EFFECTIVENESS OF LEAN SIX SIGMA METHODOLOGY FOR OPTIMAL RADIOISOTOPE UTILIZATION IN NUCLEAR MEDICINE

by

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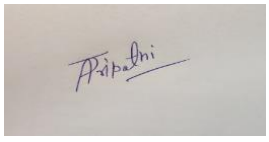

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ABSTRACT

EFFECTIVENESS OF LEAN SIX SIGMA METHODOLOGY FOR OPTIMAL RADIOISOTOPE UTILIZATION IN NUCLEAR MEDICINE

Anjali Steta, 2022

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Nuclear Medicine departments offer a large diversity of diagnostic and therapeutic procedures. To remain competitive, health care organizations have promoted the use of Lean and Six Sigma in various settings. Nuclear medicine is facing the challenge of patient management with a better quality of care and there is an enormous need to optimally use the radioisotopes and to improve the process of the nuclear medicine department.

The scope of the study was to monitor the optimal utilization of radioisotopes with the potential use of Lean and Six Sigma in the nuclear medicine department. The use of radioisotopes efficiently can be managed with time. There are sub-process steps involved in the department which are coordinated with one another, where the staffs need to speed up their work, which allows more patient scans, reduce the excessive cost for the management, and less wastage in the department. If it is not utilized properly then it is a major issue in the department and affects patient satisfaction and incur more cost to the management.

There are 3 objectives mentioned in this study which are: a) To map the process flow of the nuclear medicine department, b) To analyze the bottlenecks or gaps in the workflow with the use of Lean Six Sigma Methodologies and Tools, c) To recommend the solutions to improve the process in the department.

The data collection was done by purposive sampling and mapping process flows with Gemba walk and assessment in the department, observed patient's time, and recorded turnaround time for each process step in the department. The analysis was done by using Lean Six Sigma methodologies which include Ishikawa Diagram, 5 why's analysis or technique, lean seven wastes, and calculated Sigma assessment which includes DPU (Defects Per Unit) and DPMO (Defects Per Million Opportunity).

Overall results showed that there is a significant difference between the timing of variables and there are major defects that occur due to delays in the department. In conclusion, the sigma level 2.75 which is calculated by DPMO indicates that the nuclear medicine centre is not following the standards and is not competitive enough which needs improvement to sustain in the healthcare industry.
Keyword: *Lean Six sigma, Radioisotopes, Nuclear medicine, LSS Methodologies and tools*

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CHAPTER I:

INTRODUCTION

In the last decade and so healthcare industry is an industry has begun to adopt six sigma methodology and techniques and provided various examples of how community-based hospitals used lean six sigma to improve process (Furterer, n.d.).

After fully developed, organized, tested, and verified by different firms in the manufacturing sector such as Motorola, Allied signal, Toyota, and General Electric, the healthcare industry has encircled the lean six sigma concept and its application ensures the success of the healthcare organization by reducing the number of errors or defects, such as patient waiting time, doctor reporting time, delivery of medical reports, unnecessary medical cost, and so on. It enables healthcare providers to provide accurate results and help them to diagnose and treat the patient with patient safety and higher quality of care (Furterer, 2018).

During the last decade, the healthcare sector has changed rapidly due to increased competition and the growing influence of patient association, and a necessity to deliver health services in a more efficient and effective way. Different quality improvement approaches have been studied. The approaches include quality improvement initiatives such as; TQM, JIT, JR, PR, OR, BM among others aiming at continuous improvement (Woldegebriel et al., 2014).

In the era of the competitive environment, the service sector is under tremendous pressure to deliver continuous performance and quality improvement while being customer-focused. In recent years, it was observed that healthcare has become one of the extremely complex industries in the world (Talib et al., 2015).

Quality care has become an important aspect in the development of healthcare services. Patient satisfaction on healthcare quality plays a vital part in the assessment of healthcare frequently. A

critical challenge for health service providers in India is to find ways to make them more client-oriented.

1.1 History of Lean and Six Sigma

In 1947, a Japanese industrialist Eiji Toyoda made a visit to the U.S. to study how automobiles were manufactured at the world's largest plant Ford, and then he returned to Toyota with his experience and report on the USA's stupendous manufacturing methods. Eiji Toyoda observed that at that time we (Toyota) were producing 40 cars a day, while Ford was producing 7000 units per day (Ohno, 1988).

Eiji, during his studies in the US, wrote a letter to the headquarters of Toyota in Japan stating that there are some approaches that may open new avenues for us to improve and enhance the production of new Toyota cars. But the methods of Ford's mass production system could not help Toyota to expand so efficiently as expected and all this was attributable to the cultural and environmental differences (Ahmed et al., 2013).

In the early 1950s' quinquennium, Taiichi Ohno brought in a novel concept of "Lean Production or Lean Thinking" to lessen Muda (waste) from the production processing. This concept was first implemented by the Toyota Motor Corporation (hereafter referred to as Toyota) to reduce unnecessary waste in the production and improve the manufacturing quality of the plant (Ohno, 1988).

And the concept was known as the Japanese Toyota Production System and later this concept was known as "Lean Production" and "Lean Thinking" (Snee, 2010).

Given the fact that there was huge waste everywhere; such as in manpower, production, transportation, and facilities. They realized that they were operating on limited human and material resources and they failed to adopt and implement the production system which was being used in the US at that time (Snee, 2010). Then Ohno returned to Japan and encouraged his employees to work together under the best performance operation concept, 5S". Ohno then ushered in another famous method to reduce waste, which he called JIT or Kanban system. This system enabled the company to see how much waste was there in the mass production system.

Following the JIT system, the amount of waste generated was controlled and lessened. But this system was not so easy to implement in a place where there used to be lots of defects with the system. This meant that in case just one small part of the whole production system failed, the whole production system would stop. Taiichi Ohno contemplated all this and then he designed the system in such a way that every member of the entire production system focused on preventing potential problems and reducing waste (Ohno, 1988). And today the Toyota's car manufacturing market shares have considerably increased in the entire world.

The US market, in the early 1950s, turned down Toyota's new brand Crown due to some problems such as lack of security, lack of power, and its heavyweight and the like. Therefore, not following the traditional quality assurance system, Toyota introduced a new human-based system that included its own people, ensuring continuous improvements and empowerment via quality training (Ahmed et al., 2013; Ohno, 1988).

The successful implementation of the lean method enabled Toyota to add to the value of the automobiles and decreased all other non-value-added jobs. In 2004, Toyota beat Ford and became the world's second-largest automobile producer after the GE company. By 2006, Toyota's profits tremendously went up to the US $12 billion – nearly double GM's highest annual earnings of $6.9 billion in 1995 (Snee, 2010).

Bill Smith is considered as the "Father of Six Sigma" and in his role as a Vice President and Senior Quality Manager for Motorola, he pioneered the Six Sigma methodology for organizational improvement in 1987 in response to sub-standard product quality traced in many cases to decisions made by engineers when designing component parts.

Traditionally, Design Engineers used the "three-sigma" rule while making evaluations as to whether an acceptable proportion of manufactured components would be supposed to meet tolerances (Arnheiter and Maleyeff, 2005).

1.2 LSS concepts

As it is mentioned earlier that lean and Six Sigma have an integral relationship with each other which enables in improving the quality of care and services by reducing costs or expenses and wastes in the organization. The lean methodology uses a management structure that is based on the Six Sigma approach. Six Sigma methodology provides an effectual set of frameworks of applying lean principles according to a project-by-project approach (Heuvel et al., 2006)

On the one way, the lean approach does not analyze the financial performance indicators of a process and the main objective of this is to improve the organization's performance by reducing unnecessary costs. Lean is also known as lean production or lean thinking and lean enterprise, which involves a set of principles, methods, and practices for improving, designing, and process managing. Some lean tools are VSM, Process mapping or flow mapping, Gemba, Spaghetti (motion) diagram, Problem-Solving A3 Template, 5S, Kanban, Throughput time, Kaizen (Continuous improvement, Standardized work, Heijunka, seven wastes or Muda, these tools help in improving processes of patient care and workflow of an organization.

When lean is implementing, it involves systematic process assessment and analysis. Following are five basic lean principles:

1) Identification of customer value (defined by the customer)
2) Value stream management
3) Developing flow production's capabilities
4) To support the flow of materials, use the "pull" mechanism
5) The Pursuit of perfection through reducing forms of waste to zero (Clark et al., 2013).

On the other way, Six Sigma's DMAIC approach gives a roadmap through which to analyze, assess, and to find out the organizational performance. This approach runs with powerful methods and tools and can specifically identify the errors in the process. The Six Sigma approach has a general problem-solving framework that may undergo process inefficiencies but for those who are after process improvement and speed efficiency. This drawback can be solved by the lean-approach (Heuvel et al., 2006).

1.3 Effects of LSS on Healthcare Services:

Six Sigma approaches depend on the brief and accurate measurement of outcome variables and process with analyses design which helps to find those factors that are very important to meeting customer or client requirements. The six-sigma process improvement is also known as the DMAIC process that is Define, Measure, Analyze, Improve, and Control. It starts by examining the VOC that is used to define the CTC and CTQ metrics that provide as the outcome variables for the project improvement. CTC and CTQ variables have been influenced by the process variables that are Critical x- values, which are the goal for interference during the improved phase of the project. Recognizing how the variable outcome are related to critical x-values enables make quantitative predictions about the expected improvements in the outcome variables as in the organization for example; a six sigma can be used in a hospital to assess the number of errors in medication dosages during hospital inpatient discharge with a target of reducing error rates (patient CTQ) and readmission rate (payer CTC). The six-sigma approach level has zero error rate and defects are only three defects or errors per million opportunities. This level of performance is difficult to adopt by many industries but in the healthcare industry, as the medical system is the most critical system which deals with critical patient care, safety and better quality requiring these exceedingly low errors rated approach. Lean and Six sigma are typically combined in healthcare as they both address the two related but separate issues. The Lean is more concentrating on cost reduction and efficiency is a better accompaniment to six sigma's quest of correctness and veracity. Lean has expanded in healthcare as hospitals aspire to have efficiency (cash flow), customer satisfaction, and quality. Lean has great significance in healthcare also as the main concept is seeing the service from the customers' perspective and understanding value creation as defined by the customer (Graban, 2018). In Healthcare, a better quality of care does not mean higher costs, in Lean healthcare, it is the other way round. Actual Lean development projects have existed in healthcare since the 1990s and there are places where Lean has improved quality, and access while decreasing costs (Christopher et al., 2006). Healthcare institutions that use Lean concepts have witnessed a considerable decrease in the number of errors, shortening queuing times, and have improved and enhanced productivity (Graban, 2018). The main purpose to apply Lean philosophy in healthcare is to optimize it in an independent service or workflow (Clark et al., 2013). The quantity of waste

in healthcare is estimated to be close to 30-40% of spent time, money, or materials (Aakre et al., 2010), (Graban, 2018) lists results achieved in health care using Lean, including shortened waiting times in orthopedic surgery from 14weeks to 31 hours, increased employee engagement by 15%, reduced patient hospitalization time by 29%, and 54-million-dollar savings through cost reductions and revenue growth; Graban, Mark (2008). Many healthcare industries have started this LSS journey and some have already accomplished important business results. LSS framework is applied in the healthcare organizations because it helps in improving clinical processes of patient care and workflow of an organization.

1.4 Lean Tools:

VSM: VMS is used to show the hidden waste and to help identify the required activities to deliver products or services. VSM also helps in visualizing the whole process from start to end enabling to see opportunities for improvements (Christopher et al., 2006). The unnecessary waste is removed from current state VSM, bottlenecks are found, just-in-time thinking is applied, and specific process improvements are taken into account (Teichgräber and De Bucourt, 2011).

Process mapping or flow mapping: Process mapping is done through observation in the real environment and pursuing steps and timing a piece. All participants (staff), transportations, waiting times, and interventions are precisely documented (Cookson et al., 2011).

Problem-Solving A3 Template: It is a simple tool to analyze existing problems. First, a problem is identified, and then the same is stated and the current workflow is described. Data gathered is based on live observations. This is why questions are used to find the root causes of the problem. After implementation, it is of note that a follow up is arranged to compare expected results with actually received results (Kruskal et al., 2011).

Gemba: Gemba, or Gemba walk, means direct observation where actual work is done. The objective of Gemba Walk is to understand the value stream and its problems rather than review

results or make superficial observations. During the visit value creation, safety and efficiency can be evaluated (Kruskal et al., 2012).

Spaghetti (motion) diagram: Spaghetti (motion) diagram or Workflow diagram visualizes how people move in a selected environment. In health care, it generally describes a patient, nurse, or data path during the workflow. Its goal is to find unnecessary movement and change routes to shorten them (Kruskal et al., 2011).

5S: Five S system is a tool to improve the work environment, and it helps improve organization and efficiency in many workplaces including manufacturing environments and offices. 5S is a widely adopted technique in Japan and the term 5S is derived from Japanese words: Seiri – Sort, Seiton – Set in order, Seiso- Shine, Seiketsu –Standardize, Shitsuke- Sustain.

Kanban: Kanban is a visual technique for controlling production as part of Just-in-Time and lean manufacturing. It helps a department to cope with large numbers of items and inventory. Kanban in English means a card or sign. Building up a kanban system can cost, but in the long run, it ensures better availability with the lowest possible stock (Graban, 2018).

Throughput time: To better the whole workflow, it can be cut into separate smaller processes. Calculations can be used to find bottlenecks and places where capacity is wasted. These can be availability, a low percentage of first-time-right or long idle times. (Mast et al., 2011) stated that throughput time is affected by variation, as the greater, the variation in the process the longer the throughput time. Coping with a variation inside the process helps shorten throughput time.

Kaizen (Continuous improvement): The concept of Kaizen can be explained as a principle of continuous improvement. According to the Kaizen method, a series of small improvements made continuously over a long period of time can result in considerable improvement in business processes (Kruskal et al., 2012).

Standardized work: Standardized work is one of the most powerful but least used tools. Via documenting the current best practice, standardized work forms the baseline for Kaizen or continuous improvement. Standardized work documents can comprise checklists, work instructions, or capacity sheets. The aim is not to standardize, it is to provide care to patients (Graban, 2018).

Heijunka: Heijunka means leveling, or evenness of work or load level, leveling the quantity of production over a fixed period of time, which helps production to efficiently meet customers' demands while avoiding batching and results in minimum inventories, capital costs, manpower, and production lead time through the entire value stream. These three foundations of Lean, Kaizen, Standardized work and Heijunka are very important that help support waste elimination, but in a way that respects people (Graban, 2018).

Seven wastes or Muda: it is a core principle of leam which helps in reducing and eliminating wastes. It includes; overproduction, over-processing, waiting, unnecessary transportation, Motion (unnecessary movements), Inventories, Defects/Rework and eighth one waste is the human resource.

1.5 Six Sigma:

Six Sigma is a set of management techniques that are intended to improve business processes by considerably decreasing the probability of errors and defects. The name Six Sigma refers to a quality level defined as the near-perfect defect rate of 3.4 defects per million opportunities. Therefore, Lean and Six Sigma should be consolidated to get high organizational performance through continuous improvement.

The methodology used to improve an existing process in Six Sigma is the DMAIC process with Sub-methods for each DMAIC process, which is divided into five stages: Define, Measure, Analyze, Improve and Control.

1) **Define:** the purpose of this phase is to clarify the goals and value of a project. Define phase methods include Project selection, Benchmarking, Process elements, SIPOC process, VOC, Critical to quality factor, QFD, Project charter, Project scope, Project metrics, project plan, affinity diagram and interrelationship diagram, tree diagram and matrix diagram, prioritization matrices, activity network diagram, and PDPC.

2) **Measure:** The purpose of this phase is to gather data on the problem. Measure phase methods include Process maps, Flowcharts, Process documentation, permutation and combinations, collecting data, Stem and leaf plots and boxes and whisker plots, scatter diagram, measurement system analysis, GR &R study, Attribute Gage R&R, process capability analysis

3) **Analyse:** The purpose of this phase is to examine the data and process maps to characterize the nature and extent of the defect. Analyze phase methods include Hypothesis testing, P-value and T-test, sample test, Multivariable analysis, Correlation, regression analysis, residual analysis, and linear regression, multiple regression, root cause analysis.

4) **Improve:** The purpose of this phase is to eliminate defects in both quality and process velocity. Improve phase methods include DOE Regression, Pugh analysis, and solution prioritization matrix, SCAMPER tool, Brainstorming, Cost-benefit analysis, solution screening, and piloting.

5) **Control:** The purpose of this phase is to lock in the benefits achieved by doing the previous phases (Clark et al., 2013). Control phase methods include Control charts and analysis, Control plan and response plan, cost-benefit analysis & KPIV and KPOV, Total productive maintenance, and visual factory.

- ❖ Six sigma has 7 core concepts: Critical to quality, Defect, Process Capability, Variation, Stable operations, DFSS, Lean Six Sigma (integration with lean concepts) (Taner et al., 2007).

Reengineering (DMADV) Methods: The methodology used to improve the system for new process or products in Six sigma is the DMADV process, which is divided into five stages:

1) **Define:** the purpose of this phase is to clarify the goals and value of a project.
2) **Measure:** the purpose of this phase is to gather data on the problem.
3) **Analyze:** the purpose of this phase is to examine the data and process maps to characterize the nature and extent of the defect.
4) **Design:** the purpose of this phase is to redesign/ design (detailed) the process to meet the customer needs.
5) **Verify:** the purpose of this phase is to verify the design performance and ability to meet customer needs (Teichgräber and De Bucourt, 2011).

