ORIGINAL ARTICLE

Managing clinical risk retrospectively and prospectively with a risk management framework in an acute care hospital in Singapore

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ABSTRACT

Objective: To expound on the implementation of the clinical risk management framework in an acute care hospital to minimise clinical risks and improve patient safety on account of systemic and human risk factors and patterns.
Methods: The clinical risk management framework involves a 2-pronged approach through retrospective and prospective methods. The 5 stages of the retrospective approach include data collection, data aggregation, risk assessment and prioritisation, risk mitigation, and lastly, risk monitoring. The prospective approach entails horizon scanning which aims to detect risks early and ensure controls are swiftly implemented to prevent harm from arising. When combined, the framework seeks to be responsive to reduce the possibility and severity of patient harm. The number of incidents and risk scores for top clinical risks from 2016 to 2019 were monitored and studied to assess the effectiveness of the newly implemented clinical risk management framework.
Results: When the clinical risk management framework was implemented in 2017, the number of incidents as well as corresponding risk scores for many of the identified clinical incident types and root causes decreased over the years. Most notably, two top clinical risks, results not being reviewed or delayed, and staff inadequate skills and knowledge, saw major improvements in risk scores.
Conclusions: The systematic workflow of the 2-pronged clinical risk management framework allows the campus to manage risks comprehensively and efficiently. While retrospective risk analysis examines and reacts to reported clinical incidents, amidst volatile circumstances and advancements of technology exposing unprecedented risks in healthcare, prospective risk analysis conducted through horizon scanning is useful in anticipating and acting before harm arises, ultimately resulting in improved patient safety.

Key Words: Clinical risk management framework, Patient safety, Risk analysis, Retrospective and prospective risk approach

1. INTRODUCTION

The eagerness and passion of healthcare institutions for patient safety rekindled[1,2] since To Err is Human by the Institution of Medicine was published.[3] With a duty to safeguard patient safety in healthcare, efforts are always in place to circumvent clinical risks to minimise and prevent occurrences of clinical incidents while making the clinical environment safer.[4] As different healthcare institutions have operational processes that pose different clinical risks, there is a need to adapt their clinical risk management framework to suit their own needs.[5,6] While there is no unique method in managing risks, good practices for an effective management framework

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remain the same where it is wise to focus on risks that have a larger impact.[6] While it is easier to react to reported clinical incidents within a healthcare institution, it is also worthwhile to anticipate potential emerging clinical risks so that harm can be prevented in the first place. Consequently, a robust and responsive clinical risk management framework is required to ensure that all clinical risks are comprehensively and efficiently managed.

The JurongHealth Campus (JHC), which started its operations in 2015, established the structured clinical risk management framework in 2017, to identify, assess, mitigate, and monitor clinical risks. The framework adopts a 2-pronged approach, which encompasses both retrospective and prospective risk analyses. With retrospective analysis, the JHC can identify thematic issues by relying on reported clinical incidents. However, with rapidly evolving technologies and changes in the healthcare system, it is critical to detect potential emerging clinical risks routinely through horizon scanning so that action can be taken before an adverse incident happens. This is achieved through prospective risk analysis.

Before 2017, clinical risks were managed without a structured risk review cycle or risk calculation method. As a result, top clinical risks and thematic issues were identified based on the number of incidents as well as individual judgements from the risk team. Consequently, the severity and likelihood of identified top clinical risks were prone to over and underinflation. However, with the implementation of the clinical risk management framework, clinical risks can be appraised quantitatively through a standard risk scoring method, and qualitatively through appraisals from ground staff as well as external data such as national reports and academic articles. With a holistic approach to managing clinical risk, the clinical risk management framework is useful in curtailing top clinical risks and improving patient safety, as seen in the declining risk scores and number of clinical incidents over the years. This paper describes the clinical risk management framework adopted by the JHC, a 700-bed acute adult tertiary hospital in Singapore.

2. METHOD

The framework includes retrospective risk analysis as well as prospective risk analysis, otherwise known as horizon scanning. With a combined approach, the framework plays a vital role in enhancing patient safety by evaluating clinical risks holistically and fairly.[7,8] The number of clinical incidents as well as risk scores for identified top clinical risks from 2016 to 2019 were analyzed to assess the impact of the newly introduced clinical risk management framework.

