Evaluation of Six Sigma Applications in Patient Safety Context

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Abstract
Patient safety is the first and foremost goal, as well as it is a critical issue in the healthcare sector. To ensure achieving this goal, there is a continuous need for quality improvement. Six Sigma is known as one of the most effective improvement technologies widely adopted in healthcare systems that aims to reduce the variation and eliminate the defects. In this study, a systematic review of the literature is carried out to investigate the outcomes of implementing a Six Sigma tool in patient safety applications. The findings proved that applying Six Sigma in healthcare is valuable and useful in solving many raised issues, reduce medication errors, and increase patient safety. This paper provides opportunities, challenges, and techniques to investigate the relationship between Six Sigma and patient safety. The paper presents valuable outcomes for healthcare quality and process improvement managers.

Keywords
Six Sigma; healthcare systems; patient safety; quality improvement; healthcare operations

1. Introduction
Patient safety is considered as one of the critical issues in healthcare (Feng et al. 2008). It is the driving force that pushes healthcare systems to be aware of the importance of developing the systems to assure high-quality services (Nieva and Sorra 2003). Improving safety is useful once the organizations learn from previous experiences, which would be useful in reducing the errors and their consequences (Simsekler et al., 2015a, 2018a). Many of the reported medical errors were considered to be system-related, and those mistakes are costly in terms of human and financial impacts (Pexton 2005; Kurutkan et al., 2015). Furthermore, there is a focus on the care delivery systems that prevent the occurrence of the errors, enhance the learning from them, and built on a safety culture that comprises healthcare professionals, organizations, and patients (Hughes 2016; Simsekler, 2019).

In 1998, the Institute of Medicine (IOM) mentioned in their assessment that around 98,000 patients die annually because of medical errors, highlighting the importance of safety and quality improvement applications (Potters And Kapur 2012; AlKaabi et al., 2019; Simsekler et al., 2018b). Consequently, healthcare organizations started to implement several tools and techniques that are successfully employed in other industries (Marbouh et al., 2020; Simsekler et al., 2015b, 2019a). Six Sigma tool is one of the tools used for robust performance improvement methodologies. The idea of this technique was introduced in the middle of the 1980s by Bill Smith at the Motorola communication division (Antony et al. 2019). It can be said that the start of Six Sigma was not in the healthcare field, but it arises from the manufacturing industry. Later, it caught widespread attention in medical organizations (Antony and Trakulsunti 2018). The technique aims to minimize the variation and overcome the defects within systems (Antony et al. 2019) to guarantee compliance with the critical specifications. The ultimate goal of this optimization technique is to develop and
deliver near-perfect services. This will provide a methodology to measure the process capabilities and the probabilities of error occurrence. Furthermore, as the sigma level increases, the performance of healthcare will increase. Several outcomes of applying a higher sigma level were found to be effective in achieving patient and physician satisfaction, reducing patient waits times, and enhancing the quality of healthcare life (Antony and Trakulsunti 2018).

Six Sigma applies five step-cycle, the DMAIC cycle (Define, Measure, Analyze, Improve, and Control) for quality improvement (Plas, 2017). The strategy of this approach aims to identify the problem and the objectives, define the performance standards, identify the source of variability and influence factors, suggest and implement improvements, and finally develop a validated measurement system (Chan 2004). DMAIC has been successfully implemented in reducing errors. In addition to that, nowadays, there is a persistent need for an action from the healthcare sector to reduce and prevent medication errors; otherwise, the number of patients injured and death by medication errors will continue to increase. The implementation of an appropriate methodology that can handle this issue is one of the successful and favorable plans to minimize those errors. Furthermore, due to the promising results gained from using Six Sigma, it was found that it can play a role as a business strategy in supporting quality improvement by identifying the problem root causes and solving the raised problems (Trakulsunti and Antony, 2018).