1.6 Quality in healthcare:

Hospitals have historically modelled quality according to systems paradigm, but only recently have been able to benefit from benchmarking important new management theory from other industries. As a result, the rate of adoption of quality management within healthcare has been almost uniform in different areas and even in the smallest hospitals. During the last decade, the healthcare sector has changed rapidly due to increased competition and the growing influence of patient association, and a necessity to deliver health services in a more efficient and effective way. Different quality improvement approaches have been studied. The approaches include quality improvement initiatives such as; TQM, JIT, JR, PR, OR, BM among others aiming at continuous improvement (Woldegebriel et al., 2014).

In the era of the competitive environment, the service sector is under tremendous pressure to deliver continuous performance and quality improvement while being customer-focused. In recent

years, it was observed that healthcare has become one of the extremely complex industries in the world (Talib et al., 2015)**.**

In healthcare, service quality can be broken down into two quality dimensions: technical quality and functional quality (Dr. Kenneth et al., 2012)**.**

Based on the information gathered from the review of articles, the authors developed following dimensions as found to be influencing the quality of services offered in Indian Hospitals: (Kamalasanan et al., 2019)

a) Planning & Documentation
b) Employee Participation in Quality Management Activities
c) Existence of Policies/ Procedures/ Guidelines
d) Quality & Patient Safety Management
e) Evaluation of the Process and its Outcome
f) Perceived Effect of Quality Improvement
g) Training and Development Opportunities
h) Future Plans and
i) Other studies, which cannot be categorized under the above-stated dimensions.

Quality care has become an important aspect in the development of healthcare services. Patient satisfaction on healthcare quality plays a vital part in the assessment of healthcare frequently. A critical challenge for health service providers in India is to find ways to make them more client-oriented.

Assuring the good quality of health care services is an ethical obligation of health care providers. Research is showing that good quality also offers practical benefits to patients. Interviews with clients in Chile, for example, found that good quality clinical services reduced clients' fears, increased their confidence in the care received, and generated loyalty to the clinic (Dr. R. Venkatesh, 2015)**.**

1.7 Nuclear Medicine:

In the field of medicine, nuclear medicine is one of the most dynamic areas. ACGME program requirements describe it as ‘‘the clinical and laboratory medical specialty that uses radioactive and stable tracers to study physiologic, biochemical and cellular processes for diagnosis, therapy, and research. There have been tremendous improvements in training on nuclear medicine since its official inception in 1971(Surasi et al., 2014).

In nuclear medicine, radio nuclides are used for diagnosis, a staging of disease, therapy, and monitoring the response of a disease process. Nuclear medicine is the study and utilization of radioactive compounds in medicine to image and treat human disease. An efficient Nuclear Medicine department is mainly reliant on the proper scheduling of patients for an efficient workflow.

There is a concern of financial pressure for efficient operation of a Nuclear Medicine service, usually associated with overall Health/Trust service pressures. So, the most important thing is to manage the departmental budget judiciously so as to have efficiency and flexibility.

Generation of radiotracers:

There are some more common radionuclides that are used in diagnostic imaging. The half-lives of these radionuclides are not very long. The same helps in reducing radioactive exposure to the patients. However, it's apparent that these substances cannot be stored, but must be produced on demand, either by a nuclear reactor, a cyclotron, or a generator.

Half-Life:

The half-life of the radionuclide shows how fast the radioactivity will decay. Apparently, if the half-life is very short, the activity will decay to a very low level before imaging is started. On the other side, if it is too long, then the patient will remain radioactive for a considerable time.

1.8 LSS in Nuclear Medicine:

Nuclear medicine requires constant innovation and improvement to not only advance patient health care quality but also to improve operations and drive down costs in order to stay sustained. Six sigma and lean process improvement methodologies have been adopted from outside of the health care industry and used by many hospitals globally to address clinical and operational challenges and provide higher quality health care with better value.

These challenges that affect health care systems worldwide have created widespread perceptions of unsatisfactory quality and poor value for money spent (Surasi et al., 2014)**.**
Furthermore, health care spending as a percentage of Gross Domestic Product (GDP) has increased across all industrialized countries in the past twelve years which may suggest that more effort has been made to improve health care; however, the highest spending countries are not always providing the best results. (Boellaard et al., 2014)**.**

In nuclear medicine, there is room for improvement in reducing operational cost, remove the non-value-added items or process or the wastes which delays the process or work efficiency in the department, improve access, health care quality and patient satisfaction and most importantly patient safety with the two separate problem-solving approaches – Lean Manufacturing and Six Sigma approach.

1.9 Research Problem

There is a concern of financial pressure for efficient operation of a Nuclear Medicine service to manage the departmental budget judiciously to have efficiency and flexibility. Quality care has become an important aspect in the development of healthcare services. Patient satisfaction on healthcare quality plays a vital part in the assessment of healthcare frequently. A critical challenge for health service providers in India is to find ways to make them more client-oriented.

There is an enormous need to improve the workflow of the nuclear medicine department in reducing operational cost, remove the non-value-added items or process or the wastes which delays

the process or work efficiency in the department and patient satisfaction. However, the use of radioisotopes can be managed optimally with time. First, the time taken for each process step has always been a major factor while assessing the mapping process flow of the department. There are such areas where more defects are occurring due to delay in time and becoming obligation and needs improvement. Second, a short half-life of radioisotopes is the major factor in the nuclear medicine department which needs to be managed and utilized in time to reduce the wastage of the drug. It will cause a problem for the administrators or managers with the inefficient use of radioisotopes and it leads to delay in patient procedures. Third, there are fewer studies done in the nuclear medicine department with the use of lean six sigma methodologies. The complexity of the nuclear medicine department itself makes it more complex to use LSS methodologies and to identify which sigma level nuclear medicine stands in this competitive era of healthcare industry.

1.10 Purpose of Research

Nuclear medicine requires constant innovation and improvement to not only advance patient health care quality but also to improve operations and drive down costs in order to stay sustained. Six sigma and lean process improvement methodologies have been adopted from outside of the health care industry and used by many hospitals globally to address clinical and operational challenges and provide higher quality health care with better value.

These challenges that affect health care systems worldwide have created widespread perceptions of unsatisfactory quality and poor value for money spent (Surasi et al., 2014). Furthermore, health care spending as a percentage of Gross Domestic Product (GDP) has increased across all industrialized countries in the past twelve years which may suggest that more effort has been made to improve health care; however, the highest spending countries are not always providing the best results (Boellaard et al., 2014). Hospitals today face major challenges. Patients demand quality of care to be improved continuously. Health insurance companies demand the lowest possible prices. Lean Six Sigma is a programme that can help healthcare providers to achieve these (seemingly) conflicting goals. Lean Six Sigma is an integration of Six Sigma and Lean Manufacturing, both quality improvement programmes originating from industry. Lean and Six Sigma are highly complementary. Six Sigma provides an integrated improvement approach that increases quality

by reducing variation, defects, and costs. Lean adds tools that increases process throughput by eliminating waste. In healthcare faster means rapid access and no waiting times, while reducing defects means less complication. Increasing speed and reducing defects both lead to lower costs. Hence, Lean Six Sigma is an excellent tool to tackle present-day healthcare challenges (Heuvel et al., 2006).

1.11 Significance of the Study

In nuclear medicine, there is room for improvement in reducing operational cost, remove the non-value-added items or process or the wastes which delays the process or work efficiency in the department, improve access, health care quality and patient satisfaction and most importantly patient safety with the two separate problem-solving approaches – Lean Manufacturing and Six Sigma approach.

There is a need felt to carry out a research project in this particular area to make the department smooth and efficient. To develop interventions for improving the process flow and to reduce delays and defects in the department, there is a necessity of systematic and detailed evaluation of the process. There is a need to understand the detailed process to identify root cause of the errors or defects and to eliminate these errors by setting up some standards and by utilizing resources properly. Recommending solutions or providing roadmap to the management to eliminate defects or errors, to reduce deviation and process variation in the nuclear medicine department.

1.12 Research Purpose and Questions

The scope of the study was to monitor the optimal utilization of radioisotopes with the potential use of Lean and Six Sigma in the nuclear medicine department. The use of radioisotopes efficiently can be managed with time management. There are sub-process steps involved in the department which are coordinated with one another, where the staffs need to speed up their work, which allows more patient scans, reduce the excessive cost for the management, and less wastage of resources in the department. If it is not utilized properly then it is a major issue in the department and affects patient satisfaction and incur more cost to the management.

On the basis of identified gaps after reviewing the literature, it is found that there is a need for more study on using Lean Six Sigma methods in the nuclear medicine department to utilize optimally radioisotopes especially in the Indian scenario.

After considering all the research gaps, the present study is based on the following research questions:

1) Why Nuclear medicine department/centre should use the Lean Six Sigma methodology?

   The research will be done to explore the LSS methodology to improve the radioisotopes utilization optimally in the nuclear medicine department.

2) How can nuclear medicine centre or department utilize radioisotopes optimally?

   This research question will be answered on the basis of time management and defects identification in the departmental process.

3) What essentials will be required for developing strategies and solutions to improve defects that are identified in the department?

   When DPMO is calculated, the sigma level can be identified. If the value of the sigma level is on a higher level, it indicates that the organization is functioning efficiently. Using lean six sigma helps the organization to improve the quality, speed, and identify the defects and reduce inefficiency and wastage. So, solutions will be discussed to eliminate defects and redundancies in the department.

CHAPTER II:

REVIEW OF LITERATURE

2.1 Theoretical Framework

Healthcare is a vast sector wherein professionals and people involved are faced with the challenge of balancing lower costs with good health and better care. The healthcare organizations have introduced and fostered the use of Lean and Six Sigma so as to have the cutting edge.

Lean and Six Sigma are business managerial concepts in production industries that are used to improve the process efficiency and quality with decreasing costs and eliminating waste. Over the past decade, these methods have been applied majorly outside the manufacturing sector such as healthcare and software development, etc.

Numerous applications of an integrated Lean Six Sigma method introduced at a Dutch hospital that lessened the complexity of hiring part-time clinical staff, optimizing operating room scheduling by designing a new pre-surgical admissions process, and developing a new work plan system to quicken up completion of equipment maintenance requests (Koning and Mast, 2006).

Various examples on the use of Lean Six Sigma methods in community-based hospitals to enhance throughput in the Emergency Department, decrease Operating Room turnaround time between surgical cases, modify operating room organization, reduce linen loss, reduce unnecessary CT scans in an emergency department, implement evidence-based sepsis protocols in an emergency department, lean the surgical outpatient screening process, and design women's center processes (Cudney et al., 2013).

Six Sigma methodology was applied to improve processes that include emergency department cycle time reduction, clinic patient preparation, and medication safety, identifying and decreasing errors, bettering the process of discharging patients, and quickening up CT scan throughput (Klein and Khan, 2017).

Used the Lean Six Sigma approach which led to considerable improvement in an emergency department in Australia (Stanton et al., 2014).

Analyzed and described that Lean and Six Sigma are more adaptive to processes that have a linear sequence of events (Deblois and Lepanto, 2016).

Combined Six Sigma methodology and discrete event simulation in order that improvements to decrease overcrowding in an Emergency Department may be identified (Hussein et al., 2017).

Compared to other industries, the use of radioisotopes in nuclear medicine is particularly important because of the high stakes involved. Accurate diagnosis and treatment are critical to patient outcomes, and the handling of radioactive materials requires strict adherence to safety protocols. The consequences of errors of failures in this field can be severe, making the effective and efficient utilization of radioisotopes essential.

2.2 Lean Six Sigma for Continuous Process Improvement

The collaboration between the University Hospitals of Morecambe Bay of the National Health Service Trust and the Manufacturing Institute is an outstanding example of introducing Lean methods for continuous improvement in the healthcare sector (Cole, 2010).

The Virginia Mason Medical Centre has optimized Lean methods to identify wastes in the Centre. Through re-designing processes and technology, the Virginia Mason Hyperbaric Oxygen Centre reduced its workday up to 50%, stepped up the number of patients per attendant by 100%, and eliminated waiting times for treatment.

The Flinders Medical Centre's "lean thinking" process improvement program has helped the hospital provide easily accessible better care over a period of increase in demand. To apply Six Sigma methods to achieve a reduction of 70% in cycle time for entry of case record forms in phase III clinical trial, while maintaining a statistically acceptable error rate requirement.

A report on Lean Six Sigma methodology wherein the time required for completion of phase 1 clinical trial was improved by redesigning standardized case record forms, making a dashboard system for monitoring important performance indicators, and making available the hardware and software systems so as to decrease cycle time for data analysis.

2.3 Application of Lean Six Sigma in an Emergency Department

Various examples on the use of Lean Six Sigma methods in community-based hospitals to enhance throughput in the Emergency Department, decrease Operating Room turnaround time between surgical cases, modify operating room organization, reduce linen loss, reduce unnecessary CT scans in an emergency department, implement evidence-based sepsis protocols in an emergency department, lean the surgical outpatient screening process, and design women's center processes (Cudney et al., 2013).

Six Sigma methodology was applied to improve processes that include emergency department cycle time reduction, clinic patient preparation, and medication safety, identifying and decreasing errors, bettering the process of discharging patients, and quickening up CT scan throughput (Klein and Khan, 2017).

Used the Lean Six Sigma approach which led to considerable improvement in an emergency department in Australia (Stanton et al., 2014). Analyzed and described that Lean and Six Sigma are more adaptive to processes that have a linear sequence of events (Deblois and Lepanto, 2016).

Combined Six Sigma methodology and discrete event simulation in order that improvements to decrease overcrowding in an Emergency Department may be identified (Hussein et al., 2017).

2.4 Evaluate Quality Indicators with Six sigma scale

Endorsed the use of a Six Sigma scale (based on six standard deviations differently representing a defect rate of 3.4 per 1,000,000 opportunities) as a method of tracking on laboratory quality, establishing benchmarks, and measuring changes in laboratory performance over time (Nevalainen et al., 2000).

2.5 Lean Thinking in Healthcare

Being very important and complex in every society, the healthcare sector approved of the importance and benefits of introducing Lean and today represent one of the most promising prospective areas for further expansion in the number of involved hospitals and healthcare sectors on one side and a host of techniques, tools, approaches on the other (Mazzocato et al., 2010).

2.6 Perceived Dimensions of Quality in Healthcare

Quality is important to clients when determining the value of a service or product, and it has been considered a strategic feature for establishing business success and the ability to thrive (Alshammary, 2017). Seven categories or dimensions identified that were important to patients: (Dr. R. Venkatesh, 2015).

1) Patient-centered care
2) Access
3) Courtesy and emotional support
4) Communication and information
5) Technical quality
6) The efficiency of care Organization
7) Structure and facilities

For service organizations, quality is crucial for maintaining profit, but it is not easy to consistently handle it (Alshammary, 2017).

The intangibility, inseparability, heterogeneity, and perishability characteristics of a service are the most significant factors affecting how a customer perceives service quality (Alshammary, 2017; Naidu, 2009).

2.7 Healthcare Service Quality

Measured service quality of the hospital implementing lean management. The study found that the service quality level of the hospital implementing lean is moderate. In addition, the largest positive gap between patients' perception and expectation is in terms of tangibility. The largest negative gap is with respect to assurance (Al-Damen, 2017).

The quality dimensions and patient satisfaction were examined in a public university hospital in Ghana. Findings revealed gaps across all the SERVQUAL dimensions with SERVIQUAL dimensions. Patients' satisfaction was best explained by perceived responsiveness, followed by perceived empathy, perceived assurance, perceived tangibility, and perceived reliability (Al-Damen, 2017).

2.8 Critical literature reviews:

In this case study, "A Healthcare Lean Six Sigma System for Postanesthesia Care Unit Workflow Improvement" and the study presents a new model called Healthcare Lean comprises Six Sigma System that integrates Lean and Six Sigma methods to improve workflow in a postanaesthetic care unit. They applied the HLS model in order to help improve the process in the PACU which comprises 4 formative stages. The lean techniques or tools used to identify activities could be changed to minimize waste and improve the quality that is root cause analysis and value stream mapping. The six sigma tools that have been used in this study are HOQ, AHP, DMAIC, and DMADV processes and these concepts help identify and prioritize the critical root causes of poor workflow that could be stepped up by technology. In summary, the lean focuses on bettering the flow in value stream mapping and does away with waste, while Six Sigma focuses on diminishing variation (Kuo et al., 2011).

Another case study, "The Applicability of Lean and Six Sigma Techniques to Clinical and Translational Research", the study's prime objectives are to Improve quality, avoiding delays and errors, and speeding up the time to implementation of biomedical discoveries. The method which is adopted is to review the available literature involving the application of lean and six sigma to health care, laboratory science, and clinical and translational research is reviewed and other approaches are Business Process Modelling, Business Process Reengineering, and Workflow Mapping, as well as a variety of TQM and CQI-oriented techniques such as management accounting systems, Kaizen, and Shewhart cycles (PDCA). In the conclusion Lean and Six Sigma process improvement methodologies are well suited to help achieve NIH's goal of making clinical and translational research more efficient and cost-effective, enhancing the quality of the research, and facilitating the successful adoption of biomedical research findings into practice (Schweikhart and Dembe, 2009).

The study, "Application of Six Sigma methodology to a diagnostic imaging process", was carried out in the medical imaging department of a private Turkish hospital. It aims to apply the Six Sigma methodology to improve workflow by eliminating the causes of failure in the medical imaging

department. The methodology adopted was the Implementation DMAIC improvement cycle, workflow chart, fishbone diagrams, and Pareto charts were employed, together with rigorous data collection in the department. The findings included the most frequent causes of failure were a malfunction of the RIS/PACS system and improper positioning of patients. Subsequent to extensive training of professionals, the sigma level was increased from 3.5 to 4.2. the limitation of the study is that the data were collected over only for four months. In the conclusion, the author concluded the improvements in the workflow understudy, made by determining the failures and potential risks associated with radiologic care, will have a positive impact on society in terms of patient safety (Taner et al., 2012).