2.1 Retrospective risk analysis

The retrospective approach follows a risk cycle that comprises 5 key phases: data collection, data aggregation, risk assessment and prioritisation, risk mitigation, and risk monitoring.

2.1.1 *Data collection*

The JHC uses the lncident Reporting Information System (IRIS) to capture near misses and clinical incidents that occur within the campus. IRIS serves as the key starting point to conduct proactive surveillance of actual and potential clinical risks.[9,10] To expand the spectrum of clinical incidents, medico-legal cases, and clinical complaints are also considered in the evaluation of clinical risks.

2.1.2 *Data aggregation*

Data aggregation involves analyses and identification of thematic issues and root causes. As a single underlying root cause can later induce a wide range of problems, it is imperative to conduct a root cause analysis (RCA) for each clinical incident. By doing so, underlying issues and patterns can be exposed and understood.[9,11]

Various taxonomies already exist, classifying clinical incident types into standard categories. Adapting from the HPI taxonomy of safety events in healthcare[12] and the framework of factors influencing clinical practice,[13] while cross-examining with data collected within the JHC, the risk team agreed upon 12 clinical incident categories (see Appendix A), which can be further classified into specific sub-incident types.

2.1.3 *Risk assessment and prioritisation*

The relative impact of clinical risks is more relevant than its frequency.[7,14] As such, to assess clinical risks holistically and accurately, all cases go through an objective and a subjective evaluation (see Figure 1). In objective evaluation, clinical risks are assessed quantitatively. To evaluate the significance of individual clinical incidents, a Severity Assessment Code (SAC) score is determined from its respective likelihood and consequence rating (see Appendix B). The likelihood of each incident occurring is rated on a scale of 1 to 5, with 1 being "Rare" and 5 being "Almost Certain." The consequence level is also rated on a 5-point scale, with 1 being "Insignificant" and 5 being "Extreme." The risk score is calculated for each incident type and root cause based on the weighted average likelihood and worst actual consequence score. The average likelihood is calculated by giving more consideration to incidents with a higher individual likelihood while the consequence score is quantified based on the most conservative approach, assuming the worst actual outcome amongst all the cases aggregated in that incident type or root cause. The top 20 incident types and root causes are then

identified based on the risk score and incident count.

The top 20 incident types and root causes will then undergo a subjective evaluation which involves analyses and comparisons against significant events and thematic issues occurring within and beyond the JHC horizon. This is done by referring to sources such as the Ministry of Health's reports of major clinical incidents, court judgements, Singapore Medical Council's disciplinary tribunal judgements, and control self-assessments. By considering the trends and severity of the risk and also the practicality to act on the matter at hand, clinical risks are then re-prioritised so that resources can be allocated to tackle those of a higher clinical significance.[7] The top 5-10 clinical risks will then undergo another round of assessment and endorsement by the Senior Management.

