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TURNING INCIDENT REPORTING INTO IMPROVEMENTS

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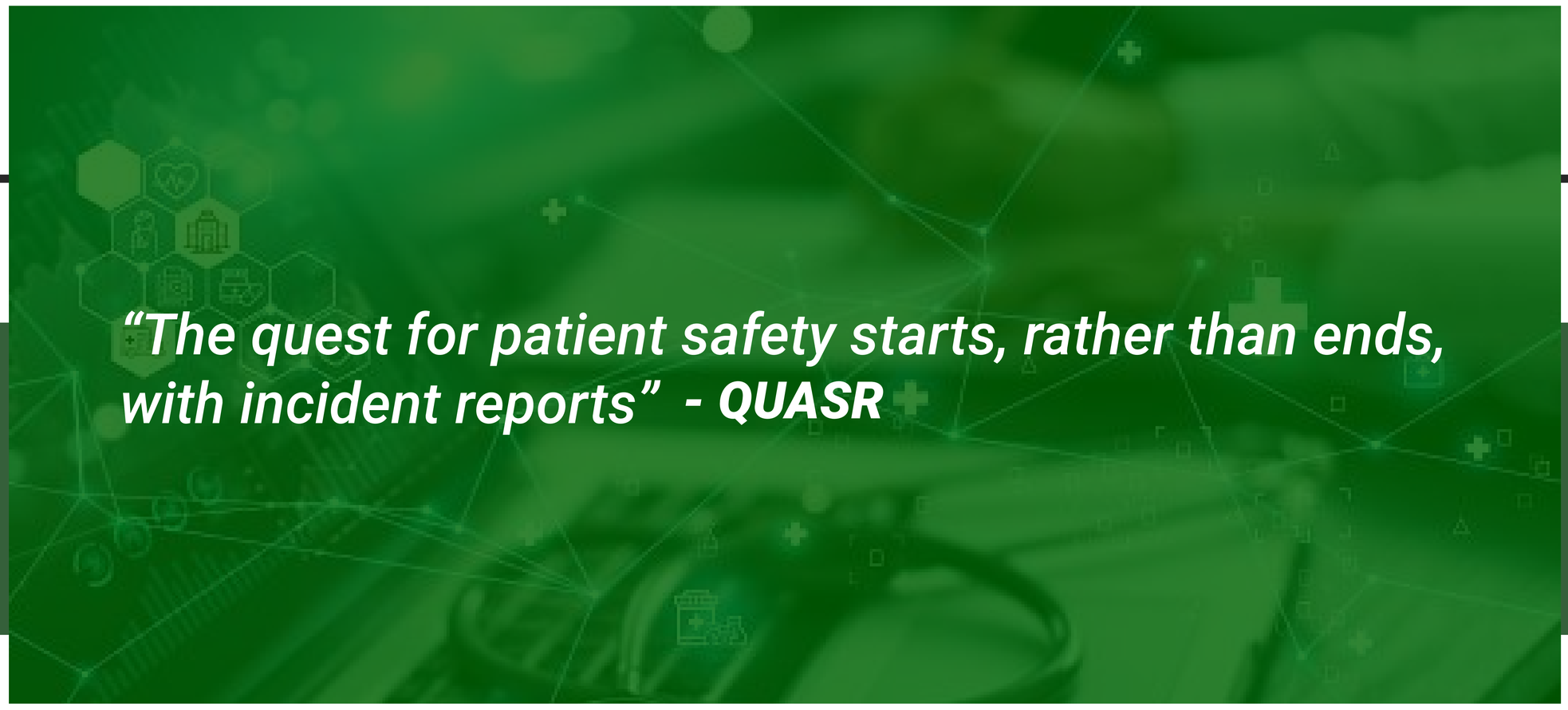
1.INTRODUCTION



Patient safety movement started more than two decades ago by placing incident reporting at the heart of patient safety programs in healthcare systems. The assumption is that through incident reporting, we can learn from what went wrong, identify risks and flaws in our health systems and take corrective actions to prevent similar incidents from recurring. However, despite advances in incident reporting practices over the last 20+ years, patient safety remains a major and persistent problem. According to the World Health Organization (WHO), patient harm due to unsafe care is a large and growing global public health challenge, and most of this patient harm is avoidable. Why is this so?

The short answer is patient safety is a systemic issue involving complex, dynamic, and technical causes. Medical errors in healthcare are rarely due to a single point of failure, but a result of a combination of factors, including human factors. Incident reporting systems are essential to create visibility to conditions that lead to errors. To be effective, incident reporting needs to be part of the safety culture, with compassionate patient engagement, effective investigation, follow-up actions, and crucially how learning takes place in the organization. Learning from insights gained from analytical data on incidents alone is of limited value unless it leads to behavioural changes and organizational improvements.