In an interventional case study, "Applying Lean Six Sigma methods to reduce the length of stay in a hospital's emergency department", the research focus is to apply the Lean Six Sigma methods to reduce the length of stay in a hospital's emergency department and to improve the patients' experience early in the process by triaging them more quickly and retaining them in the system. The study methodologies which include DMAIC and Design process, optimize cross-functional processes, Root cause analysis, Project Charter and Stakeholder Analysis, Develop cause and effect relationships, Continuous improvement cycle or PDCA cycle, and 5 Why's analysis. The author concluded that the team achieved great success in improving the Emergency Services processes. The length of stay, the percent of patients leaving without being seen, the door to doctor time, and patient satisfaction all improved significantly (Furterer, 2018).

The study, "Decreasing Turnaround Time and Increasing Patient Satisfaction in a Safety Net Hospital-Based Pediatrics Clinic Using Lean Six Sigma Methodologies", the study was carried in the pediatric clinic to analyze the problem and develop potential solutions using LSS tools. The tools which were used Lean Six Sigma methodologies such as observational lead time analysis, Spaghetti charts, 5S methodology. Following implementation, the overall cycle time was decreased from 113 to 90 minutes. Patient satisfaction ratings increased from 87% to 95%. The author concluded that using Lean Six Sigma tools can be invaluable to clinical restructuring and redesign and results in measurable, improved outcomes in care delivery (Jayasinha, 2016).

The study, “Effects of Lean Healthcare on Patient Flow: A Systematic Review”, the focus is to assess the effects of LH on patient flow in ambulatory care and determine whether waiting time and LOS decrease after LH interventions. The LSS methodologies include PRISMA, RCTs and Quasi-RCTs, and CBA. The findings include waiting time for patients before seeing a healthcare professional decreased in 24 out of 26 studies. Waiting time for treatment and waiting time for appointments were minimized in 4 and 2 studies, respectively. The limitation of the research is that the researchers did not conduct a meta-analysis and there is a lack of statistical analyses and might drive the bias as well. The researcher concluded that LH helped to reduce waiting time and LOS in ambulatory care, mainly owing to its focus on identifying and minimizing NVA activities (Ahmed et al., 2013).

The exploratory study, “Improving Sentinel Node Gamma Imaging Workflow with Lean Methodology”, at the Helsinki University Central Hospital, Medical Imaging Center, Department of Nuclear Medicine. The aim of this development project was to standardize practices, increase patient safety, and increase efficiency. For workflow, improvement needs Lean methodology was selected. Tools used to analyze workflow were VSM, spaghetti diagram, 5S, and throughput time following. The limitation of the study is when Compare to other Lean studies in the medical imaging context, the study focused more on patient safety, the most of other studies where more focused on increasing efficiency and throughput. The conclusion is that this project showed that there are many things that can be improved even in small workflows (Lähdeniemi, 2014).

In experimental study, “Lean Approach to Improving Performance and Efficiency in a Radiology Department”, the research focuses on the lean approach, which emphasizes process analysis, has particular relevance to radiology departments, which depend on a smooth flow of patients and uninterrupted equipment function for efficient operation. Lean management and process improvement tools include Value stream mapping, Root cause analysis, Team charters, 5-S Approach, Visual Systems and Cues, Level Scheduling. The author concluded that implementing a lean approach to improve organizational performance implies never losing sight of what the

customer wants, the goal, or the ideal and to apply lean principles to improve efficiency, performance, safety, and employee commitment (Kruskal et al., 2012).

The study, "Reducing Laboratory Billing Defects Using Six Sigma Principles", and its focuses in an effort to decrease healthcare costs, the researcher investigated the laboratory billing practices at a tertiary academic medical Centre to determine where they could apply Six Sigma tools to improve these processes. The LSS methodology Using SIPOC analytics, DMAIC processes, Cause and effect tree, Using a Chi-square analysis, and Control charts. In the laboratory, these methods have been used to improve the timeliness of inpatient phlebotomy, reduce the frequency of registration errors, and minimize pre- and post-analytic errors. The laboratory improved the rate of unbilled tests from 25% to 2.6%. The author concluded that the application of Six Sigma quality improvement tools to the clinical laboratory setting helped identify specific billing processes to improve, apply specific interventions to improve the billing processes and create solutions to improve and maintain the improved performance of the billing practices (Levtzow and Willis, 2013).

The study, "Lean thinking in healthcare: a review of implementation results", Healthcare systems worldwide focusing continuous pressure to reduce all types of costs for its services from one side, but also, on the other side, to increase quality, reduce the response, waiting, and lead time, improve patient safety. The most frequently used Lean Tools are 5S methodology, Kaizen, VSM, and Visual Management. The author reported impressive results with a 42% reduction in paperwork and a reduction in length of patient stay by 33%. The author concluded that the observed healthcare systems, obviously, had a high level of organization and management in the initial phase yet they realized remarkable results thorough lean concept, which should serve as an inspiration to all others, no matter their present condition and performances (Kovacevic et al., 2016).

Another study, "Lean six sigma methodologies improve clinical laboratory efficiency and reduce turnaround times", the study was carried out in the Department of Medical Biochemistry, Turkey. The research focuses on lean Six Sigma to simplify the laboratory work process and decrease the

turnaround time by eliminating non-value-adding steps. The research findings included the pre-analytical process in the reception area was improved by eliminating 3 h and 22.5 min of non-value-adding work. Turnaround time also improved for stat samples from 68 to 59 min after applying Lean. In conclusion, laboratory management is required to decrease costs, increase efficiency, and promote user satisfaction by emphasizing quality (Inal et al., 2017).

In the study, "Leveraging Six Sigma to Improve Hospital Bed Availability", the study has been done in the "Our Lady of Lourdes Regional Medical Center", located in Lafayette, this medical Centre implemented Six Sigma to resolve hospital bed availability delays. Using the Six Sigma's DMAIC process, the team set out to define the various criteria for process improvement. The author concluded that not only has this project reduced the total time of the 'discharge to bed available process,' it has also served as a force for cultural change within the hospital (Raisinghani et al., 2005).

In this case study, "Factors Affecting Provision of Service Quality in the Public Health Sector: A Case of Kenyatta National Hospital", the main purpose of this research is to explore the factors affecting the provision of service quality in the public health sector in Kenya, focusing on employee capability, technology, communication, and financial resources. The methodology or tools used in this study are descriptive survey method, stratified random sampling, Closed and open-ended questionnaires, Regression Analysis (ANOVA). The result shows that low employee capacity led to a decrease in the provision of service quality by a factor of 0.981 with while Inadequate Technology adoption in the provision of health service led to a decrease in the provision of service quality by a factor of 0.917. From the findings, the study concluded that organizations must enhance employee's capacity in order to improve the provision of service quality (Dr. Kenneth et al., 2012).

In the study, "Guiding Inpatient Quality Improvement: A systematic Review of Lean and Six Sigma", research focuses on a systematic literature review was conducted to determine whether Lean, Six Sigma have been effectively used to create and sustain improvements in the acute care

setting. The methods were used as article selection: Databases were searched for articles published in the health care, business, and engineering literatures. Summary reports, pre-post observational studies, or time-series reports. Database searches identified 539 potential articles. After review of titles, abstracts, and full text, 47 articles met inclusion criteria—10 articles summarized multiple projects, 12 reported Lean projects, 20 reported Six Sigma projects, and 5 reported Lean Sigma projects. The conclusion drawn by author is that the Lean, Six Sigma, and Lean Sigma as QI approaches can aid institutions in tackling a wide variety of problems encountered in acute care. However, the true impact of these approaches is difficult to judge, given that the lack of rigorous evaluation or clearly sustained improvements provides little evidence supporting broad adoption. The limitation of study was that the Study has provided with limited data, with only 15 articles providing any sort of follow-up data; of the 15, only 3 report a follow-up period greater than two years. There is no clear study that will improve the evidence base for understanding more about QI approaches and how to achieve sustainable improvement (Glasgow et al., 2010).

The study, "Analysis and Evaluation of Reviews on Lean and Six Sigma in Healthcare", This article characterizes the literature by evaluating and classifying 22 reviews, based on year of publication, country, taxonomy, health care setting, outcome, tools, and enabling factors. With respect to Lean and Six Sigma tools mentioned in reviews, as well as the enabling factors that allow successful implementations, value stream mapping (VSM) is the favourite tool used when performing Lean and Six Sigma projects, followed by work redesign. Findings indicate that 90% of reviews are characterized by restrictive inclusion criteria that result in the inclusion of only 3% to 66% of the literature at the corresponding time. Furthermore, there is no full comprehensive literature review available on Lean and Six Sigma in health care. The conclusion drawn by author is that this study will allow researchers and practitioners to have an updated reference to start mapping and understanding the vast literature on Lean and Six Sigma in health care. The study should have broader applications in various health care settings and multiple countries, using lean and Six Sigma tools (Peimbert-García, 2019).

The study, “Lean Six Sigma and Digitize Procurement”, the research focuses on the lean Six Sigma method can be applied to procurement, processes where there is an extensive use of information technology and communication (ICT) systems. Lean Six Sigma and digitize methodology Using the CTQs defined in the measure phase, Analyse and process design. It was found that the digitization of a procurement process which is not streamlined can generate problems. A process must be mapped to highlight waste and low quality. Only when the new process is improved, taking into account also that it will be possible to use ICT supports, can it be digitized. The new process will digitize only value-added activities recognized by the users and by the organization. The conclusion drawn by author is that the model provides a logical sequence to the activities of streamlining and digitizing processes: first streamline, and at the same time, digitize the value-added activities recognized by the customers. In this way, one can avoid to enter in the process and information systems any waste that could be the cause of delivery process delays or blocks. The limitation of the study is that the study used a broad selection of large enterprises. The final model responds to the lack in literature of a consistent method that manages and integrates the classical activities of streamlining a procurement process, with the activities of digitization. Further work is necessary also on the support of Lean Six Sigma and ICT to the procurement processes. Until now, most of the tools and systems are built to support functions rather than processes. It is necessary to analyse in more details the connections between Lean Six Sigma and ICT. There is the need of more integrated tools (Nicoletti, 2013).

Another Case study, “Improving Care Delivery Through Lean: Implementation Case Studies”, focuses on to examine the ways in which each organization has implemented Lean and identify the factors that influenced progress within individual Lean projects and on the ultimate outcomes. The focus on specific projects allowed people to better understand how Lean works practically speaking at each organization, and how variation in the project target area may affect Lean success. The tools or methods used were Data Collection Activities, Site visits with in-person interviews, Collection of documentation, Implementation Phase Data Collection Activities, Digital diary, Telephone interviews, and Collection of documentation. To ensure a consistent application of the coding system across three coders, inter-coder reliability was tested after every 20 interviews. The

average reliability for all coding was 92.8 percent. The conclusion is that the implementation of Lean at Heights Hospital has been successful, despite the challenges of a hiring freeze, reluctant senior leadership engagement early on, and the resistance of some staff and physicians. Thus far, Heights Hospital's experience provides evidence that Lean can be successful when applied to administrative and management processes. Lean has been focused primarily on administrative tasks (e.g., scheduling, patient flow, medical records, billing) within clinical settings, with success particularly in revenue management. The limitation of the study was that the use of primarily qualitative data collection techniques presents some limitations. The freedom to tailor questions and probes to each respondent is the hallmark of the qualitative interviewing methodology. Because the interviewer does not adhere inflexibly to the written questions – by asking every question, using the exact written language, in the exact sequence – the study findings are limited by two potential sources of bias. Overall, in the process of designing the new hospital using Lean principles, interviewees seemed to be concerned with the strain on staff time and with ensuring all necessary staff and patient voices were being involved in the design process. Further complicating matters, LHC experienced turnover of key management engineers and administrative personnel during the latter half of the process redesign process (Carman et al., 2014).

The study, "Effects of Lean Healthcare on Patient Flow: A Systematic Review", the research focuses on to assess the effects of lean healthcare (LH) on patient flow in ambulatory care and determine whether waiting time and length of stay (LOS) decrease after LH interventions. The methods were used Preferred Reporting Items for Systematic Reviews, Meta-Analyses (PRISMA), Randomized controlled trials (RCTs), Quasi-RCTs, and controlled before-after (CBA). The research finding is that Out of 5627 studies, 40 were included. Regarding LOS for all patients, 19 out of 22 studies reported a decrease. LOS for discharged patients decreased in 11 out of 13 studies, whereas LOS for admitted patients was reduced in 6 out of 7 studies. Waiting time for patients before seeing a healthcare professional decreased in 24 out of 26 studies. Waiting time to treatment and waiting time for appointments were minimized in 4 and 2 studies, respectively. Patients who left without being seen by a doctor decreased in 9 out of 12 studies. Finally, patient and staff satisfaction were measured in 8 and 2 studies, respectively, with each reporting improvements.

According to our findings, the conclusion is that the LH helped to reduce waiting time and LOS in ambulatory care, mainly owing to its focus on identifying and minimizing non-value added (NVA) activities. Nevertheless, evidence of the impact of LH on patient/staff satisfaction and the translation of the obtained benefits into savings is scarce among studies. The limitation of the study is that Risk of bias (RoB) using the Cochrane's tool Risk of Bias in Non-randomized Studies of Interventions (ROBINS-I) because the majority of studies were observational and ROBINS-I is a tool for evaluating RoB in estimates of the comparative effectiveness of interventions from studies that did not use randomization to allocate units. The results do not have an effect on statistical tests, as used in quantitative synthesis, the lack of randomization prevents the reported outcome improvements from being causally linked to the lean interventions, the multi-component nature of LH, along with the heterogeneity of the data (differences in time for low and high acuity, settings, triage systems, patient volume, and data collection/processing approaches) make it difficult to generalize results and the heterogeneity of the studies and RoB prevented us from conducting a meta-analysis and thus determined causal relationships, also the study have done for less than 1 year. In this research, the researchers did not conduct a meta-analysis. The lack of statistical analyses and might drive the bias as well. Follow-up results of less than one year, yet longer follow-up performance metrics (e.g, 3 to 5 years) are required to evaluate the sustainability of LH and the improvement strategies of similar processes (Tlapa et al., 2020).

The study, "Using Lean Six Sigma to Improve Rates of Day of Surgery Admission in a National Thoracic Surgery Department", the research focus is that to improve rates of day of surgery admission (DOSA) for all suitable elective thoracic surgery patients. The methods used were Pre-surgery checklist and Thoracic Planning Meeting, DMAIC process, Face to face interview, Data collection by using Gemba walk, VSM, VOC and Kaizen Pick chart. The research finding was that over a 19-month period, DOSA has increased from 10 to 75%. Duplication of preoperative tests reduced from 83 to <2%. Staff and patient surveys show increased satisfaction and improved understanding of ERAS. The conclusion is that Using LSS methods to improve both operational process efficiency and organizational clinical processes led to the successful achievement of increasing rates of DOSA in line with national targets. Time limitations were a challenge for all

group members and not readily anticipated from the outset. It was increasingly difficult to take time from clinical hours to preform Gemba assessments and patient interviews as all team members were senior staff in their areas of expertise. The sample size of patient interviews was low (n = 5), and there was a lack of repeat VOC measurement undertaken for both patients and staff in the control phase. Other limitation was that challenging LSS methods included the Actual Gemba, where team members followed the patient's pathway on the ward which did not allow for sufficient data collection. The majority of team members had limited experience working in the thoracic surgery department prior to this project (Brown et al., 2019).

The study, "Using Six Sigma DMAIC Methodology and Discrete Event Simulation to Reduce Patient Discharge Time in Kind Hussein Cancer Cente", the research focuses on the Six Sigma process improvement methodology was applied to reduce patients' discharge time in a cancer treatment hospital. The Six Sigma DMAIC methodologies, Process maps, Cause-and-effect diagrams, SIPOC analysis, Discrete Event Simulation and Control charts were used in this study. After verification and validation, analysis of the simulation results provided a means for doing scenario comparisons and identifying key process factors affecting performance of the discharge process. The total reduction in discharge time was approximately 54%. The conclusion is that the patient discharge process was complex and unstandardized and involved multi-department processing and sequential operations. Discharged patients were classified into two groups (standard and complex patients) since their discharge times differed significantly. This was due to the fact that complex patients required extra needs (medical supplies and equipment) and thus extra processing steps and time, many of which can be pre-planned and prepared before the discharge process took place. The limitation of the study is that Physicians do not feel comfortable adopting a standardization initiative unless there is transparent evidence of its impact on patient outcomes. Physicians have high levels of influence and impact on the control process steps, but their interest in these issues is low. In study researchers should have involved physicians in the analysis and development of solutions, whether through participation in the improvement team or workshops and meetings presenting and discussing quality improvement issues (Arafeh et al., 2018).

Another case study," Six Sigma Application in Healthcare Logistics", the research focuses on first, this research proposes how Six Sigma can be employed to improve healthcare logistics. Secondly, this paper introduces a novel approach to determine the critical Six Sigma projects which provide maximum benefits to the healthcare organization. Used methodologies were DMADV (define, measure, analyse, design, and verification) methodology and Lean, thinking principles, DMAIC (define, measure, analyse, improve, and control), Cause and effect diagram and Questionnaire. Research finding was that the Index was calculated for all items at the medical supplies warehouse by the Six Sigma project team. As a result of this step, the II values for "Intra-aortic balloon" and "Seroquel 300 mg tablet" are still the highest among all items. Therefore, the project selection done during the define phase is still valid, and the Six Sigma team proceeded the work with the defined project reduce the II value for Intra-aortic balloon and Seroquel 300 mg. the conclusion is that the Six Sigma is a pioneer problem-solving technique and a leading process improvement method. We presented how it can be used effectively to deal with healthcare logistics issues, including deciding the major problems to be solved and solving them. We also showed that some tools used for manufacturing applications might not be very useful in-service applications such as healthcare logistics without modifications, so we built a framework that could be used to select and implement Six Sigma projects. The limitation of the study was that some tools used for manufacturing applications might not be very useful in-service applications such as healthcare logistics without modifications. This article paves the road for research to elaborate on ways to use Six Sigma in the area of improving healthcare logistics (Al-Qatawneh et al., 2019).

