Quality Improvement Projects in Catheterization Laboratories: A Systematic Literature Review

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Abstract

A catheterization laboratory (Cath lab) is a place that has high-tech equipment that mainly allows the diagnosis and treatment of cardiovascular diseases, which represents 31% of all global deaths, according to the World Health Organization. (WHO, 2019) In an attempt to minimize process inefficiencies in Cath Lab, these organizations have been using quality improvement projects such as Six Sigma, Lean Six Sigma, Kaizen events (rapid improvement events), general quality improvement projects (plan-do-check-act) and others. However, there is a lack of publications synthesizing the literature available in this research field (quality improvement project). Therefore, this paper aim is to assess the published literature relating quality improvement projects in Cath labs in three dimensions: publication characteristics, author characteristics, and content characteristics. To achieve the purpose of this research, a systematic literature review (SLR) will be conducted to obtain the most relevant papers from three platforms: EBSCOhost, ProQuest, and Scopus.

Keywords
Quality improvement, catheterization laboratory and systematic literature review.

1. Introduction

Quality improvement is a systematic approach to analyze and improve process performance. There are a wide variety of quality improvement projects, some of the most common approaches or methodologies are:

- General quality improvement (Plan-do-check-act): a four-step process for quality improvement. The first step is developing a plan to effect improvement. In the second step, the plan is carried out on a small scale. The third step is to observe the effects of the plan. In the fourth and last step, the results are studied to establish what was learned and what can be predicted. (Siebels, 2004)
- Six Sigma: a methodology that provides businesses with the tools to improve the capability of their business processes. This increase in performance and decrease in process variation leads to defect reduction and improvement in profits, employee morale, and quality of the product. (Siebels, 2004)
- Lean: an approach that focuses on reducing waste and cycle time using different techniques and tools. For example, value stream mapping and identifying and elimination "monuments" and non-value-added steps. (Siebels, 2004)
- Lean Six Sigma: an integration of the Lean and Six Sigma methodologies creating a "best of both worlds" approach. It is the fundamental integration of an improvement toolkit that focuses on the elimination of waste and the elimination of variation (Cole, 2011)

- Kaizen events (rapid improvement event): intense short time frame, team approach event to employ the concepts of continuous improvement. For example, to reduce cycle time or to increase throughput. (Siebels, 2004)

The concept of quality improvement (QI) was first applied by an American engineer, statistician and professor William Edwards Deming around 1950 when he was recruited to help Japan after the Second World War. His work aided to revived Japan's economy by applying statistical methods to manufacturing processes, increasing its performance drastically. Decades later, he worked for Ford Motor Company in the U.S., turning the business into the most profitable American car company even though Ford´s sales were falling severely at the time. (Walton, 1986) Subsequently, the foundation laid by Deming was soon adopted by pioneers of QI in every industry.

In the late 19th-century, Ignaz Semmelweis began the QI movement in medical care by championed the importance of handwashing. Since then, many studies have been conducted with the aim of eliminating inefficiencies in processes in every level and department of healthcare organizations. For example, Varkey (2007) addresses how some of the quality improvement methods mentioned above have been used by healthcare centers and concluded that QI activities increase slowly but steady across this sector and can be helpful to increase performance and efficiency. In another example, Kaplan et al. (2010) published a systematic review of the literature in the influence of context on quality improvement success in health care. Kaplan's (2010) work was the synthesis of 47 articles where he found consistent with current theories of implementation and organization changes, data information systems and years involved in QI were suggested as important to QI success. These implementations lead to making the necessary changes to achieve better patient outcomes, better system performance, and better professional development.

QI projects have also been implemented in the catheterization laboratory. A catheterization laboratory is a place that has high-tech equipment, mainly a fluoroscopy or X-ray equipment, which generates dynamic images that are processed and digitized by a computer system to obtain clear images that allow the diagnosis and treatment of cardiovascular diseases. According to the WHO (2019), 31% of all global deaths are related to cardiovascular diseases. Additionally, Reed et al., (2018) stated in a publication that cardiac Cath labs are more susceptible to have operational inefficiencies due to its complex procedural environment and that identification and elimination of inefficiencies may allow for improved productivity and improve satisfaction for patients and health care providers. Reed et al. (2018) also specified that there are no standardized operations in Cath labs.