So far, several articles present the usage of Six Sigma in healthcare, like patient satisfaction and quality improvement. However, there is a lack of studies that evaluates the usage of Six Sigma in particular patient safety context (Montella, 2016; Çelika, 2016). To shed light on this, we evaluated the use of Six Sigma tools in patient safety context to provide a comprehensive analysis of the application, benefits, and challenges of this technique.

2. Methodology
This literature review in this study was built based on the “snowballing” technique. The way of collecting the data is based on primary and secondary literature search. In snowballing, the citations and reference list of pertinent papers were reviewed to reach to new papers. The selection of this technique was the appropriate way because the use of databases did not yield an appropriate number of articles when using keywords such as ‘applying Six Sigma in healthcare’, ‘Six Sigma in patient safety’ and ‘Six Sigma to overcome medical errors.’ Although the snowballing technique may not be ideal for identifying some pertinent papers, which can be handled by carrying an inclusive start. The reliability and efficiency of this technique are highly rival to other techniques such as database search (Badampudi 2015). The selected papers were analyzed to build up comprehensive review.

3. Literature Review
Six Sigma is considered as one of the most popular business strategies of Continuous Improvement (CI), which is used in several manufacturing and service sectors. By returning to the early 2000s, in Taiwan, a study was conducted to see the effect of the Six Sigma strategy in minimizing dispensing based errors in a pharmacy department (Chan 2004). The responsible team reviewed the data history and recognized an average of 338.8 errors per million prescriptions. The goal of the team was to decrease the defect level to be less than 3.4 errors per million prescriptions monthly; however, it was successful in reducing the errors to 230 per million. Furthermore, in Norwegian public healthcare (Antony et al. 2019) a study was done to see how Lean Six Sigma is effective in reducing medication errors. This study was based on a survey questionnaire and semi-structured interviews with healthcare practitioners.
In a recent study (Trakulsunti and Antony 2018), a project was conducted to determine the necessary changes in policy and practices that might significantly cause a reduction in medical errors such as those that occurred in prescriptions and pharmacy dispensing. The project team reviewed different errors that occurred during the pharmacy medication Order Entry process (OE) to define the possible errors. The process followed by establishing the criteria for error cataloguing by implementing root cause analysis. Another application of Six Sigma was conducted by applying the DMAIC methodology of Six Sigma to promote patient safety in a radiation medicine department (Potters And Kapur 2012). Similarly, in this department, DMAIC was used to define and decrease the number of patients affected by sentinel bacterial infections that may cause a risk of healthcare-associated infections (Montella 2016). In this research, several analyses were used, like Suppliers-Inputs-Process-Outputs-Customers (SIPOC) and the fishbone diagram. This approach leads to identifying the most predominant sentinel bacteria through infected patients.

Patient safety also concentrates on the earliest diagnoses of diseases. A study was done to determine the root causes behind the delays that limit earlier diagnosis of lung cancer (Çelika 2016). Thirteen types of causes were identified by using Six Sigma and relevant approaches, such as Failure Mode and Effect Analysis table (FMEA), SIPOC, and Fishbone diagram. In addition to that, Six Sigma was applied to decrease hemolysis cases in the emergency department (Damato and Rickard 2015). The research findings were compared against best practices to identify the causes of hemolysis. While in (Castle 2005), a study was done to discover and decrease the possible medical errors through home-delivery service. The research encourages the establishment of CI, which would be useful in ensuring that medication errors are minimized in healthcare organizations. A study in 2003 (Plas, 2017) showed that there is an administrative error that occurs in every 36% of parenteral medication administrations. Those administration errors account for about 34% of the errors that raise different drug events, which lead to an increase in the hospitalization days. The error could occur due to the wrong medication dose, wrong time, wrong duration, and errors related to the injection method. Implementing Six Sigma proved that it is an appropriate strategy for quality improvement. It helps in selecting the suitable actions to minimize and overcome errors associated with parenteral medication administration.

