Chapter 13
Principles and Implementation of Quality Management and Patient Safety Systems in Hospital

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13.1 Healthcare Quality Management: Journey

Quality management in healthcare is a promise made to the public by various health sectors, working towards the goal of providing the best possible services for each patient. First, in 1914, Dr. Ernest Codman initiated a healthcare quality initiative and challenged physicians to take a responsibility for the patient [1]. He invited physicians for the compilation of information and data and analysis of surgical outcomes. Dr. Ernest recorded relevant patient information on a pocket-sized card, which he used to evaluate and study outcomes. After these next few decades, focus preliminarily remained on assessing the poor outcome and identifying deficiencies in healthcare practitioners and possible measures taken for improvement. During the 1960s, Avedis Donabedian created the Donabedian model framework for examining health services and evaluating the quality of healthcare. According to this model, the information about the quality of care can be drawn from three categories: structure, process, and outcomes [2].

This model influenced many practitioners to identify different ways to improve patient outcomes in the broad area of the structure, process, and outcome.

Quality management in healthcare has observed a paradigm shift from expecting errors and defects to considering that a perfect patient experience is achievable. Philip Crosby supports the same principle that the system for causing quality is prevention and not an appraisal. The literature suggests that the causes of death for many patients in hospitals are medical negligence and nosocomial infections. These deaths can be easily avoided by incorporating a quality management program.

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Table 13.1 Deming's 14 points of quality management

1. Create constancy of purpose towards improvement of product and service, with the aim to become competitive and to stay in business, and to provide jobs
2. Adopt the new philosophy
3. Cease dependence on inspection to achieve quality
4. End the practice of awarding business on the basis of the price tag. Instead, minimize total cost. Move towards a single supplier for any one item, on a long-term relationship of loyalty and trust
5. Improve constantly and forever the system of production and service, to improve quality and productivity, and thus constantly decrease costs
6. Institute training on the job
7. Adopt and institute leadership. The goal is to help people and equipment to do a better job
8. Drive out fear, so that everyone may work effectively for the company
9. Break down barriers between departments
10. Eliminate slogans, exhortations, and targets for the workforce asking for zero defects and new levels of productivity to only create adversarial relationships, as the bulk of the causes of low quality and low productivity belong to the system and thus lie beyond the power of the workforce
11a. Eliminate work standards (quotas) on the factory floor. Substitute leadership
11b. Eliminate management by objective
11c. Eliminate management by numbers and substitute leadership
12a. Remove barriers that rob the hourly worker of his or her right from the pride of workmanship. The responsibility of supervisors must be changed from sheer numbers to quality
13. Institute a vigorous program of education and self-improvement
14. Put everybody in the company to work to accomplish the transformation. The transformation is everybody's job

Source: Deming, W. Edwards. Out of the crisis (MIT press) (1986:Pp. 23–24)

Shewhart highlighted that the aim of manufacturing companies shall move from inspection and specification to focus on reducing the variation in the production process and meeting customer product expectations [3]. Deming was influenced by Shewhart, recognized quality as a key driver of companies, and percolated these message methods to Japanese engineers and executives. His quality control methods helped post-World War II Japan rebuild its devastated economy and led to significant success during the 1950s and thenceforth. Deming's 14 Points [4] on Quality Management (Table 13.1), or the Deming Model of Quality Management, a core concept for implementing total quality management (TQM), is a set of management practices to help companies increase their quality and productivity. During the 1980s–1990s, contribution of Crosby [5], Deming [4], and Juran [6] was well known in manufacturing companies across the United States. Their effort took attention to overall system design, process management, and importance of the involvement of the entire team in improvement. Considering this hospital & healthcare governance team initiated using these concepts to drive organization leaders to look at quality from different lenses.

Concomitantly around 1985s, accreditation bodies and various organization forums got intensively involved in the collection and assessment of the quality of data. Chassin and Galvin highlighted the concerns of underuse, misuse, and overuse

Table 13.2 Clinical quality problems in health service provision

Overuse: The potential for harm from a health service exceeds the possible benefits
Underuse: A health service that would have produced a favorable outcome was not provided
Misuse: A preventable complication occurs with an appropriate service

Adapted from Chassin MR, Glavin RW. The urgent need to improve health care quality: Institute of Medicine National Roundtable on Health Care Quality. JAMA. 1998;280(11):1000–1005

in medication and called attention to practice variation in medicine and to the suboptimal patient outcomes associated with this variation (Table 13.2) [7].