Considering the relevance of QI projects in medical delivery systems, there is a notable lack of empirical investigations identifying the QI project in Cath labs. Therefore, this paper aim is to synthesize and assess the published literature concerning implementations of QI projects in Cath labs. To achieve this purpose, an SRL was conducted as the research methodology. SLRs identify and collect relevant publications in a specific field with a rigorous method to provide transparency and reproducibility to the research. Although this method may present limitations in the success of gathering publications as they must be indexed in the platforms that are targeted or they will not be identifiable, a strategic selection of platforms was made to ensure that as many publications as possible were captured. To assess the published literature relating quality improvement projects in Cath Labs, three dimensions were selected: publication characteristics, author characteristics, and content characteristics. To achieve the purpose of this research, the following research questions were answered:

- RQ1: To what extent quality improvement projects in Cath Labs capture the attention of different fields (e.g. health care, operations management, and others)?
- RQ2: To what extent quality improvement projects in Cath Labs capture the attention of different authors?

- RQ3: To what extent quality improvement projects have been used in all the process related to Cath Lab?
- RQ4: To what extent quality improvement projects contribute to improve Cath Lab process performance?

2. Research methodology

A systematic literature review approach based on a six-step process adapted from Keathley *et al.* (2016) was carried out to provide a complete and exhaustive summary of the current literature of the subject in question. The steps are:

a) Problem definition: the justification of the need to conduct an SRL for the issue in question is established.
b) Scoping Study: initial research is conducted to look for relevant publications related to the area of study.
c) Search strategy: terms, platforms, and search tools are identified.
d) Exclusion criteria: publications that are not directly related to the investigation scope are excluded from the search strategy.
e) Data collection: data needed from the publications gathered are identified and collected to the purpose of the investigation.
f) Data analysis and synthesis: analysis of the data collected is conducted and synthesized.

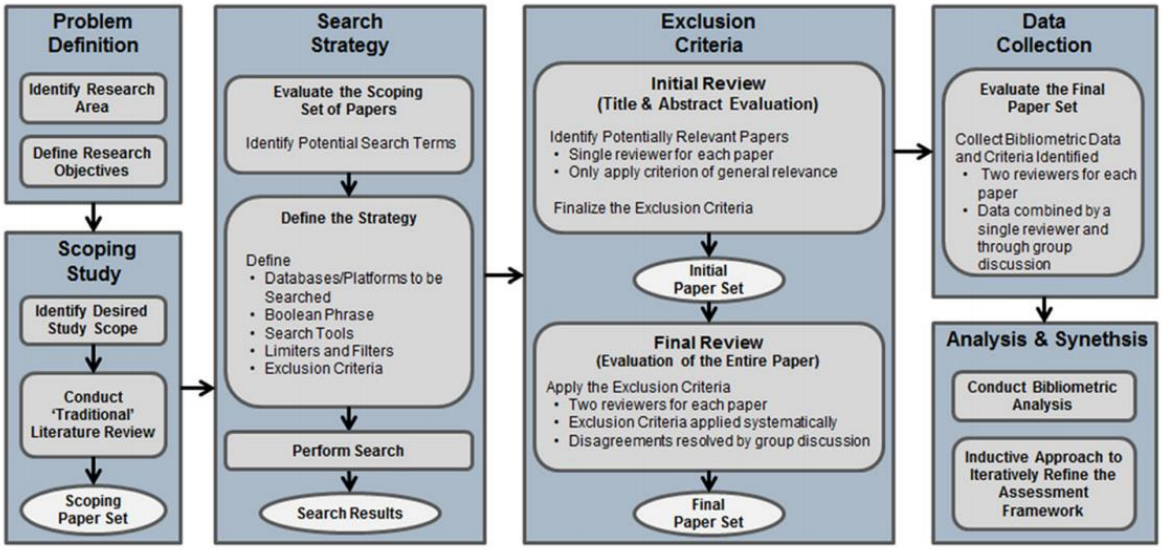

Figure 1. Systematic literature review approach

2.1 Problem definition

Healthcare providers are in need of improving their delivery systems to maximize value to patients in order to increase performance, reliability, and satisfaction. Many studies have been conducted to eliminate inefficiencies in processes in every level and department of the healthcare organizations. The catheterization laboratory is particularly in need of improvement as its complex environment generates difficulties in its operation. (Reed, 2018) To add up, according to the WHO (2019), 31% of all global

