Knowledge & Practice Series

CRISIS MANAGEMENT OF SERIOUS INCIDENTS

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> “You never let a serious crisis go to waste. [...] it’s an opportunity to do things you think you could not do before.”

Rahm Emanuel
American Diplomat

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CONTENTS

PREAMBLE

A clinical or non-clinical serious incident can precipitate an organisation crisis. No matter what its origin may be, a crisis is disruptive. It unleashes tension in its trail. Multiple stakeholders are involved. Patients, their families and staff may be affected. Resources have to be deployed to manage and contain the crisis. Investigations have to be conducted to identify the causes, while immediate and longer-term corrective actions need to be put in place. Teams are thrust into roles they may not be familiar with and time is not on their side. The list goes on.

Crisis preparedness enables organisations to face some of these challenges with confidence. A well-developed plan that addresses the processes needed to respond effectively and holistically to a crisis is an invaluable tool in more ways than one. Besides helping organisations achieve the best outcomes following a serious incident, it helps leadership identify the necessary resources and provides staff with timely guidance on activities and interventions.

In developing a crisis response plan, information is drawn from multiple sources. One important source is the insights and learning from other organisations that had faced and overcome crises. In the local context, while there are platforms and avenues to share the causes of incidents and corrective actions, very few talk about the overall organisation response and approach to the actual crisis. This book by the National Healthcare Group (NHG) focuses on the processes and activities in the aftermath of the discovery of a serious incident – from reporting the incident, managing the crisis response and addressing stakeholders' concerns, to investigating its causes and closing the gaps to prevent future recurrence.

The intent of the book is to provide a guide for crisis management as a whole. No two crises are identical and no two sites are the same. Although differentiated by corporate structure and culture, organisations share a common set of goals: to facilitate prompt closure for patients, to manage the incident with optimal outcomes for all stakeholders, and to learn and grow from the experience. There is value in learning from another's experience. In passing on the information, we are sending signals of possibilities and pitfalls. We also take the opportunity to share resources that we came across in the process of doing and learning about crisis management.

Two recent incidents at NHG entities provide the context for the book. The first involves incompletely sterilised dental instruments while the second, the use of a wrong staining process in immunohistochemistry (IHC) Human Epidermal Growth Factor Receptor 2 (HER2) tests. We acknowledge the assistance of leaders and staff of both institutions who contributed time, information and reference materials.

A/P Tai Hwei Yee
NHG Group Chief Quality Officer

OVERVIEW OF CLINICAL INCIDENT MANAGEMENT PROCESS

DAY 1 EVENT DETECTED

- Assess patient's injury and attend to immediate needs
  ACTION BY: All Staff
- **For MOH Reportable Event:**
  Report to MOH's Integrated Operations Hub (IOH)
  (Immediate/within two hours/by end of work day, depending on severity.)
  ACTION BY: COO

MOH Incident Management and Reporting Framework

DAY 2

- **For Serious Reportable Event (SRE):**
  Report to MOH's Centre for Quality, Performance and Value (CQPV) by Day 2
  ACTION BY: Clinical Governance/ Quality Management or equivalent

MOH Directives for Review of Serious Reportable Events

DAY 3

- Initial analysis of incident
  ACTION BY: Supervisor/Manager/HOD/Quality Management or equivalent

DAY 4 ONWARDS

- Thorough analysis of incident
  ACTION BY: HOD/Process Owners/Quality Management or equivalent
- Implement improvements and communicate findings
  ACTION BY: HOD/Process Owners
- Monitor recurrence and evaluate measures taken
  ACTION BY: HOD/Process Owners/Managers/Quality Management or equivalent

RECOMMENDED

Log incident in **PRISM@NHG**
(PRISM@NHG is NHG's Portal for Risk Identification and Safety Management)
ACTION BY: All Staff

*A suggested framework based on **NHG Clinical Incident Management, Open Disclosure/Open Communication and Second Victim Support Policy***
(to be used in conjunction with or as a supplement to each institution's incident/crisis management policy)

CHAPTER 1

DETECTING AND REPORTING INCIDENTS

2018

- 4 DEC — Staff 1 found an incompletely sterilised pack of dental instruments
- 5 DEC — Staff 2 found the second pack and notified supervisor; triggered incidental reporting by Staff 1
- 6 DEC — Department placed on high alert for such packs; two more packs found
- 7 DEC — Supervisor informed HOD and HOD informed senior management; the fifth pack found

INCIDENT A

HOW THE ERRORS CAME TO LIGHT

INCIDENT B

2020

- 28 SEP — Oncologist commented at Tumour Board Meeting on high rate of HER2 positive
- 23 OCT — Breast surgeon alerted HOD of a reclassification
- 26 OCT — HOD suspended immunohistochemistry services
- 3 NOV — HOD informed senior management that an investigation into possible error would be conducted
- 19 NOV — CMB and CEO informed of investigation findings confirming the error
- 23 NOV — CEO notified NHG CEO
- 24 NOV — Filed Serious Reportable Event (SRE) Report with MOH

THE COMPOUNDING EFFECTS OF DELAY

Time is of essence in a crisis. There is a limited window of opportunity for intervention, to prevent further harm to patients and ensure others are not at risk. Delay at any point in the communication pipeline hinders information from reaching those who are in a position to respond. Often, the delay is contributed by multiple parties. Hierarchy can be the Achilles heel in incident reporting. There is more than one messenger, each relaying the message to someone above him or her. At each stop up the pecking order, delay can happen for various reasons, such as fear of reprisal, denial that there is a problem or lack of knowledge on what is the right thing to do.

Failure to escalate promptly can have grave consequences.

In Incident A, the first pack of incompletely sterilised equipment was found by a dental assistant on 4 December 2018. She had wanted to inform her supervisor but could not find her. She brought the matter up incidentally on 5 December 2018 after a colleague reported finding another pack of incompletely sterilised instrument. On 7 December 2018, upon the discovery of two more packs, the supervisor escalated the matter to the head of department who notified the Management on the same day. By then, four days had passed since the issue first came to light.

In Incident B, the first person to sound the alarm was an oncologist who commented on the high positive rates in HER2 tests at a Tumour Board Meeting on 28 September 2020. The second person was a surgeon, on 23 October 2020. On 3 November 2020, the head of department escalated the matter to senior management. The hospital conducted an internal review which took 17 days to confirm the error and notified NHG five days upon the conclusion of the review. By then, two months had passed since the incident discovery.

The NHG Review Committee (NRC) found the escalation process in both incidents suboptimal. Accountability of parties contributing to the delay was sought. System accountability was achieved through the implementation of the NRC's recommendations on process improvements.

ESTABLISH ESCALATION PROTOCOL

The solution for timely escalation lies not in eliminating hierarchy, but in education as part of cultivating crisis preparedness. There are many things a department needs to grapple with when an incident occurs – fact-finding, incident containment and enacting interim measures, to name a few. Leaders can frame the work for team members, reminding all what is at stake and assisting with setting priorities when an incident happens.[1] The potential consequences of late notification on patient safety should be communicated. A person can be held to account for delays in escalation, notwithstanding the good intentions and attempts at setting things in order.

Having an escalation protocol helps in facilitating this framing process. It builds a common understanding among leaders and staff alike with regard to what the priorities are and with whom responsibilities lie. The protocol should take the form of clearly defined work instruction or Standard Operating Procedures (SOP) on the escalation process, with clear definitions on the criteria (e.g. types of events) to be escalated and by whom, the expected time-frame for escalation and to whom it should be escalated. Given the dynamic nature of healthcare, provisions should be made to review the criteria for the types of events which need to be escalated. The importance of setting clear expectations and norms, and conveying them plainly is best summarised by the words of Conway:[2]

Establish and update escalation protocols to clarify priorities, roles and responsibilities.

> Serious clinical events occur 24 hours a day, 7 days a week, and the organisational response should be the same: 24/7. No matter when discovery occurs, the culture of the organisation should be such that staff members know that leadership genuinely wants to be alerted at any time, and that staff are prepared to notify executives and activate the response.

COMPLY WITH REGULATORY REQUIREMENTS

For events that could have adverse impact on public health, access to health services, safety and security, and public confidence in the healthcare system, the Ministry of Health (MOH) requires public healthcare institutions (PHI) to report these to its Integrated Operations Hub (IOH) within a certain time-frame. Such events are termed "MOH reportable incidents". The urgency varies according to incident severity, ranging from immediate to within two hours of detection and by the end of the work day. Institutions are responsible for performing immediate situational analysis and risk assessment, categorising the incident, escalating reporting internally and to IOH.[a]

Another type of incident, referred to as a serious reportable event (SRE), must be reported to MOH's Clinical Quality, Performance and Value Division (CQPV) via its online National Quality Assurance System within two working days of its identification. This requirement applies to every healthcare institution as listed under the Third Schedule of the Private Hospitals and Medical Clinics Regulations. There are 31 incident categories that fall into any of these seven groups: Surgical or Invasive Procedure Adverse Events, Product or Medical Device Adverse Events, Patient Protection Adverse Events, Environmental Adverse Events, Care Management Adverse Events, Radiological Adverse Events and Other Patient Safety Incidents. SREs generally refer to adverse events that result in harm to a patient, but not all SREs involve death or serious injury. For example, exposure to unintended harm or risk, and unauthorised discharge or release of an infant, a child or any person who lacks capacity are reportable.[b]

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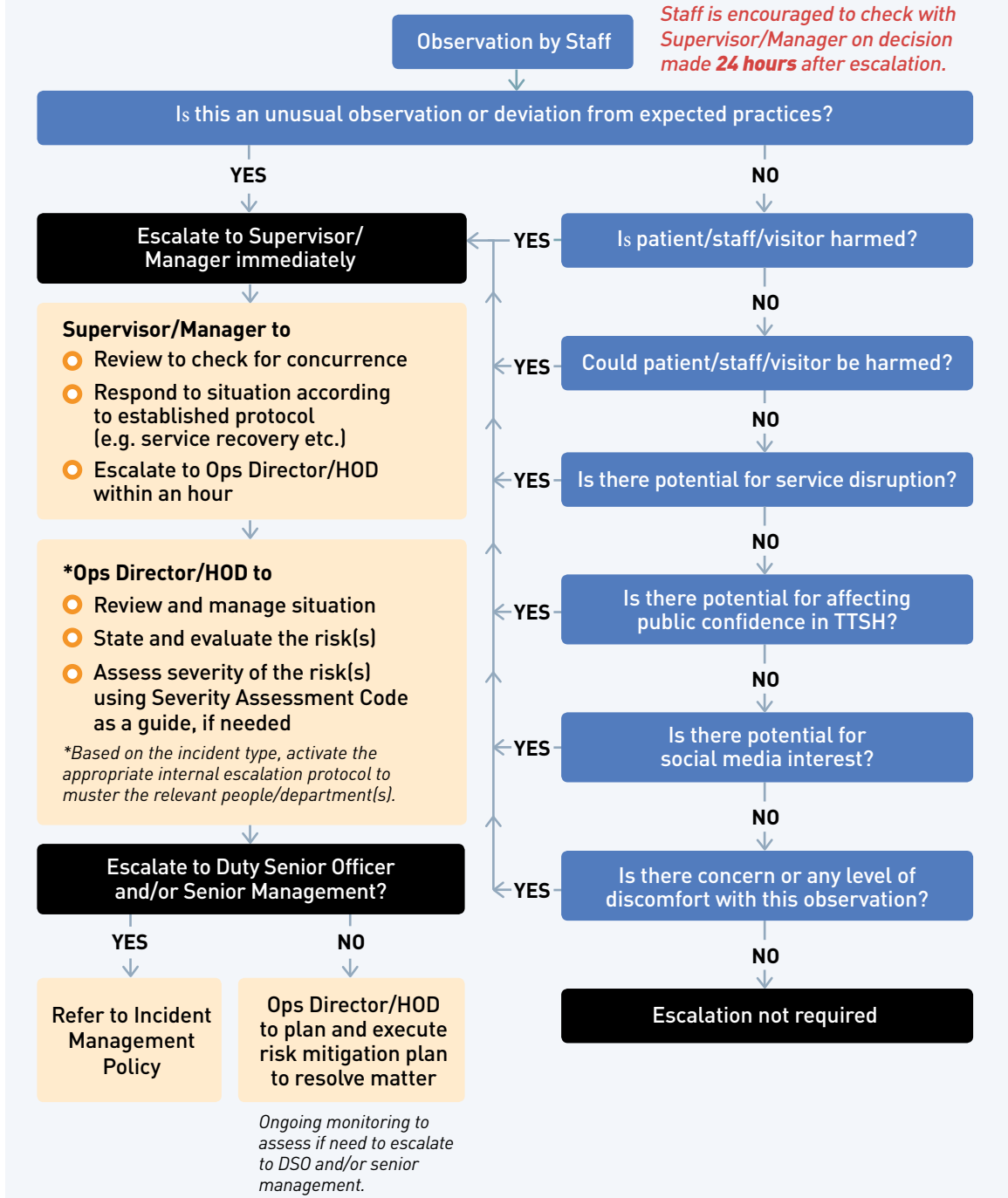
[a]MOH Circular No. 29/2017 Incident Management and Reporting Framework
[b]MOH Directive No. 01/2020 Directives for Review of Serious Reportable Events

ESCALATION PROTOCOL



Source: TTSH

In practice, there may be overlaps between incidents reported under both MOH frameworks mentioned earlier. The intent and scope of each is different. The former seeks to facilitate coordination of operational responses to manage and mitigate risks while the latter aims to encourage learning from incidents. Internally, MOH divisions will keep each other posted and if necessary, will require the healthcare institution to report an incident under both frameworks.

CATEGORIES OF SERIOUS REPORTABLE EVENTS (SRE)

I. SURGICAL OR INVASIVE PROCEDURE ADVERSE EVENTS

1. Surgery or other invasive procedure performed on the wrong body site.
2. Surgery or other invasive procedure performed on the wrong patient.
3. Wrong surgery or other invasive procedure performed on a patient.
4. Wrong implant/prosthesis/invasive device inserted.
5. Unintended retention of a foreign object in a patient after surgery or other invasive procedure.
6. Intraoperative or immediate post-operative/post-procedure death in an ASA[c] Class 1 patient.

II. PRODUCT OR MEDICAL DEVICE ADVERSE EVENTS

7. Patient death or serious injury associated with the use of contaminated drugs, medical devices or biologics provided by the prescribed healthcare institution.
8. Patient death or serious injury associated with the use or function of a medical device in patient care.
9. Patient death or serious injury associated with intravascular air embolism that occurs while being cared for in the prescribed healthcare institution.

III. PATIENT PROTECTION ADVERSE EVENTS

10. Unauthorised discharge or release of an infant, a child or any person who lacks capacity, as referred to in section 4(1) of the Mental Capacity Act (Cap. 177A).
11. Patient death or serious injury associated with patient abscondment.
12. Patient suicide, attempted suicide or self-harm that results in patient death or serious injury, while being cared for in the prescribed healthcare institution.