The study, "Using Lean Six Sigma to Reduce Hemolysis in the Emergency Care Center in a Collaborative Quality Improvement Project with the Hospital Laboratory", the study focuses on Its efforts on improving pre-analytical work flow and blood collection processes—both negatively affected by haemolyzed specimens. The methods were used as Observation method, Interview method, Root cause analysis, DMAIC methodology and Using Failure Modes and Effects Analysis. The research finding is that ECC haemolysis decreased by 91%— from 9.8% (423 haemolyzed/4,295 collected) to 0.88% (58 haemolyzed/6,560 collected). Housewide haemolysis decreased by 59%—from 3.4% (2,046 haemolyzed/60,307 collected) to 1.39% (619

haemolyzed/44,528 collected). Since the project, haemolysis has continued to trend downward; the mean percentage has consistently been < .05% for the ECC and < 1% housewide. The conclusion is that Hemolysis continues to present a patient safety issue. Reducing variation in collection practices enabled the health care system, specifically the ECC, to meet the hemolysis reduction goal of < 2%. Since the project, hemolysis has continued to trend downward; the mean percentage has consistently been < .05% for the ECC and < 1% housewide. The limitation of the study was the tracking hemolysis is not an easy task with the current laboratory system. Higher turnover rates often affect the ability to facilitate change. The new ECC hiring practices requiring multiskilled technologists to have phlebotomy experience minimized the turnover effect. ECC training challenges also triggered the decision to extend employee orientation to include a day of shadowing laboratory technicians and phlebotomists. Lean-Six Sigma tools helped to pinpoint haemolysis as a key inefficiency in blood collection and preanalytical work flow. Although focused on the ECC, the project team standardized blood collection practices and instituted quality devices to achieve haemolysis reductions housewide (Damato and Rickard, 2015).

The study, “Perceived Dimensions of Quality in Healthcare”, Research focus is to is to identify perceived dimensions of quality in healthcare and the relative importance of each dimension. Content analysis method for analyzing published papers related to quality in the healthcare field. computer-aided text analysis to determine perceptions of quality, Pareto charts or Pareto analysis, Contingency table, Chi-square test, Principal component analysis (PCA) and The Kaiser-Guttman rule were used in this study. Results indicate that access, communication, and competence made significant contributions to the first principal component (PC 1). Communication had the second highest frequency in the publications accounting for 13% of the total count. Both conformance and facilities are significant elements in the second principal component (PC 2). Facilities also had the highest frequency of occurrence within publications accounting for 15% of the total count. The constructs of features and responsiveness corresponded to the third principal component (PC 3), whereas, security and understanding made significant contributions to the fourth principal component (PC 4). In conclusion, this research indicated that at least nine constructs are necessary to define the perceptions of quality in healthcare. These constructs have a relatively high frequency

of occurrence in the sample of publications. In addition, results suggest four components (meta-dimensions) that affect perceptions of quality in healthcare. These components were compared to dimensions of quality in the cited literature to demonstrate their validity.

In this research limitation was the dimensions of quality in healthcare were only identified based on selected articles published between 1999 and 2016. No attempts were made to stratify the publications based on the size, scope, or location of the healthcare provider. For example, some publications reflected research on healthcare quality within the U.S., while others reported research in Canada and Europe. Some research targeted quality aspects for small clinics, while others were focused on healthcare organizations with a number of hospitals. Also, the scope of services ranged from emergency care to integrated service systems. Stratification of publications according to these factors may help assess their effects on the perception of quality (Wasim A, 2017).

The study, “Factors Affecting Patient Satisfaction and Healthcare Quality”, the research focuses Is to build a comprehensive conceptual model to understand and measure variables affecting patient satisfaction-based healthcare quality. A total of 24 articles from international journals were systematically reviewed for factors determining patient satisfaction and healthcare quality and SERVQUAL instrument was used as a tool. The research finding is that the patient satisfaction is a multi-dimensional healthcare construct affected by many variables. Healthcare quality affects patient satisfaction, which in turn influences positive patient behaviours such as loyalty. Patient satisfaction and healthcare service quality, though difficult to measure, can be operationalized using a multi-disciplinary approach that combines patient inputs as well as expert judgement. Physician studies show that different role expectations give rise to different patient satisfaction, perception, care take-up and other compliance behaviour. The conclusion is that the model shows how patient and health providers create and affect health service quality. Patient involvement is an inherent feature in healthcare services whereby he or she influences outcome quality through compliance, describing the right symptoms and physically undergoing treatment. Patient loyalty results in positive behaviours such as recommending health services to friends and relatives, compliance and higher service use thus positively impacting profitability. The limitation of the

study is that the paper develops a conceptual model that needs to be confirmed empirically. Also, most research pertains to developed countries. Findings are presented that may not be generalized to developing nations, which may be quite different culturally. This article, by reviewing published research, found that patient satisfaction and healthcare quality are fundamental to improving health service performance and image (Naidu, 2009).

The study, “Systematic Literature Review of Quality Management in Healthcare Organizations”, the research focuses Is to systematically explore the field quality management in healthcare by performing a rigorous and computer assisted literature review. The tools were used in this study were Qualitative literature analysis, Content Analysis, Qualitative Data Analysis (QDA) software called nVivo, cluster analysis diagram and Thematic network model. The research findings were overall, there are eight best practices in Quality Management identified from the review of literature, Leadership and Commitment 13, Quality Services 12, Quality Information Processing 9, Process Management 9, Quality Education 12, Quality Administration and Planning 10, Continuous Improvement 13 and Culture Development 10. These practices were identified on the basis of their frequency of occurrence in the literature review. The conclusion of the study is that Healthcare services and delivery focuses on ensuring the highest levels of patient safety and process efficiency. With the help of medication use systems, healthcare management information system service provider can focus on patient care activities. Quality Practitioners can use Quality Management philosophy as strategic weapon for manage the change and can achieve quality outcomes like satisfaction of patient, quality services and control over the process. The limitation of the study was There is lack of flexibility in this research. The phenomenon of quality management in healthcare systematically from an interpretive/constructivist paradigm, the extant work in this area is limited and dispersed. This research only includes the past literature reviews and reviewed the abstracts of all articles of the literature base to check for relevance to our research study (Sharma and Gupta, 2015).

The study, “Factors Influencing the Quality of Healthcare Services in Indian Hospitals: A Systematic Review”, the study focuses Is to review and analyze the factors influencing quality

management in the Indian healthcare organizations, to identify the research gap. The literature for the review was obtained from the "PubMed" and Google Scholar with Indian affiliation, Inclusion/Exclusion criteria, Selection of Articles for the Review and Article Extraction and Analysis were used in this study. The study found that after categorization of the studies into different dimensions, we observed the attempts made by the healthcare research fraternity, exploring different management aspects with 2 studies identified under Planning & Documentation, 2 studies in Employee Participation in Quality Management Activities, 2 studies on the Existence of Policies/ Procedures/ Guidelines, 24 studies in Quality and Patient Safety Management, 9 studies on Evaluation of the Process and its Outcome, 14 studies in the area of perceived effect of quality improvement methods, 3 articles in Training and Development Opportunities, 1 study on future plans for improvement and finally 2 Other Studies which cannot be categorized under the eight listed categories and it is observed that majority of the studies fell under the dimension Quality and Patient Safety Management. The conclusion is that the authors explored the literature to study the prevailing quality practices followed in health sector over the period of last 20 years and they noticed that there were studies on the application of qualitative and quantitative aspects of planning, managing and appraising the quality of care. In order to explore the studies which were carried out in the Indian healthcare system, they categorized the identified articles based on nine different dimensions and the related variables. The limitation of the study was that there were no studies on the good practices of internal or external audit/accreditation, application of quality management tools, systems to track patient safety, risk management and reporting. There were different aspects of quality management, the various factors of quality management were not addressed fully. The study has included only Indian healthcare system with the different dimensions of quality related literatures. Another different method can be used such as surveys, case study, criterion-based interviews, direct observation, working paper, questionnaire-based studies, prospective study (Kamalasanan et al., 2019).

The case study, "Healthcare Service Quality and Its Impact on Patient Satisfaction-Case of Al-Bashir Hospital", the research is to measure the impact of perceived health care service quality on patient satisfaction at a major government hospital in Jordan. The case study was conducted in

outpatient clinics at Al-Bashir Hospital, Questionnaire technique, SERVQUAL model, Descriptive and inferential statistical techniques and Regression Analysis were used. Results show that there is an impact of perceived health care service quality on overall patient satisfaction. Reliability had the most influence, followed by empathy and assurance. The study provided a set of recommendations. It was noted that majority of the respondents who took part in this research was female gender (61.6%), between ages 40- 50 years (34.2 %). Result showed that (80.8%) of the respondents hold diploma or less, having moderate income and majority residence were in the capital. The conclusion is that this study was to test the impact of healthcare service quality (reliability, responsiveness, tangibles, assurance, empathy) on overall patient satisfaction at Al-Bashir hospital. The study proved that there is an impact of healthcare service quality on overall patient satisfaction. Correlations and multiple regression techniques proved that there is statistically significant impact of healthcare service quality on overall patient satisfaction. The reliability dimension had the greatest influence on patient satisfaction, followed by empathy and assurance, only 15.0 % of the variation in patient satisfaction was explained by three variables. This study was limited to Al-Bashir hospital as a case study, which limited the generalization of the findings. This research Conceptualized service quality from the patient perspective. In this study, Researches should perceive healthcare quality from the perspective of other stakeholders also (Al-Damen, 2017).

The study, “Quality Improvement Approaches and Models in Healthcare”, the research focuses on Is to review the efforts made to improve quality of healthcare by assessing the existing healthcare quality improvement models and to approach alternative directions for future research in the area. The methodologies were used are Literature survey methods, Case study, Process map, Logical framework analysis, Analysis of opportunities and challenges content analysis and Improvement model including PDCA cycle. The research finding is that in the literature survey, different approaches of quality improvement in healthcare were reviewed. The focus of most of the approaches was on a holistic way of improvement. Accordingly, general improvement models were provided to enhance quality in healthcare. This is a good input for improvement. But an explicit focus on major activities in the sector such as; demand management in healthcare, supply

chain management in healthcare, referral system management in healthcare and others need further study as they help in bringing better and focused quality improvement in the sector than following a general approach. It can be concluded that different studies were done to improve service quality in healthcare by considering that quality cannot be compromised especially in healthcare sector. And most of the studies focused on a general approach of improving service quality for better customer satisfaction. In addition, the reviewed studies focused more on minimizing the service provision time by following a holistic problem-solving approach. Thus, from the result of the analysis and discussion, it can be concluded that results in the previous studies have a holistic nature of improving the service quality in the sector. Improving quality in healthcare is a determinant issue as there is a work of life perpetuation in the sector. This improvement should be considered in different directions regardless of following a general approach. Studies on explicit healthcare activities should be there to bring the required change in the sector. The study on explicit healthcare quality issues such as; demand management in healthcare, supply chain management in healthcare, referral system management in healthcare and others, which are more influential in-service quality improvement of the sector, are not found in the reviewed literature (Woldegebriel et al., 2014).

The study, "Impact of Service Quality Dimension on Patient Satisfaction in the Private Healthcare Industry in Pakistan", research focuses on to identify the impact of service quality dimension on patient satisfaction in district Sargodha. The tools used were Questionnaire, online survey, Likert scale, software used is SPSS and Amos, Non-probability sampling design, convenient sampling was used to collect data, factor analysis and Bivariate correlation analysis. Considering the results concerning the specific hypothesis, it is seen that all except reliability and responsiveness are supported at the 0.05 levels. All the finding of hypothesis are as follows:

H1=Reliability was found to have a negative impact on patient satisfaction.

H2=Responsiveness was found to have a positive impact on patient satisfaction.

H3=Assurance was found to have a positive impact on patient satisfaction.

H4=Empathy was found to have a positive impact on patient satisfaction.

H5Tangible was found to have a positive impact on patient satisfaction.

In this study results indicate that assurance, empathy and tangible are significant for patient satisfaction, but reliability and responsiveness are insignificant.

The conclusion is that this research examined the relationship among variables and their significance. The main objective of this study was to identify which variable impact more on the patient satisfaction by using the SERVQUAL model. This model can also apply to the range of different service companies.

The limitation of the study was that the sample size of this study was small and in order to get more reliable results it is necessary to replicate the study by using larger sample size it also can use Govt as well as foreign hospitals located in Pakistan. Selected respondents were those people who are using the services of the private hospitals situated in District Sargodha. The study presented that may not be generalized as worldwide as it is limited to private sector hospitals situated in Sargodha (Rehman and Husnain, 2018).

A study, "An Empirical Study of the Factors Influencing Quality of Healthcare and Its Effects on Patient Satisfaction", the research focuses to provide people, especially the patients and healthcare professionals with sufficient information to understand the fundamentals of quality improvement, and to provide a starting point for improvement in quality that has greater influence on patient satisfaction. The methods and tools used were Questionnaire survey, Quantitative and qualitative data were collected using standardized questionnaire, totally 272 samples were collected, 208 from patients/ attendants and 64 from hospital administrators using simple random sampling technique and Friedman test and chi-square test were used for statistical analysis. The research findings are There is significance difference between mean ranks of factors influencing quality of healthcare and patient satisfaction.

Based on mean rank, (4.80) physical facilities is the most important factor on quality, followed by food (4.50) and behavior of staff and admission procedure (4.20). The study concludes that physical facilities is the most important factor on healthcare quality, followed by food and behavior

of staff and admission procedure from patient perspective. Quality improvement initiatives like quality mission statement of the organization, redesigning and reengineering in hospital regularly, bench marking within the hospital and management walk around to identify problems and issues on quality helps the administrators to work towards quality. The limitation of the study that the hospital chosen for study were all corporate hospitals in the capital city of Tamil Nadu, India, so, the study could not be generalized. In this study, researchers have included for their sample the patients and administrators but there is no samples of doctors and nurses and other staffs to know all the aspects of quality in healthcare sector (Dr. R. Venkatesh, 2015).

2.9 Research Gaps:

After critical analysis of the literature reviews pertaining to reduce process variation and waste in the department through Lean Six Sigma in healthcare and improve the quality of the services, the following are the research gaps extracted:

1) There is no clear study with identical timing patient flow, identifying waiting times, injections times, delays between injection and imaging and imaging times
2) There is a lack of strong empirical evidence of improvement or outcome measurements in the study
3) The level of evidence that SS is being applied correctly in health care settings is relatively weak
4) There are few studies which show full benefits of the SS by applying both strategic and operational levels
5) The Lean approach does not analyze the financial performance indicators of a process
6) There is no detailed study done related to radioisotopes utilization

2.10 Human Society Theory

While the given literatures do not directly relate to the utilization of radioisotopes in nuclear medicine, they do illustrate the broad application of lean six sigma methodologies in healthcare operations. These methodologies can be applied in a variety of settings and contexts to optimize processes and improve patient outcomes. When it comes to the utilization of radioisotopes in nuclear medicine, the use of Lean six sigma methodologies can be particularly beneficial in terms of improving the efficiency and effectiveness of diagnostic and treatment processes, reducing waste and variation, and enhancing patient safety.

Lean six sigma could be applied to the scheduling and preparation processes for patients undergoing nuclear medicine scans or treatments, to ensure that they are carried out efficiently and accurately. Overall, the use of Lean Six Sigma methodologies in nuclear medicine can lead to more effective and efficient utilization of radioisotopes, leading to better patient outcomes and a more streamlined and cost-effective healthcare system.

Additionally, the use of data analysis tools and statistical process control could help identify and mitigate sources of variation in the diagnostic and treatment processes, improving accuracy and reducing errors. Lean six sigma can also be used to develop evidence-based protocols and standard operating procedures to ensure consistent and effective use of radioisotopes.

The principles and tools of Lean six sigma can be applied to a wide range of healthcare processes to improve efficiency, reduce waste, and enhance patient care. This includes processes related to the utilization of radioisotopes in nuclear medicine.

For example, the optimization of operating room scheduling and development of new work plans to quicken up completion of equipment maintenance requests can lead to improved efficiency and uptime of equipment used in nuclear medicine. Similarly, reducing unnecessary CT scans in the department can help conserve radioisotopes and minimize patient radiation exposure. Also lean six sigma approach could be used to identify and eliminate sources of waste in the use of radioisotopes, such as unnecessary steps in the diagnostic or treatment processes. It could also be used to optimize scheduling and resource allocation in order to reduce wait times and improve patient flow.

2.11 Summary

While the examples given do not specifically mention the utilization of radioisotopes in the nuclear medicine, they do demonstrate the effectiveness of lean six sigma methodologies in improving healthcare operations and patient outcomes. These methodologies can be applied to various aspects of healthcare, including clinical and operational processes, to optimize efficiency and quality.

Furthermore, the reduction of errors and improvement of patient safety through six sigma methodology can be particularly important in the handling and administration of radioisotopes, which are potentially hazardous substances. Improvements in nuclear medicine department cycle time reduction and quicker CT scan throughput can lead to faster diagnoses and treatment for patients.

In summary, while more research is needed on the specific application of Lean Six Sigma to nuclear medicine processes, the existing literature suggests that these methodologies can be relevant and beneficial in improving the effective utilization of radioisotopes in healthcare operations. There may not be specific studies on the use of Lean Six Sigma methodologies in optimizing the utilization of radioisotopes in nuclear medicine, the relevance and importance of using Lean Six Sigma tools and techniques in healthcare operations are well-established. By applying these methods, healthcare organizations can improve their processes, reduce waste, increase efficiency, and enhance patient safety, all of which are critical in the utilization of radioisotopes in nuclear medicine. Therefore, the utilization of lean six sigma methods in the effective utilization of radioisotopes in nuclear medicine is relevant and important in improving the quality of care provided to patients, reducing costs and optimizing operational efficiency.