Purpose of this eBook

This ebook has two main objectives:

- To discuss key considerations and strategies to maximize the value of healthcare incident reporting systems
- To provide guidance on the design and implementation of effective online incident reporting systems that can lead to facilitate improvements

This Guide is intended for Patient Safety, Quality and Risk managers as well as senior leadership team in all healthcare settings. The goal is to help you maximize the value of the incident reporting system by turning incident reporting into improvements in your organization. If you are currently using a manual or legacy system and are looking to upgrade, this eBook provides some guidance on key system features and functionalities to look for in healthcare incident reporting systems.

2. BARRIERS AND CHALLENGES IN INCIDENT REPORTING

"To err is human, to cover up is unforgiveable and to fail to learn is inexcusable."

Professor Sir Liam Donaldson, Patient Safety Envoy, WHO

Systemic Causes of Unsafe Care

Patient safety is a major and persistent problem. According to Patient Safety Learning, a advocate and independent voice for improving patient safety, patient safety fails for one or more of the following systemic causes:

- Patient safety is not regarded as a core purpose by healthcare leaders
- Organizations do not take all reasonable and practical steps' to improve safety.
- We don't have standards for patient safety in the way that we do for other safety issues, and those that we do have are insufficient and inconsistent.
- We focus too much on responding to, and mitigating the risk of, harm. We don't pay enough attention and take action to design healthcare to be safe for patients and for the staff who work within it.
- We don't learn well enough, share or act on that learning for patient safety.
- Staff working in healthcare are not 'suitably qualified and experienced' for patient safety and are not properly supported by leaders and specialists in safety design and human factors
- Patients are not sufficiently engaged in their safety during care and after harm; patients need to be part of the team.
- We don't have good ways of measuring whether we are providing safe care.
- A culture of blame and fear undermines our ambitions to design and deliver safer care.

Source: Patient Safety Learning. A Patient-Safe Future: A Patient Safety Learning Green Paper, 2018 [1]

While we do not necessarily agree with all the viewpoints, we believe that there are systemic causes of unsafe care.

BARRIERS IN INCIDENT REPORTING SYSTEMS

Incident reporting system is central to improving patient safety and addressing the issues of unsafe care. It creates visibility to conditions that lead to errors so that interventions can be implemented to reduce risks and prevent harm to patients. However, progress in reducing preventable harm in healthcare has been slow. Numerous studies have repeatedly shown that incident report systems have not met the expectations of making care safer.

There are inherent challenges, barriers, and limitations on incident reporting systems in healthcare, which are remarkably similar globally. The diagram below summarizes the common challenges and reasons why incident reporting systems have not been unable to reduce errors and system flaws in a significant way.

- Leaders do not make incident reporting a top priority
- Prevailing culture of blame and fear of retribution
- Under-reporting due to lack of awareness, inconvenience of paper-based system
- Inability to turn learning into actual improvements and system changes
- Unwillingness to involve patient and families in understanding what went wrong
- Tendency to implement weaker actions, instead of redesigning systems and processes
- Under-resource to handle incident volume and carry out in-depth investigation
- Focusing on reporting & data gathering, at the expense of effective response and improvements
- Lack of follow through actions after RCA
- Poor communication and collaboration among stakeholders involved

3. CREATING A POSITIVE SAFETY CULTURE

"There is no question about the motivation of the pilot community in general with respect to safety issues, none whatever.... I believe that the reporting to Air Safety Reporting System is motivated not by the sense of personal risk that attaches to flying but rather from two major factors: (1) the sincere interest in improving safety by identifying hazards (2) the sincere belief that the system to which they are reporting uses that information productively and deliberately to improve safety rather than simply a means of counting failures."

- Dr Charles E. Billings

The above was the response from Dr Charles E. Billings, the initiator of the Air Safety Reporting System (ASRS) when he was asked "Does the fact that pilots are at personal risk when flying have something to do with the success of ASRS? Is that the reason you think this system might work much better in aviation than it might be made to work in medicine"

Source: United States National ant Safety Foundation; 1998 [2]

Much has been said about the safety culture in the healthcare industry compared to other safety-critical industries and high-reliability organizations (HRO). The line of questioning and the response best illustrate that the healthcare sector in general is still lacking a matured safety culture.

