Other jurisdictions SIR Subcommittee	MoH Mental Health Branch	CEC Mental Health Patient Safety Team SPRU ACI-Network Managers, Chairs and members

Risk Category	Notifier	Lead Agency	Core Management Team Members
	PSFU		MoH Chief Advisors

3.2. Objective risk assessment to stratify 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 should 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 four-tier risk rating system. Emerging risks should 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 (Table 3B) has been developed to help describe potential system impacts and ensure NSW public health services are responsive to risks. Further information and resources are available on the Clinical Excellence Commission website.

Table 3B: Categories and impact of Risk

Risk Rating	Risks	Impact according to the NSW Health Enterprise Risk Management Policy
LOW	• medicines or medical devices with directly interchangeable alternatives • communicable disease with adequate mitigation available • food contamination of low volume with low impact • minor change in clinical practice in limited settings	Short-term impact affecting a small number of patients where treatment can be delayed/modified. • No impact to patients or service delivery • Patient discomfort impacting on daily living • Monitoring product volumes, defect trends and device rectification in progress
MEDIUM	• non-essential medicines or medical devices where alternatives are available, but not directly interchangeable • communicable disease with adequate mitigation available	Short-term impact affecting a large number of patients where treatment can be delayed/modified. • Patients requiring increased level of care • Controls applied to service delivery

Risk Rating	Risks	Impact according to the NSW Health Enterprise Risk Management Policy
	• food contamination of low volume but potential high impact • moderate change in clinical practice across specialty settings	

HIGH	• essential medicines or medical devices where alternatives are available but are either:
	  • not directly interchangeable
	  • not registered for use in Australia
	  • registered, but not currently available in Australia
	• communicable disease of high virulence
	• food contamination of moderate volume and potential high impact
	• significant clinical practice change across multiple settings
	• infection control breaches with potential high impact
		The outcome of the issue has/could have a significant impact on patient safety. Issues may have an impact on delivery of health services which is difficult to mitigate and may affect multiple locations.
		• Patients suffering permanent reduction in bodily functioning
		• Mitigating product defect risks implemented

EXTREME	• essential medicines or medical devices where:
	  • no suitable alternatives are available
	  • alternatives pose significant risks which are difficult to mitigate
	• communicable disease of high virulence and limited resources
	• food contamination of high volume, potential high impact and difficult mitigation
	• complex clinical practice change across whole system
	• infection control breaches with high impact or failure of current mitigation strategies
		The outcome of the issue has/could have a major impact on patient safety. Issues may have a substantial impact on delivery of health services which is difficult to mitigate and may affect multiple locations.
		• Service delivery stopped
		• Patient death or suffering major permanent loss of function

3.3. 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 are escalated by the Lead Agency to the Ministry of Health for central co-ordination in instances of critical public health or patient safety risk, or major operational impact. Risks that have been rated as extreme are escalated by the Lead Agency to the Ministry who escalates to the relevant Deputy Secretary and/or Chief Health Officer.

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 Health Service CEs and DCGs as soon as possible via SMS and email while system-wide communication is under development.

3.4. 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 (i.e., CHO or CEC Chief Executive) and if required, appoint a media spokesperson. 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 flag 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 should 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 (i.e., 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 Table 3A 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 team from a branch of the Ministry of Health. Medicines, medical devices, infection prevention & 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 Coordinating Agency (CEC) if a Safety Broadcast is being developed

- Submit draft Safety Broadcast, Request to Publish form and relevant background information to the Co-ordinating Agency
- Follow up Health Services who have not responded that the Safety Broadcast has been received and actioned
- Establish mechanisms to evaluate risk mitigation strategies
- Review Safety Broadcasts prior to the review date to determine if they require updating/obsoleting
- Escalation of high / extreme risks to Deputy Secretary / Secretary
- Determines 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 determined by the nature of the issue to ensure input from subject matter experts. Subject matter experts include:

- Clinical – Ministry Chief Advisors, CEC/ACI Networks or Health Service representatives
- Procurement – HSNSW, Health Service Clinical Product Managers
- Technical – Health Service Biomedical Engineers
- Legal – Legal & Regulatory Branch.