CHAPTER III:

METHODOLOGY

3.1 Overview of the Research Problem

There is an enormous need to improve the workflow of the nuclear medicine department in reducing operational cost, remove the non-value-added items or process or the wastes which delays the process or work efficiency in the department and patient satisfaction. However, the use of radioisotopes can be managed optimally with time. First, the time taken for each process step has always been a major factor while assessing the mapping process flow of the department. There are such areas where more defects are occurring due to delay in time and becoming obligation and needs improvement. Second, a short half-life of radioisotopes is the major factor in the nuclear medicine department which needs to be managed and utilized in time to reduce the wastage of the drug. It will cause a problem for the administrators or managers with the inefficient use of radioisotopes and it leads to delay in patient procedures. Third, there are fewer studies done in the nuclear medicine department with the use of lean six sigma methodologies. The complexity of the nuclear medicine department itself makes it more complex to use LSS methodologies and to identify which sigma level nuclear medicine stands in this competitive era of healthcare industry. Problem statement provides a clear and concise description of the issues that need to be addressed the use of radioisotope effectively in the nuclear medicine department.

In summary, there is a need felt to carry out a research project in this particular area to make the department smooth and efficient. To develop interventions for improving the process flow and to reduce delays and defects in the department, there is a necessity of systematic and detailed evaluation of the process. There is a need to understand the detailed process to identify causes of the errors or defects and to eliminate these errors by setting up some standards and by utilizing human resources/staff properly. Recommending solutions or providing roadmap to the management to eliminate defects or errors, to reduce deviation and process variation in the nuclear medicine department.

3.2 Operationalization of Theoretical Constructs

After analyzing the problem areas in the field of research pertaining to using LSS in the nuclear medicine department, it can be said that the following study will be carried out by defining the problem as, "There is a need to improve the radioisotopes utilization optimally with the use of the Lean Six Sigma methodologies in nuclear medicine department" which includes both clinical as well as an operational approach which covers all the aspects of the nuclear medicine department process steps integrated together, analyzed and can lead to a best possible solutions which will lead to defects reduction, process improvement and efficiently utilization of radioisotopes.

The overall result should help the organization to achieve the effective optimization of the radioisotopes effectively without any hinderance which will lead to incur high cost to the management with inefficient way of handling the operations of the department.

The overall result of this study could help to identify errors, variations in the process and helps to reduce redundancies in the organization with the use of lean six sigma methods and the Lean seven waste tools have been applied to identify the wastes in the department.

The most probable result of DPMO value could help to identify the organization's capacity or sustainability, DPMO value which falls under the sigma level indicates that where the organization stands based on its operational capacity and efficiency. It will show whether the organization could be sustained and to be competitive in the healthcare business sector.

3.3 Materials and Methods:

The research study carried out was an observational study that was descriptive in "PET-CT ST Diagnostic Nuclear Medicine & Molecular Imaging". The research design is both qualitative and quantitative design. The data collection was mainly of primary data which comprise of process flows for 120 patients' samples and mapped process flows of the department with real-time recording of TAT by direct observation.

To analyze the defects or errors in the nuclear medicine department, Lean Six sigma methodologies were used which includes; Pareto's chart to know the frequency and cumulative percentage of the defects, Ishikawa Diagram to analyze the causes of defects, 5 why's analysis/techniques to know the potential root cause of the problem, Lean seven wastes to identify the wastes or non-value-

added items in the department and DPMO, DPU, DPO to know the defects, opportunity and Sigma level for the efficient workflow of the nuclear medicine department. The statistical T-Test was conducted for each process time activity in the department that compliance with the Society of Nuclear Medicine Guideline Standards.

To recommend solutions to reduce the redundancies and defects with associated risks in the department and to improve workflow and radioisotopes utilization optimally in the department.

3.4 Research Purpose and Questions

The long-term goal of the research is to provide the effective Lean Six Sigma method to utilize the radioisotope optimally in the nuclear medicine department. The study is defined herein as the process of mapping, assessing, identifying, analyzing, and recommending solutions and strategies to improve the process.

The aim of the study is to use the lean Six Sigma methodology to improve workflow by eliminating the defects or to reduce the variations in the process for optimal utilization of radioisotopes. Particularly, the study has the following objectives:

1) To map and assess the process flow of the nuclear medicine department
2) To identify and analyze the bottlenecks or gaps in the workflow with the use of Lean Six Sigma Methodologies and Tools
3) To recommend the solutions to improve the process in the department.

3.5 Hypothesis for the Research:

After analyzing the problem areas in the field of research pertaining to using LSS in the nuclear medicine department, it can be said that the following study will be carried out by defining the problem as, “There is a need to improve the radioisotopes utilization optimally with the use of the Lean Six Sigma methodologies in nuclear medicine department” which includes both clinical as well as an operational approach which covers all the aspects of the nuclear medicine department process steps integrated together, analyzed and can lead to a best possible solutions which will lead to defects reduction, process improvement and efficiently utilization of radioisotopes.

Objective N	Statement of the Objective	Method/ Methodology	Resources Utilized
1	To map and assess the process flow of the nuclear medicine department	Observational and prospective study for a period of 3 months ▪ Data collection method ▪ Purposive sampling ▪ Recorded Turnaround Time ▪ Gemba walking for 12 weeks ▪ Sample size calculation ▪ N=120	Direct observation and staff inquiry, Microsoft Excel
2	To identify & analyze the bottlenecks or gaps in the workflow	Using Lean Six Sigma methodologies - Pareto diagram - Pivot table and graph - Ishikawa diagram - 5 why's analysis - Lean seven wastes - DPO, DPU and DPMO	Using Lean Six Sigma methodologies, Microsoft excel
3	To recommend the solutions to improve the process in the department.	After analyzing the process map the solutions recommended Providing roadmaps based on identified defects or errors in the department	

Table 3.4.1 Objective-Centric Methodology Table

3.6 Research Design

The process mapping carried out through Gemba walk and Gemba assessment to understand the workflow with the existing problems and inquired staff regarding workflow or process. The study has been done for a period of three-month, March-June 2022, which was an observational and prospective study and the research is both qualitative and quantitative design.

3.7 Population and Sample

The patient's data was collected through the observation method and the data collection was mainly of primary data which comprise of process flows for 120 patients' sample size.

The population targeted for the study were Patients in the Nuclear Medicine Centre, a total of 120 population size which was chosen by purposive sampling.

3.8 Participant Selection

Based on the process mapping, the stratification of steps for carried out in the department and TAT recorded for each process steps. TAT was recorded from the morning 8:00 A.M. to 6 P.M., with a final sample size of 120 patients. The entire process was stratified into 5 major sections, namely:

Sr. No.	**Stratification of process steps**	**Average TAT**
1.	TAT (turnaround time) from patient arrival time to patie preparation time	00:12:55
2.	TAT (turnaround time) from patient preparation time Injection preparation dispensing time	00:17:32
3.	TAT (turnaround time) from Injection preparati dispensing time to FDG dose administration time	00:12:37
4.	TAT (turnaround time) from FDG dose administrati time to uptake period time	01:24:35

5.	TAT (turnaround time) from Start of scan time to patie exit from the scan time	00:15:18

Table No. 3.6.1: Hospital Process Turnaround Time Metrics Table

The turnaround time for the average time from patient arrival to patient preparation calculated to be 12 minutes 53 seconds, TAT (turnaround time) from Patient preparation time to Injection preparation dispensing time calculated to be 17 minutes 32 seconds which needs to be improved, usually for injection preparation dispensing takes 5-10 minutes but here it is taking too much time for dose dispensing, TAT from Injection preparation dispensing time to FDG dose administration time calculated to be 12 minutes 34 seconds which is too high usually it should take a time of 5-10 minutes but here more time is taken for dose administration which definitely has to improve, TAT from FDG dose administration time to uptake period calculated to be 1 hour 24 minutes 30 seconds which needs improvement and TAT from Start of the scan time to Patient exit from the scan time is calculated to be 15 minutes 21 seconds which is too high usually it should not take more than 5 minutes.

3.9 Radioisotopes Activity Monitoring in the Department:

18F-FDG is a radioisotope of fluorine which is produced by cyclotron that emits positron and its short half-life is 109.7 min. The use of radioisotopes optimally can be managed with time and patient management at the scheduled times. Time management has been a major factor for assessing radioisotopes activities in the department can be assessed through an observational method to collect data from the departmental process flow with the help of Gemba Walk and assessment. The radioisotopes utilization can be monitored through the time taken for each process step for patient procedures.

3.10 Data Collection Procedures/Process Flow Mapping:

The process mapping carried out through Gemba walk and Gemba assessment to understand the workflow with the existing problems and inquired staff regarding workflow or process and observed for the period of three month with a sample size of 120 patients. The mapping was followed throughout the process starting from the FDG arrival to the nuclear medicine department till patient's scan done and shifting another patient on the table scan. After mapping the process, the core problem areas were identified.

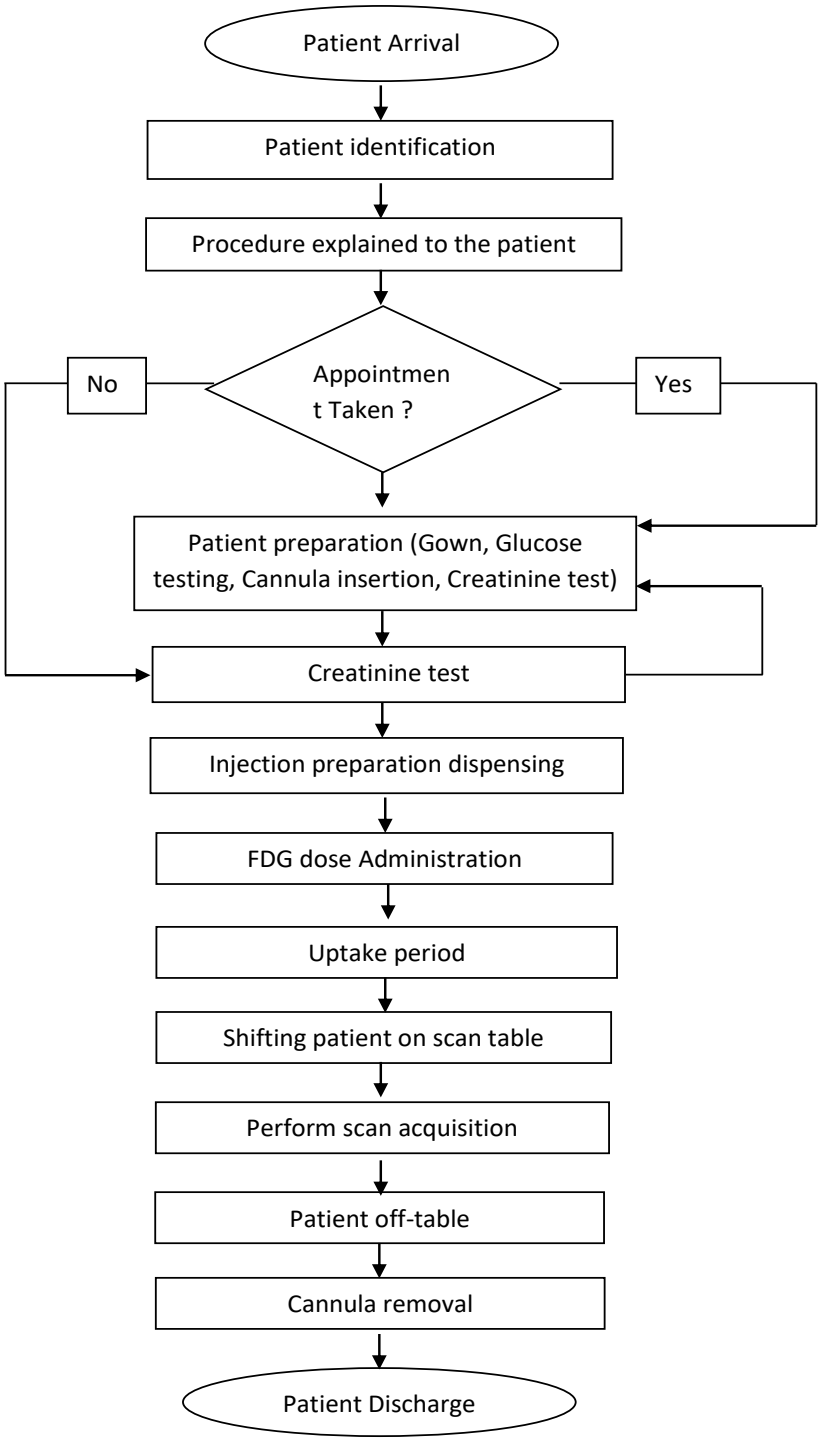

Figure 3.7.1 Hospital Workflow Visualization Diagram

In Detail Process Flow Mapping:

- The patient will come to the reception at first and it takes 10-15 minutes to make patient files and patient identification done by the receptionist.
- The receptionist sends the patient to the consultant room, where the doctor explains the procedure to the patient and takes the patient's history.
- For patient preparation, the nurse tells the patient to change the gown in the changing room and the nurse will do glucose testing, creatinine test, cannula insertion.
- If the patient has taken appointment day before then the receptionist informs the patient to do creatinine test one day before from any laboratory (to save the time) because the creatinine tests report takes one and half hours to get the test report
- If in case the patient will come without an appointment, the hospital staff will do the creatinine test in the Centre and it takes more than one extra hour to get the test report and patient has to wait for more time
- The technologist will do the injection preparation dispensing or makes the drug ready and bring from the Hot lab and the nurse or the ward boy brings the patient in the uptake room where the technologist administers the FDG drug to the patient
- The uptake period is at least 45-90 minutes, the patient has to wait in uptake room (the earliest scanning can be done after 50 minutes but should not exceed 90 minutes)
- Before the scan, the technologist or the nurse should send the patient to the Hot Toilet for emptying the bladder and the ward boy should shift the patient on a scan table
- The technologist performs the scan and it takes 18-20 minutes for full-body scanning
- The ward boy helps the patient off from the table
- The nurse removes the cannula from the patient and the patient got discharged

3.11 Data Analysis

After finding out the defects in the process during the process mapping and TAT recording for each process steps, Pareto's diagram, Pivot table, a cause-and-effect diagram/Ishikawa/fishbone diagram, 5 why's analysis, lean seven wastes, and Lean Six Sigma Assessment Metrics were analyzed for the main area of delay or defect.

3.12 Research Design Limitations

While conducting the study certain limitations were identified, which are as follows:

- The study is based on more operational level than the clinical level
- The study was only limited to PET Scans (Positron Emission Tomography)
- For finding out the FDG drug arrival time and quantity which arrives in the early morning was extracted with the help of enquiring the technician who will come early in the morning.
- Due to constraint of time, the patient's sample size collected only 120
- Few studies have been done and few literature reviews were available regarding using lean six sigma in the nuclear medicine department in Indian and International scenarios.
- Without Six Sigma knowledge and certification a person can't take up a Lean Six Sigma project, he or she needs to take a green belt or lean six sigma black belt certification course and get certified then only can take up this kind of project.

3.13 Conclusion

In nuclear medicine, there is room for improvement in reducing operational cost, remove the non-value-added items or the wastes which lead to delay in the process, improve access, improve work efficiency, health care quality, patient satisfaction, and most importantly patient safety. The entire study focused on using Lean Six Sigma methods for efficiently utilization of radioisotopes by monitoring patient procedure time and recording TAT for the entire process, identifying the gaps or defects which leads to delay in the nuclear medicine department, Analysing or finding out the

reasons for those defects or gaps with the use of LSS methodologies and providing a roadmap and solution to the department.

By studying the process flows of 120 patients, the major error areas and gaps were brought out for which Pareto's diagram and pivot graph were plotted and 5 why's analysis was done to find out the root cause of the problem. Lean seven waste tools have been applied to identify the wastes in the department. Calculated DPMO which has got 2.75 sigma level with a 1.5 sigma shift which shows the organization is not competitive at all and not efficiently working. The main defects or gaps which need improvement are delays in patient arrival time, patient preparation time, injection preparation dispensing, FDG dose administration, delay in uptake period, and delay in shifting the patient from the scan table.

Other important improvements that are needed for minimizing the cycle time by giving proper training to the staff and increase in the work efficiency of the nurse, increasing the manpower, hire a senior and experienced technician and reduce the downtime of the equipment by adequate calibration and maintenance of equipment. There will be a lot of improvement and reduction in the TAT of each process step by eliminating the defects.