For incident reporting systems to be more effective, healthcare organizations should create a positive safety culture in which reporting is encouraged, valued and blame-free. Staff should also see the purpose and benefits of reporting incidents.

Different Aspects of Safety Culture

Safety culture starts from the top. Leadership commitment, policies and practical steps should be in place to foster a supportive and positive environment. To maximize the value of incident reporting systems, healthcare organizations must create psychological safety where frontline workers feel safe and empowered to speak up. Build a just culture and create a work environment that is just and fair by focusing on system flaws rather than blaming the individuals.

On the other hand, a blame culture incentivizes people to cover up mistakes, makes an individual responsible for a failure while downplaying or ignoring the systemic causes behind an incident. This inhibits learning and improvement.

"For a safe organisation, staff need to be confident that doing the right things – reporting incidents, near misses and concerns, being candid about mistakes and talking openly about error – are all welcomed and encouraged. They need to know that the organisation will focus on system learning, not individual blame. Of course, there must always be accountability in the rare cases where individual healthcare staff have acted recklessly or have covered up. The term 'just culture' describes a culture which successfully achieves this balance."

- Patient Safety Learning, A Patient-Safe Future: A Patient Safety Green Paper, 2018

A culture of safety must also address health worker safety and wellbeing. The prevalence of burnout among healthcare professionals over the last few years has gained attention as a potential threat to healthcare quality and patient safety. High burnout rates can lead to many negative effects, including errors, infections, poor quality of care and high staff turnover, further compounding patient safety concerns.

"Creating a safety culture is the first step towards maximizing the value of incident reporting systems" ***- QUASR***

4. MAKING INCIDENT REPORTING EASIER AND MEANINGFUL

"Making incident reporting easier, meaningful and blame-free to the reporting person is one of the best ways to build a safety culture"

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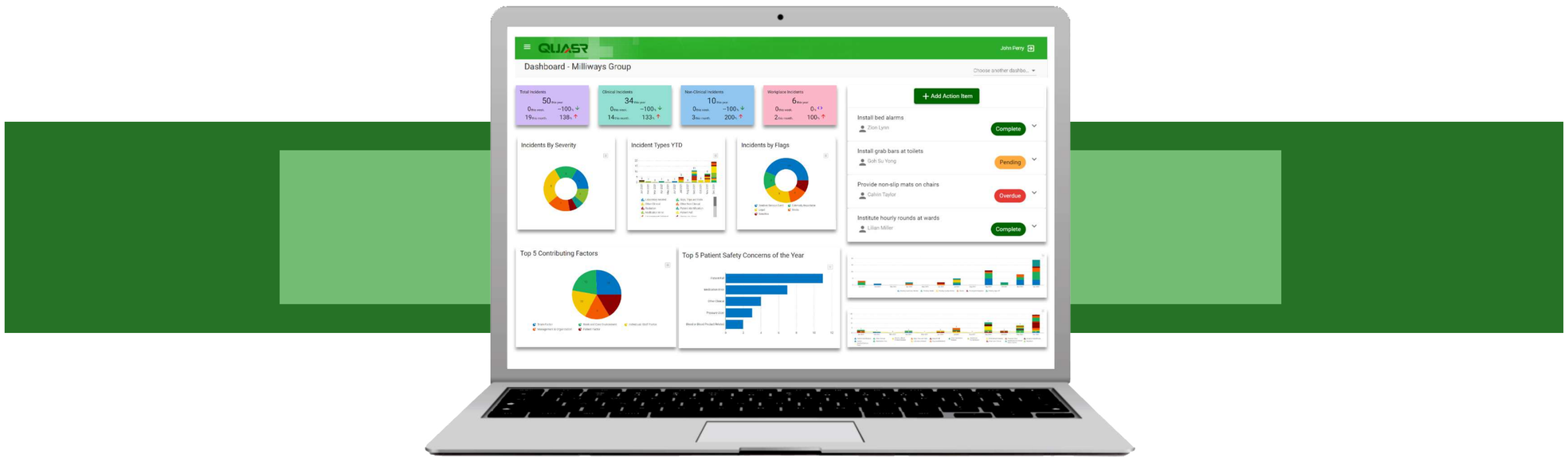
Given the challenges and barriers in incident reporting as described in Chapter 2, what can we do to enhance and maximize the value of incident reporting in healthcare? Besides creating a positive safety culture, healthcare organizations can adopt the following strategies :

1) Make Incident Reporting Easier

Traditional paper-based incident reporting is inconvenient and at times difficult for staff to report incidents, which often lead to under-reporting. Poorly designed manual incident forms with pages of information irrelevant to the incident occurred often discourage staff to report incidents. Online incident reporting systems with user-friendly design, guided forms/questions for specific incident types, automated email notification and routing, and the use of mobile phones make incident reporting much easier. Studies have shown that the number of incidents reported increased significantly after online systems were implemented.