Developing the risk mitigation strategies

The Management Team will develop risk mitigation strategies with input from members. Risk mitigation (action plans) should 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 Enterprise-Wide Risk Management Policy (PD2022_023). Key actions for each risk category are outlined in Table 3A.

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 Toolkit to Lead Agency inclusive of: Safety Broadcast template with Safety Broadcast reference number, instructions, and request for background information.

    - Quality check of draft Safety Broadcast.
    - Facilitate publication approval process for publication of Safety Broadcast.
- Distribute Safety Broadcasts to Directors Clinical Governance and Chief Executives.
- Send SMS and email to Health Service Executive On Call when a Safety Alert is published out of hours.
- Collate responses received and provide to Lead Agency for follow-up of outstanding Health Services.
- Co-ordinate periodic reviews of out-of-date Safety Broadcasts in collaboration with Lead Agency.

3.5. Multiple options 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 of Health:
    - Public health facilities
    - Licensed Private health facilities.
- CEC:
    - Designated contact via the Critical Response Register
    - Executive On Call Teams Channel
    - Clinical Networks.

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 email of the pending Safety Broadcast. The Co-ordinating Agency should also 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 available.

3.5.1. Safety Huddle

In complex situations, urgent teleconferences can be convened with Health Services Executives. During business hours, the DCGs are the first point of contact. For urgent after-hours communication, briefing will be with the 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. CEC Critical Response Register

The CEC maintains a Critical Response Register known as the Quality Audit Reporting System (QARS) with ReACT as a platform to automatically upload and register incoming TGA notices. QARS ReACT also has the capability of 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), Health Services, or the system. The CEC maintains the currency of the distribution lists to ensure that all outgoing emails reach the intended designated 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. CEC Executive On Call Teams Channel

The CEC maintains an Executive On Call Teams Channel as a platform to communicate with Health Services out of business hours. The application stores mobile phone numbers and email addresses enabling SMS and emails to CEC and 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 (e.g. Pharmacy, clinical specialties, public health).

3.5.5. Licensed private health facilities

The Ministry of Health'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 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 Health Services.

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

Criteria for publishing 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.
5. Any safety risk deemed appropriate for safety broadcast by CEC Chief Executive, CHO or a Deputy Secretary.

Out of scope

1. Updates to practice that require extensive change management.
2. Public health risks not impacting NSW Health Facilities.
3. 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 electronic Medical Record system (eMR).

Developing a Safety Broadcast

The level of risk dictates the mode of communication to the system (Table 3B). 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 Chief Executives and Directors of Clinical Governance. Only Safety Alerts, requiring immediate attention and mandatory action, may be issued out of hours. In this instance, a Short Message Service (SMS) and email will be sent by the Co-ordinating Agency to:

- 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 Health Services at a minimum:

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

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. NSW Health Strategic Communications and Engagement (Digital) team upload the Safety Broadcast to:

- Intranet: http://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 3C: Types of broadcasts, development, distribution strategies and 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: • On-call Executives • 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.
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 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 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.

Communication responsibilities of agencies are outlined in the Table 3C. The Broadcasts are available on the NSW Health website and are also circulated to licensed private health care facilities. 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 Ministry Strategic Communications and Engagement where the author specifies the sites for publication. For matters likely to be of media interest the authors should alert their agency's medica team. The holding statement will be reviewed by the Lead Agency's medica team and included for approval by the agency's CE before progressing to the Ministry of Health.

Table 3D: Agencies and responsibilities for communication

Agency	Communication responsibilities
CEC	Health Services CEs, DCGs* HSNSW Where relevant: • Directors of Pharmacy • Relevant ACI networks via network managers/clinical directors • Infection Prevention and Control and Infectious Diseases network (Communities of Practice) • Cancer Institute NSW • TGA
HealthShare NSW	Suppliers and wholesalers Clinical product managers Biomedical engineers
Office of the Chief Health Officer MoH	Professional peak bodies Primary Health Networks
Legal and Regulatory Services MoH	Licensed private health facilities Pharmacy networks and peak bodies (for example, Pharmacy Guild and Pharmaceutical Society of Australia)
Digital Communication MoH	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 OCHO.

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
- SMB - SPRU (and PSFU as required)

- 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.

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 NSW Health Strategic Communications and Engagement to move the Safety Broadcast from 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.