IV. ENVIRONMENTAL ADVERSE EVENTS

13. Any incident in which systems designated for oxygen or other gas to be delivered to a patient contain no gas, the wrong gas or are contaminated by toxic substances.
14. Patient death or serious injury associated with a burn incurred while being cared for in the prescribed healthcare institution.
15. Patient death or serious injury associated with the use of physical restraints or bedrails while being cared for in the prescribed healthcare institution.

continues on the next page...

[c] American Society of Anesthesiologists Physical Status Classification System

CATEGORIES OF SERIOUS REPORTABLE EVENTS (SRE) (CONT'D)

V. CARE MANAGEMENT ADVERSE EVENTS

16. Medication error resulting in permanent harm or death, or causing temporary harm to the patient requiring initial or prolonged hospitalisation and intervention, including measures necessary to sustain life.
17. Patient death or serious injury or risk thereof associated with the unsafe administration of blood or blood products.
18. Transmission of communicable diseases following blood transfusion or organ/tissue transplant.
19. Maternal death or serious injury associated with pregnancy or delivery.
20. Infant death or serious injury associated with labour or delivery in a low-risk pregnancy.
21. Patient death or serious injury resulting from the irretrievable loss of a biological specimen.
22. Patient death or serious injury resulting from failure to follow up or communicate clinical test results.
23. Unexpected death or serious injury as a result of lack of treatment or delay in treatment which would have been preventable otherwise.
24. Unexpected death or serious injury as a result of medical intervention which would have been preventable otherwise.
25. Any assisted human reproductive procedure which has or, may have, resulted in insemination of wrong gamete or transfer of wrong embryo.

VI. RADIOLOGICAL ADVERSE EVENTS

26. Radiological procedure performed on the wrong patient or wrong site, or the wrong radiological procedure performed on patient.
27. Ionising radiological procedure performed on pregnant patient.
28. Radiopharmaceutical and contrast media administered to the wrong patient or through the wrong route or with a wrong type/dose.
29. Radiation therapy delivered to the wrong body site or to the wrong patient or with a wrong dose.
30. Death or serious injury of a patient associated with the introduction of a metallic object into the MRI area.

VII. OTHER PATIENT SAFETY INCIDENTS

31. Unintended harm or risk thereof to a patient while being cared for in a prescribed healthcare institution.

Source: MOH Directives for Review of SRE (2020)

REPORTING INCIDENTS TO MOH'S INTEGRATED OPERATIONS HUB (IOH)

CATEGORY 1 **An incident of high severity and impact at the national or system-level, or where life is endangered.**

Definition: Disease outbreaks with high severity/transmissibility in the institution or community and no treatment is available; incidents involving loss of life or critical injuries or extensive damage to institution's property/extensive degradation of clinical service capability; incidents that could affect public confidence in the healthcare sector, MOH, the Public Service and/or the Government.

CATEGORY 2 **An incident of medium severity and impact at the national or system-level.**

Definition: Disease outbreaks of moderate severity/transmissibility in the institution or community and some treatment is available; incidents involving serious injuries or moderate damage to institution's property/ moderate degradation of clinical service capability; incidents that could affect public confidence in the healthcare sector, MOH, the Public Service and/or the Government.

INITIAL REPORT:

Category 1: **Immediately upon knowledge**
Category 2: **Within 2 hours**

- CEO to call GCEO
- Institution Quality Director to call GCQO
- Institution Quality Office to call NHG QSM: **6471 5951**
- Institution COO Office to call MOH Duty Officer and email MOH

FOLLOW-ON AND PROGRESS REPORT:

Category 1: **Every 3 hours until closure of incident** *(or unless adjusted by MOH)*
Category 2: **Every 6 hours until closure of incident** *(or unless adjusted by MOH)*

- Institution COO Office to email MOH

CATEGORY 3 **An incident of low severity and impact at the national level or moderate-low severity and impact at the institutional-level.**

Definition: Small clusters of diseases of low severity/transmissibility in the institution or community and treatment is available; incidents involving minor injuries or minor disruption to clinical service capability; incidents that could affect public confidence in the institution; incidents requiring the activation of business continuity and related mitigation plans.

INITIAL REPORT:

As early as possible, by end of business day

- Institution COO Office to email MOH and NHG QSM: **quality@nhg.com.sg**

FOLLOW-ON AND PROGRESS REPORT:

Every day until closure of incident
(or unless adjusted by MOH)

- Institution COO Office to email MOH

MOH contact for **infectious diseases:** **9817 1463**

reportidcluster@moh.gov.sg
(for both initial and progress reports), with a copy to **moh_ops_centre@moh.gov.sg** *(only for initial report)*

MOH contact for **other incidents:** **9179 2189**

moh_ops_centre@moh.gov.sg
(for both initial and progress reports)

Source: NHG Clinical Incident Management Framework

IN THIS TOGETHER

As a healthcare group, a crisis at any of our institutions is a crisis for NHG. As we are set up as a public healthcare group of institutions, reporting through a group governance structure to MOH, there is a shared accountability and responsibility in managing an incident and achieving the best outcome for all stakeholders.

Both the institution and NHG Cluster have their individual and specific roles to play in managing a crisis that occurs within one's entity. These responses to a crisis are described in several documents which provide policy guidance for incident reporting, escalation, management and investigation. The documents help to delineate the roles and responsibilities of the respective parties involved. As an example, in an incident involving multiple patients, three routes are to be activated concurrently – institution CEO contacts Group CEO, institution Quality Director contacts Group Chief Quality Officer and institution Quality Office contacts NHG's Quality Service Manager.[d] In the context of a serious incident with impact at organisation level or beyond an organisation, NHG might conduct a separate independent incident review. In Chapter 3, we look at NHG's role in greater detail. Before that, in Chapter 2, we share the experiences of two hospitals mounting a crisis response on the back of rising public interest while the clock ticked away.

Appreciate the spirit behind reporting. Fulfill what requirements there are while learning to become better at incident management and prevention, as a team and as a system.

[d] NHG Clinical Incident Management, Open Disclosure/Open Communication and Second Victim Support Framework

CHAPTER 2

MOUNTING A CRISIS RESPONSE

This chapter reviews the crisis management process at two institutions. The cases are very different in facts and the specifics but both converge on the goals and priorities which inform the actions of the responders. Certain key principles exist to help healthcare institutions navigate major adverse events involving many patients. The contents of this chapter are organised around these principles.

SUMMARY OF FACTS

INCIDENT A

Eight packs of dental instruments which were processed on 28 November 2018 had not been put through the last step of the sterilisation process. Some of the instruments were used on patients. Noting a similar incident that had occurred in Singapore in June 2017, then Minister of Health Gan Kim Yong said: "We take a serious view of the incident [...] and I am disappointed it has happened despite our efforts."

INCIDENT B

A suboptimal staining protocol was used at the laboratory for years before being discovered in late 2020. Over a hundred patients were reported to have the malfunctioning gene HER2 which they did not have. Among them, some had opted for treatment and were in various stages of it. The Ministry of Health said that it took a serious view of the incident and had requested the hospital, as a safety precaution, to review other lab protocols beyond those for the affected tests.

CRISIS PLANNING AND TEAMING

Healthcare institutions operate in an increasingly complex and uncertain environment. A more proactive stance to handling emergency contingencies is crucial. Not only must there be crisis planning, a crisis management team (CMT) must precede the plan. At the centre is the core unit whose first task to draw up a list of people to be added to the CMT so that "when the crisis hits, no one has to sit around and wonder who ought to be called in".[3]

In terms of the CMT's line-up, there is no such thing as the 'ideal' profile of representation. In prefacing a study on CMTs in Australian health organisations, Canyon identified the various arrangements advanced by researchers in business continuity and emergency planning:[4]

- A cross-functional committee designed to handle any crisis.[5]
- A taskforce constituted to match the nature of the crisis.[6]
- A committee with a core membership of five from senior management positions – CEO or designate, CFO, Chief Internal Communicator, Chief External Communicator and legal representative.[7]
- A committee with a core membership of seven people from these functions: operations, finance, human relations, public relations, legal, security, occupational health and safety.[8]
- A team where everybody of any relevance needs to be included.[9]

Returning to our cases, the arrangements that prevailed at the time of the incidents and the teams that were subsequently deployed exhibit a semblance of each characteristic noted above. In the hospital where Incident A happened, its Hospital Emergency Committee had both senior management and functional representations. This emergency incident command system provided the core structure on the back of which a team was 'calibrated' – assembled and set in motion quickly – to pivot to the characteristics of Incident A and the needs that arose. A multidisciplinary team, drawing from Corporate Communications, Emergency Planning, Operations, Infection Control, Central Supplies Service Department, Nursing, Dental and Quality, was formed to mount a response. For comparison, the line-up of the team managing Incident B is included in an upcoming diagram.

A good practice is to have a crisis management planning framework that is oriented towards patient safety incidents (the likes of Incidents A and B), as opposed to riding on emergency incident command systems for floods and pandemics, or fires and utility failures. The premise for such a targeted plan is that patient safety incidents have specific needs that can be better served with such a plan. Within this category of events, while each is factually different, there are common elements and dimensions that should be considered following an event, and in the journey moving forward to resolution. This framework is anchored in a work plan that prompts particular actions in the first hour, day, week, month and beyond.[10] A pre-established crisis management team is responsible for testing, finetuning and updating the plan. Its members undergo training not only in crisis management but in conflict resolution, patient/person-centred communication, medico-legal principles and healthcare regulations.

The effectiveness of a CMT is dependent on three things, according to King (2002).[11] The first is team composition. Team members who have had prior interactions, who have better knowledge of the tasks at hand and who are part of a heterogeneous team (where there is diversity in personality types, the values and beliefs held, and the inclination towards certain decision-making and communication styles) tend to generate more and better ideas. Second is style of leadership. A team leader who demonstrates a charismatic style of leadership may be more effective in controlling and eliminating an organisational crisis.

Have on stand-by a crisis response team as part of a crisis management plan.

The third and last factor is organisational culture. Teams are more effective when the organisation supports advance planning. By extension, this would also mean a leadership that is committed to equipping the CMT – core team members and others whose involvement will be required at some point – with the skills and abilities to do the work. Establishing and building up a team that is ready for deployment is a paramount principle in crisis management. In subsequent pages, we turn to the other principles, one at a time although in practice, some of the activities associated with the principles occur contemporaneously to contribute towards the overall crisis response.

> “Each incident is unique in its characteristics that one may not be fully prepared for. We formed a team out of the Hospital Emergency Committee (HEC). Speed is of essence. We raced against time, working and meeting late into the night to establish an account of the incident and a response plan.
>
> Frequent huddles with the entire response team and with small groups of stakeholders helped us keep up with events that were happening at the same time, and to coordinate a response. We kept staff morale up by assuring everyone that the hospital was doing everything possible for our patients, to make system improvements to prevent future sterilisation breaches.
>
> It is not an exaggeration to say it takes a kampong to manage a hospital incident. Getting everyone on board as early as possible is critical to a successful response.”
>
> **Adj A/Prof Tan Hui Ling**
> Assistant Chairman Medical Board,
> Clinical Quality and Audit

TEAMING UP IN CHALLENGING TIMES

INCIDENT A

CHAIR Chief Executive Officer*

Provides collective leadership for incident management; ensures service continuity; identifies all affected patients and provides the required recovery measures of support; lends support to care teams to communicate with and manage the patients; coordinates the various activities needed in the crisis response with the teams set forth below:

LIAISON WITH MOH (INTEGRATED OPERATIONS HUB) | Emergency Planning

Team Lead: Director, Emergency Planning
Reports incident to MOH and coordinates hospital-MOH communications.

COMMAND CENTRE AND CALL CENTRE | Operations

Team Lead: Director, Operations
Sets up facilities for coordination and control of activities, and for contacting patients.

OPEN DISCLOSURE (OD) | Dental officers; relevant physicians; Infectious Diseases specialists; Patient Relations Service

Team Lead: HOD, Dental Surgery
Identifies affected patients, informs them of incident, clarifies concerns and offers reviews.

LIAISON WITH MEDIA | Corporate Communications

Team Lead: Director, Corporate Communications
Works with media to provide public with information, to maintain their confidence in the healthcare system; prepares script used as part of OD.

CLINIC OPERATIONS | Dental Clinic; Operations

Team Lead: HOD, Dental Surgery; Manager, Clinic Operations
Stabilises clinic operations, ensures business continuity plans are implemented and clinical service is accessible to patients.

STAFF SUPPORT | Human Resources (Staff Support Scheme)

Team Lead: Manager, Human Resources
Provides support to staff who are affected by the incident to mitigate second victim syndrome.

INCIDENT INVESTIGATION, PROCESS REVIEW, SYSTEM IMPROVEMENT
Quality Office; Infection Control; Central Sterile Supplies Department

Team Lead: Assistant Chairman of Medical Board (Clinical Quality and Audit)
Investigates what led to the lapses; reviews sterilisation process and recommends actions for improvement; follows up on implementation.

*Supported by key senior clinical leads – Chairman of Medical Board, Chief Nurse, Divisional Chairman (Ambulatory and Diagnostic Medicine), Assistant Chairman of Medical Board (Clinical Development).

INCIDENT B

CHAIR Clinical Director, Office of Clinical Governance (OCG)*

Provides leadership for incident management; identifies affected patients, and provides recovery measures; lends support to care teams to communicate with and manage patients; coordinates the various activities required in a crisis response as set forth below:

COMMAND CENTRE | Operations; OCG-Medical Affairs

Team Lead: Director, Operations and Assistant Director, Medical Affairs
Communicates and gathers information; maintains command and control; coordinates and documents steps taken to implement crisis action plan.

CRISIS HELPLINE | Operations; Allied Health Services

Team Lead: Dy Director, Operations and Dy Director, Allied Health Services
Attends to calls from patients and family members on this particular incident.

LIAISON WITH OTHER HOSPITALS | OCG-Medical Affairs

Team Lead: Dy CMB/ HOD, General Medicine
Liaises with oncology centres where patients are receiving care, to make arrangements that are in their best interest.

CLINICAL CARE | Breast Surgery Service

Team Lead: Clinician Lead, Breast Surgery Service
Reviews patients' care plans together with their oncologists in light of the reclassification of diagnosis.

OPEN DISCLOSURE (OD) | Patient Experience Office; OCG-Patient Relations Services; breast surgeons and histopathologists; Medical Social Work

Team Lead: Director, Patient Experience Office (PEO)
Arranges and facilitates at OD meetings, keeps in touch with patients/family members while investigations are underway.

LIAISON WITH MEDIA | Corporate Communications

Team Lead: Dy Director, Corporate Communications
Works with media to provide news coverage; maintains channel for crisis communication with clinicians at partnering institutions and their communication teams.

COMPENSATION | Finance; OCG-Patient Relations Services; temporary staff recruited

Team Lead: Chief Financial Officer and Senior Manager, Patient Relations Services
Prepares and presents offers of financial settlement to patients/family members.

INVESTIGATION

A separate team, the Internal Review Panel chaired by Deputy Chairman, Medical Board (Clinical Informatics, Innovation & Patient Engagement), investigates the incident.

*OCG reports the incident to MOH's Centre for Quality, Performance and Value (CQPV) and oversees all hospital-MOH communication including arranging a site audit.