2) Make Reporting Meaningful to Reporting Person

For most incident reporting systems, especially the manual systems, the reporting person does not receive timely feedback after submitting an incident report. Numerous research and studies have shown that this demotivates people from reporting incidents. A well-designed system should make information available to the reporting person, so that he/she can learn from the incident, feel appreciated, and know that the organization uses the information to improve safety. The latter is what motivates staff most to actively participate in incident reporting and contribute to patient safety. A caveat is that if an incident is deemed containing sensitive information, access rights should be denied or limited to ensure confidentiality.



3) Simplify and Streamline Incident Management Process

Incident management is a long and complex process involving several stages, from notification, initial review, quality review and risk assessment, to investigation/RCA, recommendation, and closure. For adverse events, the process will involve many stakeholders. A lack of process standardization or unduly complex processes will discourage participation by various stakeholders. On the contrary, a standardized and streamlined incident management workflow makes it efficient and productive, allowing for more time to carry out system improvements. Capturing structured data enables more insightful analysis. For healthcare organizations with multiple facilities, a centralized incident reporting system with harmonized processes creates great efficiency and allows for performance benchmarking.

3) Enable Effective Communication and Collaboration

Healthcare today is too complex for individuals or small groups to work alone or independently to solve systemic problems. Incident management and quality improvement require various stakeholders to work collaboratively. To enhance the value of incident reporting systems, organizations should provide a platform that facilitates communication and collaboration among diverse stakeholders. Digitalization provides an effective solution to overcome this challenge.

4) Prioritize Events To Investigate

Healthcare organizations can adopt a risk-based approach to incident reporting, especially when facing resource constraints. The argument is that it is better to prioritize the reporting of incidents with high severity and investigate them thoroughly, than to have large volumes of incidents being reported with weak responses and superficial investigations. One such example is the mandatory reporting of Serious Reportable Events (SREs) adopted by many countries. While this approach may lead to specific corrective actions, it may come at the expense of under-reporting of other incidents and near misses (close calls), and lost opportunity for improvement.

5) Make System Improvements the Measure of Success

"The ultimate measure of success is the number of organizational improvements made, rather than the number of incidents reported"

Active participation and willingness to report incidents by staff is a good indicator of safety awareness. Number of incidents reported is a useful metric, but it is not a measure of safety performance, nor a measure of the success of incident reporting systems. The ultimate measure of success on incident reporting systems is the number of behavioural changes and organizational improvements made. A related metric for system success is the number of stronger or intermediate strength actions (as defined in action hierarchy) taken after RCAs that provide effective and sustained system improvements. From the senior management perspective, this is a more convincing argument to show the value of incident reporting systems.

5. IMPROVING THE EFFECTIVENESS OF RCA

Root Cause Analysis (**RCA**) is a structured and robust investigation process to identify the original causes of failure or inefficiency that ultimately leads to a problem, such as a clinical incident, occurring within the health system. It is one of the most widely used analysis tools in healthcare to analyze patient safety issues. In some countries, RCA is mandatory for clinical incidents which result in serious harm or death. RCA review should focus on systems and processes, not on individual's performance or to assign blame. It uses various methods to examine and understand how systems, processes and human factors may have contributed to an incident taking place. It attempts to answer three questions about an incident:

1. **What happened?**
2. **Why did it happen?**
3. **How can we prevent it from happening again?**

Improving the effectiveness of RCA, which is a critical step in incident management processes, can enhance the value of incident reporting systems.

Challenges of RCA in Healthcare

Healthcare sector has adopted the RCA practice from high-risk industries such as aviation during the patient safety movement in the late 1990s. While RCA is now widely used in healthcare for the investigation of adverse events, there are challenges in its application. Numerous studies show that RCA has had inconsistent success in improving patient safety.

Wider Systems Approach, Skills Required

Several reasons are cited. Firstly, a key problem with RCA is its name, which implies a singular and linear cause. Sentinel events and serious incidents often involve multiple and interacting contributing factors. Therefore, a wider systems approach in RCA is required to identify root causes and bring sustained improvement. Secondly, multi-disciplinary skills such as proficiency in systems thinking, human factors and safety science, and hands-on experiences in staff engagement and data analytics are required in RCA reviews. Hospitals may lack such internal resources and expertise.