deaths are related to cardiovascular diseases, which are can be diagnosed and treated in Cath labs. Publications relating quality improvements in Cath labs can be found in many database platforms; however, there is no evidence regarding a review in those studies to understand better the knowledge generated. Therefore, it is important to analyze and synthesize the current studies in literature and identify which methods have worked and which have not. Conducting an SLR in this specific field can be of benefit to guide future improvement projects to give better services to patients.

2.2 Scoping study

The scoping study was conducted through two activities. First, an initial list of search terms related to QI projects in Cath labs was created based on related terms. Second, conduction of previous literary research was made to identify main publications related to this research area to use as a baseline to create the search strategy. A total of 3 publications were selected to develop the above mentioned.

2.3 Search strategy

To obtain the most relevant papers, the search will be conducted on three platforms: EBSCOhost, ProQuest, and Scopus. In a preview search of the platforms, three papers were selected as the scoping set of papers that were later used to create the search strategy. Search concepts were identified and decomposed intro specific search terms that were used exactly the same in the three platforms. The search terms used are:

Table 1. Search terms

Catheterization laboratory	Lean Six Sigma
Catheterization lab	Lean
Cath lab	PDSA
Quality improvement	PDCA
Six Sigma	Kaizen

Other search components used were the search strategies and a delimiter which were selected as follows:

- Boolean operators: OR within search terms for each concept (e.g., kaizen OR six sigma) and AND to connect the search terms.
- Search fields were selected differently between platforms:
    - EBSCOhost: “select a field (optional)”
    - ProQuest: “any field except full text”
    - Scopus: “article title, abstract y key words”
- Delimiter: language (English and Spanish)

Moreover, six initial exclusion criteria will be applied based on the title and abstract and scanning the content of the paper to eliminate publications that will be not suitable for this research. The exclusion criteria are:

Table 2. Exclusion criteria

Duplicate publications
Publications not focused in Cath labs
Publications not related to improvement projects
Publications without academic focus
Publications for which a full text was not available in an electronic format

A total of 270 publication were found and screened through multiples step using the exclusion criteria mentioned in the Table 2. 103 of the publications were found as duplicated, 38 of this publication have not to access to the complete text and six of these publications were in a different language that was not Spanish or English. Moreover, 7 of the publications found were not related to Cath Lab, 20 of them were not talking about a quality improvement project, and 20 papers lack of academic focus that is essential to be considerate in a systematic literature review. Finally, a total of 67 publications was the final set used to develop the investigation of this study by gathering relevant data and analyzing and synthesizing the information found.

3. Results

To obtain a comprehensive perspective of the published literature on QI project in Cath labs, this section presents results of analyses conducted to address the research questions posed earlier.

3.1 Publications characteristics

Analysis of publication trends offers the opportunity to visualize trends in the frequency of publications over time in a given set of publications and to investigate to what extent frequency is changing.

Publication rate analyses are commonly used to evaluate publication trends. This analysis consists of charting the frequency of publications per year to identify potential trends (Figure 2). Base on the data, the main observations can be made from Figure 2. The first paper focusing on QI projects in Cath labs was published in 1993; thus, this particular research area extends only 26 years and appears to be rather undeveloped. It can also be noticed that this area research was introduced from 1993 to 2000. Second, from 2001 to 2011, the number of publications per year fluctuates between one and three and does not seem to demonstrate any noticeable trend. This change, however, when one considers the time period of 2012 to 2019, for which the rate increases considerably. The cumulative frequency also supports the apparent increase in interest during this period. Therefore, it seems that research interest in this area is increasing.