To Err Is Human: Building a Safer Health System was a landmark report issued in November 1999 by the U.S. Institute of Medicine that estimated that thousands of people will die from medical errors every year. This report led to a significant increase in the awareness of US medical errors, and the push for patient safety that followed its release continues. The report was based upon an analysis of multiple studies by a variety of organizations and concluded that between 44,000 and 98,000 people die each year as a result of preventable medical errors [8].

The high-value clinical care results from the most efficient cost of achieving a high level of clinical quality. Successful implementation of Six Sigma results in virtually no defects. No model has proven to be the best in quality management. Healthcare providers want to continually improve the care they provide. However, different tools or models may work in different scenarios, and to succeed it is vital to have a commitment from the governance and leadership team. Healthcare systems need proper support and control methods. The quality of healthcare comes from its fundamental parameters. According to the Institute of Medicine, the services are of quality while they are safe, effective, patient centered, timely, efficient, and equitable.

13.1.1 Components and Elements of Quality Management Program in Hospital

The components of a quality management program are often grouped into three levels:

- The strategic or organizational level from governance and leadership team—dealing with the quality policy, objectives, and management and usually produced as the quality manual
- The tactical or functional level from the managerial level who are dealing with general practices such as training, facilities, and operation of quality management

- The operational level dealing with the standard operating procedure (SOP) worksheets and other aspects of day-to-day operations such as a nurse, paramedic, and support staff

The Quality Manual

The quality manual is composed of the management documents needed to implement the quality management program. Please refer to some common topics included in the quality manual:

- Quality policy statement
- Objectives and scope of quality management
- Organization and management structure and relationship between management, technical operations, support services, and quality system
- Job description for key staff members
- Reference to relevant organization policies, manual, and operating procedures
- Document control and maintenance procedures and processes to ensure tracking of all procedures, data, and reports

Departmental Policy and Manual

All concerned stakeholders such as physicians, nurses, paramedics, pharmacists, and support staff shall be appropriately involved in the development of the departmental policies and manuals, which are based on hospital quality policy and manual. The supervisory staff is responsible for the development and implementation, while the operational staff provides technical expertise and advice. All employees must be trained on organization quality management programs and departmental policies and manuals. Also, at all stages, service personnel must be consulted on the practical aspects of any proposed change. It is their responsibility to notify the management of any concerns, issues, or changes that may affect the organization's quality program. The management shall support the allocation of appropriate resources, approve projects, assign responsibilities, and maintain accountability.

Standard Operating Procedures

Standard operating procedures are an essential tool for gaining control over your daily operating system or processes. Standard operating procedures (SOPs) explain the subtle details in documents that describe all specific operations and methods, e.g., medication prescription, dispensing, and administration. They are an internal reference guide for a specific procedure, and each appropriate step should be described. Anyone with the appropriate skill level should be able to follow the SOP. They should cross-reference and refer to other SOPs as needed. The procedure

should be written in short, clear sentences. Also, well-developed SOPs cater as an effective communication tool that contributes to employee understanding and job satisfaction. The most technically competent person should write an SOP to carry out the described procedure [9].

Training and Development

It is essential to train all staff on organization quality policies and its objectives and department policies, procedures, and SOPs. Each staff member shall receive ongoing training to maintain and advance his or her skills and knowledge. Training is crucial for any organizational growth and success, and it is essential for both employers and employees of an organization. There is much to be said for the role of practical education in a discipline dealing with the practical application of research; there is a great deal to be gained through providing those who will practice quality improvement with a sound knowledge of the theory behind it [10]. For developing a training plan, the hospital shall gather data from all relevant sources to understand its staff's ongoing education needs. Also, we need to consider the results of quality program activities as one source of information to identify staff education needs. Organization leadership supports the commitment to ongoing staff education, and adequate resource is deployed or arranged for facilities, educators, and time for ongoing in-service education.

Auditing and Maintaining Quality Assurance

When all quality assurance system documents are available, they should be tested. During this time, the quality assurance team should conduct a series of audits covering all aspects of the system. Quality consistency is achieved by defining the variables, including error definitions and their point values, and then applying the standard method for identifying errors. In order to maintain a quality management system, compliance in each area of the system should be checked periodically. This involves auditing the structure, process, or outcome to assess whether they continue to meet the defined standards or guidelines. The audit procedure should be documented formally. Data traceability is an important factor that can be verified by randomly sampling the data and tracking the data in all relevant documents before sampling. At the end of each audit, a system overview with clearly defined strengths and areas of improvement should be created. Reports of all audits should be made available to the leaders and concerned stakeholders who are responsible for the relevant work. A concerted plan should be developed to address observed deviations, and necessary corrective and preventive measures should be taken. The audit should be independent involving a multidisciplinary team where appropriate and should be comprehensive and preferably conducted at a regular workflow as an announced or unannounced audit. Feedback organizations must ensure consistency

in the application of the program among all quality assurance staff. Collaboration and training of stakeholders are key to achieving and maintaining compliance.