In general, the literature proved that the Six Sigma tool had been applied to improve the quality of patient safety by eliminating medical errors and ensuring high standards of safety services. Even though there are several applications of Six Sigma, with useful approaches, there are many challenges that organizations and individuals may face while using Six Sigma as a quality improvement technique. The following section will highlight the opportunities and challenges of the application of Six Sigma techniques in patient safety.

4. Key Findings
4.1 Opportunities
The application of Six Sigma in patient safety yielded several benefits for the healthcare sector. It was useful in reaching the root causes of many different types of errors that may affect patient safety. The results showed that some errors raised from stressful and dissatisfactory work environments (Trakulsunti and Antony 2018). This approach was notified through a patient customer satisfaction survey. Another research was done to investigate the effect of implementing Six Sigma on hospitalization days. The finding showed that Six Sigma was effective in reducing the average number of hospitalization days by 20%. In addition to that, it was efficient in decreasing the number of healthcare-associated infections (HAIs) in patients (Montella 2016). Applying Six Sigma was also effective in declining the delays that lead to late diagnosing of severe disease (Çelika 2016). The total error rate was decreased from 0.33% to 0.14% in less than six
months. This reduction leads to other reductions in labour costs to approximately $550,000 per year. Moreover, the communications and relationships among healthcare organizations were developed. Patient satisfaction was also improved (Anotny and Trakulsunti 2018). Six Sigma was successful in providing an appropriate way for hemolysis reductions house-wide (Damato and Rickard 2015). In the Emergency care centre (ECC), hemolysis reduced from 9.8% to 0.88%, and house-wide hemolysis decreased from 3.4% to 1.39%. Moreover, Six Sigma used for quality improvement methodologies in the Radiology section (Dobranowski and Amaratunga 2016). The results showed the potential of Six Sigma to decrease errors and defects, reduce costs, increase patient safety, and improve quality within radiology systems. The results showed the potential of Six Sigma not only in decreasing medical errors and defects, but also it can reduce costs, increase patient safety, and improve quality within radiology systems. In addition to that, the capability of this tool in enhancing the dispensing medication process. The results showed a decrease in the occurrence of dispensing errors by more than 13% (Chan 2004). In emergency rooms, applying Six Sigma plays a vital role in decreasing the time that the patient spent in taking the medications (Coskun 2010). This procedure will increase the capacities of the emergency department to treat more patients. Furthermore, the patients will move faster to their rooms where they can be more comfortable.

4.2 Challenges
The deployment of Six Sigma in patient safety may face several challenges. Those challenges may struggle with the improvement process and quality management. The lack of Six Sigma coaching and training is one of the main impediments. In an earlier study (Antony et al. 2019), 80% of respondents do not have any idea about CI methodologies such as Six Sigma. Also, among several factors, the need for process improvement methodologies to minimize errors was the highest-ranking factor. Other challenges were presented in the lack of support from top management and the resistance to change from the employee (Chan 2004).

In home-delivery pharmacy service, there were several obstacles like the difficulty of approvals for making changes, the fear of the unknown, and the variations in data collection processes among the pharmacies (Castle 2005). Moreover, one of the main challenges facing this tool and many other tools is the lack of communication skills among the organization stuff (Furterer 2014). There is a need to empower them, engage them in training, improve their skills, so they can effectively and happily do their work. This involvement will push them to innovate and find solutions. Table 1 below summarizes the main benefits and challenges of the Six Sigma tool. The benefits mainly related to the improvement of the techniques that may promote patient health and decrease the defects. On the other hand, the challenges were related to the way of delivering this technique and the difficulties in handling it.