A total of 63 publications were identified was journal articles, three publications were consensus, one publication was a doctoral dissertation, and another one was a conference publication from the set of 67 publications. The papers found were published in 37 different publications outlets. The most frequent publications outlets identified were *Catheterization and Cardiovascular Interventions (13), Journal of the American College of Cardiology (5), American Heart Journal (3), Circulation (3), Critical Pathways in Cardiology (3)* and *Cardiovascular Revascularization Medicine (3).* Moreover, 76% of the publications outlets were found in the subject area of medicine, 11% in quality in health care, 8% in Engineering and Computer Science, and 5% within the area of management. Also, most of these journals belong to the Q1 quartile. The quartile is an indicator that serves to assess the relative importance of a journal within the total number of journals in its area. It is a measure of a journal's position with all of its area. This gives validation to the information that is being analyzed from the set of publications.

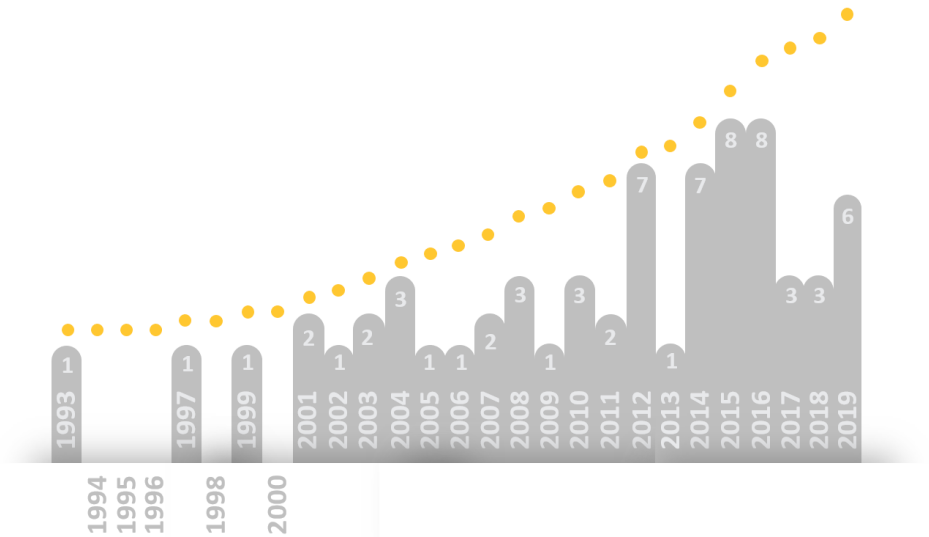

Figure 2. Frequency of publications per year

As mentioned earlier, a strong concentration of publications in the subject area of medicine suggests a higher level of maturity in this field. Although a dominant subject area was identified, the research topic has been expanding to new areas like engineering, quality in healthcare, and management.

3.2 Author characteristics

The dimension related to the author's characteristics analyzed three criteria: author quantity, author diversity, and author collaboration. The first criterion evaluates the most frequent authors and the emergence of the new authors in this research area. From the set of 67, there were 388 unique authors, whom 78% are male and 22% female. Interestingly, 55% of them have a medical degree, 8% had achieved a doctoral degree, 7% is a registered nurse, 5% have a Masters in Science, and the other 5% in Public Health. Forty-eight of the authors published more than one paper in the research topic. The most common ones were: Charles E. Chambers, Christopher B. Granger, James G. Jollis, Lisa Bergersen, and Ralph G. Brindis. Each author with four publications each. Additionally, seven authors participated in 3 papers and 36 in two publications. All other authors published only one paper appearing in the publication set. This finding seems to indicate there is not yet a defined core set of authors; however, it indicates a palpable interest in health professionals to generate new knowledge around this research area.