IDENTIFY THE AFFECTED PATIENTS AND ATTEND TO IMMEDIATE NEEDS

To identify the affected patients, crisis responders would need to first locate and assemble critical information. The information is often voluminous as was the case with Incident B. All the positive HER2 reports were traced, and the accompanying medical records assembled. The trace went as far back as 2012 (eight years earlier) when the staining protocol was first implemented. It was arduous for another reason - not all the records existed in electronic form which rendered them searchable. Some of these were paper records which had to be manually sorted. The benefits of having a robust documentation system may not be apparent on an average day but would make all the difference in a crisis of similar magnitude. The saving grace was that the lab results had been retained and archived.

Ensure that good record-keeping practices are in place to facilitate traceability when the need arises.

The number of patients whose diagnoses were reclassified following retests stood at 106. A team led by a senior member of the hospital's clinical board liaised with oncologists and oncology centres where the patients were receiving treatment to determine the next course of action. Joint care teams were formed, comprising the hospital's surgeons and the patients' oncologists, to review each care plan. The Patient Experience Office (PEO) coordinated each detail, whether it was clinical reviews, family conferences or assistance referrals. It maintained a clear line of sight of all the affected patients and focus: Those who had yet to commence HER2-directed therapy, to prevent start of unnecessary treatment while those who had embarked on HER2-directed therapy, to terminate treatment to reduce further harm. Among the patients who had commenced therapy, they were further segmented based on their treatment response, what side effects they experienced and severity. Through planning and prioritising, the team made provisions to reach out to all the affected parties, including families of deceased patients.

In incident A, the incompletely sterilised dental instruments were traced to a batch of instruments which were processed on 28 November 2018. The dental centre did not at that time have a mechanism to identify the patients on whom the instruments were used. As a result, it had to contend with the possibility that any of the patients who attended the clinics between 28 November and 5 December 2018 could have been treated with one or more of the instruments. For added measure of caution, it expanded the radar to include those patients who attended on 6 December 2018, the day on which all staff were placed on alert for such instruments in circulation while search efforts were in progress.

The outreach to the dental patients took a few days to complete. The hospital sought to assure the patients that the risk of infection was extremely low, given that the completion of the earlier steps in the sterilisation process would have removed close to 100 per cent of organisms of concern. This message was conveyed to the patients by dental officers who made phone calls during the day and through the evening from a dedicated Call Centre set up by the Operations team. Infectious Disease specialists were on hand to answer questions and assisted those who wished to make appointments for in-person reviews. Blood investigations were offered when clinically indicated. Extending the team's efforts were Medical Social Workers who helped those in need of further support.

CONDUCT EARLY OPEN DISCLOSURE

This is a process rather than a one-off meeting or conversation. At the heart of it is prompt, honest and transparent communication with patients/their family. Nothing unsettles them more than having to find out in the news what has gone wrong and being left on their own to make sense of the situation. Open disclosure encompasses rapid activation of support, a commitment to provide follow-up information and the readiness to keep channels of support open. Just as important is equipping staff with what it takes to deliver difficult news and answer challenging questions, even going as far as prompting them on what to say, if necessary. For insights on how to structure a good open disclosure process, please refer to 'Disclosure Culture Assessment Tool' in Appendix C.

In Incident A, the hospital availed itself to the first opportunity to reach out directly to the patients. By arranging for the dental officers to call the patients they treated, it found the most natural way of getting the message across, leveraging on the doctor-patient rapport built prior. A script prepared by the Corporate Communications department guided the dental officers on how to broach the subject with patients, assuage their anxiety and offer them help by way of follow-up reviews with the hospital's ID specialists. The team worked tirelessly to reach out to the majority of the patients who were contactable to inform them of the incident and how they might be affected. This was accomplished ahead of media release.

In Incident B, the timing of open disclosure, not just its content, was a matter of careful thought and planning. The hospital scheduled each OD meeting to coincide with the patient's consultation with her oncologist. If this was not possible, it was scheduled as close as possible to the consultation, before or after. An OD team comprising a breast surgeon, a histopathologist and a staff from the Patient Experience Office (PEO) conducted the open disclosure. Each member understood what lay within the team's sphere of control to respond, affirm or commit. There were facts surrounding the incident that had been established and verified; these were shared with the patient or family. There were other areas such as causation and accountability which were the subject of an ongoing independent investigation. On these matters, the OD team appealed for the patient's understanding to let the process run its course. PEO kept in touch with the patient to provide updates and further information as these became available. They did their part to expedite the claim processing work by obtaining the consent from patients (or their proxies) for release of information needed for this process. They were also trained to look out for "the 3 Harms" (adversity suffered by the patient physically, psychologically or financially) and arrange help and support.

Initiate open disclosure process as early as possible to build trust.

"WALK THE JOURNEY WITH YOU"

I. OPEN DISCLOSURE (OD)

APPROACH:

- **Priority:** Patients (1) who are undergoing treatment; (2) who have not begun treatment.
- Collaborate with oncology care partners in other institutions.
- Schedule oncologist appointment as close as possible to OD (to minimise anxiety felt by patient/next-of-kin).

Follow-up call post-OD:

The next day → The third day → Thereafter, as and when necessary

II. ENGAGEMENT

OBJECTIVES:

- Reach out to patients.
- Apologise and acknowledge.
- Explain the reclassification of HER2 test result.
- Address questions to the best of ability.

APPROACH:

- Show empathy and sincerity.
- Provide continuity post-OD.
- Listen to feedback.
- Assess and attend to "3 Harms" (physical, psychological, financial).
- Assure and offer support.

III. RESOLUTION

- Close the loop with meeting with patient/next-of-kin.

Each stage was tracked and progress reported to senior management. Completion timelines were set for each phase of activity for different patient cohorts. What was discussed and addressed at each communication session was documented and the notes filed in patient's dossier (physical and electronic).

Source: KTPH

DIFFICULT CONVERSATIONS

> "Can you even imagine the pain and side effects of my treatment? Now you tell me I have taken a drug that is not necessary!"
>
> - A patient

A KNOWLEDGEMENT

- Acknowledge the impact of the incident on the patient/family.
- Be mindful that certain words or phrases (e.g. "I understand how you feel") may come across as trivialising the patient's situation.

S ORRY

- Be sincere in expressing regret for what has happened.
- Be sensitive about patient's predicament. In addition to physical suffering, she is also anxious over longer-term or irreversible impact.

S TORY

- Give patient time to share.
- Listen for insights and understanding.

I NQUIRE

- Gently nudge patient back to focus on what can be done presently.
- Seek the patient's views on the way forward and on options for resolving immediate needs.

S OLUTIONS

- Explain what the hospital will do - to work with her oncologist to manage her treatment, to look into the side effects, bear responsibility for the error and provide the necessary support.

T RAVEL

- Demonstrate willingness to walk the journey with patient.
- Provide/arrange relevant support services.
- Maintain contact with the patient/family during the course of the incident investigation, keeping them updated on progress.

**The A.S.S.I.S.T model was developed by Medical Protection Society (MPS), UK*

COMMUNICATE WITH STAFF HONESTLY AND WITHOUT DELAY

A rule in public communication states: "Whoever informs the first story informs the overall story." Organisations must get ahead in this race, to supply the truth as soon as it is available before misinformation starts filling up the vacuum and becomes hard to correct later. This principle can be extended to the communication with staff.

In Incident A, the management emailed staff about what had happened and the course of action the hospital was taking. In Incident B, there was sustained public interest for months catalysed by media reports at key junctures. At each turn, staff learnt about the developments from the hospital before the media. Corporate Communications and HR joined hands to craft messages for three audience groups – employees in the department where the incident happened, members of staff and senior management. In the next two pages, we enclose excerpts as examples of how communicators defined the essential messages clearly and concisely, and centralised the flow of information by designating contact persons to whom queries should be channeled to.

Develop an internal communications plan predicated on providing accurate and timely information.

Staff should hear directly from the organisation and not have to rely on the news mill to get information about something that had happened at their workplace. They want to know what happened, and they need to know for there are patients and members of the public who will be asking questions. In addition, communicating widely, fully and contemporaneously helps place everyone in the organisation on the same page. A shared context is created within which support, insight and growth can occur.

THE AFTERMATH

11 December 2020

Dear Yishun Health Colleagues,

The KTPH Laboratory recently detected an issue with one of its test procedures. This will affect patients and all test related to this procedure have ceased. The hospital views this matter seriously and will be conducting an internal review of this issue. NHG and MOH have been informed.

At this point, we urge everyone not to speculate or share further information with external parties in person or on online platforms.

As we will be issuing a media release at 4pm, this circular serves to inform all staff before the public hears about it. HR will start engaging Heads of Department and different staff groups from 2pm to 4pm today. NHG will also be sending a staff circular concurrent with KTPH's release.

The circular included an advisory on handling enquiries from the media, patients/family members and the general public. It provided scripts on possible responses:

To the general public

We are very sorry this has happened. We are actively reaching out to the affected patients. Please bear with us. Thank you for your understanding. You may refer to the media statement for more information.

To the patients/family members

We are very sorry this has happened. We are actively reaching out to the affected patients. Please bear with us. Thank you for your understanding. You may call [tel no.] which is a dedicated hotline for this incident. Thank you.

This is a very difficult period for everyone, in particular our colleagues from the Laboratory. Should anyone require a listening ear, please do not hesitate to approach your Head of Department or the PALS team [tel no.].

We hope everyone will display the same unity and cohesiveness that we have shown in our ongoing fight against COVID-19. We will get through this together.

<Letter was signed by CEO and CMB>

continues on the next page...

CLOSURE, THE LESSONS AND FORGING AHEAD

3 May 2021

Last December, we informed you about an incident [*provide a summary*]. Following the incident, the NHG Review Committee (NRC) was convened to conduct an investigation [*describe objectives*]. NHG will be making a public announcement this afternoon on the findings. We would like to share the key points with you ahead of time.

The NRC's investigation concluded that the inaccurate HER2 tests were caused by [*state cause and department involved*]. This was due to human error during the establishment of the protocol. [*explain the other factors contributing to the delay in error detection*].

The NRC has made recommendations to improve our systems and processes, to prevent future recurrence. [*cite measures*]

We view these lapses identified by the NRC seriously. Disciplinary actions have been taken against [*x*] members of our management and staff who had not adequately discharged their duties and responsibilities [*state actions taken*].

As a campus, we must reflect and learn from this incident. Let us be proactive to identify risks, mitigate them, and ensure a high standard of quality and safety in our hospital processes. Our patients' well-being must be our top priority, we must work hard to earn their trust.

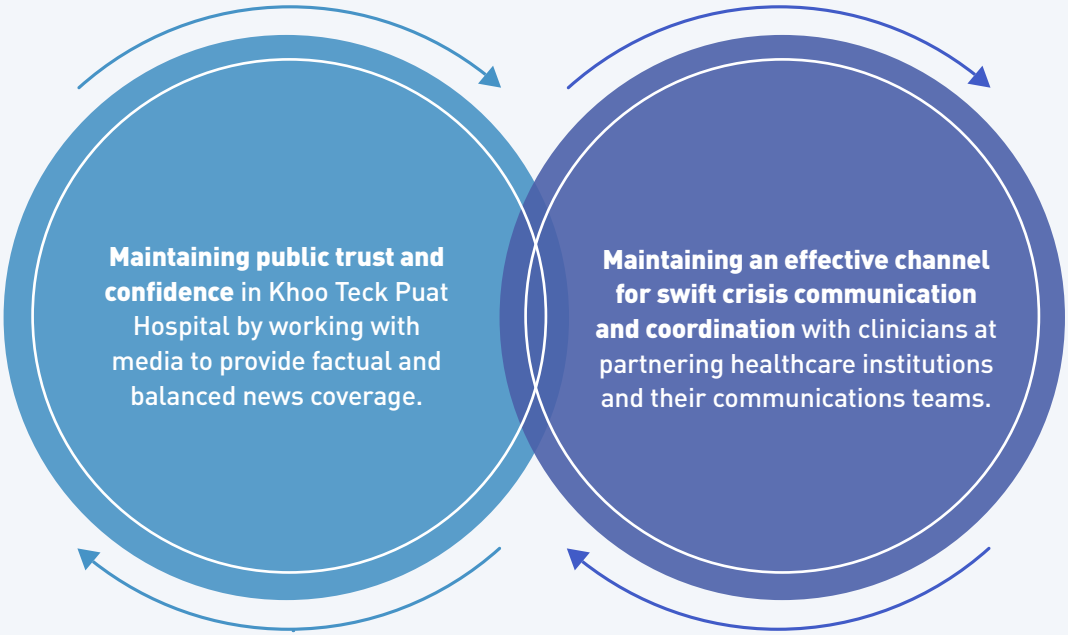
We recognise the last few months have also been very challenging for our staff. [*acknowledge the difficult circumstances faced by 'second victims'*]. During times like this, let us encourage and support one another to move on from this episode and commit ourselves to do better for our patients. Yishun Health's senior management team stands with you.

<Letter was signed by CEO and CMB>

It carried an advisory on the handling of enquiries from members of the public (staff to refer them to the NHG press release) and the media (staff to advise them to email Corporate Communications).

*In each instance, there was a corresponding move by NHG CEO to communicate with staff across NHG institutions ahead of media release in December 2020 and May 2021.

A TWO-PRONGED APPROACH TO PUBLIC COMMUNICATION



AIM

Working to ensure that every public announcement provides timely and accurate information to key stakeholders (patients/next-of-kin; partnering healthcare institutions and staff) without compromising the ongoing work of the NHG Review Committee.

- Apologising to patients/next-of-kin unreservedly where errors had been made, showed empathy, assured them of hospital's full support.
- Explaining to the public that prompt corrective actions had been taken to prevent similar incidents from happening again.

CHALLENGES

- Making a public announcement as soon as possible despite the complex and evolving situation.
- Maintaining an active media monitoring process, including the information circulating on social media and public sentiments .
- Addressing public concerns/feedback promptly and nipping falsehoods in the bud.

Source: KTPH

PROVIDE SUPPORT FOR SECOND VICTIMS

In every crisis, there is a group of individuals for whom policies such as Psychological Support for Staff (KTPH - HP-HR-30) and Second Victim Support Framework (NHGHQ-QRM-GEN2) are written. These are staff who themselves have become "second victims" of adverse events. They grapple with a sense of guilt of having failed their patients and begin to doubt their skills and abilities. Some face added pressure from having to appear before a committee of inquiry to assist in the investigations.

In Incident A, staff who were involved in the processing of the instruments in question received emotional support through the hospital's 3S (Staff Support Staff) process. In Incident B, staff who were directly involved in conducting HER2 testing and reporting test results, their colleagues, the breast surgeons and possibly many more could, in varying degrees, be considered second victims. HR and members of senior management made regular visits to the incident site to engage with staff, hear them out and keep their morale up. PALS (Peers Around Lending Support), a crisis support programme run by psychiatrists, psychologists, medical social workers and HR officers, was available to anyone in need of a listening ear and a safe space to receive advice.

Widen the support to include those who are indirectly affected by the crisis.

