Course Book

QUALITY ASSURANCE AND RISK MANAGEMENT IN HEALTH

DLMIHMQARMH01

iu
INTERNATIONAL
UNIVERSITY OF
APPLIED SCIENCES

LEARNING OBJECTIVES

The world faces significant planetary and health challenges, which can also bring unprecedented opportunities for innovation and change using sustainable and humane methods. There is no doubt that many communities and individuals have limited or no access to healthcare, and even fewer have high-quality healthcare. Low-quality healthcare services negatively affect economic and social development, increase morbidity and mortality, and depreciate human capital (McCaskill, 2021). Additionally, COVID-19 has put immense pressure on health systems and uncovered gaps and shortcomings in the ability to handle healthcare crises. It is through the discipline of quality management, with a strong focus on risk management, that healthcare organizations and professionals are equipped to provide services that are effective, efficient, safe, timely, people-centered, and accessible.

Quality Assurance and Risk Management in Health begins by defining the concept of high-quality healthcare and exploring why it is important. Once this baseline is established, various quality management models are explained. Further, healthcare quality standards that are currently used in the healthcare industry are discussed.

One key area in the creation of a healthcare quality management program is a strong risk management mechanism. This course book describes risk management concepts and strategies, as well as the importance of critical incident reporting. These risk management strategies increase patient safety and ensure organizational resilience.

To control the quality of processes, a quality management system should conduct internal audits and may receive external audits from accrediting agencies, insurance companies, or other stakeholders. Key concepts for setting up an internal audit program are presented, as well as valuable insights regarding external audits.

Finally, quality management systems require process and project management. Both are essential to the monitoring, control, and improvement of healthcare services. These sections introduce select strategies, techniques, and tools that help ensure that projects meet defined requirements on time and as planned.

UNIT 1

QUALITY ASSURANCE AND RISK MANAGEMENT IN HEALTHCARE

STUDY GOALS

On completion of this unit, you will be able to ...

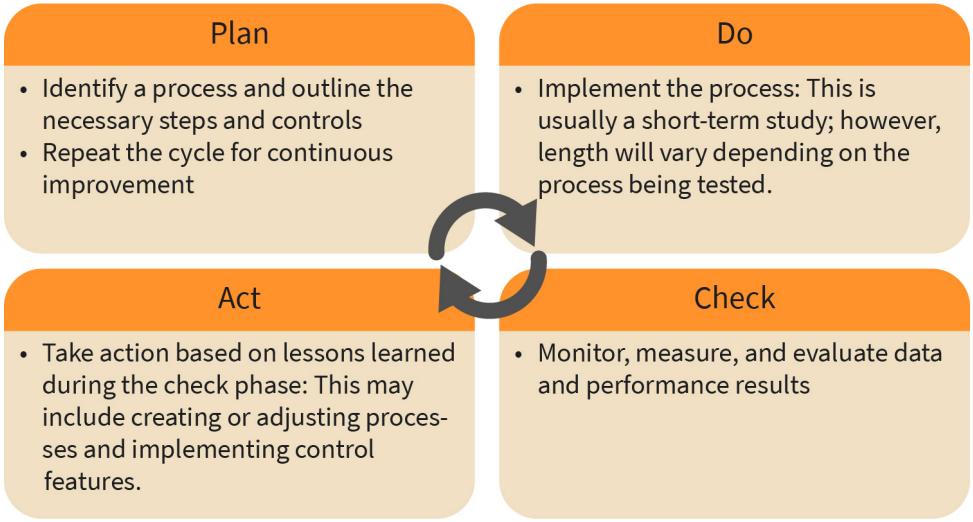
- define the main components that make up high-quality healthcare.
- describe why high-quality healthcare is important.
- explain societal factors that affect healthcare quality.
- articulate the importance of measuring quality.
- understand the concept of pay-for-performance or “value-based” payment.

1. QUALITY ASSURANCE AND RISK MANAGEMENT IN HEALTHCARE

Introduction

The idea of quality control has been around since the early 20th century and began with a focus on statistical control in the 1920s. The study and practice of statistical process control became more popular in the 1950s with the works of W. Edwards Deming, who invented the timeless plan, do, check, act (PDCA) cycle (Management Mania, n.d.). Initially, the idea of quality was associated with a physical product; yet, over the past few decades, it has been extended to include services.

Figure 1: PDCA Cycle



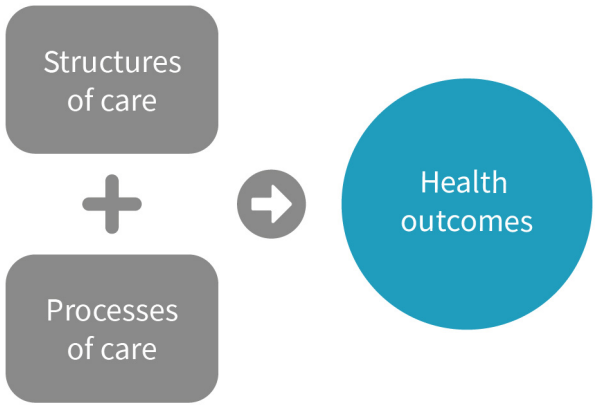
Source: Angela McCaskill (2023), based on Management Mania (n.d.).