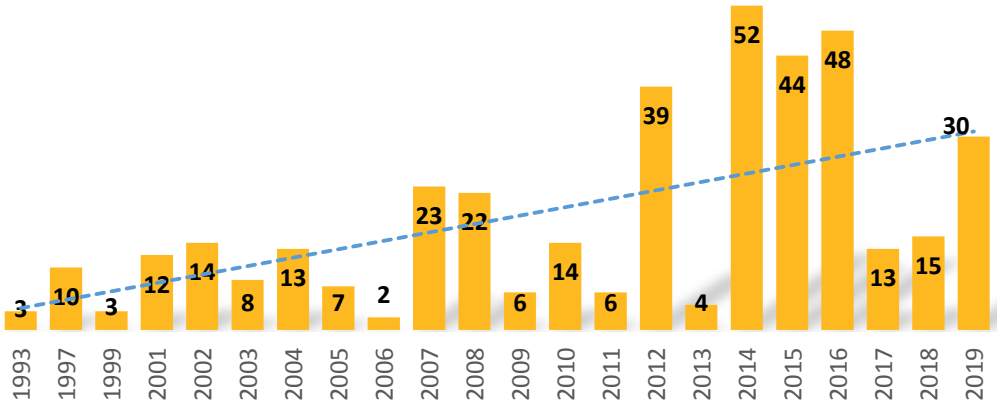

Figure 3. New authors per year

An analysis of the frequency of new authors publishing in this research area was conducted, as shown in Figure 3. Although the number of new authors did not continue to increase every year throughout the time, there have been new entrants publishing in this area every year since 2001; further, the cumulative frequency seems to support the ability of this research area to capture the attention of researchers. An important analysis conducted in the characteristic of the diversity of the authors is their origin country; this data may show the research area is primarily found attractive to the author in one country or if it is dispersed around the world. The 300 unique authors represent a total of 15 countries. The country with a majority of authors is the U.S., with 131 (81%) of the authors in this set of publications. With a much lower number of authors Pakistan with ten authors (3%), Canada with nine, Egypt, Germany, and Saudi Arabia with six (2%). Other countries represented are The United Arab Emirates with five, Malaysia with three; and Mexico, Brazil, Indonesia, UK, Poland, Colombia, Chine, and Ireland, with one author each. This evidence indicates that there is attracting interest from authors around the world representing all continents; however, the interest is concentrated in one country (USA) accounting for most of the author.

Although it is encouraging to see that this research area is found in all five continents, it can benefit from border participation from authors around the world that can bring a diversity of perspectives, methods, and application contexts. An important data also recollected was the affiliations of each author. The analysis concluded that 65% of all the authors are practitioners. This means, they are affiliated to a company, where most of them (85%) represented hospitals, 7% represented companies such as consultants, insurance and technology companies, and 3% represented research institutes. Moreover, 38% were in the cardiology department, 18% in the cardiovascular department, 14% in pediatrics and 13% in others. There were also authors affiliated to universities 35%, inside the departments of school of medicine (82), systems science and Industrial Engineering (3%), Bioscience (2%) and others (13%). Lastly, there were few authors affiliated to foundations and non-profitable organizations (3%).

The last criterion used to analyze the characteristics of authors is their collaborative network. Of the 67 publications, on average, seven authors participated in each publication and 64 of the papers were written by two or more authors where nine of the publications represent multi-country collaborations (13%). These collaborations occurred between 14 countries. This relatively modest level of multi-country collaboration indicates that QI projects in Cath Labs are still an emerging research area. The remaining 58 publications were written solely by authors within one country. Collaboration between authors was also analyzed using a special social network program called Gephi. This software is an open-source network analysis and visualization that can be used to analyze authors' network to assess direct and indirect interactions between them or a group of them using nodes and edges. In this case, each node represents a unique author and the number of publications in which he/she has participated is represented by the size of the node. The lines connecting the nodes are the edges. The edges represent a collaboration between authors. Figure 4 shows the entire social network found between the authors of the 67 publications analyzed.