Stronger Measures Needed

Thirdly, risk control strategies and corrective actions taken are often not strong enough to bring about sustained improvement. Studies have shown that there is a tendency for investigators to recommend administrative and perhaps "weaker" action, rather than addressing latent causes such as poorly designed processes or defective operating systems. This requires strong management commitment and support.

Failure to Act and Learn

Next, the general lack of emphasis on follow-up actions and timely implementation after RCAs are conducted. RCA does not end with analysis and will be a waste of time and effort if no necessary actions are taken. Finally, failure to learn from incidents and share control measures due to poorly functioning feedback loops and communication channels.

Refer QUASR RCA EBook, 2022[3]

Improving the Effectiveness of RCA

To maximize the value of incident reporting systems, healthcare organizations should ensure that they have an effective RCA process. The National Patient Safety Foundation of US recommends the following key steps in conducting RCA:

- Identify hazards and vulnerabilities that impact patient safety. Prioritize actions to be taken.
- Identify systems-based corrective actions.
- Ensure timely execution of an RCA and formulation of effective sustainable improvements.
- Ensure follow-through to implement recommendations.
- Measure whether corrective actions were successful.
- Ensure leadership at all levels support and participate in RCA reviews and corrective actions are implemented.

Source: NPSF, RCA2 – Improving Root Cause Analyses to Prevent Harm, 2015[4]

6. COMPASSIONATE PATIENT ENGAGEMENT

"Often there is a focus on process, rather than identifying what a patient wants and needs in terms of putting the situation right. Little is known about the emotional and psychosocial harm stemming from medical errors and adverse events. Yet emerging data suggest that these secondary impacts may be just as harmful, or even more injurious, than the underlying event."

The Patients Association, Response to the Green Pap "A Patient-Safe Future." 2018 [5]

One of the key weaknesses of incident reporting systems is failure to engage patients and families, learn from them, and invite them to be part of the solution. Healthcare organizations should empower patients and their families to play a more active role in identifying risk and potential harm. Their feedback can be helpful in designing safer systems. Engaging patients in their care increases patient safety, reduces harm and potentially reduces costs.

"The patient and family are the only people who are present throughout the continuum of care. They are a repository of critical information and, when engaged and empowered, can play a significant role in ensuring a positive health-care experience. For the same reason, engaging patients and families who have experienced harm can provide insights and learning concerning system failures."[6]

- WHO, Patients for Patient Safety: Partnerships for Safer Health Care 2013[6]

Putting Patients and Families at the Center of Incident Response

National Health Service (NHS) UK released the Patient Safety Incident Response Framework (PSIRS) in August 2022. PSIRS sets out NHS's new approach to developing effective systems and processes for responding to patient safety incidents for the purpose of learning and improving patient safety. Under PSIRS, there is a shift in focus towards engaging patients, families and staff affected by the incident. The new system aims to focus on understanding how incidents happen and the contributing factors. It recognizes that human beings are fallible. When an incident happens, we should treat everyone involved with compassion.

The PSIRF puts patients and families at the center of incident reporting to maximize opportunity for learning and improvement. It supports an effective patient safety incident response system that integrates four key aims:

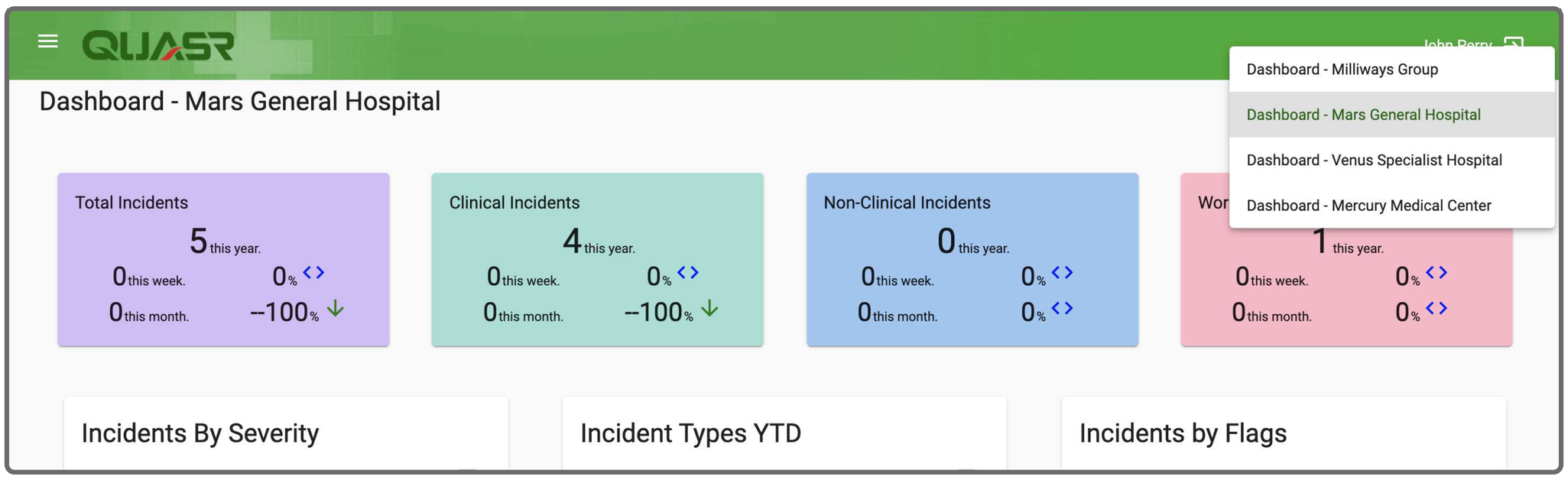
- Compassionate engagement and involvement of those affected by patient safety incidents.
- Application of a range of system-based approached to learning from patient safety incidents.
- Considered and proportionate responses to patient safety incidents.
- Supportive oversight focused on strengthening response system functioning and improvement.

Source: Adapted from Patient Safety Incident Response Framework (PSIRF)[7]

7. TURNING INCIDENT REPORTING INTO IMPROVEMENTS

"Learning from insights gained from incident reports alone is insufficient unless it leads to behavioural changes and systems improvements".

Is the primary function of incident reporting an oversight system to show whether organizations are compliant with serious reportable events management, or to facilitate organizational learning and improvement? How do we respond to patient safety incidents, learn from them, and improve? Are there opportunities for learning in less serious incidents and near misses?



Incident reporting systems fulfil multiple functions which are not always compatible. On the one hand, incident reporting is central to improving patient safety and is the foundation for learning. On the other hand, it plays the oversight role on accountability, which can be punitive and stifle our potential to learn and improve. We believe incident reporting systems should always put the safety and needs of patients, families, and staff first. This is a mindset shift and is aligned with the culture of safety. Healthcare leaders should view patient safety as a strategic priority.

"Incident reporting systems should always put the safety and needs of patients, families, and staff first"

Organization Learning is Key to Improvement

The term “learning” has been loosely used in the context of patient safety. While there is extensive research literature on organizational learning, little research is done on the processes and practices of learning in patient safety incident reporting systems. A tight and limited definition of learning refers to sharing and discussing incident details, insights and lessons learned among a group of people.

However, the simple creation of analytical reports need not necessarily lead to any sustained improvement. To turn incident reporting into improvements, healthcare organizations must adopt organizational learning that engages wider participation and involves changes to behaviour. The output should be actual changes and improvements in the organization’s processes and systems, along with changes in behaviours. Learning from analytical data gained from incident report alone is of limited value unless it is translated into behavioural changes and systems improvements.

Continuous Learning and Improvement

Healthcare can learn from HROs which have consistently demonstrated a strong culture of continuous learning and improvement. HROs have one thing in common when it comes to learning: a visible and transparent learning system, and open discussion on incidents. An effective learning system must be transparent and focus on continuous learning. And it must provide for improvement and measurement to learn and grow.

In healthcare settings, notwithstanding resource constraints, organizations should look for opportunities for learning in less severe incidents and near misses (close calls). Any incidents can be looked at to decide if a response is needed to generate new insight to feed into a program of continuous improvement .

Source: Patient Safety Incident Response Framework [7]

8. GUIDE TO EVALUATING ONLINE INCIDENT REPORTING SYSTEMS

"Make incident reporting system user-friendly, easy to deploy, affordable and accessible to hospitals and other healthcare settings"

Digitalizing incident management processes can greatly enhance operational efficiency and effectiveness of incident reporting in healthcare. To maximize the value of incident reporting, you should evaluate the software solution based on the system capabilities and features to meet your requirements. This includes features and functionalities on incident details, quality review, risk assessment, investigation/RCA, and action management for improvements to be carried out. The solution should also offer a platform for collaboration and engagement among various stakeholders.

The following serve as a guide on evaluating online incident reporting systems, particularly for small to mid-sized health organizations.

