

BMJ Open Quality **Lean thinking: using 6S and visual management for efficient adverse event closure**

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ABSTRACT

Background We focused on a busy Adult Oncology Department having over 130 staff members, with around 70 of them being physicians with different levels of specialties. A multidisciplinary committee was formed in the department, consisting of physicians, nurses, pharmacists, a medication safety representative and a quality specialist to look after all reported incidents.

Local problem The department staff at the institution in question in this study expressed their concern about the surging number of reported incidents, delays in closing reports within the set timeframe, ambiguity of individuals' roles at the committee level and errors in using the safety reporting system (SRS). Accordingly, this study focused on the development of a visual aid through the creation of a functional process map to help clarify team roles and stipulate the steps for adverse event closure.

Methods The Sort, Set-in order, Shine, Standardise, Sustain and Safety and visual management lean principles, as well as the eight lean wastes—Transportation, Inventory, Motion, Waiting, Overprocessing, Overproduction, Defect and Staff underutilisation—were introduced in early May 2016 and used during SRS committee meetings over 3 years.

Intervention The indicators used were the average number of days for both medication and non-medication incidents from the day of reporting until the closure. The extent that the limit was exceeded was compared.

Results The average number of days until closure showed a reduction from 67 to 37 and 134 to 61 between Periods I (2016) and III (2018) for medication and non-medication incidents, respectively.

Conclusions The developed process map was a useful communication tool. It helped to sort process activities, team roles and streamline the process. It brought the average number of days until closure within the acceptable 45-day limit for medication incidents. Thus, using visual aids in the working environment is helpful in improving communication among the workers.

INTRODUCTION

Our institution is one of the largest healthcare systems in the country. It has 2 academic medical centres affiliated with 2 tertiary hospitals, 3 secondary care hospitals with more than 1500 beds and 10 of primary care centres. This operational improvement project in the central region was conducted in an oncology department—a high-risk and high-cost arena

for any healthcare system. The institution uses the National Coordination Council for Medication Error Reporting and Prevention Index Categorisation to establish the level of harm for each incident ([figure 1](#)).¹ These incidents, which could lead to injury, loss of functionality or even death,² are categorised from (A) through (I). (A) indicates an event that, while seemingly insignificant, has the potential to cause an error; and (I) indicates an event that is catastrophic, leading to death. The institution has fostered a blame-free environment. The main corporate quality and patient safety (QPS) department introduced the just/accountability culture policy. It has provided training to front-line staff and unit managers (liaison officers) in using the electronic safety reporting system (SRS) to encourage them to report incidents in which they were involved directly or as an eyewitness within 24 hours.² The pace of corrective action depends on two significant factors: (1) the following of the technical process to communicate the adverse event to higher management in either paper or electronic form and (2) the speed at which the adverse event is discussed, factual findings disclosed, and results communicated to concerned parties.

Problem description

The departmental staff raised concerns about the surging number of reported incidents, inability to close reports within the set timeframe, and ambiguity of individuals' roles at the committee level. Moreover, the generated lists of adverse events were not fresh; usually prepared 24 hours in advance. They failed to reflect events that could have occurred moments before meeting commencement. Further, committee members were not adequately documenting the meeting conclusions in the SRS. The conclusions were either not followed up or not closed within the specified timeframe. All these contributing factors led the committee to exceed the 10–45 days adverse event closure timeframe established by the QPS department.