Investigations are solemn affairs but administrators should provide a touch of humanity. In one institution, a staff facing charges from the hospital's Board of Inquiry (BOI) had preferred to respond in writing. The charges were drafted to his attention. Another, a union member, had requested for union representation at the BOI and this was also granted. In the other institution, a trained counsellor from Human Resource's Wellness Programme lent her expertise to responders who helped staff through the course of the investigations and transition back to work after the stop-work order (imposed earlier as a patient safety timeout measure) was lifted.

MAKE FAIR RESTITUTION TO PATIENTS

There are three ways to make amends – service recovery, reimbursement and compensation. Service recovery helps patients "recover" by identifying the issues faced and resolving them or reducing their impact on the patients. Reimbursement is paying the patients for expenses with or without an admission of fault. Both should be attempted proactively; patients and family members should not have to ask. In our case examples, the measures taken include facilitating a review of the care plan in light of the reclassification of diagnoses, waiving the costs incurred for pscyho-emotional support (or reviews by ID specialists in the case of Incident A), reimbursing costs incurred for unnecessary treatment, transportation and other relevant expenses.

Compensation is a financial remedy offered to an individual who has sustained an avoidable harm or loss caused by the error in question, with the intention of restoring him or her. To enable this, it is important for medical establishments to maintain an up-to-date health and medical practice cover with sufficient indemnity provisions. Assessment of the loss incurred by patients is not an exact science and technicalities abound. In Incident B, the hospital considered the facts of each case against any legal precedence and made decisions aided by clinical, medico-legal, finance and actuarial inputs. The objective was to make a reasonable, just and fair compensation of the loss incurred. The work preparing over a hundred compensation packages was massive and intricate. Three additional headcounts were recruited to assist while staff from Patient Relations Services presented the offers to the patients.

Service recovery, reimbursement and compensation are remedial measures taken reactively in response to an error. What they seek to achieve is to make restitution to the patient but only insofar as money would allow. Very often, harm done cannot be reversed and the injured cannot be returned fully to his/her pre-accident state despite the resources poured in. There must be a better and more sustainable alternative to all these, and that is the pursuit of safety as an imperative and the avoidance of preventable harm. In the next chapter, we surface some safety principles and considerations that guided the review committees in making recommendations to address system and process vulnerabilities.

Consider all possible channels to help patients attain closure.

LEARN AND IMPROVE

In reflecting on what worked, what did not and what could have been done better, crisis teams can refer to the first two resources in the Appendices. One presents the key elements in a crisis plan and the other is a workplan to guide their implementation within time guidelines. The documents provide the healthcare institution with the context for assessment, a reality check of sort, to evaluate its present crisis handling capacity against good practices. The assessments can be used to finetune an existing plan, or develop one.

Reflect on the crisis management process. What worked, what did not, and what could be done differently?

Effective crisis management takes practice. Organisations cannot wait for the next crisis, and the next, with the hope that practice will make them better responders. This is clearly untenable as crises are high-stake occurrences to be avoided at all cost. When faced with one, however, remember the advice of Italian Renaissance writer, Niccolo Machiavelli: "Do not waste the opportunity offered by a good crisis." There are real insights from a crisis which drills cannot provide.

There are lessons on patient safety from the incident itself. In the next chapter, we look at how both institutions galvanised as many departments as was necessary to effect change at the system level.

> "Coordinating a response to an incident like this is a mammoth task. It would have to involve multiple stakeholders with expertise and domain knowledge in operations, human resources, corporate communications, patient engagement and clinical governance. Support from senior leadership was so important and I am very grateful that CEO, CMB, COO, CFO, CHRO and Dy CMBs rallied behind us in this challenging work.
>
> The staff involved in the incident, even those on the crisis management team could have been second victims of this unfortunate incident. Those who had not voiced their worries and concerns could in fact be suffering in silence. A stronger staff network and support system might have helped to manage the heightened emotions during the immediate aftermath of the incident discovery and response."

A/Prof Edwin Seet
Chairman,
Crisis Management Team

CHAPTER 3

ROOT CAUSE ANALYSIS AND ACTION (RCA²)

Root Cause Analysis is a systematic approach for identifying the causal factors that have contributed to an adverse event. Following an adverse event, the first step is to determine whether RCA is required. This should be done expeditiously to increase the chances of securing equipment, devices and supplies, and as much information as possible from the incident location before these are being removed or adjusted by others.

An Incident Decision Tree (IDT) helps administrators decide if RCA is suitable to be performed for an incident. We will look at the IDT in more detail later in the chapter. When the IDT points to an unintentional action (omission or commission) behind a failure, it signals that the system has failed. Such events are good candidates for RCA. RCA is unsuitable when there is evidence of intent and/or incapacity accompanying the actions under consideration. In these cases, refer the matter to the relevant authorities and occupational health practitioners, and consult with union representatives, if applicable.

An article entitled 'The Problem with Root Cause Analysis' in the British Medical Journal (BMJ) has unwittingly created doubts in readers' mind about the appropriateness of RCA.[12] A closer reading reveals that the issue lies not in RCA itself which, in the author's words, "is a promising approach with considerable face validity as a way of producing learning from things that have gone wrong." The concern is with the manner RCA is handled (or mishandled), and the way RCA reports are utilised (or underutilised).

In this chapter, we will examine some of these factors and juxtapose NHG's experience to demonstrate how we sought to overcome this concern. The NHG Review Committee (NRC), appointed by NHG CEO, conducted investigations and made recommendations for improvement. The formation of the NRC was a matter of urgency, done in the aftermath of the incident detection and notification. The NRC's investigations were conducted contemporaneously with incident management work undertaken by the respective institutions.

RCA IS NOT A SINGLE TECHNIQUE

Before we begin, a note on RCA is in order. There is a common misconception stemming from the conflation of RCA with the techniques/concepts used to conduct RCA. It has gone on to fuel the perception that RCA has been replaced by HFACS, a framework developed by Shappell and Wiegmann to address human error in the Navy and Marine Corps.[13] Another misconception results from the tendency to equate criticism of a technique or tool with the invalidation of RCA.

Choose the technique that confers the best understanding of the issue/operation in question, and latent failures.

RCA is a process. There exist multiple techniques, perspectives and concepts that inform the process and many more documentation tools. Being developed for a particular industry such as rail, nuclear or aviation, they were shaped by the respective milieus and the needs that were borne out of each. Tools that have been adapted for the healthcare industry include the Joint Commission's Action Plan Tool and the Canadian Incident Analysis Framework, which incorporate human factors concepts.[14,15] Which technique(s) an organisation chooses depends on what would confer the best vantage point to understand its operations. To be sure, organisations have not abandoned RCA.

PUT ON SYSTEM LENS

Peerally et al., writing in the BMJ notes that incident investigation too often results in a simple linear narrative that displaces more complex, and potentially insightful, accounts of multiple and interacting contributions of how events unfold. This tendency is exacerbated by the use of certain techniques such as timelines and 5-whys that tend to favour a temporal narrative vis-à-vis the wider view of systems.

Establishing a timeline of events is one of the first tasks to be done in an incident review. It is a way to reconstruct the most probable flow of events leading to the accident in a factual manner without being influenced by value judgement of any party. For a team with several reviewers on board, this overview facilitates a shared initial understanding of an incident they are about to review. As useful as it is in establishing the facts and tracing the trajectory of the incident, it should, however, not be the basis on which we draw causal relationships because time correlation does not necessarily imply causation. For this task, NHG looked further to focus on a web of interdependent factors.The Human Factors Analysis and Classification System (HFACS) framework was used to analyse unsafe acts in the context of the respective operating environments.[a] The reason for using HFACS rests upon two principles.

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[a] Another framework that foregrounds human factors is WHO's Human Factors Review.

I. Appreciation of system and latent failures

The HFACS taxonomy ("HF") depicts the type of environment that we work, one that is complex and made up of interdependent parts. Achieving a safe outcome for each patient depends on a range of factors, not just the competence of one individual. The HF approach is also compatible with our effort to achieve patient safety goals through sustained improvements instead of quick fixes. Fixing visible human errors (active failures or 'sharp' ends) alone may address some of the shortcomings of the operator committing the acts but does not prevent another person from doing the same.

When unsafe acts are committed, it is necessary to consider why that might have been. In the inquiry into each case, the NRC examined the system level by level, from the site closest to the unsafe act to the furthest. Sources of various failures were found in each level corresponding to the unsafe act itself, conditions predisposing the unsafe act, unsafe supervision and organisational factors. The issues were also identified, level by level.

Working within the HF framework enables the discovery of latent failures – defects in system design that have yet to surface. While such resolve to locate dormant factors runs counter to the popular maxim "if it ain't broken don't fix it", it is an imperative when viewed in the light of the Swiss Cheese Model.[b] Latent failures can surface when triggered by the 'right' combination of factors, permitting the error to break through the system's defences and safeguards. Two examples are included in this chapter to illustrate what insights are possible from deploying this framework.[c]

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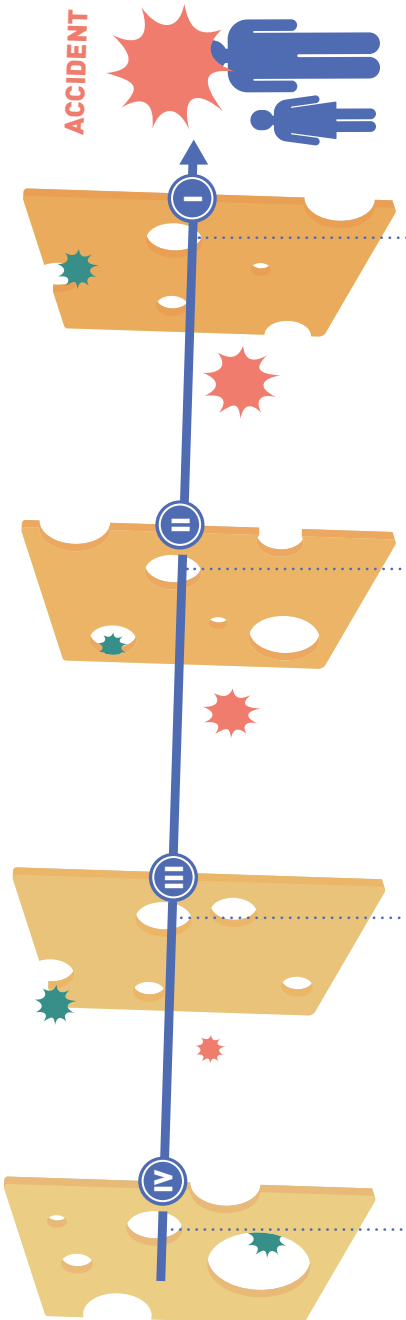
[b] A theory propounded by James Reason which views safety from a system perspective involving organisational factors, human and technical factors.

[c] NHG's Institute of Healthcare Quality (IHQ) conducts Human Factors workshops for the patient safety and quality improvement community.

IDENTIFYING LATENT FAILURES

INCIDENT A: INCOMPLETELY STERILISED INSTRUMENTS

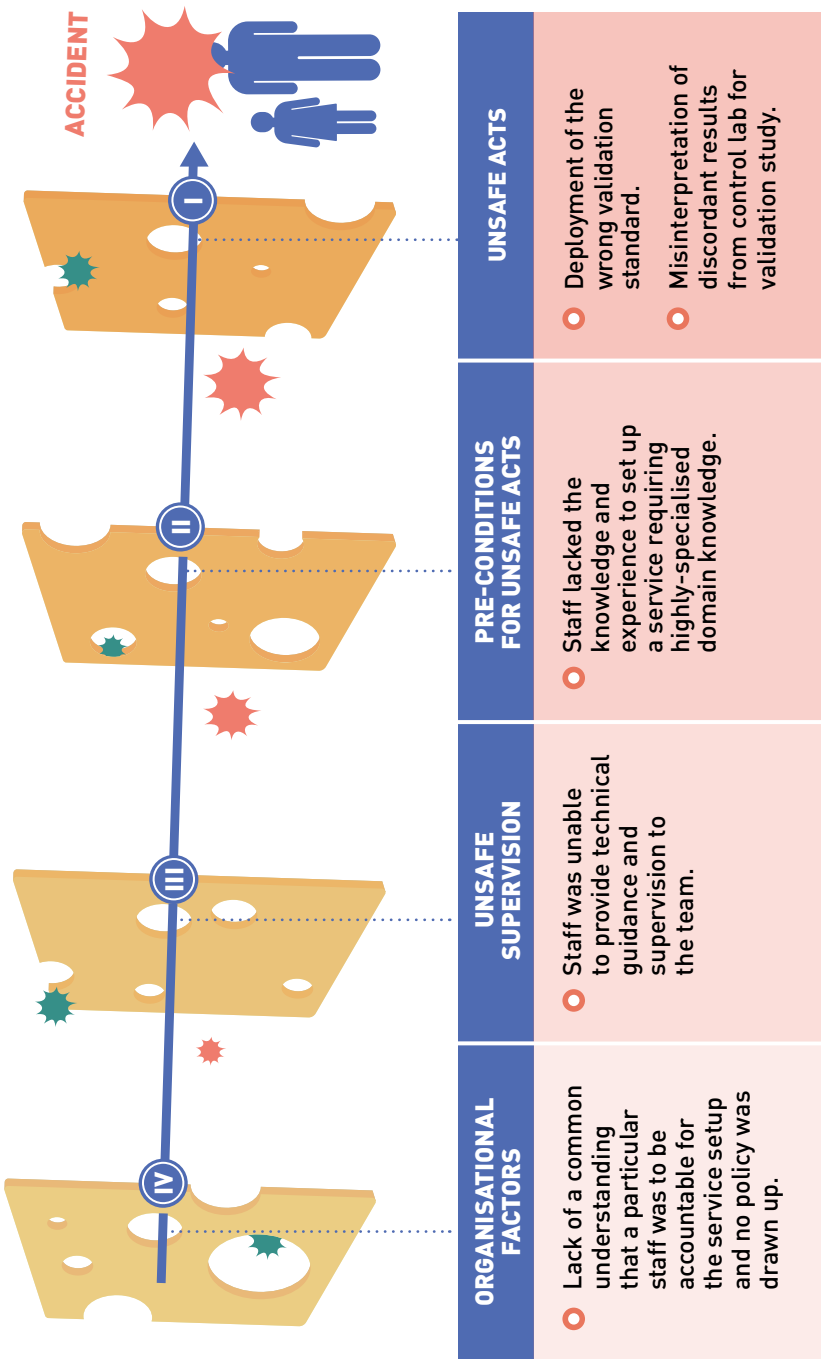


ORGANISATIONAL FACTORS	UNSAFE SUPERVISION	PRE-CONDITIONS FOR UNSAFE ACTS	UNSAFE ACTS
• Role assignments in each critical step of the sterilisation process were unclear, resulting in multi-operators, and multi-tasking of tasks.	• Variations in practice and deviations from Work Instruction arising from inadequate supervision.	• Staff had to rely on visual inspection of external chemical indicators on packs. • Staff were expected to be able to discern subtle changes in colour shades on the indicators. • Staff helped one another to finish off tasks with little communication at handover.	• Staff did not notice the lack of colour change on packs before unloading the batch of instruments (perception error). • Staff assumed that someone else had verified and documented the sterilisation status of this batch. • Non-adherence to Work Instruction to keep pack in autoclave during cooling. • Non-adherence to Work Instruction to check individual packs during unloading and storing.