<table>
<thead>
<tr>
<th>Opportunities</th>
<th>Challenges</th>
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<tbody>
<tr>
<td>• Decrease medication errors raised from:</td>
<td>• Lack of coaching and training</td>
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<tr>
<td>▪ Pharmacy dispensing</td>
<td>▪ Lack of top management support</td>
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<tr>
<td>▪ Wrong medication dose</td>
<td>▪ The resistance to change</td>
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<tr>
<td>▪ Stressful work environments</td>
<td>▪ Fear from unknown consequences</td>
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<tr>
<td>• Early disease diagnoses</td>
<td>▪ Teamwork, engagement, and communication (Furterer 2014)</td>
</tr>
<tr>
<td>• Decrease hospitalization days</td>
<td></td>
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<tr>
<td>• Increase quality and patient satisfaction</td>
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5. Discussion
The findings proved the ability of Six Sigma to improve patient safety. The benefits can be classified into two groups based on the earlier studies. The first group is reducing errors that can occur through delivering medication in a hospital or pharmacy through the dispensing medication process. The root causes of those errors were successfully reached by applying different techniques like DMIAC and SIPOC. Some of those errors raised due to the stressful environments and lack of rest. By implementing Six Sigma, solutions may be offered to solve this issue by rescheduling the physician’s duties or hiring new physicians. The second group represents the effectiveness of Six-sigma in enhancing patient safety by promoting early disease diagnosis and improve the quality of services. This step increases the chances of successful treatment, saves lives, and accurate medication services.

On the other side, using Six Sigma would not be successful without the corporation of all healthcare organization members. As presented in Table 1, most of the challenges were raised from the lack of knowledge about the technique due to the lack of training and coaching sessions. The variation in data collection methods is an excellent example of such a case. If the physicians and nurses were trained in recording the errors, this might improve the recording technique. In addition to that, training would increase the self-confidence of the employee. Also, this competency will let them be flexible in accepting changes due to their knowledge about dealing with any sudden change.

The top management bears much responsibility in supporting and arranging training for the employee. So, it can be considered as institutional cooperation to achieve the development of patient safety. In general, working hard to arrange training, educate the employees, and keep communicating are the critical solutions to overcome the raised challenges.

In addition to that, it has been found that the usage of six sigma in patient safety context was mainly centered on three main goals, which are: (1) error reduction, (2) early diagnoses, and (3) safety enhancement. Figure 1 presents the percentage of the usage of the Six Sigma tool according to the earlier studies. It is appearing that most of the usage of six sigma in patient safety was to decrease errors as six sigma can provide opportunities to reduce defects with statistical process control, while the usage of the tool for early diagnoses and safety enhancement are almost the same.
The world is becoming more complex, and many issues are raising, which require specific tools to handle the issues. The Six Sigma tool is successful in solving many raised issues in the healthcare sector in general and patient safety specifically. Due to the need for CI, applying Six Sigma in healthcare will increase and spread widely. Moreover, it will remain as one of the essentials to improve the management process rather than being just a fad (Anbari and Kwaka 2006). It is essential to highlight that the primary focus of using Six Sigma should be to improve overall management performance, not only to search and point on the defects. To enhance the deployment of Six Sigma in different organizations, researchers are working on combining Six Sigma tools with different innovative management practices, potentially through recent disrupting technologies intelligence (Ellahham et al., 2019; Simsekler et al., 2019b). By doing this, the Six Sigma technique may be more attractive to others who have not started implementing it. In general, the future of Six Sigma is expected to be abounding of improved and successful processes not only in healthcare but in many other sectors.

6. Conclusion
Six Sigma is one of the most effective improvement technologies adopted in healthcare organizations to reduce the variation and eliminate the defects. For each error, there is a specific cause that needs to be identified and mitigated. Six Sigma proved its abilities in enhancing patient safety by reaching the core of the errors and finding optimal solutions for them. Thus, Six Sigma is a successful tool in promoting patient safety. The opportunities and challenges of implementing Six Sigma in patient safety will benefit the healthcare organizations in improving their systems. Moreover, it will help in saving the lives by implementing it in earlier diagnoses researches and overcoming the causes of specific diseases, as discussed earlier. Future work is recommended to implement the use of Six Sigma in patient safety widely and to spread the knowledge of improving tools in the health care sector.

Figure 1: Usage of Six Sigma in patient safety context
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