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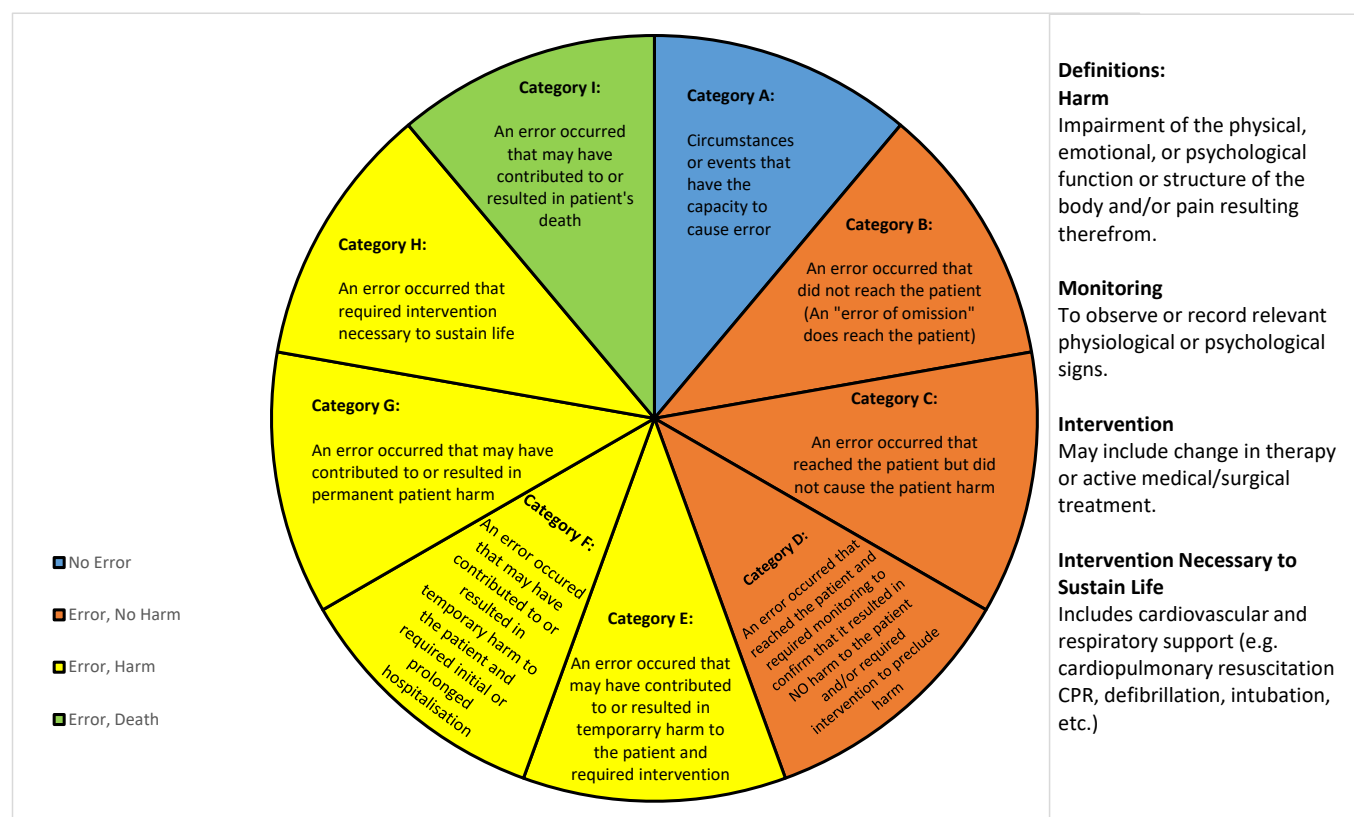


Figure 1 National Coordination Council for Medication Error Report Prioritisation index for categorising medication errors. CPR, cardiopulmonary resuscitation.

Available knowledge

Owing to role ambiguity at the committee level, meetings to discuss committed errors can be stressful. Departmental representatives do their best to shift the blame to others, which distracts their focus from tackling the issues and ensuring they are not repeated. Since committee members' roles are not clearly defined, there emerged a pattern of the average time for adverse event closure remarkably exceeding the 45-day limit. Furthermore, the distribution of printed papers exposing confidential information about patients as well as reported incidents was problematic.