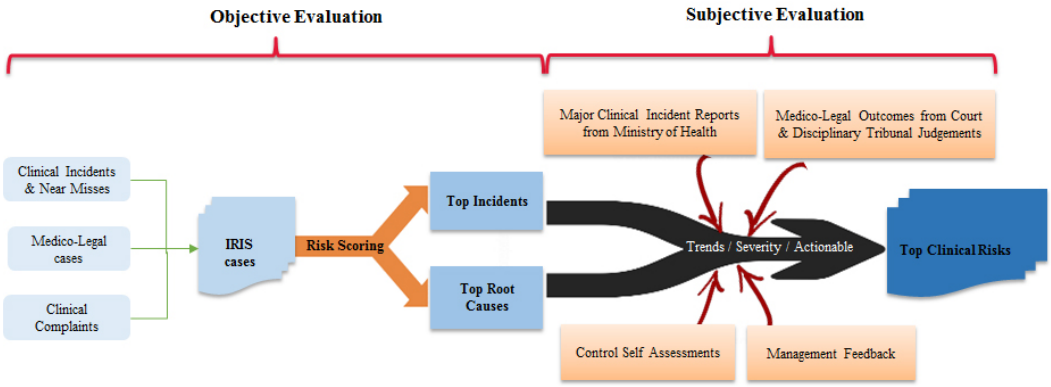

Figure 1. Retrospective risk approach - clinical risk identification process

2.1.4 *Risk mitigation*

Respective risk owners are then engaged to review existing risk controls and strategize new measures to minimize clinical risks and prevent the recurrence of clinical incidents. Key risk indicators will also be proposed to monitor the effectiveness of controls. At this juncture, risk owners are guided by the risk register, where easy reference to details regarding past major clinical incidents can be performed while conducting the review.

2.1.5 *Risk monitoring*

After approval of proposed risk mitigation strategies, risk owners will proceed to review and implement risk mitigation controls while the risk team continues to monitor the clinical risk trends to ensure that the risks remain under control.

It should be noted that the overall cycle for the retrospective approach spans through a year. Thus, there may be a significant lag from the moment an incident is reported to when risk mitigation strategies are implemented. To reduce this lag time, Quarterly Risk Monitoring (QRM) is also conducted for a quick turnaround. Should there be any alarming trend, prompt actions can be swiftly put in place before the situation worsens.

2.2 Prospective risk analysis - horizon scanning

The framework also entails a prospective risk analysis. This is carried out by scanning the horizon to detect emerging risks. Due to consistently improving standards and ever-growing patient safety concerns, the healthcare industry is susceptible to spikes in clinical incidents.[15] To remain proactive and vigilant on the latest trends, the risk team consistently scans the clinical climate for new technologies or shifts in work processes that can cause detrimental harm if not quickly identified and managed.

The process starts with data collection where news reports and journals are evaluated for any introductions of novel treatments, technologies, or workflows as well as clinical accidents from existing processes. Thereafter, associated potential risks are identified through literature research. This is followed by an internal forum within the risk team to assess the probability of the identified risk occurring in the JHC. Relevant stakeholders are then engaged to inquire about the existing controls and monitoring systems. Finally, the inputs are consolidated before highlighting to the stakeholders for any necessary action. The risk team then continues to monitor the risks identified (see Figure 2).

3. Results

3.1 Past years' trends

Table 1 lists the top clinical risks together with their respective frequencies and risk scores from the year it was first identified as a top clinical risk up till 2019. Since the implementation of the clinical risk management framework, the JHC has seen a decrease in the number of reported incidents relating to the top clinical risks. The risk scores also decreased or remained stable over the years.

3.2 Top improvements

The risk trends from 2016 to 2019 were analysed to assess the effectiveness of the clinical risk management framework. Significant improvements were notably seen in clinical risks relating to results not reviewed or delayed (results management) as well as inadequate skills and knowledge.

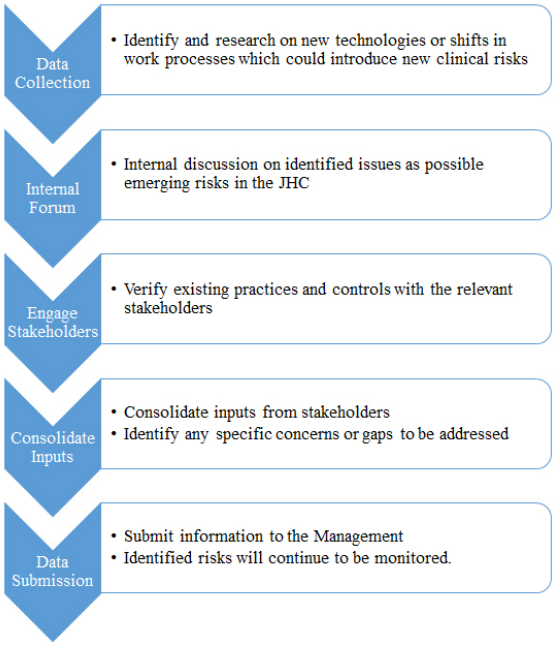

Figure 2. Horizon scanning for emerging risks

3.2.1 *Results management*

In 2017, a study of the Electronic Medical Record (EMR) system was done to assess the clinical quality rendered to patients. It was then discovered that a significant number of finalised test results were left unacknowledged in the EMR system. This included 13 patients with abnormal test results which necessitated a follow-up. The risk team recognised an imminent threat to patient safety resulting from the delayed and missed diagnoses. Hence, "Results not reviewed/ delayed" was identified as one of the top clinical risks in 2017.