Represents one part of the Review Committee's analysis. Analysis was based on James Reason's Swiss Cheese Model and Scott Shappell's Human Factors Analysis and Classification System.

IDENTIFYING LATENT FAILURES (CONT'D)

INCIDENT B: FALSE POSITIVE RESULTS



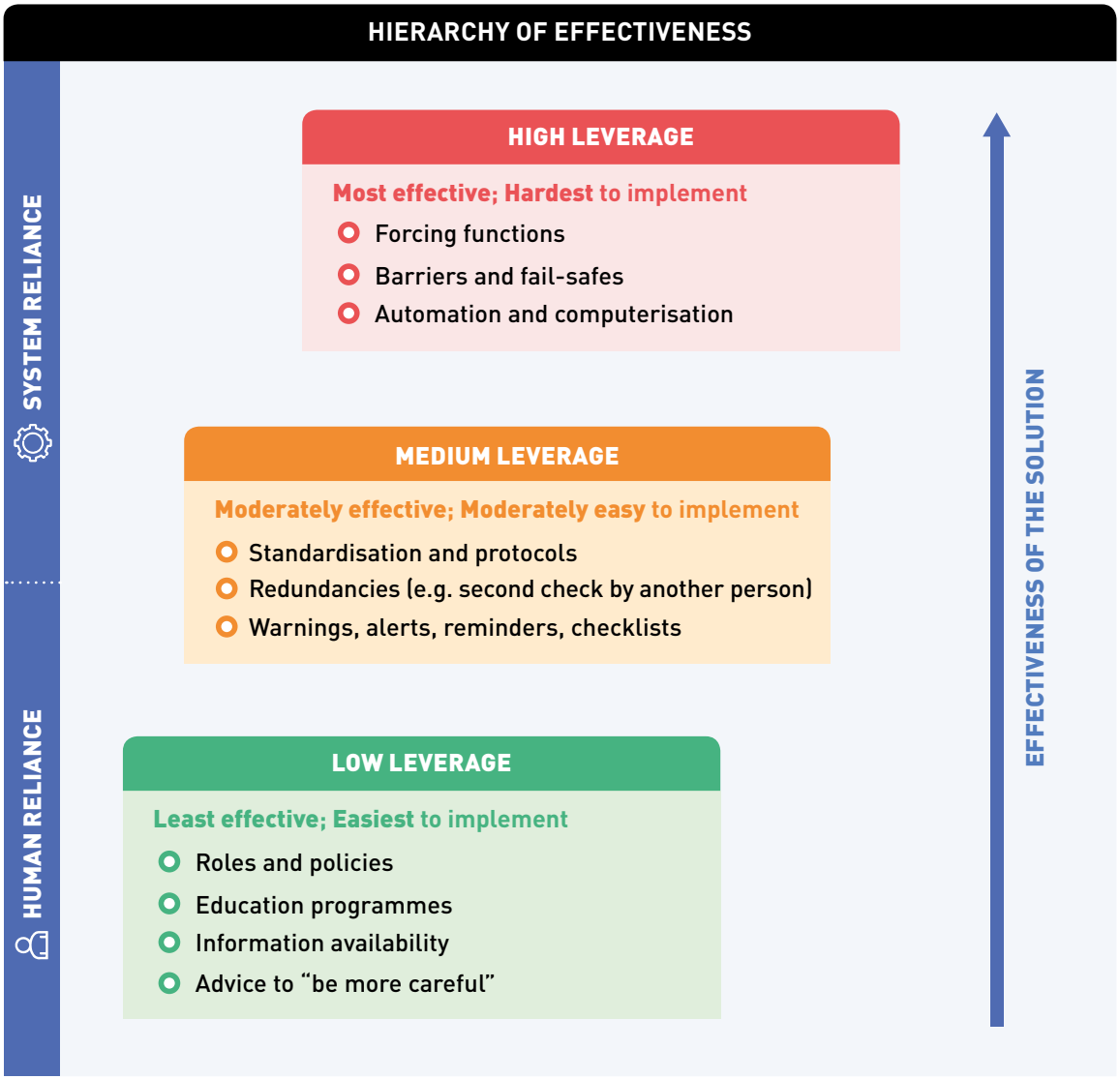
Represents one part of the Review Committee's analysis. Analysis was based on James Reason's Swiss Cheese Model and Scott Shappell's Human Factors Analysis and Classification System.

II. Recognition of human fallibility

A human factors perspective pushes for the adoption of mitigation strategies that augment human abilities while compensating for limitations. This principle finds expression in the Hierarchy of Effectiveness developed by the Institute for Safe Medication and Practices which guides choices between system-focused and people-focused solutions, and trade-offs.[16] The less reliant a solution is on behavioural changes of people (such as education), the more effective it is but harder to implement. Design features that prevent a user from committing an unsafe act such as forcing functions and constraints are more effective compared to reminders and checklists, which in turn are more effective than suggestions to the user to be more careful.

Consider this example from Incident A, which involves a work process comprising a series of tasks, each performed by different people depending on who happens to be free. Over time, the 'boundaries' of the tasks have become blurred so that it is not possible to determine where one task ends and the other begins. The process is error-prone when staff help complete an upstream task based on subjective impressions (at times erroneous) of what else needs to be done. One way to improve the process is to delineate the boundaries (i.e. separation of tasks) and institute proper handovers at each point. The other is to have one person performed all the tasks as one contiguous process. The second is a more effective solution but would entail rationalisation of duties department-wide and mobilisation of additional manpower.

Seek solutions that are the least reliant on human behavioural changes.



Source: Institute for Safe Medication Practices

FIT AND FREE FROM FEAR OR FAVOUR

Writers commenting on RCA have pointed out RCA reports being unduly influenced by the need to preserve relationships and by hierarchical tensions and partisan interests. The lack of independence can result in RCA being compromised. Its findings may not reflect fully the content of discussions and prevalent realities. Causes that are inconvenient or require responses deemed to be beyond the remit or capacity of the organisation to provide get edited out.

It is not a coincidence that the two Review Committees were appointed by NHG CEO (NHG HQ). Helming the committees were members of NHG's Senior Management who did not hold concurrent management positions in the institution under review. In addition, professionals who were appointed to each committee were either from non-NHG organisations or other NHG institutions. In the matter of constitution of the Review Committee, care was exercised to ensure its independence. The process must be neutral and be seen to be so.

Just as important is the group makeup. The Ministry of Health's Directives for Review of Serious Reportable Events specifies that the Quality Assurance Committee (QAC)[d] should minimally comprise 1) a doctor registered with the Singapore Medical Council who has experience in the relevant discipline; 2) a medical, nursing or allied health professional; and 3) a non-clinical staff (e.g. an administrator, Quality Coordinator, Quality Manager or equivalent).

The Director of Medical Services may appoint additional person(s) as he deems fit. In a situation like Incident A wherein the sterilisation of dental instruments was the issue of concern, the appointment of a dentistry-trained professional registered with the Singapore Dental Council fulfilled the first requirement. The essential roles that have to be fulfilled collectively by any RCA team (a member may have more than one role) are that of a leader, facilitator, senior leadership representative, human factors expert, subject matter expert, process reviewer and scribe.

Subject matter experts are needed to contribute material information and think critically about the system factors that may have led to the event in question. Process reviewers, having the experience and knowledge in a related field, would have a sense of what constitutes acceptable practice or otherwise. They can bring their knowledge to bear on the critical review of practices and standards, and in the identification of vulnerabilities. A human factors expert ensures that inherent human limitations are taken into account in the identification of root causes and contributing factors. If the circumstances permit, the inclusion of a patient (and/or family) in the RCA can provide a valuable perspective. Such an arrangement, however, will have to be approached with extreme sensitivity to ensure the experience is constructive, not defensive or acrimonious.

Form an independent committee that has the relevant domain knowledge to review issues in question and to apply a particular method of inquiry chosen.

[d] The equivalent of the QAC (referred to in MOH Directive 01/2020) is the NHG Review Committee.

We include more details in a diagram here to demonstrate NHG's attempts to fit the right people to the task, to inject depth, accuracy and focus to the RCA process.

<table>
<tr><th colspan="3">NHG REVIEW COMMITTEE</th></tr>
<tr><th>ROLE</th><th>INCIDENT A:
INCOMPLETELY STERILISED INSTRUMENTS</th><th>INCIDENT B:
FALSE POSITIVE TEST RESULTS</th></tr>
<tr><td>Leadership, facilitation and guidance</td><td>Two senior leaders from NHG Group, including a Quality representative</td><td>Two senior leaders from NHG Group, including a Quality representative</td></tr>
<tr><td>Subject matter experts and process reviewers</td><td colspan="2">Assisted by Singhealth, NUHS and NHG personnel</td></tr>
<tr><td></td><td>• A director overseeing a healthcare group's dental services
• A senior Human Resource Officer
• Two directors - one from Support Operations and the other, Nursing</td><td>• Two pathologists; a medical oncologist
• A manager overseeing laboratory operations</td></tr>
<tr><td>Guidance on Human Factors</td><td colspan="2">Senior Principal Human Factors Specialist</td></tr>
<tr><td colspan="3">Supported by a secretariat</td></tr>
</table>

DO NOT WRITE OFF INDIVIDUAL ACCOUNTABILITY

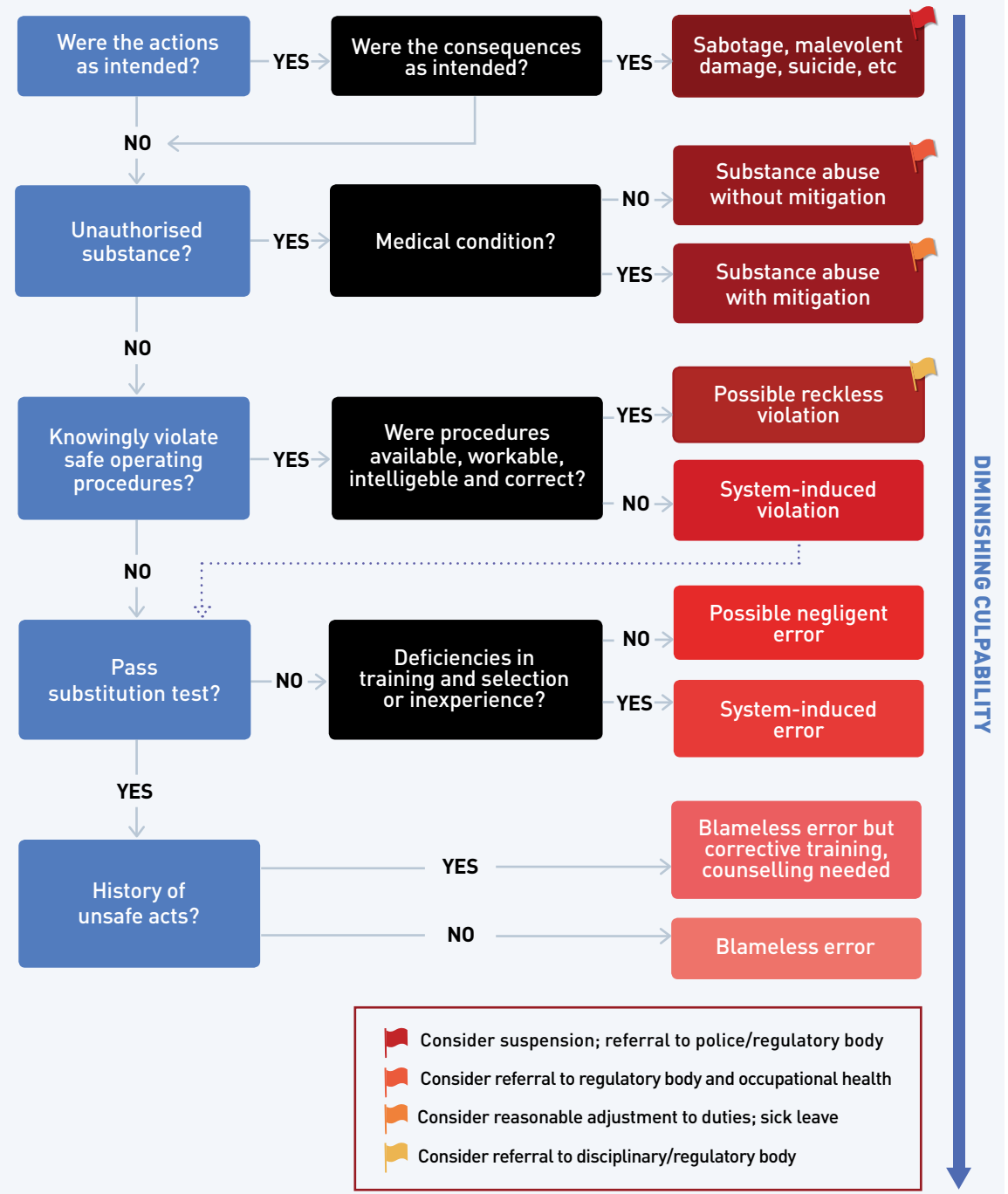
During an RCA, systems and processes come under scrutiny, and latent failures will be flagged out. Blatant transgressions, neglect and unacceptable behaviour, if found, will be sequestered. Unfortunately, reviewers tend to do only the first part of the job, Peerally et al. noted, influenced by the exhortation of healthcare institutions to embrace a no-blame culture. In everyday conversations, we encounter terms such as "non-punitive response to error" and "a no-blame culture" used in an unbounded way and possibly propagated in like manner. This creates confusion in the minds of staff when they see colleagues being called to account for errors. It sets back efforts in instilling the correct beliefs and building a just culture, one that requires both parties to be accountable – staff for adhering to safe practices and the organisation for putting in place robust systems.

One solution is to delineate errors. James Reason's Incident Decision Tree (IDT) was applied in the investigation of both incidents. This method features a succession of questions to be considered in an order of decreasing degree of culpability, as follows:

1. Did the individual intend to cause harm?
2. Did he/she turn up at work impaired?
3. Did he/she do something with the knowledge that it was unsafe?
4. Would three other individuals with similar experience and in a similar situation and environment act in the same manner as the person being evaluated?
5. Has he/she been involved in this kind of incident before?

Cycling through Question 1 to 3 on the first branch, a 'Yes' to any of these would lead to questions on the second branch that attempt to determine the degree of culpability. Consecutive 'No's to Question 1, 2 and 3 advances the assessment to Question 4 which is a substitution test. If the unsafe act fails substitution test ('No' to Question 4), assessors would be led to questions on the second branch to establish the degree of culpability. Conversely, if it passes the substitution test ('Yes' to Question 4), the act concerned is a blameless error; depending on whether it is a repeat or first-time error, the course of action could be remedial training /counselling or no action at all.

DECISION TREE FOR DETERMINING CULPABILITY OF UNSAFE ACTS



RECOGNISING SOCIAL FORCES AT WORK

Critics of the IDT point out that the calculus-like manner in apportioning blame between individuals and system is too simplistic. In practice, people and system are intertwined, and both interact in a mutually constitutive way as opposed to being distinct categories. System is operated by people, and people design and interact with system.