Incidents are events that are often unexpected or accidental and deviate from the traditional standard operations or care.³ Per the American Board of Professional Liability Attorneys, an incident is equated with medical malpractice 'when a hospital, doctor, or another healthcare professional, through a negligent act or omission, causes an injury to a patient. The negligence might be the result of errors in diagnosis, treatment, aftercare or healthcare management'.⁴ In addition to the severity of adverse events, where the majority of them are preventable.⁵ The cost of medical practice has been surging year after year. This has prompted healthcare leaders to base their institutional strategies on better utilisation of available resources.⁶ Owing to their level of experience and the time they have spent in the medical field, healthcare workers can consider themselves above the need to be

reminded of their daily activities or be questioned about their delegation of work.⁷ Further, overlapping activities within a single process can create considerable uncertainty.⁷ Therefore, efforts are required to avoid confusion, which has been identified as the main issue hindering healthcare workers from doing their work satisfactorily.⁷

Articles published over the past 5 years have cited the importance of using lean thinking as an improvement approach in the healthcare industry.^{6 8–10} The benefits of the application of lean thinking are not restricted to front-line staff; it has helped create more influential leaders by making meetings more productive and efficient.⁷ Lean thinking is a cultural phenomenon rather than a set of tools and techniques; thus, healthcare leaders must be the driving force shaping a comprehensive lean orientation.⁶ As an improvement methodology, the lean philosophy has two primary elements: (1) it is data driven, with the processes focused per end-user needs and (2) it involves respect for the people delivering the service. The main goal of lean thinking is to improve customer value by designing systems and processes without waste, delay or errors.¹¹

Young and McClean proposed a framework to define value in healthcare per the following dimensions: (1) clinical, which refers to delivering effective care that achieves the best medical outcome; (2) operational, which refers to the effectiveness of care relative to cost and (3) experiential, which refers to how patients

perceive the care they receive, interaction with staff, and the care environment.¹¹ Several case studies in the health-care industry have demonstrated that lean principles are successful in cutting costs, reducing wait times and redesigning the process around patient-centred care dimensions for better outcomes.⁶ For example, in addition to the reduction in paperwork, better team communication, and decreased inpatient length of stay, a study at a well-recognised National Health System hospital showed a 36% mortality reduction after the introduction of the lean thinking culture.⁸

Rationale and specific aims

One of the lean principles vital to this project was visual management (VM). This is because the vast majority of information is negotiated using a functional process map, which makes it easy to visualise the standardisation of the process and sort roles among committee members.⁸ This paper explores how integrating the lean principles (Sort, Set-in-order, Shine, Standardise, Sustain, and Safety (6S) and VM) and the eight wastes Transportation, Inventory, Motion, Waiting, Overprocessing, Overproduction, Defect and Staff underutilisation, as defined by Liker⁸ at the meeting level, has helped rectify these issues and improve committee performance from an operational perspective. The case sheds light on over 3 years of observation, data comparison and committee members' feedback.

The main goal of this project was to establish a factual and reliable systematic management review process at the departmental level that aids in (1) managing meetings more efficiently; (2) standardising the process; (3) identifying and eliminating non-value-added activities and (4) based on severity, bringing down the average days taken for the closure of adverse events within the policy range. This newly developed visual functional process map (figure 2), as well as the policy drafted around it, could impact system-wide patient safety when handling such reported incidents.

METHODS

Context

The SRS data from January to April 2016 period I (figure 3A,B) formed the baseline as this was the period when departmental stakeholders held a meeting about possible improvements resulting from the use of the lean principles and theory of wastes as an operational improvement approach at the committee level. This was subsequently put into effect in May 2016. The year was split into three periods of 4 months each: period I (January–April), period II (May–August) and period III (September–December), with period I from 2016 serving as the baseline (figure 3).