Subsequently, throughout the years, various risk mitigation strategies were implemented. Reports were generated monthly for clinical department heads to track unacknowledged test results. A work instruction on reviewing results was also created. Later, an institutional policy detailing the results management workflow was established to formalize and disseminate institutional expectations. Additionally, the EMR system was enhanced to facilitate the process of test results acknowledgement. This includes configuring a forced function to acknowledge all open results before discharge, automatically tagging clinical results to a nominated resident physician and above to ensure accountability, and setting up an in-basket message drop-off as well as an out-of-office functionality to prevent alert fatigue and reduce the risk of results from being missed.

Table 1. Top clinical risks (year 2019) past years' trends

	Risk	CY2016		CY2017		CY2018		CY2019	
		Count	Score	Count	Score	Count	Score	Count	Score
C1	Patient Fall	235	8.91	276	11.83	343	11.91	322	8.84
C2	Results not reviewed / Delayed	8	16	5	9.6	11	7.64	4	6.5
C3	Non-Compliance to SOP	126	8.6	113	8.84	108	10.25	116	6.78
C4	Medication related (Wrong dosage/ strength/ frequency/ rate)	38	8.92	41	7.98	59	8.44	26	5.85
C5	Inadequate Skills or Knowledge	123	11.67	125	11.71	79	8.09	78	7.77
C6	Patient Misidentification	80	8.59	69	5.88	76	6.23	66	6.82
C7	Diagnosis and Treatment-Related	-	-	-	-	31	11.23	17	7.94

Legend			
Low Risk	Medium Risk	High Risk	Extreme Risk

As part of quality assurance, a system audit was conducted to ascertain if appropriate follow-up took place. Control self-assessments (CSA) on results management conducted in 2019 also revealed a high level of awareness among clinicians in acknowledging results within the stipulated timeframe of 14 days. Out of the 150 clinicians (with the position of Associate Consultant and above) who responded to the 2019 CSA, 149 (99%) indicated that they were aware that all clinical results must be acknowledged within 14 days. Furthermore, all clinical department heads responded that an orientation program was already in place to ensure that all clinicians are aware of the 14 days' timeframe to acknowledge clinical results. With consistent efforts in raising awareness of the process of clinical test results acknowledgement while

simultaneously implementing systemic improvements, the number of significant clinical incidents resulting from the missed and delayed acknowledgements of clinical test results as well as the corresponding risk score declined over the past four years (see Figure 3). Subsequently, results management was dropped out of the list of top clinical risks in 2020. Nevertheless, the risk trend continues to be monitored by the risk team.