3.6. 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 the Incident Management System (ims+), the Health Quality Reporting System (HQRS), PHREDSS, system 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

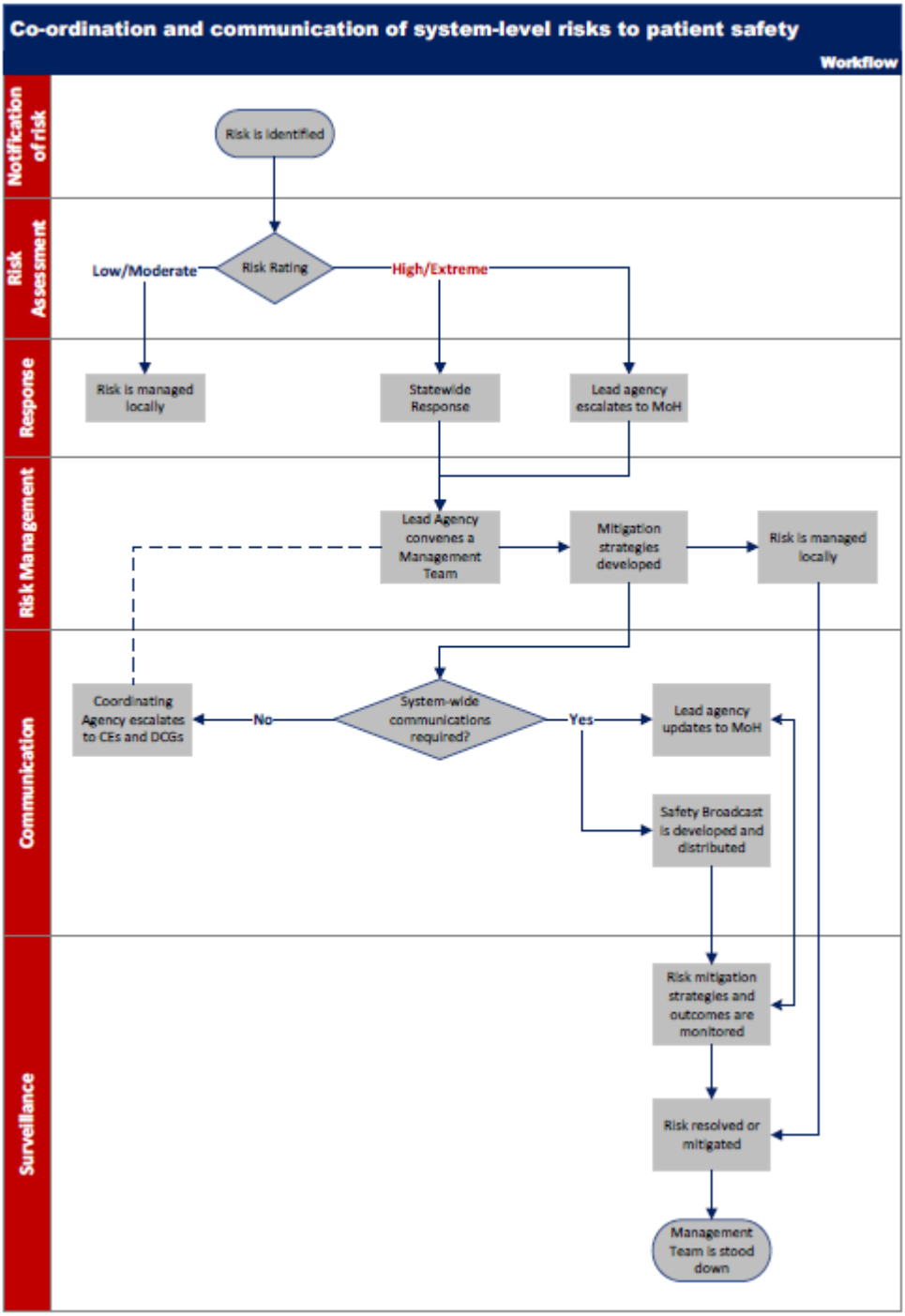
The Lead Agency decommissions the MT when the risk no longer requires central coordination and can be managed locally.

4. REFERENCES

1. 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].
2. 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].
3. 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. System-level Workflow



5.2. Clinical Networks

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

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