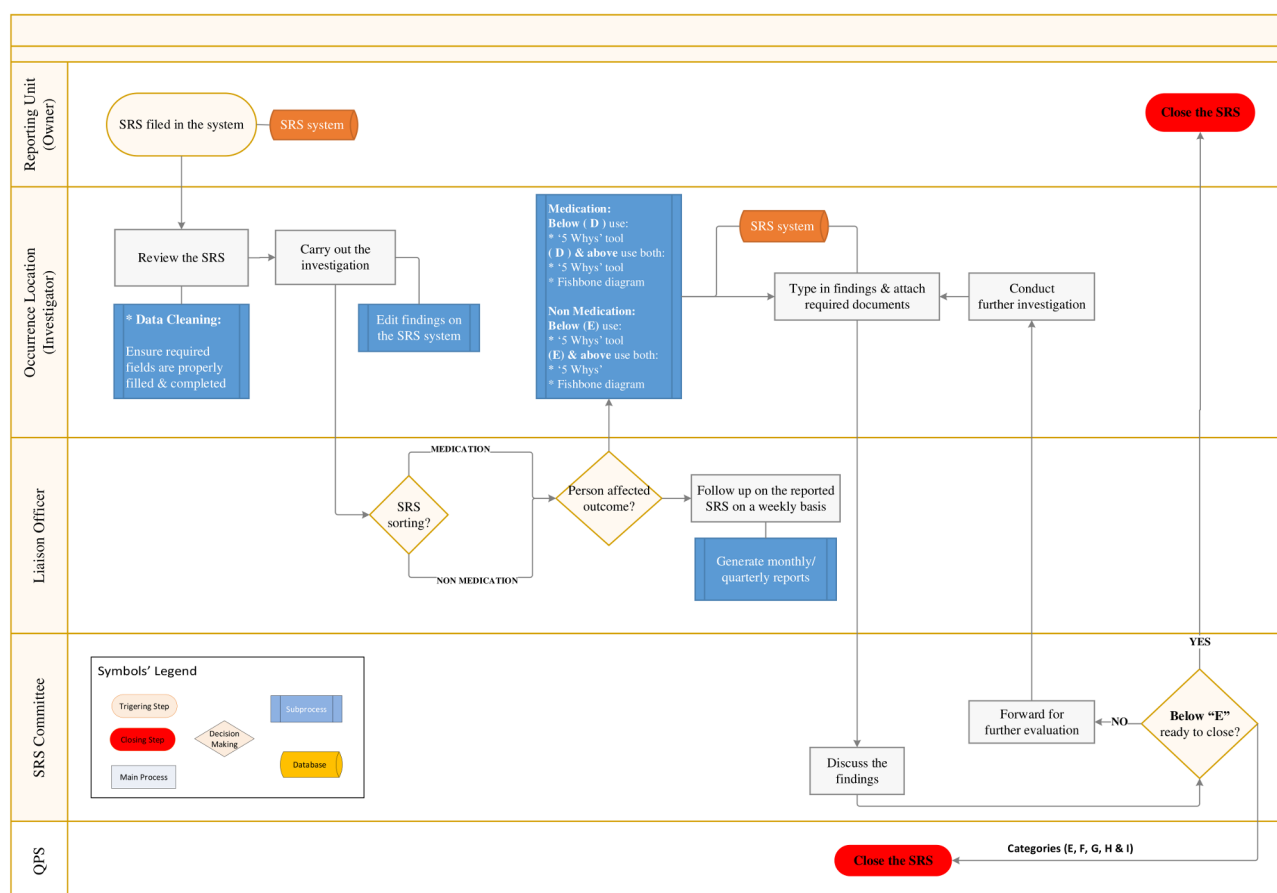


Figure 2 Functional process map. SRS, safety reporting system; QPS, quality and patient safety.