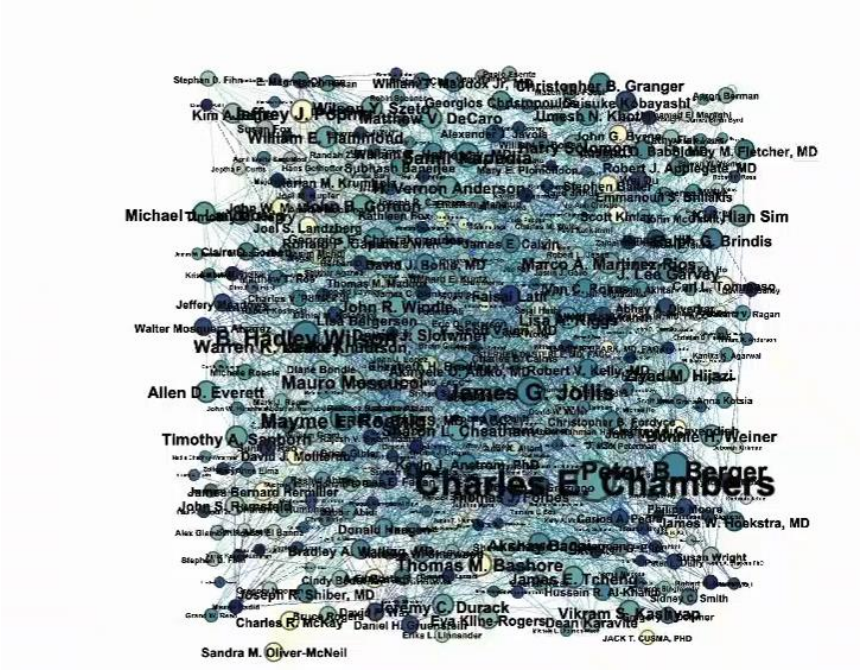

Figure 4. Authors' Network

3.3 Context characteristics

To analyze the context characteristics, the identification of processes carried out in the Cath lab that has been targeted for the implementation of the QI project was made. There were two different types of processes been intervened with quality improvement methodologies. One of them was the operative processes, which are the main activities that make everything get moving to provide the services to the patient. And, on the other hand, the intervention processes. These are the methods that healthcare professionals use to intervene in patients surgically. Fifty-five of the publications aim to perform a QI project to operative processes and 11 to intervention processes. One of the publications aims to perform a QI project for both an operative and an intervention process. Inside the first group, a division was identified between publications that aim to implement the QI projects specifically to the Cath lab itself (37) and publication that seeks to implement the QI projects to a holistic system where Cath lab was a part of. In the intervention process group, all the publications aim to perform QI project only inside the Cath lab as a whole. Fourteen different topics of performed the QI projects were identified, as shown in Table 3.

Findings in the context were that the QI project performs to intervention processes is an even more recent research area as the first paper aiming this was published in 2012. This indicated that the area research had not been explored yet and is in the introduction stage while publication seeking to perform QI project to operative processes dated from 1993. Twelve of the publications mentioned 4 of the most recognizable quality improvement methodologies. four publications stated to have implemented Six Sigma for QI projects, 3 implemented Lean Six Sigma, two used a lean approach, two work the designed a program to perform PDSA cycles in a guided way and 1 of the publications utilized a rapid improvement approach.

In this section, the contribution of the QI project to improve Cath lab process performed was analyzed as well. OF the 67 publications, 3 were consensus, 4 were SRL studies, 13 were descriptive studies and 47 were case studies. OF the 47 case studies, 16 publications aimed to prove a hypothesis and 31 aimed to achieve a goal or a set of goal. However, just 13 of the 31 publications with goal targets have the sufficient quantitative information to be part of this analysis. Of the other 19 publications, 13 have not

sufficient quantitative information, 2 have no initial metrics and 3 have no quantitative goals indicated. This lack of quantitative information indicates a weak control in the metrics and indicator used to implement the QI project in these publications.

Table 3. Topic related with implementation of QI project in Cath labs

Operative process	Cath lab only	Big Data (9) Reduce radiation (9) Maximizing efficiency and productivity (7) Quality assurance (4) Best practices and standardization (4) Reduce treatment time (1) Assess readbacks (1) Employee engagement (1) Reduce false activation (1)
	Holistic system	Reduce time to treatment (15) Reduce false activation (1) Reduce costs (1) Quality assurance (1)
Intervention process	Cath lab only	Improve patient treatment (3) Reduce vascular complications (3) Technique improvement (1) Design of device (1) Reduce treatment time (1) Database Program (1)

In twelve out of the 13 publications stated that were a single-center study while just one was a multi-center study. The previous analysis shows that the QI projects implement cannot be generalizable as they do not represent the results in every Cath lab. The average duration of the QI projects was 21 months. This outcome resulted of the fact that several QI projects were implemented each year for four or five years with improvement in the project.

