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## Abstract

Researchers have established that health care associated infections are much higher in developing countries and a major threat to patient safety. However, The Central Sterilization Supply Department (CSSD) is an out of site out of mind facility, and when things go wrong in there, it has a major negative impact on the entire hospital. The goal of this paper is to focuses on the quality and patient safety improvement in the central sterile supply department of the authors organization. To achieve this goal, the author argues that using the FOCUS- PDSA as a quality framework and Swiss cheese model as patient safety framework will help improve the system and reduce errors. Many changes were done to the CSSD staring by structure and process which ultimately led to a desirable output. The surgical instruments where traced and maintained well and the surgical site infection decreased. The author found that Risks, challenges, and cost will arise, but senior management must commit to quality if things are to change.

Keywords: Patient Safety; Sterilization; Impact; EBP

## **Introduction and Discussion**

There are a wide variety of quality improvement methodologies, approaches, and tools, many of which share some basic principles, including a focus on: understanding the problem, processes and systems within organizations, analyzing the service, involving staff and patients and evaluating and measuring the effect of a change. Regardless of the method used or how change is applied, including leader-ship, clinicians and financial resources is essential [1].

Evidence suggests that operating rooms (OR) are underutilized, and that many patients in need of surgery are not operated upon. While there are many reasons for this underutilization, cancellation of operations on the day of surgery is frequently cited [2]. The average cancelation rate in the author's organization was approximately 15% per month in 2015, as compared to the hospital's standard of 8% per month, primarily for reasons that could have been avoided. Many studies have found that the establishment of a preoperative assessment clinic (PAC) can significantly reduce operating room cancellation rates as well as provide cost savings and positively impact patient health outcomes postoperatively.

The most profitable services a hospital provides are surgical procedures. However, they also represent the greatest cost for any healthcare organization, with the salaries of the OR personnel accounting for the majority of that cost. This high cost is due to the fact that each patient requires several healthcare providers in the OR. This is in addition to the high cost associated with both building a well-appointed OR and then maintaining it. Therefore, looking to increase the utilization of the OR while preventing patient harm and reducing cost is crucial [3,4].

## The importance of evaluation, research and measurement

Evidence based practice (EBP) can be defined as the careful use of the best, most recently available evidence in combination with clinical expertise and patient principles to assist in healthcare decision making [5]. EBP is considered an important aspect of the healthcare

industry today, as it is used to ensure the delivery of standardized, high quality, effective and efficient patient-centric care. It also enables healthcare providers to remain abreast of the most cutting-edge technologies and latest knowledge available in their area of practice [6].

There are multiple models that can be used to assist in the implementation of EBP by healthcare organizations and professionals. Regardless of which model is used, healthcare organizations must understand the characteristics of knowledge and organize that knowledge in the best way possible [7]. To assist in doing so, healthcare organizations could integrate Hayward's "5 A's Cycle" with Sackett's "Hierarchy of Evidence" [8,9], as depicted below in figure 1. Although the pyramid of evidence is extremely appropriate for questions of therapeutic efficacy, many other questions addressed in the medical literature, especially those related to the effectiveness of therapies, find limited or no value in it. Therefore, stakeholders must be involved and decide on the degree to which the study design implemented is appropriate for the questions being asked and their organizational context [10].



Figure 1: The 5 A's Evidence-Based Cycle integrated with Hierarchy of Evidence [8,9].

Implementing research and EBP in any healthcare organization can be challenging. Dealing with complex systems, healthcare providers and leadership ultimately requires a change of culture. With that said, there are some evidence-based strategies that can be used to assist in the implementation of the best EBP, which ultimately promotes improved patient safety practices. These strategies include planning, educating, involving stakeholders, researching, measuring, and evaluating [11].

Evaluation is the process that determines the value and worth of anything [12]. When referring to healthcare evaluation, these values would be compared with acceptable standards to judge any given improvement initiative [13]. Evaluators should understand that different evaluation methods must suit the process, and the sooner that they become involved, the greater the influence they have over data collection, and the broader the spectrum they have to choose from with regards to evaluation design options [1,14].