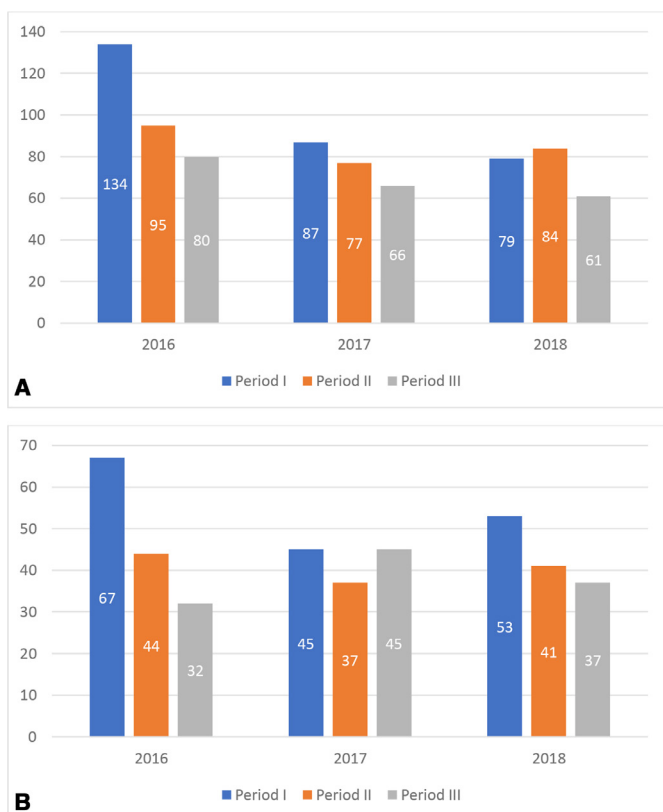


Figure 3 Average closure days for medication and non-medication incidents throughout the periods over the years.

Intervention

After reviewing the established institutional policy, the autogenerated indicator of average closure days was chosen from the SRS. In period I for 2016, the average time for the closure of reported medication incidents was 67 days, while that for non-medication incidents was 134 days (figure 3). The overall closure compliance percentile per the 45-day set forth policy in 2016 was 87% and 60% for medication and non-medication events, respectively; while the longest time taken for closure of medication and non-medication events was 523 and 820 days, respectively (figure 4). Meetings were generally held every week. However, this could change if the committee chairperson or most representatives could not

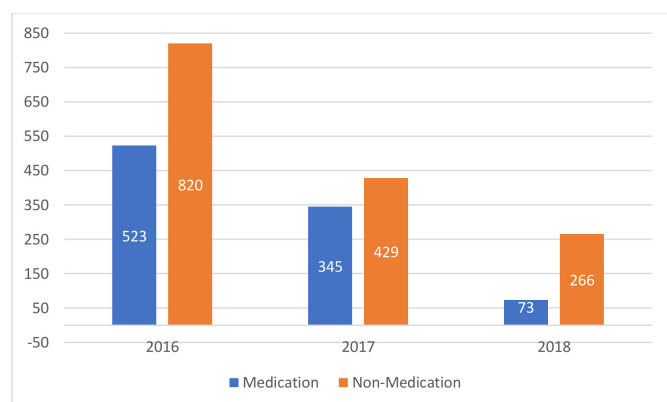


Figure 4 Decline in maximum closure days for the non-medication and medication groups over a 3-year period.

attend for whatever reason. An interesting finding is that each committee representative defined the process activities from his/her perspective, creating confusion about what the next step should be.

Study of the intervention

The following implementation approach was followed: (1) observation, (2) current process analysis, (3) identification of business goals, (4) process redesign, (5) testing the new process and (6) regular repetition and control.⁹

Observation and current process analysis steps

The departmental committee comprises four physicians, seven nursing practitioners, four pharmacists, one quality management specialist and one administrative assistant. I joined the committee in late 2015, and after attending several meetings, presented some observations to the departmental stakeholders—departmental chairman and deputy chairman for QPS—summarised as follows: the lack of a systematic review process for adverse events; ambiguity regarding committee members' roles; the disuse of the 62-inch flat screen monitor in the conference room for the examination of adverse events; and the reams of printed notes from the previous meeting, exceeding 100 pages. All institutional departments rely on reports generated by the main QPS, which manages all adverse events across the system. The trained liaison officers at the departmental levels across the system are not invested in generating these reports independently. These reasons made the process inefficient. I made these observations per the eight wastes.¹²

Identification of business goal step

The main goal was explained clearly to all participants as stated previously under rational and specific aims. I proposed the 6S lean principle as a quality improvement methodology for this project.^{8 13} The 6S is known for itemising and organising the workplace; however, for this project, I decided to use it for (1) introducing a new improvement methodology instead of the traditional continual improvement cycle (Plan-Do-Study-Act) and (2) observing its application at the meeting management level, especially in the absence of a standardised process.