Table 4 shows a comparative table of the percentage of goal achievement and performance target area. The publications are divided by the methodology each used to perform the QI project. This shows that three out of four of the publication that used Six Sigma provided sufficient quantitative information. Three out of the three publications that used Lean Six Sigma have enough quantitative information to analyze the data, and seven publications used other methodologies, generally a custom-designed program for QI. From the 13 publications, a total of 27 goals where established. Each publication had between one and six quantitative goals. Fifteen of the goals were related to a reduction of time to attend of patients, while six were related to an on-time start, one to cost reduction, one to patient satisfaction increases, one to complete readbacks, one to unnecessary activation of the cath lab reduction, one to maximize capacity for any given day in the cath lab, and finally one to lower FTE nurses and technicians achievement.

Table 4. Methodology, goals, achieved goal and performance target area per paper

Methodology	**Paper**	**Goal**	**Goals' Specifics**	**% GA**	**% PTA**
Six Sigma	P34	G1	Reduce preprocedural patient prep time 47.3 to 35 min	110%	29%
		G2	Decrease costly bleeding complications 18% to 6%	96%	64%
		G3	Decrease overall hospital stay from 1.35 to 1.0 days	31%	8%
		G4	Elevate patient satisfaction scores from 78% to 85%	121%	11%
	P57	G1	70% complete readbacks in all categories	75%	34%

	P7	G1	100% of cases starts at 7:30 am in 4 of the 5 Cath Labs	54%	58%
Lean Six Sigma	P40	G1	Turn time = < 20 min	23%	33%
		G2	Physician downtime = < 35min	19%	19%
		G3	On-time patient arrival = >75%	527%	7%
		G4	On-time physician arrival = > 75%	107%	36%
		G5	On-time start = > 60%	115%	51%
		G6	Sheath pull inside Cath Lab = < 33%	137%	63%
	P28	G1	100% of DTB cases < 90 min	95%	357%
	P54	G2	100% of DTB cases < 90 min	85%	32%
Other	P44	G1	85% of cases start time of 7:45 am	86%	32%
		G2	Turn time < 17min	117%	20%
		G3	100% of open cath lab at max capacity for any given day	75%	904%
		G4	Stable or lower of FTE nurses and techs	NA	18%
	P30	G1	100% of DTB cases < 90 min in work hours	84%	47%
		G2	100% of DTB cases < 90 min in “off-hours”	77%	50%
	P29	G1	100% of DTB cases < 90 min	883%	33%
		G2	30 min from arrival to Cath lab to first ballon inflation	156%	18%
	P11	G1	100% of DTB cases < 90 min	100%	29%
		G2	Reduction of unnecessary activation of cath lab	NA	57%
	P48	G1	75% of DTB cases < 90 min	44%	33%
	P3	G1	75% of DTB cases < 90 min	122%	201%
	P10	G1	100% of DTB cases < 90 min	100%	100%

4. Limitations

This study has several important limitations. First, the findings may have unique characteristics that may not be widely generalizable. Some of the reasons may be that valuable papers may have been lost in the search due to the use of a reduced number of databases. However, the databases were selected strategically so that as many publications related to the research area as possible may be collected. Second, it was not possible to gather a significant sample of quantitative information to develop a robust data analysis to evaluate goals achievement and area improvements due to the modesty of the quantitative information recovered in the set of publications. Third, the SRL methodology generally is conducted by several participants to have different perspectives and ideas in the search and the analysis of publication, this SRL was conducted by two authors. This may cause a lack of profound analysis in the study.

5. Conclusions

In conclusion, this work may be of interest to practitioners as this investigation offers synthesized and comparative information about the methodologies and own designed programs that have helped improve processes in the Cath lab. For academics, this study gathers valuable information about the topics of interest in the research area that needs validating and improvement. On the other hand, it also shows the areas of opportunity where new lines of investigations can initiate. At last, it may be of interest to the medical community, in general, to better understand how this research area has developed, and the importance of improving its processes to achieve superior medical services.

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