13.1.2 Common Quality Improvement Methods and Tools

Process Mapping

Process mapping involves reviewing the entire process through a variety of techniques, including photography, video recording, field observations, interviewing and feedback from stakeholders, and role-playing as needed. Process mapping allows review and mapping of the entire patient journey or pathway with all stakeholders. It aids in identifying inefficiencies, non-value-added steps, duplication, variation, discrepancies, and opportunities for improvement.

Used for?

Map the process or pathway to identify process improvement opportunities.

When to Use It?

When the process or pathway is complex with associated inefficiencies.

How to Use Process Mapping Effectively?

Process mapping is key for any quality improvement project; hence, start with a high-level process map, outline the scope of the process and key issues step-by-step, and create a more comprehensive process map. This exercise provides all participants with broad insights into the process under consideration and, in contrast to the participants' ideas, shows exactly what is actually happening. Process mapping promotes ownership of employees in each phase of the process and allows all concerned stakeholders to share views to avoid the domino or adverse effect of changing one phase of a process to another phase. Mapping should be done between teams and departments, showing the entire process from start to finish, allowing quality improvements to flow between teams and departments. Below is the high-level map by a detailed process map, which looks at the MRI investigation process carried out in a major hospital (Fig. 13.1) [11].

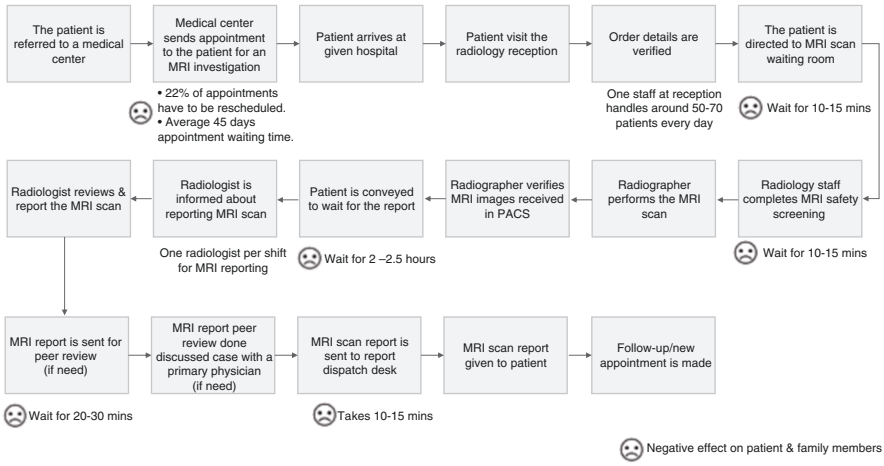

Fig. 13.1 Sample process mapping

Flowchart

The flowchart shows the individual steps of the process in sequence. A flowchart identifies the beginning, between, and end of the process and how one part of the process is dependent on another. It is a generic tool that can be used for different purposes and can be used to describe different processes, e.g., blood sample transportation process and admission process. It is one of the widely used analysis tools and also one of the seven basic quality tools. The elements that can be included in a flowchart are a series of actions, materials, or services that go in and out of the process, decisions made, stakeholders involved, time involved in each step, and/or process measurements.

Used for?

To identify or to know the actual flow of events in a process that follows.

When to Use It?

When any process needs improvement or to know the complexity and recognize the non-value-added loops and identify where simplification and standardization may be possible. It can also be used to weigh the actual flow of the process against the ideal flow to identify opportunities for improvement.