Process redesign and testing steps

I was new to the committee, and it was not easy to convince the members about the need for change. Moreover, none of them had used the lean principle as an improvement methodology. Thus, after obtaining the support of the key players (committee chairperson and departmental quality specialist), followed by the stakeholders (departmental chairman and deputy chairman for QPS), I introduced the new functional process map, tested it, and obtained feedback from the committee members.

Regular repetition and control step

I delivered several educational sessions about the lean principles to the committee members. I also presented the new functional process map at the beginning of each meeting

Table 1 6S lean principles

Phase	Item/s
Sort	<ul style="list-style-type: none"> ▶ Newness of the SRS. ▶ Lack of focused training for the liaison officer ➔ (Defect and Staff underutilisation). ▶ Flat screen monitor ➔ Value-added, 'Not used'. ▶ Lack of definition of members' roles in the committee ➔ (Defect). ▶ Absence of a built-in report template in the SRS ➔ (Waiting and Defect). ▶ Overabundance of printed meeting minutes to review cases ➔ (Overprocessing and Overproduction).
Set	<ul style="list-style-type: none"> ✓ Create an orientation checklist to conduct full training/facilitate understanding of all items in the SRS (online supplemental appendix). ✓ Create a functional process map (figure 2). ✓ Create the required departmental report templates. ✓ Create a tracking log and conduct reviews through the flat screen monitor.
Shine	<ul style="list-style-type: none"> ▶ Communicate the new process to committee members. ▶ Solicit members' feedback and perform Plan-Do-Check-Act whenever needed.
Standardise	<ul style="list-style-type: none"> ▶ Execute the final process for each meeting and ensure changes are understood and followed per the planned process map.
Sustain	<ul style="list-style-type: none"> ✓ Create a departmental policy and procedure to sustain gains and monitor compliance.
Safety	<ul style="list-style-type: none"> ❖ Cases' confidentiality maintained through direct documentation over the SRS.

6S, Sort, Set-in-order, Shine, Standardise, Sustain, and Safety; SRS, safety reporting system.

and reminded them to adhere to the roles of each. When changes got accepted and were understood by all members, a new detailed policy was drafted against the new process, we obtained the necessary approval, and communicated with them.

Measure

The SRS has many autogenerated measurable indicators; the indicator comparing average closure days for the specified periods was chosen to ensure that the policy target of 10–45 days was met.

Analysis

The observations were listed in the sort phase, with each type of waste identified as mentioned (table 1). For example, the lack of a well-trained departmental liaison officer was categorised under 'Defect' and 'Staff underutilisation', and the lack of a functional process map was categorised under 'Defect'. In the first case, the conclusion derived was that the department was relying on the main QPS for periodic reports. In the second case, the committee members' roles were not defined clearly. Thus, a process map for the time's ongoing process was drafted. Subsequently, a checklist addressing the non-value-added activities identified in the process was created in the sort phase. The proposed corrective actions using the most common quality tools: a flow chart, track sheet, fishbone diagram, and five whys, were developed and explained to tackle these defects and listed in the set-in-order phase. For example, to address the 'lack of focused training for the liaison officer' in the sort phase, which was categorised under 'defect' and 'staff underutilisation' types of waste, an orientation checklist to conduct comprehensive training about all items in the SRS was created and

incorporated in the drafted departmental policy (online supplemental appendix). Further, the required departmental report templates were created under the SRS's departmental account as well as the related wards operating under oncology, eliminating the need for periodic report requests from the main QPS. This initiative tackled the 'waiting' and 'defect' types of waste in the process. In another example, 'undefined members' roles', categorised in the Sort phase under 'defect', was tackled by 'creating a functional process map' (figure 2) in the set-in-order phase, which explicitly defined the roles of reporting unit 'owner', occurrence location 'investigator', liaison officer, SRS committee and the main QPS in the departmental policy. Furthermore, an overabundance of printed meeting minutes to review cases was categorised under 'overprocessing' and 'overproduction', subsequently addressed by 'creating a tracking log' containing nothing but the required information without disclosing incident details. The review of the reported incident was to be conducted as a group through the flat screen monitor, as stated in the set-in-order phase.