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A well-designed evaluation is planned in such a way that the data collected will answer any question being asked for any change intervention under evaluation; whether it caused improvements or created problems, how it worked or why it didn't work, who it worked for, and whether it will continue working in the future. Additionally, a well-planned evaluation will secure the engagement of as many stakeholders as possible, as early as possible in the process. This may cause some limitations to arise for the evaluation, such as a tighter timeframe, more effort needed, varying expectations and increased costs both in terms of resources and finances. Therefore, ensuring that the evaluation is integrated in the intervention early enough will eliminate wasted efforts and the lack of reliability as a result of poor or missing evaluation, which may ultimately undermine the effort to improve patient safety [1,14].

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Although the characteristics of evaluation and measurement can be similar, they differ in many ways. Measurement collects data and analyses the outcome of an improved initiative and focuses on the compliance of individuals to policies. This often leads to frustration as workers feel they are being monitored [15]. Evaluation, on the other hand, focuses on data collection to assess effectiveness and efficiency throughout the improvement of structure, process, and outcome [16]. Evaluation is not about monitoring and managing, but rather is about assessing the improvement implemented and its impact on the organization, focusing on making judgments and decisions about how an intervention should carry [1].

Similar to evaluation and measurement, healthcare research is about collecting data, though the aim of data collection is different. It can be defined as the field of scientific analysis that studies how people, behaviors, costs, organizational structures, and processes affect quality and cost of healthcare and eventually patient safety [17]. Figure 2 below shows the similarities and differences between evaluation, measurement, and research. According to Burns and Grove [18], different methodologies can be used to gather data when conducting any research; deductive, inductive or a mixture of both.

- In deductive research, actual numbers are being examined. There is only one truth to the knowledge analyzed and it is objective as the researcher looks at the topic from the outside. The method used for data collection is usually a survey or questionnaire.
- In contrast, inductive research uses observation and analyzes knowledge to theory. Truth here is created by experience and often evolves and changes. The researcher is very much involved and digs deep into the topic of research. The method used is usually interviews or free text in questionnaires, as this gives the opportunity to express feelings.



Figure 2: Venn diagram showing characteristics of evaluation, measurement and research.

# **Problem description**

Cancellation of elective procedures on the day of surgery are inefficient for organizations and patients [19]. In the author's organization, these cancellation rates have reached up to 21% per month in 2015, as can be seen in figure 3 below. The highest surgical service cancellation rates were recorded by orthopedics and general surgery, as shown in figure 4. Data was collected on the reasons for these cancellations and is collated in figure 5. From this data, it was observed that the highest cancellation rate recorded was 34% for patients not showing up on the day of surgery, with the majority listing anxiety as the reason. This was followed by 28% of surgeries being cancelled due to patient's requiring further consultations and investigations of their condition. Other reasons listed were no ICU beds available, patients were not fasting, patients refused surgery and time limit.



Figure 3: Cancellation rate per month for the year 2015.





Figure 5: Demonstrating the reasons for OR cancellation.

Currently in the author's organization, patients are seen the night before surgery by the on- call anesthetist to be evaluated and assessed. Anesthetists face problems with this procedure because the patients are not found in the wards, either because they are simply elsewhere or because they are outpatients. Another issue they may face is that the on-call is busy with emergency surgeries and has no time to evaluate patients at night [23].

Based on the reasons for cancellation, evidence suggests that establishing a PAC can reduce OR cancellations. Not only will it allow patients to be medically examined to see if they are still fit for surgery or need further investigations, but it will also provide them with necessary psychological preparation and thus reduce their fear of surgery. Pamphlets could be distributed to guide them on preoperative preparation including fasting times [19]. This requires an intervention in the service provided to patients undergoing surgery [14].

## Available knowledge

Cancellation of surgical procedures on the day of surgery is a world-wide problem. It is considered the main reason for ineffective utilization of OR time and wasted resources. The excellence of quality management and patient care of a hospital can be measured by the rate of cancellation of elective surgeries. Acceptable rates of cancellation of surgeries in different parts of the world vary from 1% - 30% [34]. The author's organization has a target set at 8% and below.

There are many reasons behind cancellation of elective procedures, some of which are avoidable such as scheduling errors, unavailability of equipment or inadequate pre-operative assessment. In contrast, some reasons for cancellation are unavoidable, such as unexpected changes in a patient's condition, the patient did not show up for surgery or an emergency case overriding the elective case. With that said, many of the causes for cancellation are preventable [2].