Since the early days of Deming, other popular frameworks have been conceptualized that specifically address quality in the healthcare. In 1966, major advances in the understanding of quality and its role in the delivery of healthcare services were made when doctor and researcher Avedis Donabedian published his S-P-O model, which is still widely used in research and practice today. The model is based on the belief that information about healthcare service quality can be found in three foundational elements: structure, process, and outcomes (Donabedian, 1988).

"Structure" refers to the organizational and physical structures in which services are provided. This includes facilities, equipment, human resources, financial factors, and technology. "Process" addresses the actual actions performed in healthcare facilities, which includes patient care. This covers topics such as patient treatments, diagnostics, the admission process, and employee handwashing. Lastly, "outcomes" refers to the actual

effects on the patient population and whether or not the structures and processes worked effectively to achieve goals. Examples of outcomes include patient safety measures, number of hospital readmissions, patient experience and satisfaction data, and reduced mortality (ACT Academy, n.d.).

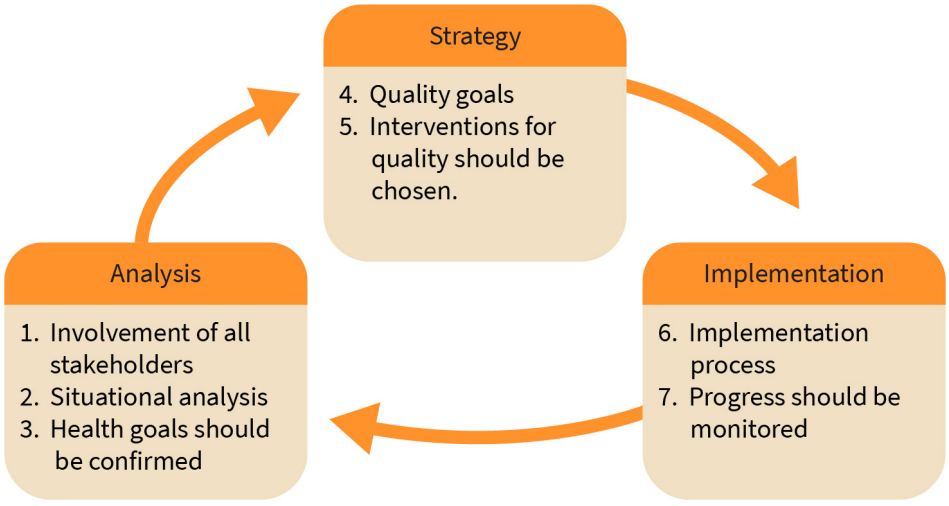
Figure 2: Donabedian Model



Source: Angela McCaskill (2023).

In 2006, the World Health Organization (WHO) published a guidance document about quality of care, in which they propose a framework for creating quality health systems. It contains seven elements grouped within three categories: analysis, strategy, and implementation (WHO, 2006).

Figure 3: A Process for Building a Strategy for Quality



Source: Created by another author, based on WHO (2006, p. 14).

More recently, the Lancet Global Health Commission on High Quality Health Systems (HQSS) in the **Sustainable Development Goals** (SDG) Era was formed to define and describe quality care (HQSS, n.d.). They further identified measurement and structural

Sustainable Development Goals
These are the 17 goals adopted by the United Nations (UN) Member States in 2015 to achieve peace and prosperity for humans and the planet. Specifically, Goal 3, "Good Health and Well-Being," outlines 13 targets and related indicators (UN, n.d.).

approaches for quality improvement. The Commission published an article exploring high-quality health systems, calling for a "revolution." The outcome of their work is a comprehensive conceptual framework with three key components: foundations, processes of care, and quality impacts (Kruk et al., 2018).

Figure 4: High-Quality Health System Framework Components

	Components
Quality impacts	
Better health	Level and distribution of patient-reported outcomes: Function, symptoms, pain, well-being, quality of life, and avoiding serious health-related suffering
Confidence in system	Satisfaction, recommendation, trust, and care uptake and retention
Economic benefit	Ability to work or attend school, economic growth, reduction in health system waste, and financial risk protection
Processes of care	
Competent care and systems	Evidence-based, effective care: Systematic assessment, correct diagnosis, appropriate treatment, counseling, and referral. Capable systems: Safety, prevention and detection, continuity and integration, timely action, and population health management
Positive user experience	Respect: Dignity, privacy, non-discrimination, autonomy, confidentiality, and clear communication. User focus: Choice of provider, short wait times, patient voice and values, affordability, and ease of use

Source: Kruk et al. (2018). CC BY 4.0.