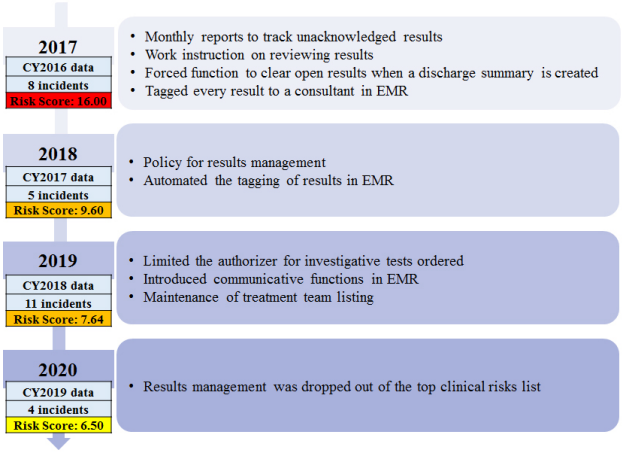

Figure 3. Timeline for managing the workflow of results management

3.2.2 *Staff inadequate skills and knowledge*

Staff inadequate skills and knowledge have led to several types of clinical incidents such as medication errors, diagnostic errors, and delays in escalation. Risk mitigation strategies were devised to equip staff with relevant clinical competencies to reduce the recurrence of similar incidents. Institutional and departmental protocols were formulated to guide staff in their daily operations while annual checks were carried out to ascertain staff competency. A drug dilution chart was also placed at the Emergency Department for reference to prevent medication error. To upkeep staff risk awareness and attitude, past cases from the repository were shared during department meetings and workshops on recognising patient deterioration, and the JHC escalation protocol were organised. Over the years, the number of clinical incidents attributable to inadequate skills and knowledge reduced tremendously. Following this optimistic trend of the decreasing number of incidents as well as severity for most of the incidents, existing controls continue to be monitored by the risk team (see Figure 4).

4. Discussion

4.1 Effective and efficient

Overall, since the implementation of the clinical risk management framework in 2017, most of the top clinical risks identified previously saw a reduction in the number of reported incidents. Moreover, the corresponding risk scores either decreased or remained stable over the years.

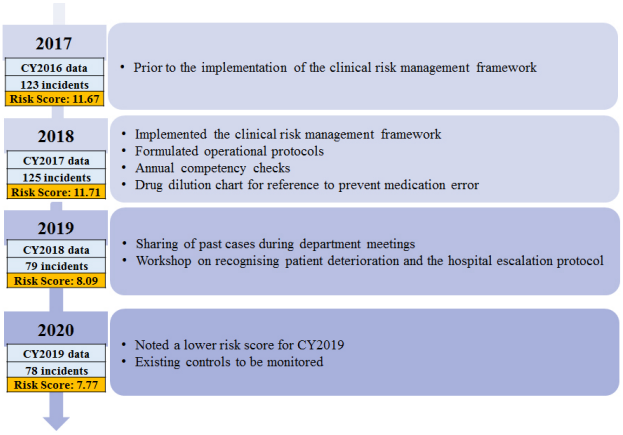

Figure 4. Timeline for managing staff inadequate skills and knowledge

Before the implementation of the clinical risk management framework, top clinical risks were identified and assessed based on the number of incidents. Thematic issues were then identified through individual judgement, without much appraisal clinically from external sources. Without an appropriate quantitative scoring system, the severity and likelihood levels assigned to clinical risks were prone to over and under-inflation. Hence, it was difficult to accurately prioritise top clinical risks and select which ones to focus on. A clinical risk with a high rate of incidence could be identified as a top clinical risk, even if it has a low clinical impact which may not be of concern to the JHC. Likewise, a clinical risk with a low number of incidents, but with the potential to cause significant harm could be easily overlooked. In such an instance, the JHC would miss the opportunity to identify a possible emerging clinical risk and subsequently, miss the opportunity to take action before the clinical risk leads to further, significant harm to the JHC.

Additionally, the newly implemented framework adds a layer of subjective evaluation, on top of objective evaluation, which cross-refers to external sources, usually from the Ministry of Health's reports of major clinical incidents, court judgements and the Singapore Medical Council's disciplinary tribunal judgements. In this manner, instead of relying on the subjective judgement of the risk team, top clinical risks can be appraised for clinical significance more accurately so that the JHC can best allocate resources to counter them. Having both objective and subjective evaluations allow the JHC to assess clinical risks more holistically, thus providing a more balanced understanding of its clinical impact.

Furthermore, before the implementation of the framework, thematic issues were identified and presented, with no structured timeline to monitor the clinical risk progress. No proper workflow was established to follow through with respective risk owners to devise plans to prevent the recurrence of adverse incidents. The framework provides the JHC with a systematic workflow to analyse, prioritise and manage clinical risks comprehensively and efficiently. By assigning top clinical risks to specific risk owners, the framework ensures accountability in staff to take necessary action. The annual risk review cycle also ensures that the workflow progresses by providing a timeline for mitigating controls to be proposed, implemented and reviewed. The newly implemented framework encompasses QRM, which allows for a more responsive reaction. If need be, more controls can be implemented or the controls can be enhanced to better curtail the clinical risk. Nonetheless, there needs to be a balance in the interventions stemming from the framework; While the JHC strives to be quick in responding to clinical risks, it is essential not to introduce too many changes too frequently to combat the unremitting wave of clinical incidents. Otherwise, it can result in staff fatigue and confusion, which may counter-intuitively, undermine patient safety.