Table 13.3 Commonly used in symbols in detailed flowcharts

	Use for mark start or endpoint	→	Flow from one step to the next one
	Process		Link to another
	Decision		Document
	Data-Input-output		Delay

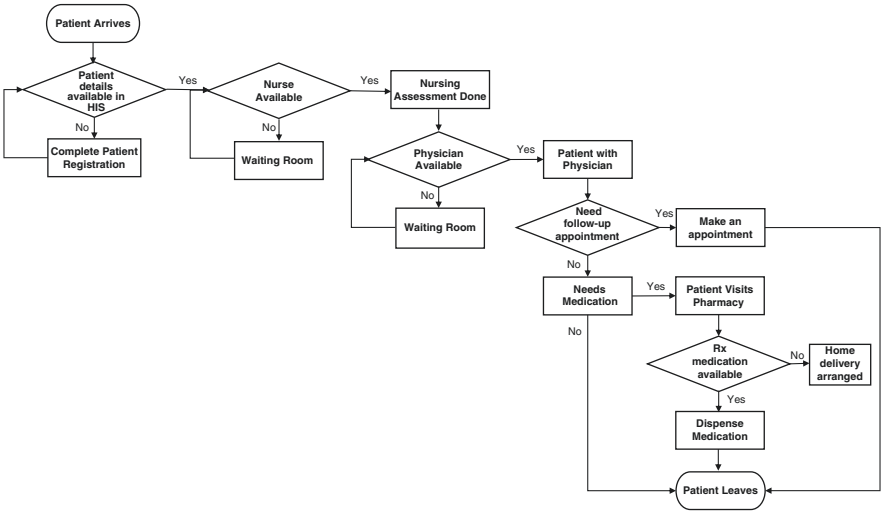

Fig. 13.2 Example of outpatient physician consultation visit flowchart

How to Use a Flowchart?

First, start with identifying the boundaries of the process, and clearly define where the process begins and ends. It is essential to identify and involve all concerned stakeholders in the charting process. This includes doctors, nurses, paramedics, managers, supervisors, biomedical engineers, pharmacists, housekeepers, etc. whoever are involved in the selected process. All stakeholders should decide on the level of detail to be included in the flowchart. To have a brainstorming session about the process and identify, then write each step of the flow and arrange the activities in proper sequence. Once all the activities are included, review the activities, have concurrence from all members that the sequence is correct, and draw arrows to show the flow of the selected process. Please refer to Table 13.3 to know what is commonly used in symbols in detailed flowcharts (Fig. 13.2).

Clinical Audit

A clinical audit is a quality improvement method that helps to measure the gap between ideal practices, which are determined from evidence and guidelines and actual practices. A clinical audit is not done to pinpoint the patient care team or individual practitioners but aims to improve the system in individual work. If it is applied correctly, the clinical audit can bring changes and improve practice and patient outcomes and enhance safety and clinical effectiveness.

Used for?

To check the delivered clinical care meets the defined clinical guidelines or protocol and monitor improvement to address identified noncompliances.

When to Conduct a Clinical Audit?

Clinical audit is often used on an ongoing basis to measure compliance against evidence-based clinical guidelines and standards or as a quality improvement initiative to assess the clinical outcome based on the care delivered.

How to Use It Effectively?

Clinical audit is a multidisciplinary team activity wherein aspects of structure, process, and outcome (Table 13.4) of care are selected and evaluated against the criteria derived from evidence-based clinical standards. The clinical audit process typically involves the following steps:

- Select the clinical audit topic based on the organization prioritization matrix.
- Select the criteria based on objective measures.

Table 13.4 Example of structure, process, and outcome criteria

	Structure	Process	Outcome
Criteria	Staffing in the NICU	Door to balloon insertion time	Surgical site infection rate
Target	1:1 nursing staff for ventilated patient	<30 min	<1%

- Define and design the data collection tool and decide on data collection methodology and sample size.
- Multidisciplinary team conducts the audit and collects the data.
- Data analysis, interpretation, and identification of improvement, and develop an action plan to address deficiencies.

The clinical audit cycle cannot be completed until there is evidence that changes are made on identified areas of improvement and have been effective. Typically, clinical audits are often carried out retrospectively; however, growing digital technology also enables the team to record ongoing real-time data collection. The clinical audit findings identified areas of improvement, and the action required should be shared with all concerned clinical care team members to facilitate learning.

Plan-Do-Study-Act

This process is also referred to as the Shewhart cycle or PDSA method. It is the quality improvement model that is a combination of building and applying knowledge to make a continuous improvement. PDSA (Plan, Do, Study, Act) iteratively helps to evaluate the impact of test changes and ensures that new ideas improve quality before they are rolled out on a large scale. Since process changes can lead to unexpected results, it is safer and more efficient to test quality improvements on a small scale prior to large-scale implementations, and a sample of relevant stakeholders has been suggested. You can evaluate the execution of changes. With the introduction of these small changes, it is also possible to test the interaction with other systems without having a significant impact on the quality of service; for example, pilot a new fall risk assessment tool in one unit with a limited patient group before using the new tool across the facility patients.

Used for?