In the continuous pursuit of patient safety, consider what social forces may be promoting or impeding safe practices.

From an ethnographic study conducted across five hospitals in UK and Africa, Aveling et al. concluded that systems and individuals co-created the conditions of safety. Without the individual healthcare worker assuming personal moral responsibility and exercising agency, getting the work done and getting it done safely both become impossible. The opportunities to 'be good' are institutionally organised and structured. Individuals contribute towards the creation and reproduction of beliefs, values, practices (i.e. normative conditions) as well as the criteria to which they (and their actions) are to be held account.[17] Viewed in this light, an errant act (or omission) could be the result of one's conscious choice and action that is heavily conditioned by strongly reinforced norms and constraints, some of which are deeply institutionalised and historically established.

The IDT is a practical instrument for the administration of justice. If the aim is to understand the social forces and cultural norms that promote (or impede) patient safety, the right tool would be a patient safety culture survey.

A FORUM THAT IMPOSES CONSEQUENCES

In Incident A, a Human Resource Officer from NHG Group was on the NHG Review Committee to provide inputs on staff accountability matters. The hospital's HR team held an internal review to look into the NRC's recommendations and was responsible for the disciplinary decisions meted out on the staff concerned. In Incident B, a separate committee, the NHG Board of Inquiry (BOI) advanced the NRC's work to examine the roles, responsibilities and accountability of the staff involved.[e] A Disciplinary Committee was subsequently convened by the NHG Board to recommend the actions to be taken. The move to adjudicate separately, with HR and legal inputs on personnel matters, was appropriate in view of the circumstances surrounding Incident B. When an error of professional judgement had occurred with serious consequences on many patients, nothing short of a judicious hand was expected by internal and external stakeholders.

Regardless of the platform or pathway taken to address personnel matters, the review process as a whole should accommodate the dual need for learning and individual accountability. In Incident A, the measures taken were counselling, retraining and re-education, and disciplinary action in the forms of warning and financial penalty. In Incident B, the actions taken ranged from cessation of employment, financial penalty and/or stern warning, counselling, retraining and re-education.

Investigation findings and conclusions were conveyed to management and staff NHG-wide. Communications may be handled differently at Group (Cluster) and institution levels. The institution may instruct staff on the finer points of the incident or learning moments. Notwithstanding, all communicate in a manner that leaves no room for doubt that there is a time and place for learning and for individual accountability.

[e] BOI members are not employees of the institution under review.

TAKE ACTION TO CLOSE FEEDBACK LOOPS

Investigations that are not accompanied by effort to make findings actionable can frustrate efforts to secure change. It is not sufficient to focus efforts locally at the site of the safety incident. NHG's approach reflects the belief that although no two crises are the same, if it can happen in one place, it can happen elsewhere. Organisational amnesia must be avoided.

In both incidents, the reports of the NRC set in motion activities at two interconnected levels – at Cluster level through the NHG Implementation Committee (IC), and institution level through the Institution Implementation Committee from the organisation where the incident occurred, and representatives from other NHG institutions. NHG IC was tasked with overseeing the implementation of NRC's recommendations at the institutions, harmonising changes and improvements and monitoring progress. Given such a role, it was advantageous for the NHG IC to have amongst its members, someone who had been involved in the NRC's deliberations. This person plays a critical role to onboard parties responsible for the implementation, elucidating the recommendations and clarifying what response is needed. This can reduce the possibility of the recommendations being lost in translation.

Ensure good handover between review and implementation committees so that follow-up actions are carried out as intended.

The process review undertaken was on a scale far greater than fixing the triggers at the local level (the site of the incident). In Incident A, it covered not just key sterilisation locations but decentralised sites such as dental clinics, intensive care units and endoscopy centres across all NHG entities and vendors' premises. The hospital established a committee to look into the re-processing of reusable medical devices so that there was continuous review and risk management of this area. The tracking of reusable instruments was improved through the implementation of a Sterilisation Management Programme designed to help staff track the key steps in re-processing of medical devices while ensuring that the staff use devices that have been completely sterilised. These efforts were facilitated by the hospital's Quality Office. Incident B had also prompted a process review NHG-wide. At the hospital level, review and improvement work was carried out through the Implementation Committee. Readers can get a sense of the scope and rigour of its work from an interview which we conducted with the Chairman, presented towards the end of the chapter.

KEY ACTIVITIES PERFORMED AT INSTITUTION AND CLUSTER IN SYNCHRONY

INCIDENT MANAGEMENT · INVESTIGATION

Activities occur in parallel

INSTITUTION LEVEL	CLUSTER LEVEL
Internal Review Panel investigates incident. Reports to CEO. Findings shared with NHG Review Committee.	NHG Review Committee identifies root causes of incident and recommends remedial and preventative actions. (1)
Office of Clinical Governance notifies incident to MOH's CQPV, responds to its queries in connection with a Parliamentary discussion, and coordinates site inspection and audit.*	NHG Board of Inquiry determines roles, responsibilities and accountability of staff involved. (2)
Crisis Management Team engages with key stakeholders.	NHG Disciplinary Committee decides the actions to be taken on staff. (3)
*Centre for Quality, Performance and Value	• (1), (2) and (3) report to NHG CEO. • (1) submits report to MOH. This report serves as reference for (2) and (3).

IDENTIFICATION OF IMPROVEMENT OPPORTUNITIES · IMPLEMENTATION

NHG Implementation Committee, reporting to NHG Clinical Board:

- Oversees implementation of recommendations of the NHG Review Committee.
- Guides implementation planning, sets timeline and tracks progress.

Chairperson of Institution Implementation Committee attends at NHG Implementation Committee meetings.	Other institutions nominate **representatives** to NHG Implementation Committee.

UNCHANGING FACTS ABOUT THE NATURE OF RCA WORK

RCA is both time-consuming and time-sensitive, two characteristics that are in tension with one another. In Singapore, the Ministry of Health requires review reports on adverse events to be submitted within 60 working days. NHG did it within 30 days in both incidents. There was much to do in a relatively short time.

The work encompassed site visits, interviews and document reviews. These were crucial processes to gather the necessary information for the analytical work ahead. The HER2 lab incident and the dental clinic incident were complex in each own way. One revolved around a highly-specialised practice affecting multiple patients over several years. The other involved a common process that was complicated by many hands.

In one incident, investigators channelled their time into process flow charting in order to illuminate the critical points of failure and the wrong turns. This was an iterative one, requiring multiple rounds of sharing, feedback incorporation and review. In the other incident, investigators had the benefit of background insights contained in the final report of the hospital's Internal Review Panel. They built upon the work done, conducting more than 10 interviews, reviewing more than 50 types of documents and analysing data culled from the review.[f] For interviews, some of the work preceded the sessions, to identify interviewees, gather background information and prepare questions. It takes a systematic process to plan and conduct interviews and to document information derived from them. The tool in Appendix D will be beneficial to incident reviewers, patient safety staff and administrators as it contains guidance for each step in this process. Both review committees were supported by a team of staff seconded for secretarial and administrative duties even as they continued to carry out their primary duties.

Ready a team to support the work of the review committees as and when needed.

Given the resource-intensive nature of RCA, considerations should be given to derive the most value out of it, some of which are discussed in this chapter. We conclude with a caveat by Lundberg et al. Accident investigation, according to Lundberg, is not a rational process. It frequently departs from the ideal principle of "what you find is what you fix" for a good reason. To the organisation, considerations of the possibilities (and constraints) of the situation where safety takes place are as important as they are sensible. Some of the remedial measures are reasonable while others do not make sense from a practical point of view. The bottom line suggested by Lundberg is: Believe not in the rationality of incident investigations but in its sensibility.

[f] A total of 17 interviews were conducted with NHG and non-NHG staff. The number of individual documents perused ran into the thousands, as certain types of documents such as minutes of meetings, training records and competency assessments were reviewed as a series spanning 8 to 10 years.

DISCOVERING OPPORTUNITIES IN A CRISIS

An interview with A/Prof Tan Kok Yang, Dy CMB (Service Development) and Head of General Surgery at Khoo Teck Puat Hospital, on his work as Chairman of KTPH Implementation Committee.

Can you give the background on the formation of the Implementation Committee?

There was an incident involving the misclassification of HER2 test results at Khoo Teck Puat Hospital that came to light in November 2020. The NHG Review Committee investigated, identified gaps and made recommendations for improvement. Our Chairman of Medical Board appointed an Implementation Committee tasked with ensuring that the recommendations were implemented by the respective timelines.

What were some of the considerations in the selection of members?

The members are KTPH personnel who were not directly involved in the incident. Each has domain expertise in a particular area of governance. Collectively, we worked on the recommendations of the NHG Review Committee straddling the various aspects of governance.

For example, one group of recommendations targeted processes and practices governing the use of laboratory developed tests (LDTs). Three of our 14 members are from the Department of Laboratory Medicine; they contributed inputs on this while a quality and risk management representative looked into concerns raised on the quality control and quality assurance front. It is a broad-based team with representations from Accreditation and Credentialing, Office of Clinical Governance, Breast Service and Human Resource. This arrangement provided a holistic approach which is vital.

HR Development and HR Management were also involved to look into issues raised in connection with organisational responsibilities and governance. We have to think about the systematic development of staff so that all are equipped, up-to-date and competent to meet the demands of their work.

How did the Committee approach its work?

We worked closely with the NHG Implementation Committee through both formal and informal meetings. Separate discussions were convened with key individuals in the NHG Committee to delve deeper into particular areas of concern. Outcomes and insights from these sessions were brought back to KTPH for discussion and implementation. In addition, there were meetings with various departments to facilitate implementation of new measures in the Department of Laboratory Medicine. We also met with stakeholders of Tumour Boards to discuss and identify the process for future tumour board meetings.

There is the concurrent need to chart the future of pathology services at KTPH. After the incident and an audit, the Ministry of Health limits the laboratory procedures under the Anatomic Pathology to frozen section only. We consulted with chief pathologist of Tan Tock Seng Hospital on the direction we should take.

continues on the next page...

It does sound like there are many things going on at one time. Where was the team heading?

It is easy to get caught up in the activities and actions, but we should not lose sight of the focus which is: Firstly, to establish well-defined roles and responsibilities for clinical work in the department concerned, the mechanisms to track staff competency and trainings, and well-defined pathways for staff development. Secondly, to enhance existing quality assurance and quality control processes, align existing policies and guidelines with reporting structure and proper governance.

How much ground has been covered?

Out of the 19 recommendations that are applicable, we are done implementing 18 recommendations. The remaining recommendation is a work-in-progress and involved collaboration with the Workgroup appointed by NHG Implementation Committee. The agreed timeline is 31 December 2021.

We would need to fully account for each of the 19 recommendations through implementation of new policies, communication and dissemination of information, training and going through multiple check points to ensure staff understand their roles and responsibilities. Even when that is done, the momentum will continue. Those who effect policies play an important role in ensuring policies are up-to-date and are complied with. There must be ongoing staff engagement – to preserve clarity of purpose that drives people to maintain a high standard of work. Continuous effort, in short.

Summing up the experience, what stood out for you?

We must constantly be aware of our vulnerability and press on to strengthen processes and improve governance. We received valuable guidance from Prof Lim Tock Han and A/Prof Tai Hwei Yee, the co-leads of the NHG Implementation Committee. One good thing that came out of this incident was that it compelled us to identify other potential vulnerabilities within the organisation and seize every opportunity to address them.

> “The importance of frequent review of standards and processes is highlighted clearly through this incident. We mustn’t be complacent. Failures can occur even when there are policies in place. When things don’t work, one should have the courage to make changes of impact but these must be sustainable.”

CHAPTER 4

PREVENTION

When an adverse event happens, even the most indomitable organisation would feel a sense of exasperation. The horses have bolted and it's too late to shut the barn door. The options ahead are limited. The clock cannot be turned back and certain harm is irreversible. The costs of business disruptions are difficult to justify for never events – serious incidents that are considered to be wholly preventable because guidance or safety recommendations that provide strong systemic protective barriers are available at a national level, and should have been implemented by all healthcare providers.[18]

The ability to mitigate the impact of a crisis is valuable. Much more is the ability to prevent it. In the previous chapter, we shared about the preventative nature of work done by the Implementation Committee which drew insights from a particular incident that had occurred recently. We now focus on error prevention as an ongoing concern, to identify practices and habits that can be developed or honed to help keep crises at bay. This chapter occupies the last pages of the book, only because there are editorial considerations for book structure. In a different context, it needs to be at front and centre of the healthcare institution's priorities.

RISK MANAGEMENT AND TRAINING

The quest to improve healthcare has the unintended consequence of increasing its complexity. Hazards, seen or unseen, exist as a web of interwoven factors - environmental, technological, human and organisational. Hazards can cause harm in themselves, or through pre-disposing healthcare workers to commit unsafe acts. While these concerns may not materialise now, the possibility (or risk) of them materialising at another time cannot be completely ruled out.

Risk management is the systemic identification, assessment and evaluation of risk factors, and implementation of control measures to prevent adverse events, or mitigate the impact. The NHG Enterprise Risk Management (ERM) has been in place since 2010. It traces its roots to clinical risk management which went back further, to 2002 when NHG conducted an Adverse Events Study (AES), the first among healthcare clusters in Singapore. The AES provided a platform for NHG to set patient safety goals, including the vision to achieve zero preventable harm through the reduction of preventable adverse events by 50 per cent every three years. In 2007, NHG incorporated Failure Modes and Effects Analysis (FMEA) in its training programme to guide institutions on the proactive evaluation of processes to identify risks and avoid potential pitfalls. Today, clinical risk management constitutes a key domain in the ERM framework alongside other domains – strategic, financial, operational, infrastructure and equipment, legal and regulatory, technology, human capital, education and research.

NHG Group Quality plans and organises clinical risk training which is being rolled out progressively, beginning with the identification of immediate risks. Training resources are shared with its institutions, to be adapted and used with the guidance of the respective risk trainers. Entitled *Ask SRI²*, participants are trained to ask questions that matter – Safety ("S"), potential Risks ("R"), Improvement and Innovation ("I²") – when contemplating a new workflow, a new service and other endeavours. The next course is on identification of emerging risks and the curriculum is being developed.

Contextualise risk management principles to each site/setting to make them actionable by process owners.

EMBRACING MESSENGERS

Besides keeping sight of risks, having a safe space for staff to communicate feedback and concerns at work is important. When little is surfaced, it may mean that all is well and good. It may also be a situation illustrated by the tale *The Emperor's New Clothes*, where an overwhelming majority feel inhibited to speak up for fear of being punished or ridiculed.

There are plans at NHG to implement programmes such as SpeakUp and GoodCatch to encourage staff to raise concerns, flag out mistakes and contribute ideas. We are mindful though that programmes tend to spotlight staff as the ones who need to be more forthcoming. This is where leaders – in the C-suite, in teams, at the frontline or in the backroom – come in to create the necessary conditions for psychological safety, to define the terms and set the climate in their respective spheres of influence. While awards single out a few acts which the judging committee considers deserving and incentives go only so far, the best expression of psychological safety is through people practising it on work sites day by day, with leaders showing the way.