1. Is the solution designed for patient safety and the healthcare industry?

An out-of-the-box healthcare-specific solution comes with healthcare incident reporting best practices and content, hence requires less effort and time to implement. On the other hand, you can expect a generic incident reporting solution to require much more effort and time for customization before it can be deployed.

2 . What is the software licensing model?

Generally, there are two main licensing models: enterprise license or user license. Subscription model is more common. For incident reporting, you would want most if not all your employees to have access to the system, hence enterprise license will suit you better.

3 . Is it cloud-hosted or on-premise deployment?

Cloud-hosted solution means the vendor will provide the hosting facilities for the solution – it is a subscribe and use model. You will want to ask where/which country the solution is hosted, and who is the cloud service provider. For on-premise deployment, you will need to involve your IT/Infrastructure team to set up the IT environment or look for a cloud service provider, which requires additional budget.

4 . Are incident categories, types, and forms configurable?

This is an important consideration as your organization will have specific sets of requirements and definitions. Typical incident categories are clinical incidents, non-clinical incidents, and workplace incidents. IT-related and data breach incidents can be a separate incident category. A patient safety solution will provide you with pre-configured clinical incident types and forms. You should look for flexibility to easily configure incident types and forms to capture specific incident data (eg. to meet local regulatory requirements) without any code changes to the system.

5 . Is the solution user-centric?

Look for solutions with user-friendly interface, easy navigation and intuitive to users. This will greatly encourage system usage and adoption. Also look for solutions that provide mobility to users to capture data from the floor and view actions and reports on the move.

6. Is there workflow automation and email routing?

The common workflow for healthcare incident reporting is Reporting > Initial Review > Quality Review > Investigation/RCA > Signoff. You would like this workflow to be out-of-the-box, streamlined for all incident types with flexibility for minor customization. Email routing is a must and ideally should be configurable.

7 . Can the solution manage actions?

This is an essential system functionality. Based on RCA recommendations, or during the incident management process, you want to assign actions and monitor them to closure.

8 . What are the actions to be performed by quality managers?

Typically, Quality Managers will review incident details, conduct quality review and risk assessment, determine whether an investigation is required, and assign a team of investigators. Quality Managers also involve in investigation and RCA to determine the final root causes and contributing factors.

9 . What are the reporting capabilities?

The solution should have a set of out-of-the box reports and patient safety dashboards. Automating report generation can raise productivity and ensure timeliness. These reports and dashboards should also contain data and trend analysis.

10 . Are there self-configuration and administrator tools?

Self-configuration tools will greatly enhance the value of the solution in terms of quick response to user needs. You want the flexibility to configure incident types and incident forms by your internal team, rather than depending on the vendor. Administrator tool to manage users and set up organization structure, department, location etc, is essential.

11 . How does the solution support team collaboration?

Given that healthcare incident management is complex and involves multiple stakeholders, having features that support team communication and collaboration bring great value. Features to notify other stakeholders, delegate tasks and chat room are useful, in addition to email routing and triggers.

12 . Is the software HIPAA compliant?

Online incident reporting systems that keep protected health information (PHI) must have physical, network, and process security measures in place and follow them to ensure HIPAA Compliance. Many online incident reporting systems are standalone applications that do not keep patient data and medical records, in which case HIPAA compliant is not a must.

13 . What are the data protection and security features?