Use for potential quality improvements, test them, and make small improvements before implementing them on a large scale.

When to Use It?

If you need to change a process or system, or if you want to introduce a new procedure, process, or system.

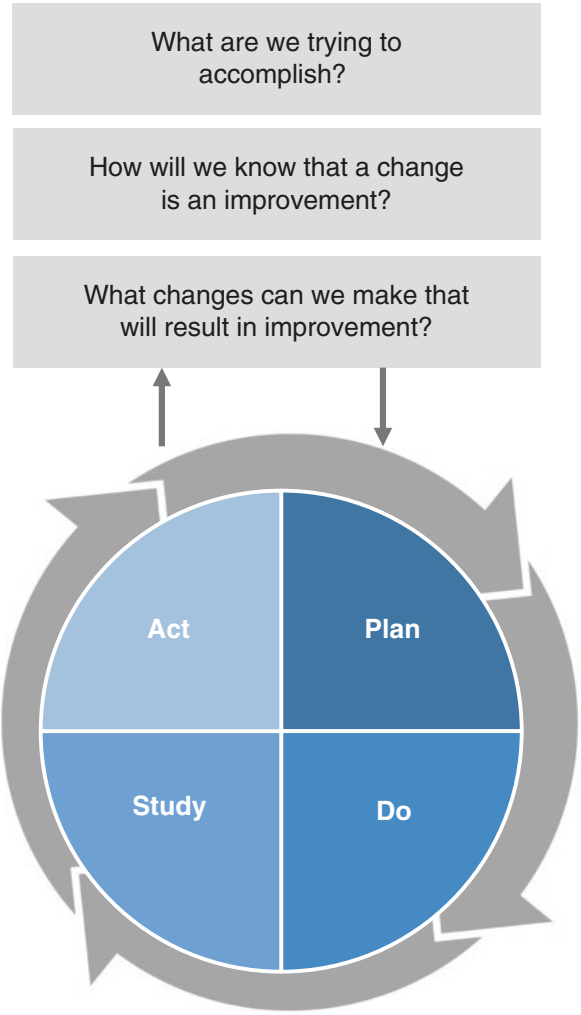

Fig. 13.3 Reference—key topics in healthcare management: understanding the big picture. (By Robert Jones, Radcliffe Publishing, 2007)

How to Use PDSA Effectively?

Processes or systems that require change, or new processes or systems that are planned and implemented on a small scale for a specified period of time with a minimum cohort of stakeholders (do), evaluated (study) and adjusted (act), with repeated PDSA cycles, until it is fit for purpose and wholesale implementation. Engaging all concerned stakeholders in all four phases of the PDSA cycle facilitates involvement in proposed changes and provides input for adaptation when potential users are aware of barriers to change. Please refer to the PDSA cycle (Fig. 13.3) [12]:

Plan—the implementation you are going to do.
Do—Carry out the test or changes preferably on a small scale to start with.

Study—Study the result before and after to know whether a plan works and what was learned.

Act—Based on the results, plan the next cycle with required changes and/or go for full-scale implementation.

Ishikawa Cause-and-Effect (Fishbone) Diagram

A cause-and-effect (fishbone) diagram is a quality improvement tool that helps find out the reason(s) for defects, variations, or problems within a process. The defect, variation, or problem is placed as the fish head facing on the right and the causes extend to the left as the bones of the skeleton; the ribs branch off the back, branch reflects the major cause, and sub-branches denote root causes. The fishbone diagram enables the source of a defect, variation, or problem to be identified so that resources for quality improvement can be appropriately directed towards the true cause, rather than towards the symptoms. A fishbone diagram is often used as a reactive method to identify the cause of the defect, variation, or problem.

Used for?

Use to identify the physical, human, and hidden and real causes of events affecting the service or product.

When to Use a Fishbone Diagram?

To identify the root causes of events for quality improvement which is affecting the service or product.