RESULTS

Per the data retrieved from the SRS, a gradual annual decline in average closure days was observed and monitored throughout the 3 years: 2016, 2017 and 2018 (figure 3). The average number of days until closure for non-medication incidents reduced from 134 in period I (2016) to 61 in period III (2018), which represents a reduction of over 54% (figure 3B). The average number of days until closure for medication incidents reduced from 67 in period I (2016) to 37 in period III (2018), which represents a reduction of almost 45% (figure 3A).



The average days until closure for the non-medication incidents group was impacted. It exceeded the 45-day limit owing to the need for additional reported incident forms (such as skin/tissue and fall incidents), which are discussed by those in nursing service because these types of incidents are not a part of the department of oncology committee agenda. The closure compliance within the 45-day established policy was improved for the medication group from 87% at baseline in 2016 to 92% and 94% in 2017 and 2018, respectively. For the non-medication group, the closure compliance was improved from 60% at baseline to 73% in both 2017 and 2018. Compared with the baseline, there was a decline in maximum closure days for the medication group from 523 to 73, which represents an 86% reduction, at the end of 2018; while, in the non-medication group, the decline was from 820 to 266, which represents a 68% reduction (figure 4). In addition to the approved governing departmental policy, which mandated compliance by staff members, the results demonstrate that the functional process map played a vital role in sorting out functions among the team and improved the management of reported incidents. The functional process map acted as a self-regulating visual representation of tasks among the committee members, helping them answer the questions of 'who', 'what', 'where' and 'when'. Communication among the committee members improved, with a shared focus on how to improve the process as well as patient care. A one-page survey of six questionnaires was administered to the committee members a year later to sense their perceptions of the lean principle methodology used and solicit their feedback about the changes. Primary members who had used the principles (6S and VM) as a model for similar meetings in other departments provided positive feedback (table 2).

In January 2018, when the team members seemed to thoroughly understand their roles, to ensure the prioritisation of patient care, the weekly meetings reduced by 50% for the next 12 months to a biweekly frequency. This reduction in the number of meetings helped restore healthcare professionals' direct patient care skills.

The data from a review conducted in early 2019 supported scheduling committee meetings once a month instead of twice and reducing the number of meetings by a further 50% annually based on the severity of reported incidents, without jeopardising the efficiency of the streamlined process. Undoubtedly, the departmental policy centred around the visual functional process map has played a significant role in the achieved improvement, which became a comprehensive regulatory reference for the SRS committee members. The drafted policy was ultimately used to sustain the gains. Using the policy as a reference has helped committee members use the SRS as a communication platform from their offices and reduce the number of meetings to the bare minimum.

DISCUSSION

Summary

Using VM represented in the functional process map helped the committee members to understand their roles during the incident reporting processes. The functional process map cleared ambiguity among the team members. It also enabled them to show up without stress at meetings with an ultimate focus to improve processes for the best interest of patient care. The development of team spirit among the committee members as well as the understanding regarding when and how it is appropriate to get involved in a reported incident has contributed immensely in ensuring a vast majority of incident closures within the specified 45-day time frame policy.

Interpretation

Introducing a new methodology is usually unlikely to be welcomed by the staff. Thus, the six-step implementation approach described in this paper can help ease resistance to lean principles, helping streamline the process for the closure of adverse events.¹⁴ In this study, the functional process map helped the committee members to visualise all the steps of reviewing the reported incident on one page. Furthermore, the approved departmental policy drafted around the functional process map has clearly stated the compliance requirements by the committee

Table 2 Samples of feedback received through a survey question: 'How do you think the departmental SRS process map would be beneficial for other departments?'

'Their systematic way of dealing with incidents and teamwork could be a model for other departments' Medication Safety Officer representative.