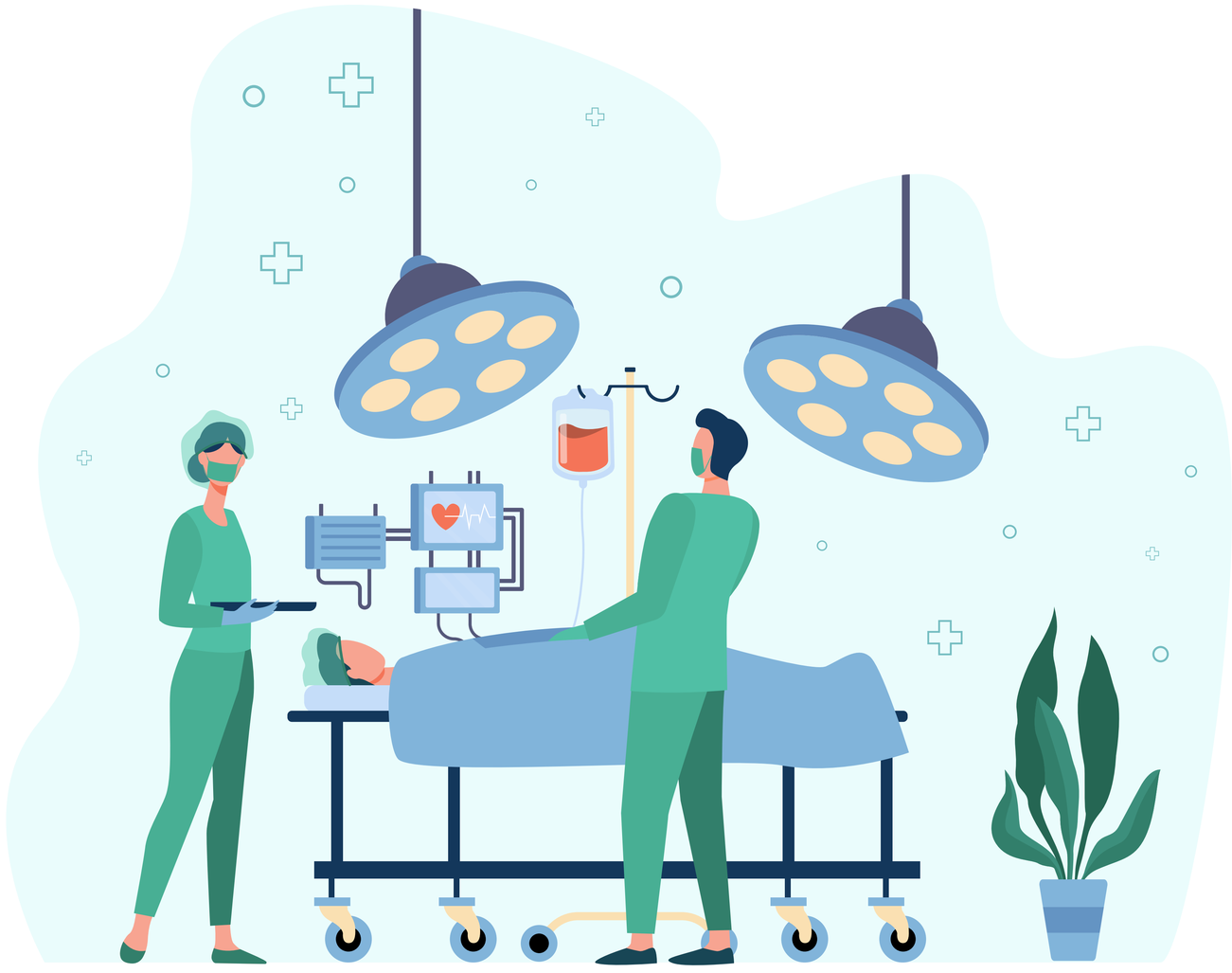
The solution should have all the necessary data security measures in place, including encryption controls, access controls, integrity controls (audit logs), confidentiality controls (role-based access, password policy) and recoverability (data back-up). Subscription terms and conditions should include clauses on compliance with PDPA regulations.

14 . Does the solution support system interface?

It is a key advantage if the solution can easily integrate and exchange data with other healthcare systems such as EMR/EHR, Hospital Information System and HR System. For large healthcare organizations, system interface is a must. For smaller healthcare settings at the early stage of digitalization, system interfaces may not be required, and a standalone incident reporting system may suffice.

15 . Is there post system go-live support?

Having post system go-live support by vendors is a must. There should be a Service Level Agreement (SLA) in the software subscription contract. Most SaaS solutions offer 24-hours online support for customers to log tickets.



9. PUTTING IT ALL TOGETHER

"Make patient safety a strategic priority and incident reporting the foundation of patient safety programs in healthcare" - QUASR

Incident reporting systems are the cornerstone of patient safety programs in healthcare. They provide valuable insights into risks, system flaws and unsafe conditions that exist in healthcare systems. These findings are the basis for continuous improvement in patient safety and quality of care.

Creating a positive safety culture is the first step towards maximizing the value of incident reporting systems. This should start from the top - a culture that focuses on system learning, not individual blame, Senior management should consider patient safety as a strategic priority. Making incident reporting easier and meaningful will encourage reporting and feed into a positive cycle of wider articipation and open discussion. Effective RCA with stronger follow-up actions to change behaviours or redesign systems will bring about sustained improvements. The value of incident reporting can be further enhanced with compassionate patient engagement and involvement.

While a positive safety culture forms the foundation of good safety performance, digital transformation of incident management processes is an effective enabler. A well-designed online incident reporting system can overcome many of the barriers and challenges encountered in manual or legacy systems. We can maximize the value of incident reporting by learning and taking actions that lead to behavioural changes and organizational improvements. This is the ultimate measure of success.

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