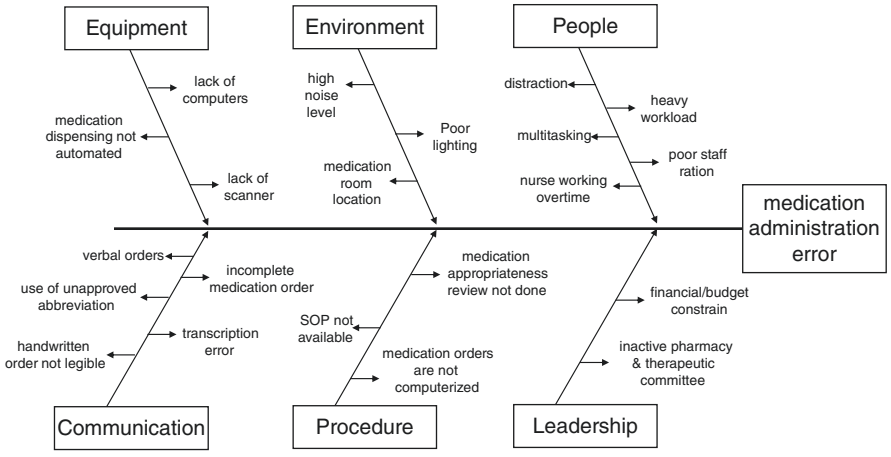

Fig. 13.4 Sample medication administration error in fishbone diagram

How to Use It Effectively?

The fishbone diagram helps identify a wide range of all possible causes behind the defect, variation, or problem and the associated effects. The defect, variation, or problem is placed as the fish head facing on the right, e.g., medication administration error; the causes extend to the left as the bones of the skeleton; the ribs branch off the back; the branch reflects the major cause such as process, environment, manpower, and material; and sub-branches denote root causes. All direct and indirect concerns of stakeholders such as physicians, nurses, and pharmacists should be involved in conducting the root-cause analysis using a fishbone diagram to identify the cause of the defect, variation, or problem. In an event when the patient is affected, then whenever appropriate the patient or family member should be involved to add their valuable perspective and insight during a root-cause analysis process. The fishbone diagram allows identifying the cause of a defect, variation, or problem so that efforts and resources for quality improvement can be appropriately navigated towards the real cause of the deviation, variation, or problem, rather than towards the symptoms (Fig. 13.4).

Statistical Control Chart

The process typically has two types of variation, abnormal variation that arises under unusual circumstances and normal variation that occurs under normal conditions, and often can be traced to a source or cause. The control chart is a graph used to investigate how a process changes over time. The data is plotted in a chronological order. The control chart always has a central line for the average, an upper line for the upper control limit, and a lower line for the lower control limit, and these lines are derived from historical data. By comparing the present data with these lines, we conclude whether process variability is consistent (controlled) or unpredictable or uncontrolled, affected by a particular source of variation. The statistical control chart has been widely used in many other industries to control quality in the management process. It is known as one of the seven basic quality tools.

Used for?

Often it is used to measure and control processes against predefined parameters.

When to Use Statistical Control Chart?

When determining whether a process is stable or requires monitoring and control to maximize its full potential. Also, to analyze patterns of process variation from unusual causes or common causes and to determine whether quality improvement

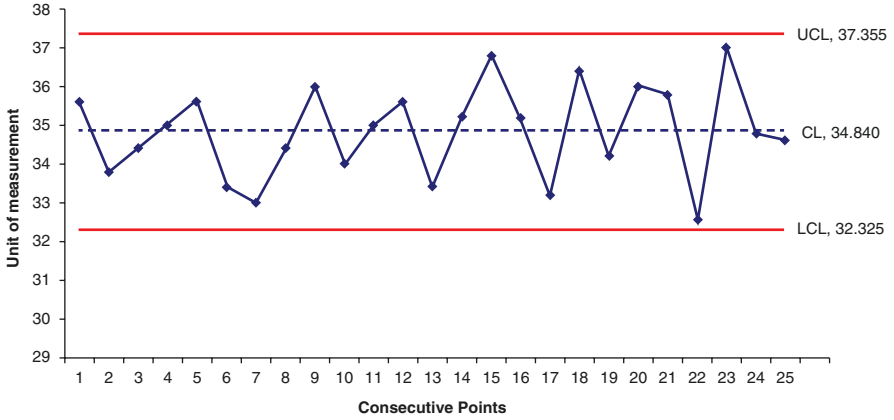

Fig. 13.5 Sample statistical process control chart

should aim to prevent specific problems or to make an essential change to the process.

How to Use It Effectively?

A lower control limit and an upper control limit are set using standard deviations from past or baseline data, and outputs are plotted for variation in quality (Fig. 13.5). Data must be collected for charting and for statistical rigor, and the number and frequency of measurements are important; the more measurements that are charted, the graph will give a more robust overview of variation in output. Analysis of variation makes it possible to identify shortfalls in the baseline and highlights opportunities for improvement. Such gaps require targeted investigation, process modification, and ongoing monitoring to know that the changes made have reduced variation or led to further variation, which may appear at a different point within the process. Control charts can be used throughout the life cycle of a process improvement project, during project identification, setting baselines, checking progress, reviewing the project impact, and knowing whether the changes made are sustainable.