CHAPTER IV:

RESULT

4.1 Variations in a Process Flow

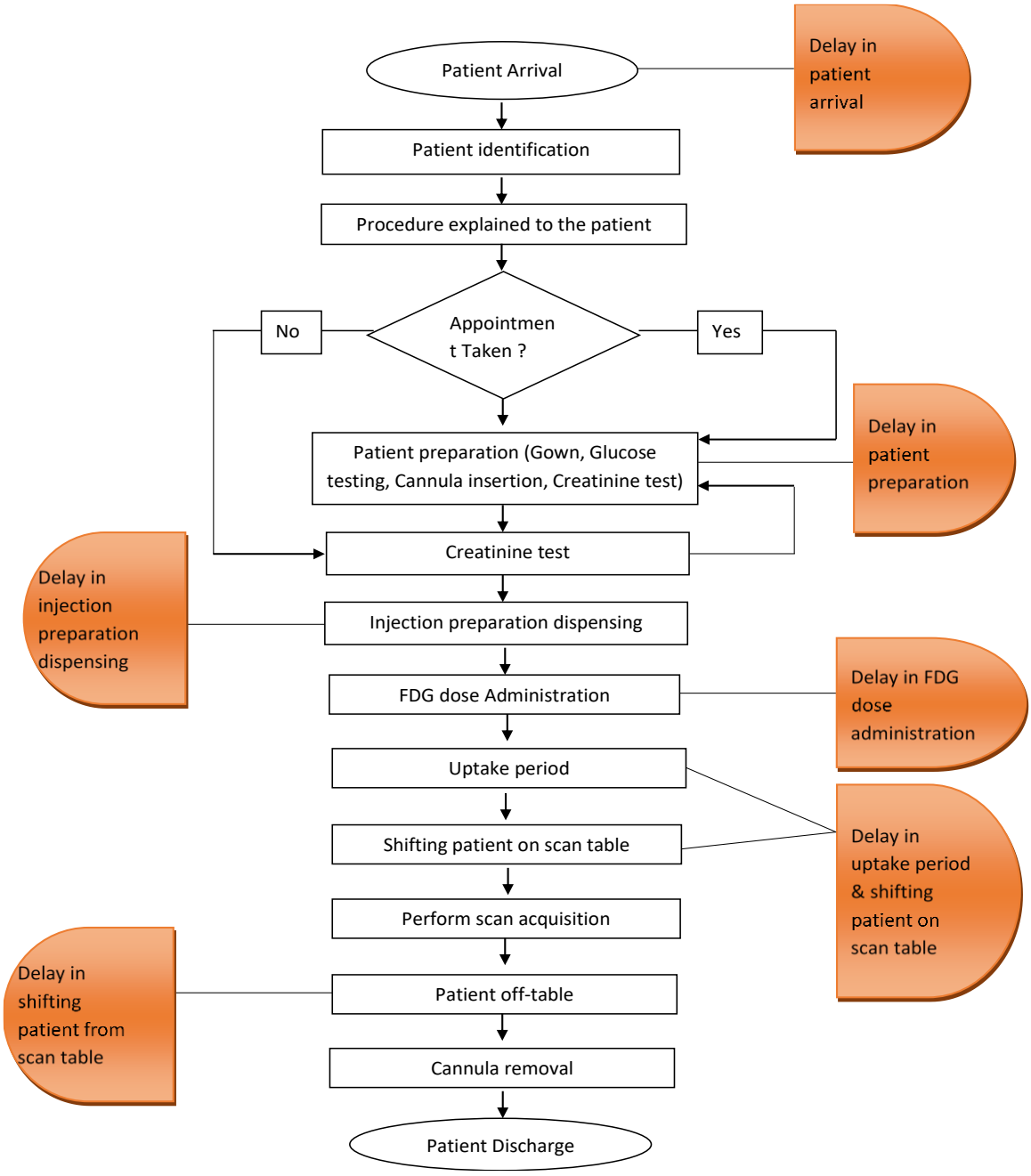

Figure 4.1 Hospital Process Flow Variability Chart

In the departmental process, I have got 7 areas where delays and defects occurred, there are so many causes that are leading to defects and delays.

These are the following areas:

1) Delay in Patient arrival
2) Delay in Patient Preparation
3) Delay in Injection Preparation Dispensing
4) Delay in FDG Dose Administration
5) Delay in Uptake Period
6) Delay in shifting patient on a scan table
7) Shifting Patient from Scan Table

According to the Society of Nuclear medicine Guidelines, the average standard time for each process are: (Boellaard et al., 2014, 2010).

Stratification of Process	**Average Standard Time**
Patient Preparation	12.5 minutes
Injection Preparation Dispensing	7.5
FDG Dose Administration	7.5
Uptake Period	60
Scanning	18.5
Gap Between Next Patient for Scanning	5

Table No. 4.1.1: Standard Time According to European Association of Nuclear Medicine Guidelines

4.2 To Analyze the Bottlenecks or Gaps in the Workflow

After finding out the defects in the process during the process mapping and TAT recording for each process steps, Pareto's diagram, Pivot table, a cause-and-effect diagram/Ishikawa/fishbone diagram, 5 why's analysis, lean seven wastes, and Lean Six Sigma Assessment Metrics were analyzed for the main area of delay or defect.

PARETO'S DIAGRAM:

Pareto's chart was plotted for the defects identified in the department to find out the major areas which are causing a delay in the department process.

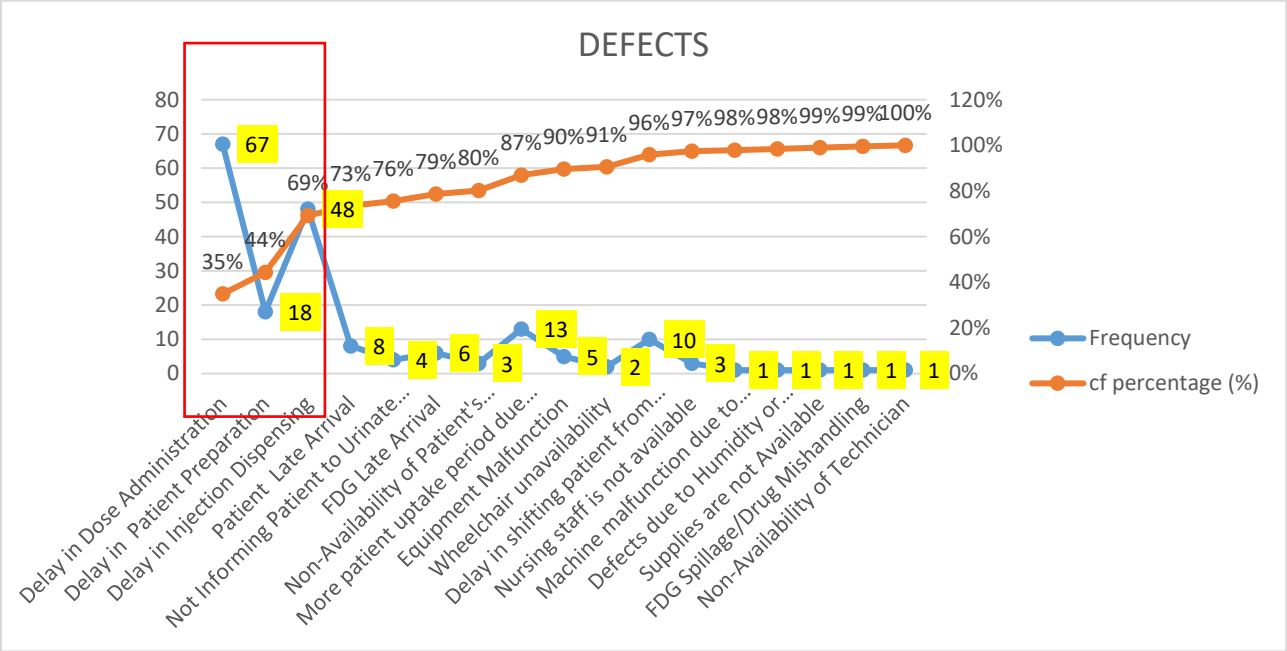

Table No. 4.2.1 (a) Defects Pareto Analysis Table

By plotting a Preto's chart it can be observed that most of the time consumed in dose administration which is about 35%, then next one is a delay in preparing patient which is about 44%, next one is a delay in an injection dispensing which is about 69% of the overall time consumed. These are all

three areas of defects are consuming more than 80% time which is causing delays or errors or defects in the departmental process which needs to improve and minimize.

PIVOT TABLE:

There are a total 192 number of defects found in the departmental procedure which are causing a delay in each and every process that leads to cause defects.

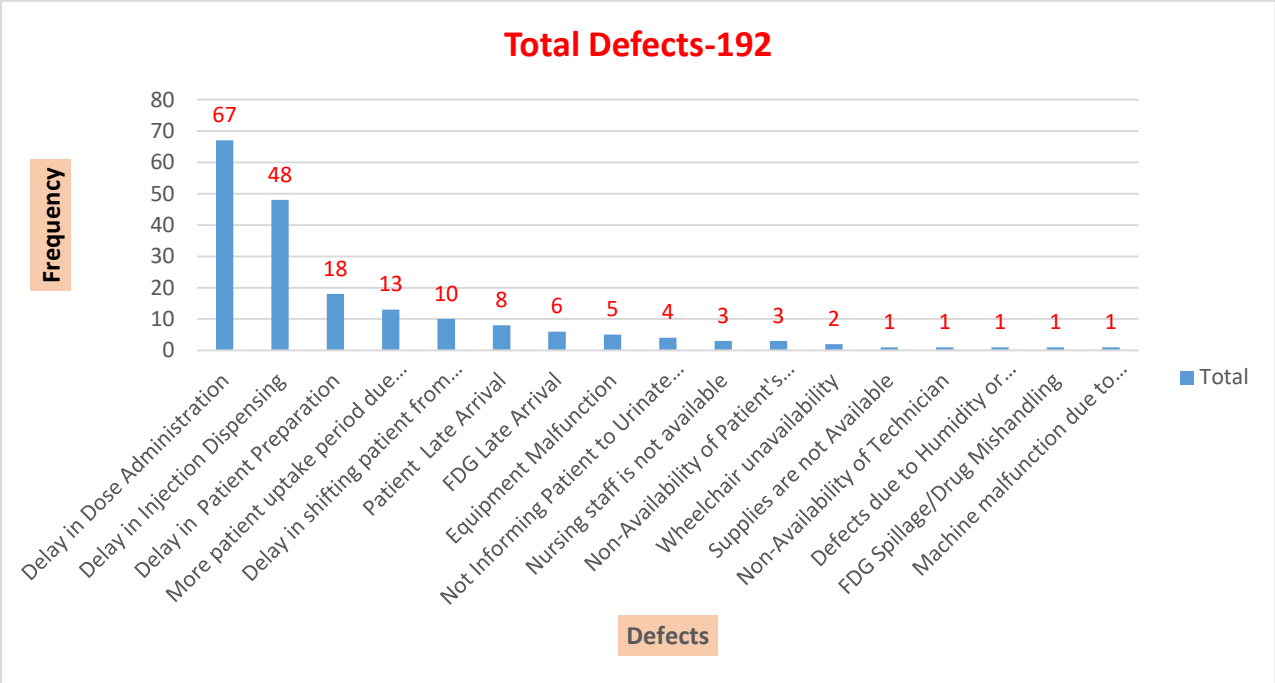

Table No. 4.2.1 (b) Defects Pivot Analysis Table

In the pivot table, it is clearly shown that most of the defects are in the dose administration area, delay in preparing patients and delay in an injection dispensing.

ISHIKAWA DIAGRAM:

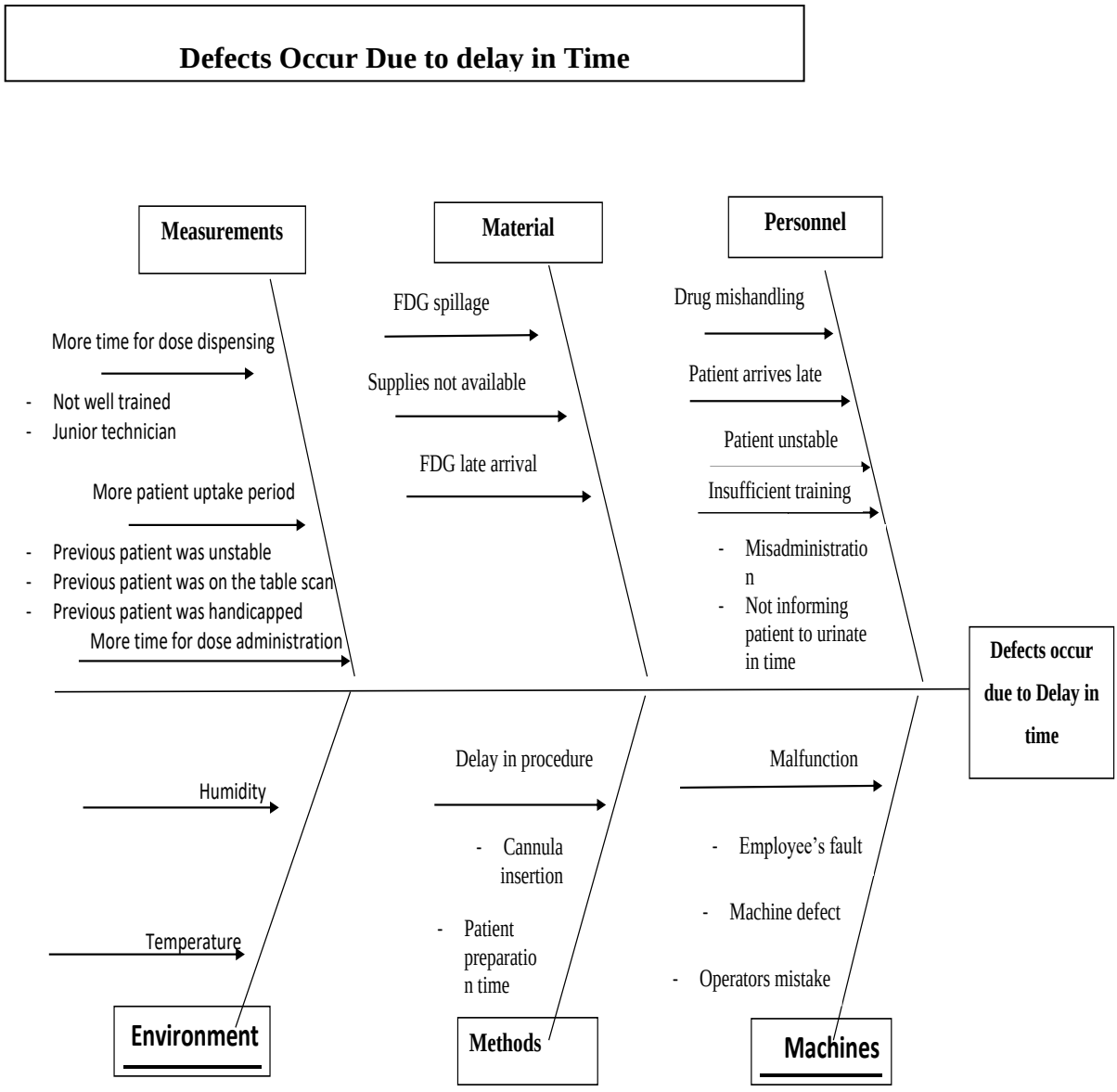

Figure 4.2 (a) Fishbone Analysis Chart with Source Attribution

Defects that occur due to delay in time is the overall main reason in the department. one of the main reasons in the department is Personnel or the Human resource that there is the mishandling of the drug by the technician while injection preparation dispensing, second reason is that the

patient arrives late in the department or not arriving in the given time. Thirdly, patient is unstable in the acquisition room and could not shift the patient from the table scan, the previous patient vomits in the acquisition room, etc. there is insufficient training to the staff from the management and the staff is inexperienced causing delays in the process, they have hired a junior technician who has less work experience and causing delays. There will be defects like misadministration, not informing the patient to urinate 10 minutes before the scanning, and delay in preparing the patient by nursing staff.

Another reason which causes defects due to delay in the department is material, accidentally FDG spillage over the area where the drug is dispensing in the hot lab then the procedure or the departmental work has to stop for at least 6 hours so that radiation should not affect the patient as well as staff, sometimes supplies are not available like cannula, catheter, gown, etc. and has to bring from another inventory store which takes time to bring to the patient preparation room which causes a delay for patient preparation and another reason is sometime FDG arrives late in the morning which causes a delay in scanning and whole procedure and patient has to wait for more.

Another parameter is the measurement, more time for dose/injection dispensing is the main reason which is causing a delay in the process due to not well-trained staff especially the technician is junior who has less work experience, another reason for the delay is more time in patient uptake period which is due to previous unstable patient, patient vomits in the acquisition room, the previous patient was handicapped and for shifting the staff needs to bring or arrange wheelchair and needs support and the previous patient is on the table scan and no staff or patient's attendant is not available to shift the patient from scan table.

Another parameter is Machine, sometime delay occurs due to malfunction of machine and operator by mistake pressed another button of the machine which stops the scan or freeze the machine and employee's fault by mistake they switch off the AC button or turned off the machine's main switch.

Another parameter is the method that causes delays in the procedure by nursing staff, delay in cannula insertion, and patient preparation time due to the non-availability of the staff. There are fewer human resources in the department and that is the main reason for delays.

Another last parameter is Environment, for equipment humidity and temperature plays an important role, sometimes due to more humidity and temperature the machine does not start and takes longer time to start and shut down in the middle and sometimes by mistake the staff switch off the AC which increases the temperature in the acquisition room which causes equipment shut down and takes longer time to run again the machine and causes a delay in the scan.

5 why's Analysis/Technique:

PROBLEM	Not Utilizing FDG drug Effectively and efficiently	
SR. NO.	**WHY**	**ANSWER**
1	Why not utilizing FDG drugs effectively a efficiently?	Because there is a delay in the procedure
2	Why there is a delay in the procedure?	Because there is not well-trained staff and there are a shortage of staff
3	Why there is not well- trained staff?	Because the management is not providing the staff with proper training
4	Why management is not providing the staff wi proper training?	Because the management is not conducting any audits in the department
5	Why management is not conducting any audits in t department?	Because they don't have a quality manager

Table No. 4.2.1 (c): Root Cause Analysis Table with 5 Whys Analysis

The problem area which is identified through the 5 why's analysis or technique is the FDG drug is not utilizing efficiently and effectively in the department because there is a delay in the process or procedure. one of the main reason in the department is that there is not well-trained staff because they have less experience and they have a junior technician who is taking more time for injection preparation dispensing and FDG dose administration and nurse is taking more time for patient preparation, other than that the management is not providing training to the staff which is causing a delay in every procedure in the patient management in the department apart from this there is no one from the management which is going to conduct departmental audits for better quality and improvement wherever is needed because they didn't hire any quality manager who will conduct audits and maintain the quality of the department.