A study conducted by McKendrick, Cumming, and Lee [19] proves that the introduction of a PAC reduces the cancellation of scheduled operations, which is contrary to Craig [20] who states that it was uncertain whether PACs reduced the rate of elective surgery cancellations. The author feels that because patients undergoing surgery are seen in the outpatient department months before the actual surgery

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date due to surgeon's long waiting lists, cancellation rates will go down with the establishment of a PAC in the organization as 25% of these patients wouldn't have needed to be scheduled for surgery in the first place had they been examined prior to the day of surgery.

Ferschl., *et al.* [21] conducted a retrospective chart review study on the impact of PAC visits on cancellation rates. They concluded that the visits can significantly impact the cancellations and delays on the date of surgery. Cancellations due to time limit can be related to the delay of scheduled surgery starting times, resulting in a ripple effect on the remaining scheduled surgeries and eventually causing a cancellation in the last scheduled procedure of the day. This would be beneficial to the author's organization as one reason for cancellation is time limit.

There are many arguments regarding the timing of preoperative evaluation and the need for out-patient PAC assessment. However, there is no strong evidence in the literature on the ideal timing for PAC. Usually, patients undergo PAC screening 1–30 days prior to surgery and are admitted the day before their scheduled procedure [22].

Ezike, Amucheazi and Ajuzieoegu [23] concluded in their study that the major problem that anesthetists encounter during the preoperative visit is not finding patients on their beds at the time of evaluation. This contradicts the purpose of pre-operative assessment, which is to ensure that every patient has a suitable and adapted anesthesia plan. It is worth mentioning that more than 70% of patients not in bed were for outpatient surgeries. This problem can be avoided by proper planning and educating patients for day case procedures when seen in the PAC.

## **Rationale and context**

Traditionally, elective surgical patients were admitted to the hospital a day before surgery to go through pre-anesthetic assessment and preoperative preparation. This practice is no longer routine in many parts of the world, due to its lack of cost-effectiveness and high cancellation rates [22].

Using Øvretveit's [14], 5 Questions as a guide to finding the reason behind improving the cancellation rate and proposing the establishment of a PAC, the following can be found.

- What? The evaluators need to evaluate whether there was improvement in the rate of cancellation after the establishment of the PAC, and whether it meets the set target of 8%.
- How much? It would cost the organization an allocated time for a nurse and anesthetist -led clinic.
- Who? Patients and healthcare providers.
- Why? To ensure surgical patients are well prepared for their surgery and postoperative recovery.
- Value? Reducing OR cancellation increases patient satisfaction, optimizes the use of OR staffing and improves OR utilization [23].

#### Objectives for the proposed quality improvement/change intervention

Creating objectives is the foundation for monitoring the implementation of plans and the improvement towards achieving goals as well as the establishment of targets for team liability and are a source for program evaluation questions. They are more immediate than goals, as they set the indicators that organizations need to reach in order to achieve their goals [24,25].

Outcome objectives assist organizations in measuring quantifiable improvements against standard benchmarks. They provide knowledge on where goals exceeded the benchmarks, by how much, and where failures occurred and by how much. Outcome objectives need to be SMART (please refer to table 1), meaning that they are: specific, measurable, achievable, relevant and timely [26].

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#	Outcome Objective	Measurement
1	By the end of March 2016, 80 - 90% of patients scheduled for orthopedic surgery will be seen in the PAC four weeks before surgery date.	OVR's gathered for orthopedic patients not seen divided by total number of orthopedic cases preformed per month.
2	By the end of June 2016, 80 - 90% of patients scheduled for general sur- gery (GS) will be seen in the PAC four weeks before surgery date.	OVR's gathered for GS patients not seen divided by total number of GS cases preformed per month.
3	By the end of September 2016, 80 - 90% of patients scheduled for ENT and urology, will be seen in the PAC four weeks before surgery date.	OVR's gathered for ENT and urology patients not seen divided by total number of ENT and urology cases preformed per month.
4	By the end of December 2016, 80 - 90% of patients scheduled for obstet- rics and neurosurgery, will be seen in the PAC four weeks before surgery date.	OVR's gathered for obstetrics and neurosur- gery patients not seen divided by total number of obstetrics and neurosurgery cases pre- formed per month.
5	By January 2017, 80 - 90% of patients scheduled for surgery will be seen in the PAC four weeks prior to the scheduled surgery date.	The number of cancelled procedures for pa- tients not seen in the PAC divided by the total number of cases preformed per month.