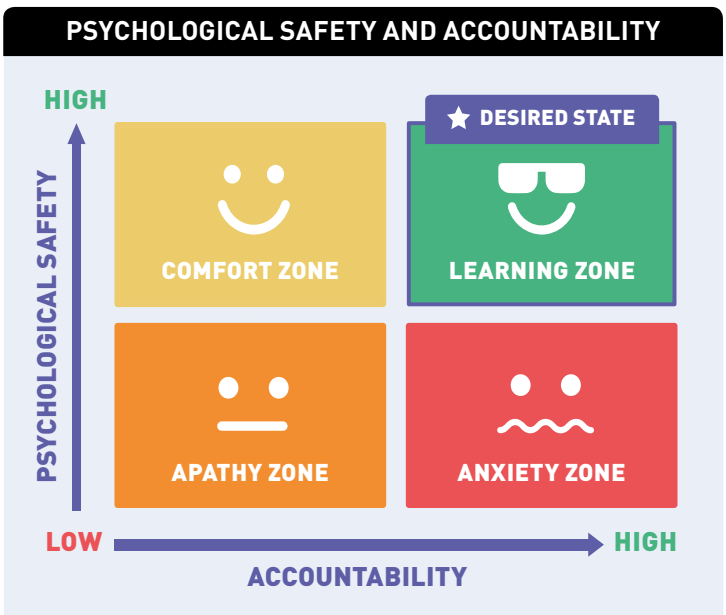
Leaders can create the conditions of psychological safety in a number of ways. One of these is by displaying candour and acknowledging fallibility – that there are instances they would need help and to be alerted to situations that are not within their line of sight. When alerted, acknowledge the feedback and make it a positive experience for the messenger.

KEY LEXICONS IN PATIENT SAFETY	
Hazard	A situation or an object that can cause harm in itself, or through the creation of conditions for unsafe acts.
Unsafe act	Error of omission or commission which can take any of these forms: **Slip** A failure in the execution of an intended action due to a lack of attention. Occurs when one routinely performs highly practiced activities with little conscious effort. **Lapse** Similar to a slip but is due to memory failures. **Mistake** A failure in the plan of action i.e. one's prior intention does not translate into the intended consequences. While the action is correct, the plan is inadequate to achieve its desired goal. Occurs when one applies the wrong rule to a situation; or fails to apply the correct rule; or in novel situations where no precedents exist, relies on his/her existing knowledge to get through. **Violation** Deliberate deviations from rules, procedures, instructions or regulations. Reasoned violations occur when one believes there is a good reason to deviate from, for instance, a particular policy which does not meet the need of a situation at hand; reckless violations occur when the doer consciously disregards a visible, significant risk and puts the patient in the way of harm; routine violations occur when short cuts are regularly taken and non-compliance becomes the norm. *[Definitions adapted from Patient Safety Handbook (2012) published by NHG Quality Resource Management]*
Near miss	An error that does not result in harm to the patient.
Good catch	The detection of a deviation in practice which helps stop an unsafe act (or effects) in its track.
Risk	The possibility of a hazard causing harm to anyone – patients, healthcare workers and the community.
Risk management	The process of thinking, assessing (likelihood and severity of outcome), taking and managing risk.

Another way is by asking good questions, for example, using Ask SRI[2] mental model mentioned earlier to elicit inputs from staff. The skill to ask good questions is taught as part of a course on process facilitation by NHG College. Divergent tools are especially useful for leaders facilitating at meetings and discussions, to gather information about a particular work situation and generate ideas/solutions to address a particular concern.

Another approach that leaders can take is framing the work.[19] Frames help remind staff the nature of work they do, and clarify what is at stake. The risks of failing can happen when undertaking a new improvement project, preparing a patient for dialysis and performing a cardiac surgery. The differences in the nature of work translate into different implications of failure. Intelligent failures, which are the result of thoughtful experimental foray, should not be censured. For high-volume, repetitive work, failure is rare but can be consequential, hence it is vital that people notice, report, or correct deviations from standards. For highly complex operations, risk of failure lurks in every turn, so vigilance and teamwork are crucial to prevent avoidable failures. When leaders practise framing of work, they are in effect clarifying the corresponding behaviours and accountability expected of employees, instead of tarring failures with one brush which is not helpful.

Emphasise the role of leaders at every level in creating the conditions for psychological safety.



Leaders would do well to note what psychological safety is not, so that the boundaries of "safe space" and its implementation are clear to team members. To be sure, it is not a retreat for people to complain and do nothing about their situations. On the contrary, workplaces with high psychological safety (e.g. Google Inc) are performance-driven where lines of accountability and expectations are clearly delineated. Nothing should detract from the eventual goal of creating high-performance teams. For us in healthcare, this goal is attaining safe outcomes for patients, consistently. Psychological safety is a means to this end.

A LEADER'S TOOLKIT FOR BUILDING PSYCHOLOGICAL SAFETY

LEADERSHIP TASKS	OUTCOME
SETTING THE STAGE	
FRAME THE WORK ○ Set expectations about failure, uncertainty and interdependence to clarify the need for voice **EMPHASISE PURPOSE** ○ Identify what's at stake, why it matters and for whom	 **Shared expectations and meaning**
INVITING PARTICIPATION	
DEMONSTRATE SITUATIONAL HUMILITY ○ Acknowledge gaps **PRACTISE INQUIRY** ○ Ask good questions ○ Model intense listening **SET UP STRUCTURES AND PROCESSES** ○ Create forums for input ○ Provide guidelines for discussion	 **Confidence that voice is welcome**
RESPONDING PRODUCTIVELY	
EXPRESS APPRECIATION ○ Listen ○ Acknowledge and thank **DESTIGMATISE FAILURE** ○ Look forward ○ Offer help ○ Discuss, consider and brainstorm next steps **SANCTION CLEAR VIOLATIONS**	 **Orientation toward continuous learning**

Source: Fearless Organisation, Amy Edmondson (2019)

CULTIVATING SITUATIONAL AWARENESS

This revolves around a set of principles, known as high-reliability principles, each corresponding to a practice that is consistently demonstrated by an organisation's leadership. The principles originate from what Weick and Sutcliffe termed "high reliability organisations" (HROs) such as aircraft carriers and nuclear power plants. Despite operating in highly hazardous and unpredictable conditions, HROs maintained performance at high levels of safety over long periods of time.[20] The HRO approach is driven by collective mindfulness that directs all staff to jointly detect and report small problems or unsafe conditions at the nascent stage before these develop into substantial risks. To put it succinctly, what is fragile should break early while it is still small. Nothing should ever become too big to fail.[21]

High reliability principles can be summarised as follows: 1) pre-occupation with failure - preferring to view near misses as opportunities to improve, not proof of success; 2) sensitivity to operations - being very aware of the state of systems and processes; 3) commitment to resilience - prioritising emergency training for many unlikely, but possible, system failures; 4) deference to expertise - valuing insights from staff with the most pertinent safety knowledge over those with greater seniority; and 5) reluctance to simplify - recognising that work is complex with the potential to fail in new and unexpected ways.

From principles to strategies

HRO principles are relevant to healthcare settings which deliver care through complex and interrelated dynamic systems that are potential sources of accident risks and harm. A growing number of health care systems are taking a leaf from these principles and translating them into practice. There are two publications of note.

Make every step count towards patient safety and the journey towards high-reliability would not have to be an abrupt stride.

The first is by the Agency for Healthcare Research and Quality (AHRQ). In 2008, it published a seminal white paper describing the application of the five key HRO principles in healthcare settings, and a guidebook.[22] The second is by the Department of Veterans Affairs (VA). In February 2019, it undertook a systematic review of HRO literature published between January 2010 and January 2019. The materials were evaluated in terms of applicability in guiding the development of best practice, identification of barriers/facilitators to implementation, measurement of progress and impact of implementation on process and patient safety outcomes, detection of knowledge gaps, and the spread of implementation initiatives to other systems. There are five HRO strategies and eight tools (frameworks) to guide the implementation of the principles.[23] A summary is presented on the next page.

In charting the path towards high reliability, healthcare organisations will not be starting on an empty slate. In all likelihood, work had been done through the years to improve systems, processes and safety culture and these are in various stages of maturity. While advancing patient safety is not new, approaching it in a steady and sustained manner calls for new ways of thinking and doing. As we write this, public healthcare institutions in Singapore have set off on each own change journey, facilitated by MOH under its programme, Ensure Safer Systems. NHG institutions too have onboarded under the baton of our Cluster Deployment Lead.

HRO IMPLEMENTATION STRATEGIES	
LEADERSHIP TASKS	**FRAMEWORK THAT RECOMMENDS IT**
DEVELOPING LEADERSHIP	
Leadership's commitment to the goal of zero patient harm.	JCI
Leaders to facilitate and mentor teamwork, improvement, respect and psychological safety.	IHI
Prioritising safety in the selection and development of leaders; establishing a compelling vision for safety.	ACHE
Leadership accountability.	JH Operating Management System; Air Force
Equipping QI leaders with formal degrees to support their work.	JH Safety and Quality Framework
Developing mentors to guide evidence-based decision-making.	ARCC
SUPPORTING A CULTURE OF SAFETY	
Trust, accountability, identification of unsafe conditions to strengthen systems, and assessment of culture.	JCI
Psychological safety, accountability, teamwork and communication, and negotiation.	IHI
Lead and reward a just culture, establish organisational behaviour expectations.	ACHE
Trust between leaders and staff, respectful communication, and willingness to admit errors within their domain.	Air Force
Assessment of culture.	ARCC
Behavioural choices, not severity of outcome, to guide responses to poor outcomes.	High Reliability Team Model

Frameworks: JCI (HRHCM)[24]; IHI Framework for Safe, Reliable and Effective Care[25]; ACHE Culture of Safety framework[26]; Johns Hopkins' Armstrong Institute for Patient Safety and Quality[27,28]; Office of the Air Force Surgeon General's Trusted Care Framework[29]; ARCC Model[30]; High Reliability Team Model by Riley W et al.[31]

HRO IMPLEMENTATION STRATEGIES (CONT'D)	
BUILDING AND USING DATA SYSTEMS TO MEASURE PROGRESS	
Track and display quality measures; involve IT in the development of solutions to quality problems.	JCI
Open sharing of data/information concerning safe, respectful and reliable care; continually improve work processes and measure progress over time.	IHI
Share and synthesise data for insights to make new discoveries and improve processes; evaluate processes.	John Hopkins Operating Management System
Data management and outcomes monitoring.	ARCC
PROVIDING TRAINING AND LEARNING OPPORTUNITIES FOR PROVIDERS AND STAFF	
Track and display quality measures; involve IT in the development of solutions to quality problems.	JCI
Open sharing of data/information concerning safe, respectful and reliable care; continually improve work processes and measure progress over time.	IHI
Share and synthesise data for insights to make new discoveries and improve processes; evaluate processes.	John Hopkins Operating Management System
Data management and outcomes monitoring.	ARCC
IMPLEMENTING QUALITY IMPROVEMENT INTERVENTIONS TO ADDRESS SPECIFIC PATIENT SAFETY ISSUES	
Robust process improvement.	JCI; Air Force
Improvement and measurement.	IHI
Evidence-based practice implementation.	ARCC
Involvement of safety and quality experts in designing and directing system improvement efforts.	JH Safety and Quality Framework
Simulation training for teams to practise briefing, huddles and debriefing strategies.	High Reliability Team Model

Frameworks: JCI (HRHCM)[24]; IHI Framework for Safe, Reliable and Effective Care[25]; Johns Hopkins' Armstrong Institute for Patient Safety and Quality[27,28]; Office of the Air Force Surgeon General's Trusted Care Framework[29]; ARCC Model[30]; High Reliability Team Model by Riley W et al.[31]

Source: Veteran Affairs[32]

AFTERWORD

There can be no doubt that a crisis triggered by an adverse event leaves an indelible mark in the corporate memory. Besides engaging with patients and their family members, those at the forefront of incident management will remember the various interactions with external regulators, site audits included.

Beyond regulations

The healthcare industry is tightly regulated, and policies and directives permeate the various spheres of practice. In hospitals here, there are departments set up to liaise with the Ministry of Health on clinical governance matters routinely on matters of clinical standards, and in times of crisis. Regulations push hospitals to do right by the patient, but may fail us at times as lessons from Mid Staffordshire NHS Trust had shown. These words from Donald M. Berwick point towards a better way:[33]

> Neither quality assurance nor continual improvement can be achieved through regulation based purely on technically specific standards [...] In the end, culture will trump rules, standards and control strategies every single time.

We illustrate with an example and a reference to MOH Directive 1/2020. Under this Directive, public healthcare institutions are obliged to report medication errors that are associated with temporary/permanent harm or death. Nothing hinders (in fact, it is highly encouraged) an organisation from paying additional attention to: (1) circumstances/events that have the capacity to cause error because they can at any moment; (2) errors that did not reach patients because they may at the next turn; (3) errors occurred that reached patients but did not cause harm because another patient could have reacted poorly. Clearly, each instance is an opportunity to improve and strengthen defences if these, not luck, are to be relied upon time and again to keep our patients safe.

Beyond reporting

The practice of reporting near misses is a good habit to cultivate. To facilitate this at NHG, a channel to report near misses is created for our institutions and business units through the Portal for Risk Identification and Safety Management at NHG (PRISM@NHG). The system is equipped with clinical quality review and harm surveillance tools for detection, learning and improvement. But there remains some distance to cover, to develop the 'software' – a culture of reporting where the impetus for speaking up, change and improvement surpasses inhibitions. Establishing the appropriate culture and conditions continues after the 'hardware' has been built. When making our way to the next stop, the following words from Chassin and Loeb serve as a compass:[34]

> ...based on the lessons of high-reliability science and past efforts to improve health care quality, we believe that leadership commitment, full implementation of a safety culture, and thorough adoption of robust process improvement tools and methods together are the pathway most likely to lead to success.

Beyond reliability

Quality improvement is a continuous journey. For some, it is a journey of simultaneous pursuits. While pressing on with error prevention (Safety-I), organisations are discovering that compared with the occasional errors, things are going right much more often! Research done in resilience engineering, known as Safety-II, has sparked interest amongst healthcare organisations to harness the intrinsic ability of systems/microsystems/teams through adaptive tactics – mechanisms that help systems adjust their functioning prior to, during or after disruptions so as to sustain the required operations under expected or unexpected conditions. The BMJ's International Forum on Quality and Safety in Healthcare (Europe/June 2021) showcased the application of resilience principles at Princess Alexandra Hospital in Brisbane during the COVID-19 pandemic to triple the capacity of its Emergency Service and ICU. [35] Another development, also in the realm of Safety-II, is the formulation and use of the Functional Resonance Analysis Method (FRAM) for event analysis, risk analysis and design evaluation.[36]

Safety-II is concerned with maximising the number of acceptable outcomes while Safety-I, a product of reliability engineering, seeks to minimise errors. As not all errors are preventable and not all crises originate from within the organisation, resilience is the way to respond to unexpected events that cross an organisation's path like curveballs. We are duty-bound to provide safe care consistently (Safety-I) and part of rendering safe care is about ensuring availability of care to whoever needing it, which in turn depends on operations continuity (Safety-II). Achieving both – reliability and resilience – is becoming less a matter of choice than necessity. At the same time, we owe it to the organisation's stakeholders to be prepared for contingencies. There is no substitute for an up-to-date crisis management plan.