LEAN SEVEN WASTES:

Additionally, in lean wastes, one more waste involve that is Human Resource

Overproduction:

- Unnecessary imaging examinations
- Retaking new images

Transportation:

- Poor patient flow in the department process
- Poor patient flow downtimes in the utilization of equipment as well as the use of the personnel
- Transportation of drug also takes time from Hot lab
- The resources of the service provider are under-utilized

Inventory:

- Excessive radioisotope supply in the nuclear medicine department inventory

Motion:

- Excess supply inventory located in numerous places of the department causes extra walk for the personnel

- Patients queuing several times to examinations, or patients' lack of one-stop service
- Poor workstation ergonomics in service counters can be a cause for this

Defect/Rework:

- Not informing the patient to urinate in time
- Machine malfunction
- Operator’s mistake
- Defects due to temperature variation and humidity
- FDG spillage
- Drug Mishandling
- Misadministration
- Supplies are not available

Over-processing:

- Over-processing consumes resources
- Too many approvals from a consultant before taking a scan
- More than one time scanning for a few patients, the patient flow becomes slower

Waiting:

- Poor patient scheduling
- Appointment time is not confirmed or given properly
- Less working staff
- Equipment downtime
- The nursing staff is taking more time for patient preparation
- The junior technician is taking more time for injection preparation dispensing and dose administration
- Sometimes the patient has to wait if some events occur like drug mishandling due to technician’s mistake, FDG spillage in the Hotlab, the previous patient is unstable on the scanning room
- No patient’s attendant and staff available to shift the patient

- A patient has handicapped and needs a wheelchair to shift and take more time

Human resource:

- Less human resources are in the department
- Inexperienced nurses and they have a junior technician who has less experience causes a delay in the procedure

Six sigma Assessment Metrics:

It used to assess the performance of a business.

DPU (Defect Per Unit): It is the average number of defects per unit of a product.

$$DPU = \frac{\text{Total number of defects}}{\text{Total number of units}}$$

$$DPU = \frac{192}{17}$$

$$DPU = 11.2941176$$

DPMO (Defects Per Million Opportunities): DPMO or Non-conformities per million opportunities (NPMO), is a measure of process performance.

$$DPMO = \frac{\text{Total number of defects}}{\text{Total number of opportunities}} * 10^6$$

Total number of opportunities = Units * Number of opportunities per unit

= 11*170

= 1870 total opportunities

$$DPMO = \frac{192}{1870} * 10^6$$

= 1,02,673 DPMO

Sigma Level:

It is a measure of the error rate of the process. Sigma levels are generally based on DPMO. 1,02,673 defects per million opportunities which has got 2.75 sigma level according to the Six sigma conversion table (Huba et al., n.d.)**.**

In Six Sigma, sigma is a quality level that characterizes process variation and the number of defects or errors. A low sigma process results in a large number of defects and large variation. A high sigma process results in a small number of defects and small variation. The following table provides the quantitative relationship between the quality level and the number of defects per 1 million opportunities (dpmo):

- 1-sigma level: 691,400 dpmo
- 2-sigma level: 308,700 dpmo
- 3-sigma level: 66,810 dpmo
- 4-sigma level: 6,210 dpmo
- 5-sigma level: 233 dpmo
- 6-sigma level: 3.4 dpmo

Traditional non-Six Sigma operations run at about a 3-sigma level, while Six Sigma organizations adopt the 6-sigma level. The number of defects differs significantly between the two levels. Traditional organizations are satisfied with 66,810 dpmo; Six Sigma companies aim at having no more than 3.4 dpmo.

Table No. 4.2.1 (d): Six Sigma Metric Conversion Reference Table

4.3 To Recommend the Solutions to Improve the Process in the Department.

During the process mapping, the variations in the process were identified which includes delays in the department process. Based on the process mapping, the stratification of process steps was carried out and recorded TAT for each process step which shows delays in the department. The bottlenecks and defects were identified with the use of Lean Six Sigma methodologies in which applied Ishikawa diagram, Pareto's chart, 5 why's analysis, lean seven wastes, and lean six sigma assessment metrics. These tools and methods were analyzed for the main area of delay and defects through which we have come to know that there is inadequate manpower, sometimes malfunction

of the equipment which also leads to delay in patient scanning, the patient is not aware of the procedure, the communication gap between the staff and patients, nursing staff and the technician is redoing the same work and there is no senior technician who will work efficiently without causing any delay and quality manager for better quality control checks in the nuclear medicine department.

1) Adequate Human Resources: First and foremost, there should be trained and experienced staff. If, in spite of having experienced staff, there are delays in the process which is due to not having sufficient staff. There is a need to hire more human resources which includes nursing staff for patient preparation, a senior technician who will not take a longer time for injection preparation dispensing and dose administration, and ward boys or helpers who help the patient to shift from the table scan.

2) Equipment Calibration/Daily QC Checks: There should be regular QC (Quality Control) check every morning so that there is no malfunction or glitch in the machines, detector failure, and electronic drift being used at the centre as this might lead to cancellation of patient's appointments or patients may have to wait for a longer time. There should also be regular checks for humidity and room temperature which should below 22 degrees Celsius for proper utilization of equipment.

3) A Clear Explanation of the Procedure to the Patient: It has been observed that sometimes delays are made by the patients which arise from lack of understanding or information about the procedure. So, the patients should be given clear and easily understandable instructions and complete information about the procedure so that there will be no delays caused by patients.

4) Improving Communication: There should be proper communication within the organization between staff and patients. They should coordinate with each other as one procedure links with another procedure in the department process for patient scanning. If there are any communication gaps, it leads to delays in procedures like injection dispensing, dose administration, and shifting patients from the acquisition room. So better communication and coordination play a major role in smooth workflow within the department.

5) Eliminating Duplication of Work: Injection dispensing, dose administration and patient preparation time have such areas where there are so many delays in the department. One of the reasons for the delay is the redoing of work. If the technician has not accurately dispensed a dose or if by mistake the drug or injection falls from the hand or any kind of drug mishandling happens, it leads to duplication of work and takes more time which results in delay in the procedure.

6) Hiring a Quality Manager: The management needs to hire a good and experienced quality manager for the better-quality control and smooth workflow of the department. if the centre needs to improve the radioisotope utilization with efficiency, then there should be one quality manager who periodically checks the quality of the work and records their time with work efficiency, and inspects if the staff is not doing work on time. The quality manager provides some set of standards and rules and quality control checks for the departments so that the work goes smoothly in the department.

Implementation plan for better workflow and operational efficiency are as follows:

Based on the identified defects or delays in the process flow, the implementation plan has been discussed for better workflow and operational efficiency in the department. it includes two types of strategies:

A) Administrative strategies: which includes Induction programs, introduce activity logs and audit controls, training Programs, contingency plan, initiate early morning drills or discussions, Introduce the concept of labeling the patients, Formulate strict appointment rules, maintaining TAT records, Conduct multidisciplinary team meetings, application of departmental policies and procedure, QUANUM program, development of protocols, using Lean Six Sigma methodology to reduce the defects and variation in the process flow.

B) Risk analysis and management plan: which includes Risk assessments, incident training, radiation protection training program, hospital/ centre incident logbooks and job analysis.

A) Administrative strategies:

Implementation Plan	Further Information
Orientation/Induction Programs must be organized	Orientation or induction programs should be organized to fully enable the staff to optimize time and provide information about the half-life of the drug which has to be managed within a specified time. If the time is not managed properly then there will wastage of radioisotope which will add to the costs of the department. It is the responsibility of a new employee's manager to ensure that induction training is properly planned. An induction plan should be issued to the new employee on their first working day if not before and sent to all staff involved with the training.
Introduce activity logs and audit controls	The audit controls required to check the quality and technical issues like equipment malfunction, detector failure, and electronic drift. Audits within the service should cover the following areas: 1. Change or implementation of clinical practice. 2. Changes in service provisions with the best patient care practice. The activity log should be used to register the activity and the record with date and time
Training Programs must be Implemented	Training schedules must be introduced to raise awareness on how to utilize radioisotopes effectively and how to manage time and patients efficiently. The management of an organization should periodically organize training programs for their staff in order to increase the effectiveness and efficiency of their work where the staff can manage patients without any unnecessary delays in

	patient preparation and scanning. It's important to provide training to the staff so that they can do things quickly and efficiently. It will help minimize or lower down the frequency of any near miss or sentinel events that prevents any drug misadministration and FDG drug spillage which leads to more patient waiting time and drug wastage in the department. Such training programs will help the staff and management save time and money.
Develop a contingency plan	In the event of an emergency, a contingency plan must be kept ready to reduce the probability of any eventuality which might result from being exposed to radiations, Drug misadministration, FDG spillage, or drug mishandling, etc.
Initiate early morning drills or discussions	Every morning there should be a drill or discussion on how to manage the number of cases with roles and responsibilities of the staff in their different capacities with complete effectiveness and efficiency so that there will be no redundancies or unnecessary delays in pursuit of the process.
Introduce the concept of labeling the patients	In order to avoid confusion or drug misadministration, there should be a system where patients are temporarily labeled on their gown and given wrist tags with patient name and age mentioned on it. This not only helps in quickly identifying the patients but also deters misadministration of drug and other risks involved therein.
Formulate strict appointment rules	Before giving an appointment to the patient the receptionist should inform the patient clearly about the half-life of the drug as it decays with time. If a patient does not come at a given time then there will be a wastage of the drug and delay in time which leads to more patient waiting time.

Start maintaining TAT records	Since there are major delays in the procedures, the department can record the TAT for the department to monitor their procedure time after brining in necessary improvements. It will help the staff to know about their work efficiency and effectiveness.
Conduct multidisciplinary team meetings	Multidisciplinary team meetings allow a team approach to patient management to take into account and evaluate all aspects of the patient's disease and operational activities. It should be possible to review all relevant examinations in a multidisciplinary meeting, especially when there is a discrepancy between clinical and Operational uncertainty. The results of the discussions should be recorded, and discrepancies noted, if necessary.
Application of Departmental Policies and procedure	The policies generally are developed from the point of view of good practice, including radiation protection, health and safety, and infection control. The policy and procedure for documentation and reporting should be there as the report is the main mode of communication between the physician interpreting the imaging study and the referring physician, and frequently leads to relevant changes in patient management. There should be a policy of written documentation of verbal reporting in the medical record. All policies should be applied with the full knowledge and co-operation of all branches of personnel within the department (nuclear medicine physician/radiologist, physicists and radiographers/technologists) and should be

	made known to all clinicians and departments making use of the range of services offered by the Nuclear Medicine department.
QUANUM Program	QUANUM program includes detailed checklists, very specific to nuclear medicine, and covering all aspects of its practice, including clinical applications, radiopharmacy, general and radiation safety, and quality assurance (QA). The program aims at promoting a culture of continuous improvement of quality management aspects of nuclear medicine practice as a whole, including thorough training on quality improvement, through the implementation of internally managed self-audits.
Development of Protocols	It is intended to standardize technical factors, the timing of imaging, and the views obtained during imaging to provide the best information from which the scan may be reported. By making these protocols available within the department, either electronically or on paper, new or rotating staff/personnel may be kept up to date on the latest changes in techniques. These factors can include: ▪ Equipment used – in a multi-camera department some equipment may be more suitable than others. ▪ Quality Assurance and pre-set Gamma Maps ▪ Radioisotope – isotope channel, peak, and acceptance window to be used. ▪ Acquisition Parameters: Matrix size – can vary either for the type of acquisition required (dynamic;

	planar; tomographic) or within a specific acquisition ▪ Time of acquisition/count statistics – some images may be ended by reaching either time or count limit or in terms of gated studies by the number of cycles completed. ▪ Patient Preparation – of vital importance in the production of diagnostic scan results, ▪ Scan time delays – some examinations require that scans be performed at certain time intervals, be they minutes, hours or days. These timings should be included in the protocol listings ▪ Images/views taken – whilst many examinations can be performed as pre-programmed imaging
Start using Lean Six Sigma methodology to reduce the defects and variation in the process flow	It will help the management in cost reduction through proper utilization of radioisotopes which is a very expensive drug and to improve the workflow of the department, improve process variations, reduce defects and eliminate wastes and reduce redundancies in the department.

Table No. 4.3 (A): Hospital Administrative Tactics Matrix

B) Risk Analysis and Management Plan:

Implementation Plan	**Further Information**
Risk Assessments	Risk assessments should be carried out before any new work within Nuclear Medicine commences. The most common types of risk assessments are based on radiation risks and health and safety issues.
Incident Training	Unfortunately, incidents do happen in Nuclear Medicine, even when assessments are made. When an incident does occur, it must always be documented, with records filed. A review must take place following the incident, so the risks associated can be minimized further, if possible.
Radiation Protection Training Program	The radiation protection supervisor should have a training program, which all staff working in relevant areas of Nuclear Medicine should undergo, before commencing work. The training should consist of the following: ▪ To read and follow the local rules for the department ▪ To be familiar with the procedures when a radiation incident occurs ▪ To be aware of the documents that need to be completed when an incident occurs ▪ To be cognizant of the staff that has to be notified.

Hospital/ Centre Incident Logbooks	Incident logbooks can be used for logging incidents. Although a purpose-made record is just as good. Following an incident, a record should be drafted as soon as possible. Depending on the severity of the risk, incidents should be followed up quickly, reviewing systems of work to minimize the risk. All incidents should be discussed at the next radiation safety committee, where further support can be acquired if needed.
Job Analysis	It is necessary to ask what the job consists of and whether it is likely to be any different than that of the previous postholder. Nuclear Medicine covers many areas and the skills required of a Nuclear Medicine Technologist post will vary. It may be that a specialist such as a Nuclear Cardiology Technologist is essential or a technologist who is newly qualified, to ensure that the right 'mix' of staff is there supporting the clinical work and providing career progression.

Table No. 4.3 (B): Hospital Risk Analysis and Management Plan

4.4 Summary of Findings

After calculating DPMO, the value is getting 1,02,673 which falls under the 2.75 sigma level which is indicating that the organization is not efficiently running and is not even reaching the average level and needs definitely an improvement to sustain in the healthcare business sector and has to be competitive. It is not even in the 3-sigma level which is considered as an average level that the organization is running on an average level which meant the organization is running smoothly in the business sector and the organization who is getting 5 and 6 level sigma that means the

organization is running more efficiently and giving more competition to another organization and each process contains zero defects rate. The centre has to improve their departmental processes, workflow and have to reduce the defects and the process variations.

4.5 Conclusion

The study conducted the scope of the investigation in all terms, all the potential defects were identified analyzed in-depth giving a clear picture of what has to be eliminated and reduce variation in the process and delays and minimize the errors or defects. The six sigma assessment metrics which include DPU (Defects Per Unit) got 11 value, DPO (defects Per Opportunity) got 170 value, where total 10 units are there in the process steps and found total 17 defects in that unit (10*17 = 170 defects per opportunity) and DPMO (Defects Per Million Opportunity) got 1,02,673 value and assessed sigma level which measures the error rate of the process which is based on DPMO which has got 2.75 sigma level with 1.5 sigma shift which shows that the organization is not efficiently functioning and not competitive at all and needs improvement in terms of patient management, time management, and operational activity management. And the calculated DPMO result shows that the department is not following the standards and there is a significant difference between the timings of variables that needs a lot of improvement for better sustainability in the healthcare industry.

CHAPTER V:

DISCUSSION

5.1 Discussion of Results

The result shows that there is a significant difference between the timings of variables which is indicating that the nuclear medicine department is not following the international standard.

In the paper, "A Healthcare Lean Six Sigma System for Postanesthesia Care Unit Workflow Improvement", that integrates Lean and Six Sigma methods to improve workflow in a postanaesthetic care unit (Kuo et al., 2011).

Another study, "Application of Six Sigma methodology to a diagnostic imaging process", was carried out in the medical imaging department of a private Turkish hospital. It aims to apply the Six Sigma methodology to improve workflow by eliminating the causes of failure in the medical imaging department. The methodology adopted was Implementation DMAIC improvement cycle, workflow chart, fishbone diagrams, and Pareto charts were employed, together with rigorous data collection in the department and Subsequent to extensive training of professionals, the sigma level was increased from 3.5 to 4.2 (Taner et al., 2012)

Another study, "Reducing Laboratory Billing Defects Using Six Sigma Principles", focuses on an effort to decrease healthcare costs, they have applied lean six sigma tools to improve their processes. The LSS methodology Using SIPOC analytics, DMAIC processes, Cause and effect tree, Using a Chi-square analysis, and Control charts. Lean and Six Sigma quality management is increasingly being applied to clinical laboratories to reduce errors and waste. In the laboratory, these methods have been used to improve the timeliness of inpatient phlebotomy, reduce the frequency of registration errors, and minimize pre- and post-analytic errors (Levtzow and Willis, 2013).

One of the studies "Guiding Inpatient Quality Improvement: A Systematic Review of Lean and Six Sigma", is based upon to determine whether Lean, Six Sigma has been effectively used to create and sustain improvements in the acute care setting (Glasgow et al., 2010).

Another study, "Analysis and Evaluation of Reviews on Lean and Six Sigma in Health Care", focuses on health care is a complex industry in which professionals are facing the challenge of balancing lower costs with better health and quality of care. To remain competitive, health care organizations have promoted the use of Lean and Six Sigma in various settings (Peimbert-García, 2019).

The Study, "Applying Lean Six Sigma methods to reduce the length of stay in a hospital's emergency department", focused on applying the Lean Six Sigma methods to reduce the length of stay in a hospital's emergency department and to improve the patients' experience early in the process by triaging them more quickly, and retaining them in the system (Furterer, 2018).