Healthcare Failure Modes and Effects Analysis (HFMEA)

Healthcare failure modes and effects analysis (HFMEA) is a systematic, proactive quality improvement method for process evaluation, used to identify where and how a process might fail and to assess the relative impact of different failures, for identification of the process elements in most need of change. HFMEA includes a review of the following [13]:

- Steps in the process

- Failure modes (what could go wrong)
- Failure causes (why would the failure happen)
- Failure effects (what would be the consequences of each failure)

Used for?

It is used to systematically and proactively evaluate the processes to identify improvement opportunities.

When to Use HFMEA?

When a process needs a meticulous and systematic review and further improvement to avoid failure.

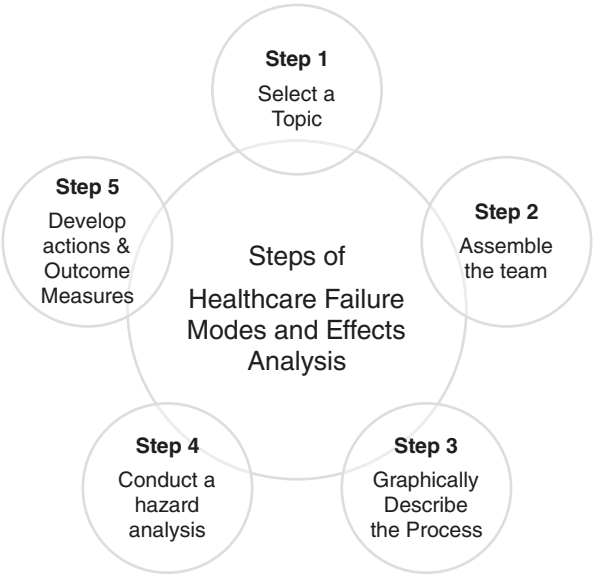

Fig. 13.6 HFMEA steps (source: Cohen, M. R., & American Pharmacists Association. (2006). *Medication errors*. Washington, DC: American Pharmacists Association)

How to Use It Effectively?

The multidisciplinary team collaborates to conduct HFMEA to prevent errors by proactively reviewing and modifying the process, rather than responding to post-error adverse events. Focusing on prevention reduces the risk of harm to patients, visitors, and staff. HFMEA is especially useful for assessing new critical processes prior to implementation or for evaluating the impact of proposed changes on current critical processes.

Failure mode contains any issue or process that could go wrong and that can prevent the execution of process steps. There are multiple possible causes for each failure mode. The causes are prioritized, eliminated, controlled, or accepted by systematic risk classification.

Control measures should be included in the process as early as possible. You can manage a single hazard with multiple controls, and each control can be used multiple times in a process. To seek feedback from the process owner or representative, each recommended process change requires simulation for testing before it is implemented across the facility. Please refer to the HFMEA steps (Fig. 13.6) [14].

Pareto Chart

A Pareto chart is a bar graph; it helps to show the relative contribution of the different causes of the problem. The Pareto principle states that 80% of the results are determined by 20% of the causes. So, one should try to find 20% of the types of issues and defects that cause 80% of all problems. Pareto chart bar lengths represent frequency and are arranged with the longest bars on the left and the shortest bars on the right. Thus, the diagram clearly shows which situations are more significant. Without analyzing or inspecting the data, the leaders may assume that all causes contribute equally to poor quality or that one or more causes are the leading ones.

Used for?

To identify the most common causes resulting or leading to poor quality.