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RESOURCES

APPENDIX A

CRISIS MANAGEMENT WORKPLAN

ELEMENT	DIMENSION
Organization Culture of Safety	Board and Leadership
	Systems, Policies, Procedures Guidelines, Crisis Management Plan
Internal Notification	CEO, Executive Leaders, Risk Management, QI and Patient Safety, Counsel, Comms etc.
	Board
Crisis Management Team	Threshold Met for Activation
	Membership
	Chair
	Facilitator
Priority 1: The Patient and Family	Who's on Point
	Acknowledged Pain, Express Regret
	Patient/Family Needs Meet
	Patient Fully Assessed
	Personal Safety
	Primary Physician Notifed
	Hearing What
	Apology Extended
	What Do They Want Said
	Provide Ongoing Support, Reimbursements
	Compensation Approach
	Mailings Suppressed
	Root Cause Analysis (RCA) Participant
Priority 2: The Frontline Staff	Who's on Point
	Personal Safety
	Hearing What
	Ongoing Support and Visibility
	RCA Participants

PRE-EVENT	FIRST HOUR	FIRST DAY	FIRST WEEK	FIRST MONTH	THEREAFTER
Trust, Respect, Human Rights, Forgiveness, Repentance					Learning and improvement
Approve	Assemble	Annotate	Annotate	Annotate	Revise
Learning System	Activated	Engaged and Visible	Engaged and Visible	Engaged and Visible	Learning and improvement
-	Pending	Activated	Updated	Updated	
Plan	Activated	Meeting	Schedule	Schedule	Stand down with plan
Plan	Activated	Refine	Refine	Updated	Formal debrief
Plan	Activated	Refine	Ongoing	Ongoing	Revise plan
Plan	Activated	Ongoing	Ongoing	Ongoing	
-	-	Establish	Report	Report	To resolution and learning, including any external professional or judicial actions
-	-	Acknowledged	Ongoing	Ongoing	
-	-	Established	Ongoing	Ongoing	
-	-	Assessed	Update	Update	
-	-	Assess	Update	Update	
-	-	Notified	Update	Update	
-	-	Report	Report	Report	
-	-	Assessment	Assessment	Assessment	
-	-	Establish	Update	Update	
-	-	Offer	Update	Update	
-	-	Review	Review	Establish	
-	-	Activated	Updated	Updated	
-	-	Activated	Invited	Complete and Reported	
-	-	Establish	Report	Report	To resolution and learning, including recognition of the efforts of staff, resolution of any external professional or judicial actions.
-	-	Assess	Update	Update	
-	-	Report	Report	Report	
-	-	Offer	Report	Report	
-	-	Activated	Invited	Complete	

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CRISIS MANAGEMENT WORKPLAN

ELEMENT	DIMENSION
Priority 3: The Organization	**THE EVENT**
	Who's on Point
	RCA and Executive Sponsor
	What Happened
	Patient Clear and Present Danger
	Who Knows What
	Hearing What
	Priorities: What, Who Is on Point
	Materials to Be Sequestered
	System for Urgent News
	Billing Stopped (Hospital-Acquired Condition Policy, etc.)
	INTERNAL AND EXTERNAL COMMUNICATIONS
	What Prepared to Say
	Who Is (Are) on Point
	What Patient/Family Want Said
	Press Release/Talking Points
	Internal Communications: Patients, Families, Staff
	External Communications: Media, Community, etc.
	"Friendly" Experts On Call
	EXTERNAL NOTIFICATIONS AND UNANNOUNCED VISITS
	State Public Health
	Joint Commission, Others
	Risk Insurer
	Law Enforcement Agency

PRE-EVENT	FIRST HOUR	FIRST DAY	FIRST WEEK	FIRST MONTH	THEREAFTER
-	-	Establish	Update	Update	Revise plan
-		Activated	Progress	Complete	Closed all risk reduction items
-	-	Report	Report	Report	Learning and improvement
-	-	Assess and Report	Update	Update	
-	-	Report	Report	Report	
-	-	Report	Report	Report	
-	-	Set	Update	Update	All items addressed
-	-	Immediate	Update	Update	Ultimate disposition
-	-	Set	Update	Update	Revise plan
-	-	Stop	Update	Update	Per statute/ Patient and family understanding
-	-	Establish	Update	Update	Learning and improvement
-	-	Establish	Update	Update	
-	-	Establish	Update	Update	
-	-	Prepare	Update	Update	
-	-	Prepare	Update	Update	
-	-	Prepare	Update	Update	
-	-	Consider	Update	Update	
-	-	Consider	Update	Update	All requirements and conditions met; Demonstrated learning and improvement
-	-	Consider	Update	Update	
-	-	Notify	Update	Update	
-	-	Consider	Update	Update	

APPENDIX B

MANAGEMENT OF SERIOUS CLINICAL ADVERSE EVENTS CHECKLIST
(Note: Adaptation to fit local practice is encouraged.)

ELEMENT	DIMENSION	STARTED	COMPLETED
Organization Culture of Safety	Have expectations been set? Are board and leadership accountable?		
	Are there established systems, policies, and a crisis management plan?		
Internal Notification	Have the CEO, Executive Leaders, Risk Management, QI and Patient Safety, PR, Legal Counsel, and other relevant leaders been notified of the event?		
	Has the board of trustees been notified?		
Crisis Management Team (CMT)	Has the threshold been met for activation of the CMT?		
	Is the team membership in place?		
	What executive leadership will chair the team?		
	Is there a need for an independent facilitator?		
Priority 1: The Patient and Family	Who is the organizational 24/7 contact person for the patient and family?		
	Has the organization acknowledged the pain, expressed empathy and regret?		
	Are the immediate needs of the patient and family met?		
	Has the patient had a full clinical assessment?		
	Has the organization assessed the personal safety of the patient and family?		
	Has the patient's primary care physician and extended care team been notified?		
	What is being heard from the patient and family?		
	Has the organization apologized, as appropriate?		
	Does the organization understand what the patient and family want said to others about the event?		
	Is the organization providing ongoing support to the patient and family, including reimbursement of out-of-pocket expenses?		
	Is the organization prepared to have open discussions about compensation, if deemed appropriate?		

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MANAGEMENT OF SERIOUS CLINICAL ADVERSE EVENTS CHECKLIST
(Note: Adaptation to fit local practice is encouraged.)

ELEMENT	DIMENSION	STARTED	COMPLETED
Priority 1: The Patient and Family (cont'd)	Has the family been engaged in the immediate investigation and then invited to participate in the root cause analysis (RCA) of the event?		
	Has the organization suppressed all normal PR and other communications to the patient or family that could inflict further pain?		
Priority 2: The Frontline Staff	Who is the organizational 24/7 contact person for staff involved in the event?		
	Has the personal safety of frontline staff been assessed?		
	What is being heard from the frontline staff?		
	Has the organization expressed empathy and been visible?		
	Have frontline staff been invited to participate in any investigation and the RCA?		
Priority 3: The Organization	**THE EVENT**		
	Has an overall organizational point person been established?		
	What is known about what happened? What is the system for updates?		
	Is there clear and present danger to other patients, given what we know?		
	Has the root cause analysis been initiated? Is there an executive sponsor?		
	What about the event is known internally and externally?		
	What is being heard internally and externally in response?		
	What are the priorities to be addressed and who is the point person?		
	Are there materials that need to be sequestered?		
	What is the system to be used for urgent updates?		
	Has billing stopped per hospital-acquired condition policy?		

continues on the next page...

MANAGEMENT OF SERIOUS CLINICAL ADVERSE EVENTS CHECKLIST
(Note: Adaptation to fit local practice is encouraged.)

ELEMENT	DIMENSION	STARTED	COMPLETED
Priority 3: The Organization (cont'd)	**INTERNAL AND EXTERNAL COMMUNICATIONS**		
	What is the organization prepared to say internally and externally?		
	Who is (are) on point for communications?		
	Is there clarity on what the patient and family want said to others? Have they had input into all communications materials?		
	Has a press release been prepared in case it is needed?		
	Have there been communications to trustees, patients, families, staff, and internal/external members of the patient's extended care team?		
	Have there been external communications to the media, the community?		
	Are there "friendly" experts available?		
	Should outside media help be obtained?		
	EXTERNAL NOTIFICATIONS AND UNANNOUNCED VISITS		
	Are there required notifications to state public health, Centers for Medicare & Medicaid Services?		
	Is this event being reported to The Joint Commission, others?		
	Have risk insurers/outside legal counsel been notified?		
	Are there federal agencies to be notified (e.g., Health and Human Services, National Institutes of Health)? Does the Food and Drug Administration need to be contacted?		
	Do law enforcement agencies need to be notified?		
	Are there others that would benefit from learning from this event (e.g., Institute for Safe Medication Practices)?		

APPENDIX C

DISCLOSURE CULTURE ASSESSMENT TOOL		
	ELEMENT*	✓ / ✕ / ◔
Internal Culture of Safety	The organization, board, and leadership are grounded in the core values of compassion and respect, and the responsibility to always tell the truth.	
	Harm is seen as the failure of systems and not people, and is considered in a fair and just culture with policies and practices.	
Malpractice Carrier	There is a commitment to rapid disclosure, compensation, and support.	
	There is a written understanding of how cases will be managed with carrier.	
	Mechanisms are in place for rapid, respectful resolution.	
Policies, Guidelines, Procedures, Practices	There is a policy on patient and family compassionate communications.	
	Informed consent policies and practices are up-to-date and effective.	
	There is a policy on patient and family partnerships.	
	There are policies on disclosure and documentation.	
	There are procedures in place for internal and external communication.	
	Guidelines/policies support a fair and just culture, and reporting of adverse events.	
	Root cause analyses commence immediately, are closely managed with an executive sponsor. Results are shared, including with the patient/family.	
	There is a written crisis management plan. This plan is centrally located.	
	Policies/guidelines exist for reimbursement of out-of-pocket expenses.	
Training	Training programs are in place for all staff on communication,expectations, policies, procedures, guidelines.	
	There is just-in-time coaching (training) for disclosures.	

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DISCLOSURE CULTURE ASSESSMENT TOOL		
	ELEMENT*	✓ / ✗ / ◕
Disclosure Processes	There is rapid notification of patient/family and activation of support — typically, the organization shares what is known about the event.	
	There is a team to support staff in preparing for disclosure.	
The Disclosure	The organization is transparent and honest.	
	Responsibility is taken.	
	We are empathetic, apologize and/or acknowledge.	
	There is a commitment to providing follow-up information.	
	The caregiver is supported throughout the process.	
	Ongoing support is provided for the patient and family.	
Ongoing Support	Resources are available to assist families experiencing unanticipated outcomes—support is defined by the patient and family.	
	Resources are available to assist staff at the front line of unanticipated outcomes—support is defined by needs of the clinician.	
	Procedures are in place and are known to ensure ongoing communications with patients, families, and staff over months and possibly years.	
Resolution	Procedures are in place and are known to bring the case to closure respectfully, as viewed by the patient and family.	
Learning	Mechanisms are in place to ensure learning by the board, executive leadership, Medical Staff Executive Committee, and across the organization.	
	Measurement systems are in place to assess the impact of communication, disclosure, and support on premiums, claims, cases, and payments.	

**Adapted from Medically Induced Trauma Support Services (MITSS)*

APPENDIX D

EVENT REPORT INTERVIEW CHECKLIST

PREPARING FOR THE INTERVIEW

01. Determine the interviewer, such as:

- supervisor/manager of the department/service involved in the event
- risk management staff member
- patient safety staff member

02. Determine the interviewee(s), including:

- the person who initiated the report
- those directly involved in the event
- those present at event site
- co-workers of those involved in the event
- co-workers who perform the same tasks as those involved in the event

03. Schedule and conduct interviews:

- as soon as possible after the event
- at a time when the interviewee will be better able to concentrate
- at the scene of the event, if possible, and if privacy can be ensured; otherwise, a private, comfortable area free from distractions
- with one interviewee/witness at a time, beginning with those most directly involved
- with consideration given to a second round of interviews (within one to two weeks) to resolve any discrepancies or to obtain additional information

04. Work with legal counsel to determine the need for:

- the presence of legal counsel during interviews (if the event proceeds to litigation or settlement, legal counsel can protect information obtained under attorney-client privilege)
- taking notes and/or recording interviews (considering "legal discovery" of information)

05. Collect background information, such as:

- medical records
- electronic health records
- staff shift schedules
- possible environmental factors
- other extenuating circumstances.

06. Develop list of questions to identify the "who, what, where, when, why, and how" of the event.

CONDUCTING THE INTERVIEW

07. Be aware of body language and consider:

- sitting beside interviewees, not opposite
- remaining objective and compassionate

08. Begin interviews with assurances that all those involved in the event are being interviewed to gather facts — not to place blame — as described in the facility's safety culture and event policies.

09. Begin with background questions (e.g. how long have you had your current responsibilities in this facility?) before asking questions related to the event.

10. Ask open-ended questions (e.g. "What happened next?") rather than leading questions (e.g. "Did you then call the pharmacy?").

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EVENT REPORT INTERVIEW CHECKLIST

CONDUCTING THE INTERVIEW (CONT'D)

11. Encourage interviewees to keep speaking:

- allow interviewees to tell the story at their own paces and in their own words.
- use head nods and other nonverbal cues.
- refrain from interrupting the interviewees.
- resist the urge to fill silence or pauses—allow interviewees the space to do so.

12. Ask some of the same questions in slightly different ways at different points in the interview to verify the accuracy of statements. Repeat important statements from interviewees to verify accuracy.

13. Be mindful of interviewees' perspectives:

- do they seem to remember events accurately?
- does the potential for disciplinary action, criminal or civil liability, or discharge from employment exist for the interviewees?
- have others spoken to the interviewees and influenced their recollection of events?

14. Take notes (see next section for more details).

15. If the interview is lengthy, take breaks to help the interviewee regain focus.

16. Tie up any loose ends before the conclusion of the interview.

17. End the interview on a positive note, by:

- once again, emphasizing the purpose of the interview as fact finding rather than assigning blame.
- thanking interviewees for their time and cooperation.

DOCUMENTING THE INTERVIEW

18. Consult with legal counsel to determine how notes should be documented and retained. Consider if there are laws concerning the potential discovery of such information.

19. Once the conversation begins, tell interviewees notes will be taken to ensure accuracy. If interviewees seem nervous:

- refrain from taking notes at the beginning of interviews
- ask more general questions to put interviewees at ease

20. Record factual information, not observations or judgments.

21. Jot down notes while maintaining eye contact with interviewees.

- Avoid looking only at the notepad and writing continuously while they are speaking.

22. Do not enter results of the interview in a patient's medical record or an employee's personnel file.

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