Most of the study has been done in the manufacturing industry, emergency department, Pharmaceutical industry, Surgical admissions, Discharge time, Laboratory with Use of lean six sigma methods based on an operational level and other studies has been done in the radiology department, nuclear medicine, postanaesthetic care unit, Acute care, quality in healthcare which is based on more clinical aspects of patient care. However, a fewer study has been done in the nuclear medicine department using lean six sigma methods and tools in an operational level.

This study is based upon radioisotopes utilization in the nuclear medicine department with the use of Lean Six Sigma methodologies and fewer literatures are available and no study has been done nationally and internationally in radioisotopes utilization in the nuclear medicine department with the use of Lean Six Sigma methodology.

5.2 Discussion of Research Question One

To improve the process flow and to reduce defects and variations in the nuclear medicine department, the technician, nursing staff, and the ward boys should work efficiently in the department in order to optimize radioisotopes utilization optimally and the management has to analyze the problem and develop potential solutions using LSS tools. Process flow mapping used to detail every step of each subprocess for both the patient and the staff workflow.

After the entire analysis, it is clear that there are major problems in the processes are concerning the late patient arrival, delay in patient preparation time, delay in injection preparation dispensing, delay in FDG dose administration, delay in uptake period and the start of scan and delay in shifting the patient from scan table.

The turnaround time for the average time from patient arrival to patient preparation calculated to be 12 minutes 55 seconds, TAT (turnaround time) from Patient preparation time to Injection preparation dispensing time calculated to be 17 minutes 32 seconds, it needs to be improved, usually for injection preparation dispensing takes 5-10 minutes but here it is taking too much time for dose dispensing, TAT from Injection patient dispensing to FDG dose administration calculated to be 12 minutes 37 seconds which is too high usually it should take a time of 5-10 minutes but here its more time is taken for dose administration which definitely has to improve, TAT from FDG dose dispensing to uptake period calculated to be 01:24:35 which needs improvement. The total turnaround time for the entire process is 130 minutes approximately, which definitely needs an improvement for efficient and smooth workflow in the department. The next most crucial area which needs improvement is the more injection dispensing time, more patient preparation time, and more time for dose administration.

5.3 Discussion of Research Question Two

During the process mapping, the variations in the process were identified which includes delays in the department process. Based on the process mapping, the stratification of process steps was carried out and recorded TAT for each process step which shows delays in the department. The

bottlenecks and defects were identified with the use of Lean Six Sigma methodologies in which applied Ishikawa diagram, Pareto's chart, 5 why's analysis, lean seven wastes, and lean six sigma assessment metrics. These tools and methods were analyzed for the main area of delay and defects through which we have come to know that there is inadequate manpower, sometimes malfunction of the equipment which also leads to delay in patient scanning, the patient is not aware of the procedure, the communication gap between the staff and patients, nursing staff and the technician is redoing the same work and there is no senior technician who will work efficiently without causing any delay and quality manager for better quality control checks in the nuclear medicine department.

The value of DPU which have got in this study is 11 value, DPO (defects Per Opportunity) has got 0.37816 value and DPMO is 1,02,673 and it is showing 2.75 value of sigma level, which shows that the organization is not functioning efficiently and needs improvement for better workflow, defects, and process variations needs to reduce. 2.75 sigma level shows that the nuclear medicine Centre is not competitive at all and needs too much improvement in terms of operational management and patient time management. Sigma level is a measure of the error rate of the process. Sigma levels are generally based on DPMO. After calculating have got 1,02,673 defects per million opportunities which have got 2.75 sigma level according to the Six sigma conversion table. (Table No. 4.2.1 (d): Six Sigma Conversion Table)

5.4 Discussion of Research Question Three

After analyzing all the bottlenecks, defects and areas of improvement the suggested roadmap has been given in this study for the continuous improvement and sustainability of the nuclear medicine department which includes the adequate human resource in the department to hand the work, Equipment calibration and QC checks needs to be conducted on regular basis, a clear explanation of the procedure to the patient to avoid issues, proper communication between staff and patient to avoid any confusions, Eliminating duplication of work to avoid delays, Hiring a Quality manager to improve or assess the utilization of radioisotopes in the department without any wastage of drug and to maintain the quality of work.

Based on the identified defects or delays in the process flow, the implementation plan has been discussed for better workflow and operational efficiency in the department. it includes two types of strategies:

Administrative strategies which includes Induction programs, introduce activity logs and audit controls, training Programs, contingency plan, initiate early morning drills or discussions, Introduce the concept of labeling the patients, Formulate strict appointment rules, maintaining TAT records, Conduct multidisciplinary team meetings, application of departmental policies and procedure, QUANUM program, development of protocols, using Lean Six Sigma methodology to reduce the defects and variation in the process flow.

Risk analysis and management plan which includes Risk assessments, incident training, radiation protection training program, hospital/ centre incident logbooks and job analysis

CHAPTER VI:

SUMMARY, IMPLICATIONS, AND RECOMMENDATIONS

6.1 Summary

Most of the study has been done in the manufacturing industry, emergency department, pharmaceutical industry, Surgical admissions, Discharge time, Laboratory with Use of lean six sigma methods based on an operational level and other studies has been done in the radiology department, nuclear medicine, postanesthetic care unit, Acute care, quality in healthcare which is based on more clinical aspects of patient care. However, a fewer study has been done in the nuclear medicine department using lean six sigma methods and tools in an operational level. This study is based upon radioisotopes utilization in the nuclear medicine department with the use of Lean Six Sigma methodologies and fewer literatures are available and no study has been done nationally and internationally in radioisotopes utilization in the nuclear medicine department with the use of Lean Six Sigma methodology.

6.2 Implications

From the finding of descriptive analysis, we can conclude that there is a requirement to improve the workflow and proper optimization and utilization of radioisotopes in the nuclear medicine department and needs to improve the patient time management.

The defects have been identified for the organization after the analysis is significant. Some defects can be acceptable for a while, some are unacceptable and some are totally unacceptable.

So, the organization must take some actions to patient time management, reduce the defects, and utilize the radioisotopes effectively and efficiently.

The overall result from the data analysis and Lean Six Sigma methodology used for defect analysis shows that the defects have been identified for the organization can be taken into consideration. The recommended solutions and implementation plan are significant and that can be used for further improvement of radioisotopes utilization efficiently with time management in the nuclear medicine department.

6.3 Recommendations for Future Research

By keeping all these limitations in mind and other aspects of the nuclear medicine department which were not incorporated in the study, the future recommendations for future research are as follows:

- The study was conducted only in Isolated Nuclear medicine centre, so further studies can be conducted in a hospital setup nuclear medicine department as well.
- Due to the constraint of time, the study conducting was only limited to PET-CT and the study can be done on SPECT-CT (Gamma Camera)
- This study is based upon using the Lean Six Sigma methodology for analysing the process flow, finding the defects and variations in the department and assessed the sigma level and provided solutions for improvement but the study has not implemented the provided solution and strategies in the department so that the defects and variation can be reduced for the departmental process improvement and the Lean Six Sigma can be reimplement to know at what extent Sigma level has improved.
- The study was conducted for a short period of time due to privacy and data confidentiality; the researcher can do study for more time period for better results of the research study.
- There is a scope to study the cost-benefit analysis by analysing the quantity of FDG and drug arrival.

6.4 DISCUSSION:

To improve the process flow and to reduce defects and variations in the nuclear medicine department, the technician, nursing staff, and the ward boys should work efficiently in the department in order to optimize radioisotopes utilization optimally and the management has to analyze the problem and develop potential solutions using LSS tools. Process flow mapping were used to detail every step of each subprocess for both the patient and the staff workflow.

After the entire analysis, it is clear that there are major problems in the processes are concerning the late patient arrival, delay in patient preparation time, delay in injection preparation dispensing, delay in FDG dose administration, delay in uptake period and the start of scan and delay in shifting the patient from scan table.

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378,151 defects per million opportunities which have got 1.8 sigma level according to the Six sigma conversion table.

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Another study, “Analysis and Evaluation of Reviews on Lean and Six Sigma in Health Care”, focuses on health care is a complex industry in which professionals are facing the challenge of balancing lower costs with better health and quality of care. To remain competitive, health care organizations have promoted the use of Lean and Six Sigma in various settings (Peimbert-García, 2019).

The Study, “Applying Lean Six Sigma methods to reduce the length of stay in a hospital's emergency department”, focused on applying the Lean Six Sigma methods to reduce the length of stay in a hospital's emergency department and to improve the patients’ experience early in the process by triaging them more quickly, and retaining them in the system (Furterer, 2018).

Most of the study has been done in the manufacturing industry, emergency department, pharmaceutical industry, Surgical admissions, Discharge time, Laboratory with Use of lean six sigma methods based on an operational level and other studies has been done in the radiology department, nuclear medicine, postanaesthetic care unit, Acute care, quality in healthcare which is based on more clinical aspects of patient care. However, a fewer study has been done in the nuclear medicine department using lean six sigma methods and tools in an operational level. This study is based upon radioisotopes utilization in the nuclear medicine department with the use of Lean Six Sigma methodologies and no literatures are available and no study has been done nationally and internationally in radioisotopes utilization in the nuclear medicine department with the use of Lean Six Sigma methodology.

6.5 Conclusion

In nuclear medicine, there is room for improvement in reducing operational cost, remove the non-value-added items or the wastes which lead to delay in the process, improve access, improve work efficiency, health care quality, patient satisfaction, and most importantly patient safety. The entire study focused on using Lean Six Sigma methods for efficiently utilization of radioisotopes by monitoring patient procedure time and recording TAT for the entire process, identifying the gaps or defects which leads to delay in the nuclear medicine department, Analysing or finding out the reasons for those defects or gaps with the use of LSS methodologies and providing a roadmap and solution to the department.

By studying the process flows of 120 patients, the major error areas and gaps were brought out for which Pareto's diagram and pivot graph were plotted and 5 why's analysis was done to find out the root cause of the problem. Lean seven waste tools have been applied to identify the wastes in the department. Calculated DPMO which has got 2.75 sigma level with a 1.5 sigma shift which shows the organization is not competitive at all and not efficiently working. The main defects or gaps which need improvement are delays in patient arrival time, patient preparation time, injection preparation dispensing, FDG dose administration, delay in uptake period, and delay in shifting the patient from the scan table.

Other important improvements that are needed for minimizing the cycle time by giving proper training to the staff and increase in the work efficiency of the nurse, increasing the manpower, hire a senior and experienced technician and reduce the downtime of the equipment by adequate calibration and maintenance of equipment. There will be a lot of improvement and reduction in the TAT of each process step by eliminating the defects.

The study conducted the scope of the investigation in all terms, all the potential defects were identified analyzed in-depth giving a clear picture of what has to be eliminated and reduce variation in the process and delays and minimize the errors or defects. The six sigma assessment metrics which include DPU (Defects Per Unit) got 11 value, DPO (defects Per Opportunity) got 170 value

and DPMO (Defects Per Million Opportunity) got 1.02,673 value and assessed sigma level which measures the error rate of the process which is based on DPMO which has got 2.75 sigma level with 1.5 sigma shift which shows that the organization is not efficiently functioning and not competitive at all and needs improvement in terms of patient management, time management, and operational activity management. The calculated DPMO result shows that the department is not following the standards and there is a significant difference between the timings of variables that needs a lot of improvement for better sustainability in the healthcare industry.

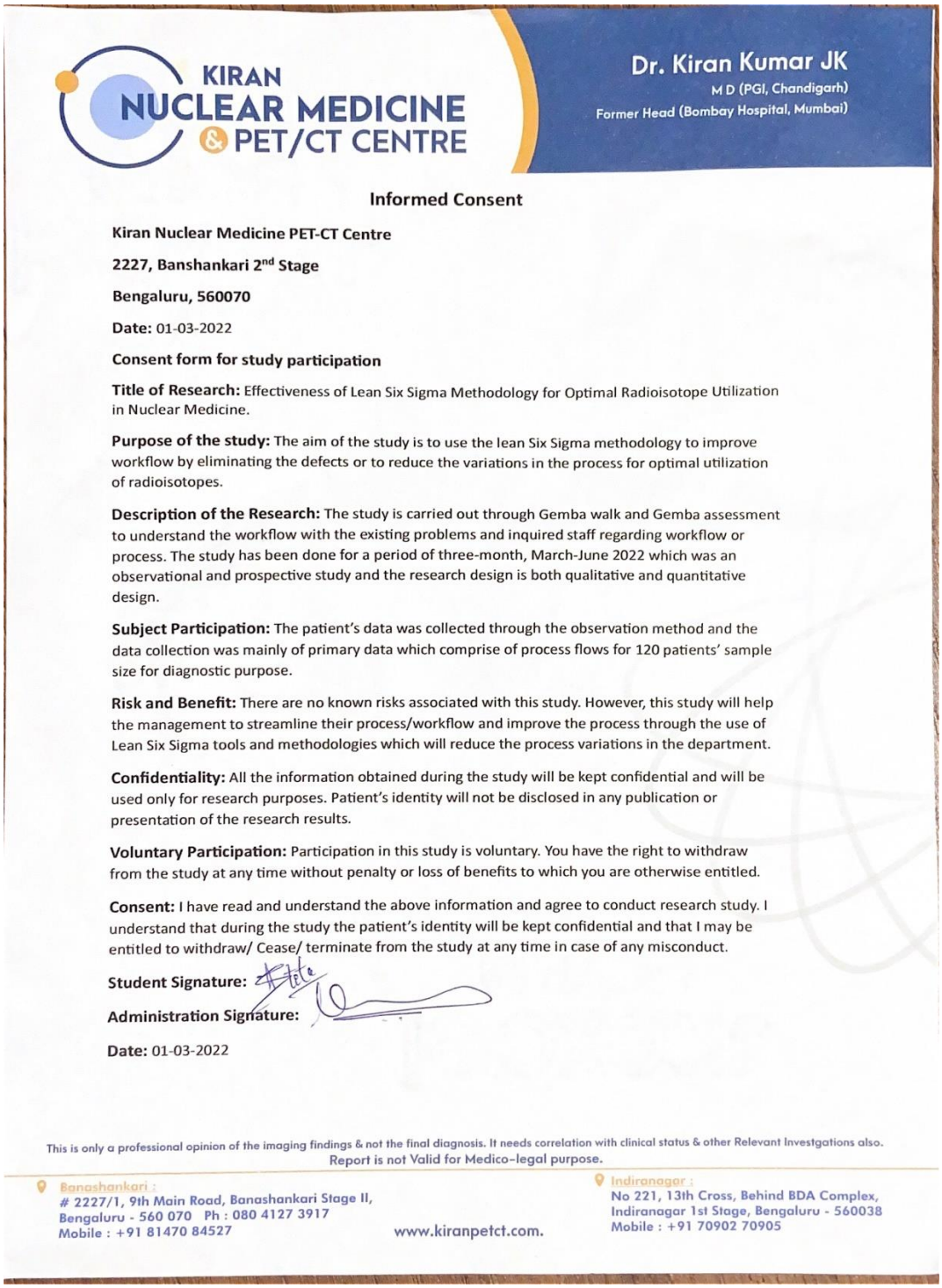
APPENDIX A

SURVEY COVER LETTER

The data collection plays a key role for the hospital outcome measures. Prospective observational sudy with the use of purposive sampling has a potential with the completeness of data capture. The purpose of this data collection/survey was to gather information, feedback from the patient who are visiting nuclear medicine department for diagnostic purpose and through observation to find out the defects and bottlenecks in the department which includes the department employees - the way they manage their daily routine work, patient handling, appointment management, waiting time, injection dispensing, shifting patient. The Lean Six Sigma tools were used for the survey output results to identify the area of strengths and the areas need more improvements and assessement of the Sigma level which shows the sustainibility of the organization.

APPENDIX B

INFORMED CONSENT



KIRAN NUCLEAR MEDICINE & PET/CT CENTRE

Dr. Kiran Kumar JK
M D (PGI, Chandigarh)
Former Head (Bombay Hospital, Mumbai)

Informed Consent

Kiran Nuclear Medicine PET-CT Centre

2227, Banshankari 2nd Stage

Bengaluru, 560070

Date: 01-03-2022

Consent form for study participation

Title of Research: Effectiveness of Lean Six Sigma Methodology for Optimal Radioisotope Utilization in Nuclear Medicine.

Purpose of the study: The aim of the study is to use the lean Six Sigma methodology to improve workflow by eliminating the defects or to reduce the variations in the process for optimal utilization of radioisotopes.

Description of the Research: The study is carried out through Gemba walk and Gemba assessment to understand the workflow with the existing problems and inquired staff regarding workflow or process. The study has been done for a period of three-month, March-June 2022 which was an observational and prospective study and the research design is both qualitative and quantitative design.

Subject Participation: The patient's data was collected through the observation method and the data collection was mainly of primary data which comprise of process flows for 120 patients' sample size for diagnostic purpose.

Risk and Benefit: There are no known risks associated with this study. However, this study will help the management to streamline their process/workflow and improve the process through the use of Lean Six Sigma tools and methodologies which will reduce the process variations in the department.

Confidentiality: All the information obtained during the study will be kept confidential and will be used only for research purposes. Patient's identity will not be disclosed in any publication or presentation of the research results.

Voluntary Participation: Participation in this study is voluntary. You have the right to withdraw from the study at any time without penalty or loss of benefits to which you are otherwise entitled.

Consent: I have read and understand the above information and agree to conduct research study. I understand that during the study the patient's identity will be kept confidential and that I may be entitled to withdraw/ Cease/ terminate from the study at any time in case of any misconduct.

Student Signature:

Administration Signature:

Date: 01-03-2022

This is only a professional opinion of the imaging findings & not the final diagnosis. It needs correlation with clinical status & other Relevant Investgations also.
Report is not Valid for Medico-legal purpose.

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APPENDIX A: MASTER CHART

Master Chart - Copy - A.xlsx

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APPENDIX A: LEAN SIX SIGMA GREEN BELT CERTIFICATION

Certified Lean Six Sigma Green Belt.png