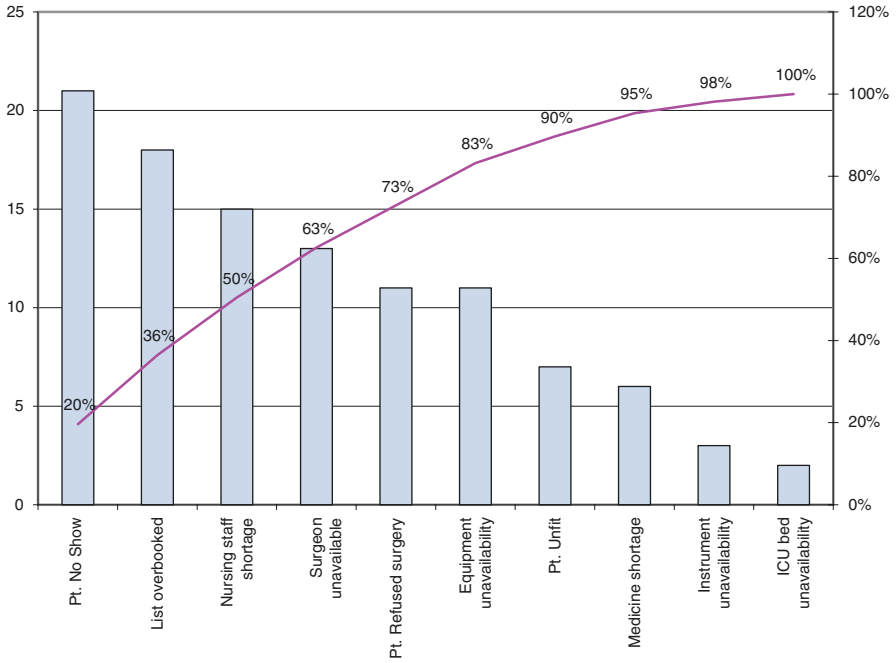

Fig. 13.7 Sample surgery OT cancellation—Pareto chart

When to Use Pareto Chart?

When analyzing data about the frequency of problems or causes in a process. There may be many problems or causes, but only a significant one or more causes needs focus for quality improvement.

How to Use It Effectively?

The multidisciplinary team collaborates to identify the causes resulting in poor quality using the Pareto chart. A multidisciplinary team should group the causes into specific categories and choose appropriate measurements. The team shall define the period of the time chart, which will cover and use the data collected and compute the subtotal for defined categories. Then adjust the scale of the left axis to accommodate the largest subtotal from the different defined categories. Based on those constructed bars, the tallest bar is at the far left, and the shortest bar is at the far right. The percentages for each subtotal category are then calculated, dividing them by the total of all categories that represent 100%, as indicated by the right vertical axis. The cumulative sum is calculated, starting from the far left to the right, and a line graph represents the percentage of the sum relative to the right vertical axis. Please refer to the sample Pareto chart (Fig. 13.7).

Six Sigma

Six Sigma is a data-driven methodology that provides tools and techniques to define and evaluate each step of a process and seeks to improve flow in the value stream and eliminate waste. The aim of Six Sigma is to achieve a level of quality that resides in the 6-standard deviation of average performance, resulting in an error rate of 3.4 defects per million opportunities. Six Sigma uses the framework to define, measure, analyze, improve, and control (DIMAC) process, which is a data-driven quality strategy used to understand root causes of variation, reduce them, and improve processes. Six Sigma provides a structured approach, to reduce the variation in medical services; it also helps in ensuring a consistently high-quality patient experience, reduces waste, and aids in concentrating resources in the most effective locations. The statistical process control chart is a subset of Six Sigma, and it helps in monitoring the variation. The data is plotted in chronological order, showing the average centerline determined from historical data, the upper line for the upper control limit, and the lower line for the lower control limit bounds. After the process is set up, it helps in concluding the variability of the process by comparing the current data with these lines.

Used for?

To evaluate the systems to study the cause of variation, to eliminate waste, and for continuous improvement.

When to Use Six Sigma?

When the systems are unproductive, inefficient, and varying.

How to Use It Effectively?

Six Sigma uses process mapping, and it should be done by involving all concerned stakeholders to identify inefficient or non-value-added steps, which are affecting the service and aiding action planning for quality improvement.

- Define the problem, specify the target group, identify goals, and plan the target process.
- Measure: decide the criteria or indicators to be quantified and find a way to measure them. Then collect the required baseline data and measure again after changes have been applied.
- Analyze: identify the gaps between actual performance and defined goals, find the causes of those gaps, determine how process inputs affect output, and aim for further improvement.

- Improve: formulate potential solutions, identify the most feasible solutions for implementation, trial hypothetical solutions, and implement the improvement solutions.
- Control: develop a detailed solution monitoring strategy, observe implemented solutions for success, and update on a periodical basis.

13.2 Continue Development in Healthcare Quality

The credible reports from the Institute of Medicine and other organizations have raised significant awareness of medical errors, patient safety, and quality concerns in the medical system. Patient safety remains the top priority as healthcare professionals are becoming more and more aware, and quality improvement will be the focus for many coming years. Also, medical schools, regulatory bodies, and healthcare accreditation bodies around the world have adopted various initiatives to bridge the gap and improve patient safety and quality. It is essential that healthcare providers make every possible effort to instill knowledge of quality improvement in their healthcare workers to improve patient safety and quality of care.

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