**Table 1:** SMART outcome objectives for improving OR cancellation rate.

# Study, measures and evaluation for the proposed quality improvement/change intervention

It is important for healthcare stakeholders involved in any improvement and evaluation process to understand why it is vital to do so [14]. To assist in doing so, Lazenbatt [27] provides a systematic approach to health evaluation though a cycle consisting of nine states that could well be Donabedian's [28] model of structure, process and outcome (SPO). Applying the evaluation cycle to the author's improvement intervention is demonstrated in figure 6.



Figure 6: Evaluation Cycle of introducing the PAC, (Adapted from [27]).

Comparison is an integral part of an evaluation as it provides feedback. Therefore, data collection and measurement before and after the improvement initiative (e.g., establishment of PAC) allows the comparison of results and assists in the judging and decision-making process [14].

Many studies indicate that a comparative health evaluation design can be used to compare OR cancellation rates before and after the establishment of the PAC and proves that cancellation rates were reduced when patients visited the PAC before undergoing surgery, please refer to figure 7 [19, 21]. In another comparative study, Fischer reported a decrease in the rate of day-of-surgery cancellation from 1.96% in the year before implementation of the PAC to 0.21% in the year following its implementation at the Stanford University Hospital [29].

In order to convince management to establish a PAC, multiple descriptive evaluation designs need to be done on a small scale through evaluation of the SMART objectives. In this way, evaluation of process and measurement of outcome can be conducted after the completion of each objective (i.e., every three months), providing information on whether or not assessing patients before surgery prevents cancellation, and whether more improvements need to be applied to the process. Please refer to figure 8.

Finally, to ensure the improvement is sustained in the future, re-evaluation and measurement need to be done regularly to provide constant feedback on the improved process and implement changes where and when necessary [1].



*Figure 7:* A comparative evaluation design for operation cancellations before and after the establishment of the PAC, (Adapted from [14]).



*Figure 8:* A descriptive evaluation design of orthopedic surgery cancellations before and after being assessed pre-operatively, (Adapted from [14]).

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#### **Ethical Considerations**

It is important for healthcare managers to understand that perspectives on ethical challenges vary depending on the stakeholder's role. Acknowledging these differences can help managers take useful steps to address ethical challenges [30]. Managers can benefit from knowledge available from the evidence-based studies to determine whether their attempt to protect resources as well as promote effective care is accomplished.

A press release by Uppsala University, discussed the ethical issue of cancelling elective surgery from a patient's perspective. They argue that patients who are prepared for surgery and who then have their procedures cancelled, experience significant disappointment. The amount of preparation required of them to re-book a surgery date is exhausting and the psychological preparation they had done for themselves has gone to waste [31].

With that said, to effectively utilize operating rooms by reducing cancellation rates may leave OR personnel feeling rushed. For example, nurses are often pressured to reduce delays between surgeries (turnover time), while physicians are required to see more patients in shorter times, In both cases, staff are left feeling burned out, ultimately compromising their patient's health and satisfaction and leading to medical errors [32].

Ethical considerations need to be acknowledged at all stages of evaluation, from gathering data to sharing the feedback found. Additionally, evaluation involves research, and therefore research ethics must be considered as well at all stages of the evaluation process [13]. Evaluators need to be trustworthy professionals, with no hidden agendas, must avoid being biased and finally, they need to respect the privacy of others involved in the research [33].

# Limitations

The most restrictive factors for implementing a PAC are the lack of resources, both financial and human, to run the clinic. With that said, the advantages and cost effectiveness of establishing a PAC are greater than the lack thereof [22]. Hospital leaders and management must be on board to support a change such as this.

Another disadvantage of assessment in a PAC is that the anesthetists evaluating a patient may not be the same anesthetists responsible for intraoperative anesthetic management and may have a different view, opinion or management style. However, with the establishment of standard clinical guidelines for patient assessment as well as adequate communication (i.e. proper documentation and telephone calls when necessary) safe patient care can be provided [23].

As referenced earlier, Research has shown conflicting evidence for the benefits that a PAC will provide. That in itself is a confounder for proceeding with the proposed intervention at the author's organization. Thus it is essential to intimately implement the PAC on a small scale and conduct extensive evaluation on the data collected.

#### Conclusion

Introducing a PAC in an organization has been shown to be of remarkable benefit for the optimization of patients' conditions, reducing surgical delays and cancellations on the day of operations for numerous reasons, including patients being deemed unfit and/or unprepared for surgery [23]. PAC's can increase operating room productivity on the day of surgery and have a major financial impact on a hospital with a busy operating room [22].

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