'The oncology SRS process map should be shared with all departments to facilitate feedback and improve interdepartmental communication' Manager of Nurse Service representative.

'It would be beneficial by facilitating teamwork and ending the culture of blaming others, thinking of ways to improve the system instead' Departmental Quality Specialist representative.

'It would be beneficial in enhancing communication between departments, accelerating the resolution of pending and trending incidents' Pharmaceutical Service representative.

'It provides the opportunity to explore other resolution methods to incidents. It also helps in tracking trending incidents' Manager of Nurse Service representative.

SRS, safety reporting system.

members. Therefore, the project has improved staff satisfaction, teamwork, and communication, and also improved operations, which indirectly affects the cost toward patient-centred care.

In this regard, it is important to note that to ensure any project's sustainability, lean six sigma practitioners should obtain approval for a governing policy with embedded monitored measures as the final control stage. After project completion, ensuring compliance with the approved policy should be the responsibility of the project scope's owner.

Regarding some of the reported incident forms (eg, skin/tissue and fall incidents) being discussed by other committees, the main QPS made an amendment in the system-wide policy such that incidents of categories 'E' and above must be closed by them. These two factors contributed to some of the incidents exceeding the 45-day closure limit.

The main QPS also introduced initiatives to communicate periodic quarterly reports to all the departments throughout the system; however, owing to staffing issues, this initiative could not be sustained. In this regard, recommendations to the QPS can be made to ensure the ultimate benefit of a system-wide project improvement in terms of operation, staff satisfaction and patient-centred care. It is necessary to (1) procure the visual process map and the developed departmental policy and procedure, which each department can use as a model with limited customisation; (2) create folders per the specialty or service lines for the most required reports; (3) direct all correspondence relating to departmental incidents to a well-trained non-medical liaison coordinator, who works closely with the liaison officer at the departmental level, to ensure compliance before closure and (4) enforce periodic renewal of the certificate of online training on SRS use.

Limitations

The project was conducted at one department within an extensive healthcare system, thus complicating the process of ensuring liaison officers' compliance with the proper closures. To meet the appropriate closure criteria, there are specific incident details that need to be entered in the SRS to enable statistical analysis. While the committee members received several educational sessions on proper closure, non-compliance was not eliminated. Certain incidents were substantial enough to attract the attention of the departmental stakeholders and committee members, such as changes in incident severity level from 'I' (a catastrophic event) to 'A' or 'B' (an insignificant event) (figure 1), without documenting the proper justification in the SRS database.

There were several efforts to help committee members efficiently use the quality tools specified in the functional process map. However, few could master these tools and use them when presenting adverse event findings. This poor usage can be attributed to (1) computer illiteracy, (2) workload and (3) non-use in daily tasks.

In addition to the recent policy change requiring categories 'E' and above to be closed only by the main QPS team, these factors impacted results in some periods. It led to recorded closure days that were on the borderline or slightly exceeded the limit, especially for medication, which is stakeholders' central focus.

The lean principles helped streamline the process from an operational perspective. However, most of the issues observed in the annual departmental reports remained, such as the default timeframe for prescribed medication being set to 28 days. The justification given to the committee was that the electronic health system, where changes could not be customised to the department in question, was restrictive. The ensuing redundancy, with the same types of incidents being reported in different forms without any resolution, could lead to physicians being penalised for system errors while the committee members blamed the electronic health record system's custodian for inadequate management. This vicious cycle, if allowed to continue, would consume the whole system.

CONCLUSION

It is human nature to be resistant to change. The decentralisation of authority is a product of the lean organisation culture, which is an outcome of the new roles and responsibilities of healthcare professionals. However, this has led to challenges in lean implementation.¹⁰ Dealing with healthcare professionals, particularly physicians, is not an easy task for lean six sigma practitioners. For the past two decades, lean principles have proved efficient in the context of patient-centred care, improving safety as well as satisfaction. Therefore, it is advisable that healthcare leaders use the lean culture as a management philosophy and core strategy in the total quality management programme.

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