On top of aggregating the clinical incident types to observe the overall risk trends, it is equally worthwhile to understand the root causes as well. For example, non-compliance to Standard Operating Procedures (SOP) was identified as a top clinical risk in 2017. Thereafter, an RCA for SOP non-compliance revealed negligence rooting from staff attitude and personality as one of the root causes. Thus, by diving deeper into a clinical incident by exploring its root cause, thematic matters such as organisational culture issues can be exposed for a better understanding of the risk climate in the JHC.[16–18]

4.2 Looking ahead and anticipating emerging risks

Before the implementation of the framework, the JHC was vulnerable to emerging clinical risks which could eventually cause significant harm, insidiously or suddenly. A key trait of the framework is that it addresses both existing and emerging risks; clinical risk data collected comprise both reactive (through IRIS) and proactive (through horizon scanning) sources. Through horizon scanning, emerging clinical risks can be quickly identified and managed before an incident happens.[19] This would not be possible if JHC solely relied on retrospective risk analysis. For instance, when the COVID-19 pandemic fuelled the adoption of telehealth options, the risk team saw the use of telemedicine as a possible emerging risk. Desktop research was performed to identify potential risks associated with the use of telemedicine. These include reduced continuity of care, diagnostic errors, delay of care, and breach of data security.[20–22] To ensure that these risks do not inflict any harm to the patients, the Telemedicine Committee was engaged to verify that risk mitigation strategies are in place to manage these identified potential risks. Ultimately, horizon scanning is imperative in detecting clinical risks early and ensuring that risk mitigation strategies are in place before an incident happens.

The advantages and drawbacks of utilising both prospective and retrospective risk methods simultaneously, complement one another, culminating in enhanced clinical risk management.[7] Undoubtedly, the clinical risk trends show very promising results under the scope and management of the framework. With reducing risk scores and frequencies observed for many of the clinical incident types and root causes, the framework employed by the JHC is observed to be effective in managing clinical risks.

4.3 Areas for improvement

Due to the subjectivity inherent in SAC score assessments, the scoring criteria can be improved. From the onset, once a clinical incident occurs, respective process owners are tasked to draft and submit clinical investigation reports which entail the SAC score. However, there are no fixed criteria to judge and assign a SAC score that is consistent across the JHC. Although the perception of the severity of a clinical incident is approximately the same across departments, the judgement for the likelihood of the clinical incident usually differs based on the evaluator's experience.[23,24] Hence, the same clinical incident could be assigned to a different SAC score. To improve this process, in collaboration with the clinical departments, a fixed criterion can be drafted, specific to each of the clinical incident types, to work toward a more reliable risk evaluation of clinical incidents.

Moreover, risk identification has also been largely a top-down approach where the risk team plays a critical role in coordinating the workflow from start to end. Ideally, the respective department staff should be engaged and trained to identify clinical risks for a more holistic review. Not only will this foster accountability at the department level, but it will also accelerate the workflow as clinical investigations and reports can be completed from the ground up.

5. Conclusion

Clinical risk management will always remain highly important and relevant to healthcare. The systematic workflow of the framework allows the JHC to manage risks comprehensively and efficiently. The clinical risk management framework employed by the JHC utilises both retrospective and prospective risk analyses to fully scope and respond to var-

ious clinical risks that can harm the hospital, its staff, and patients seeking medical attention at the JHC. While retrospective risk analysis examines and reacts to reported clinical incidents within the JHC, amidst volatile circumstances and advancement of technology exposing unprecedented risks in healthcare, prospective risk analysis conducted through horizon scanning is useful in anticipating and acting before harm arises, ultimately resulting in improved patient safety.

CONFLICTS OF INTEREST DISCLOSURE

The authors declare no conflicts of interest.

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