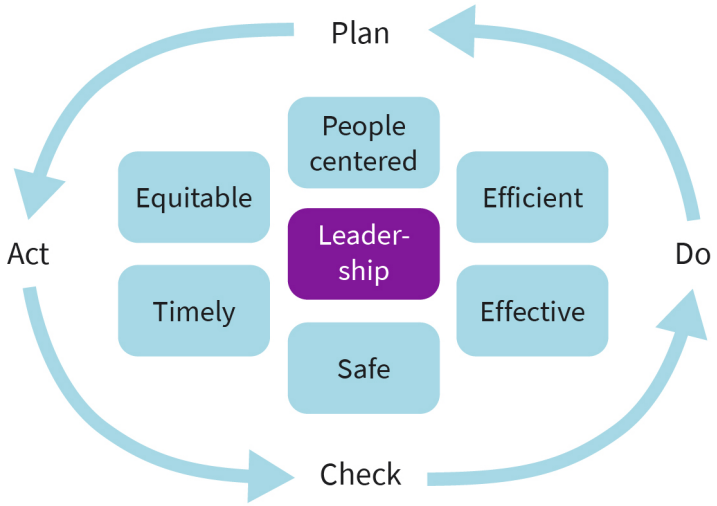
It is evident that, over the years, healthcare quality models have evolved to meet the needs of modern healthcare delivery trends, science, new technologies, and user expectations. Researchers and healthcare professionals have continued to gather more information and data about what constitutes "healthcare quality." This unit describes current expert thought on high-quality healthcare.

1.1 Definitions and Practical Application

What is High-Quality Healthcare?

In July 2020, the WHO announced that there is agreement among global experts that quality health services should be "effective, safe, people-centered, timely, equitable, integrated and efficient" (McCaskill, 2021, p. 92).

Figure 5: Elements of High-Quality Healthcare Framed in the Continuous Improvement Cycle of PDCA



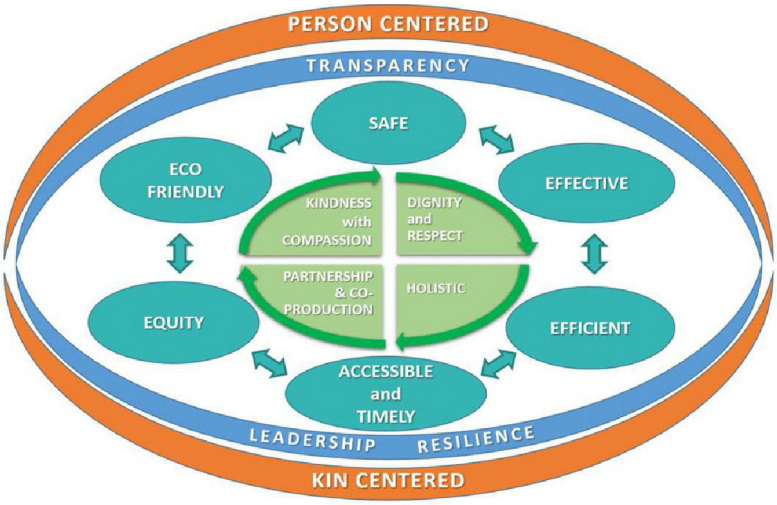
Source: Angela McCaskill (2023).

In keeping with the WHO's model, a 2021 article addressing healthcare quality describes a similar multidimensional model of care. It outlines domains of quality for the "new era" of health, defining a system that is effective, safe, efficient, accessible, timely, equitable, and **eco-friendly**, as well as either person- or **kin-centered** (Lachman et al., 2021; WHO, 2021a). It is important to note that climate change and planetary health have multiple impacts on population health. Therefore, "eco-friendly" care and the "greening" of healthcare facilities are emerging themes in healthcare quality.

Eco-friendly
designed to have little or no damaging effect on the environment

Kin-centered
This type of care emphasizes "the shared humanity of people involved in the interdependent work." It replaces person-centered care, realizing that "delivery of health and healthcare requires people working in differing roles, with explicit attention to the lived realities of the people in the roles of professional and patient" (Lachman et al., 2021, pp. 1–2).

Figure 6: The Domains of Quality for the New Era of Health



Source: Lachman et al. (2021, p. 7). CC BY 4.0.

It is necessary to have a foundational understanding of what constitutes high-quality healthcare because, if these elements are not defined, a quality management system cannot adequately measure and control those specified indicators. Further, defining key elements or indicators allows for the associated operations to be monitored, evaluated, and improved upon.

Why is Healthcare Quality Important?

According to a 2018 report from the Lancet Global Health Commission, "high-quality health systems could save over 8 million lives each year in low- and middle-income countries (LMICs)" (Kruk et al., 2018, p. 1196). In addition to pre-pandemic healthcare access and equity issues, the quality of care that is delivered in LMICs, as well as in high-income Organization for Economic Development (OECD) countries, can be inconsistent, poorly funded, and without adherence to science-based best practices (McCaskill, 2021).

Healthcare quality both affects and is affected by numerous factors. The following explains how societal issues, such as population growth and ageing, economic impacts, workforce shortages, new technologies, and climate change, are all related to healthcare quality.

Population Growth and Ageing

Populations are ageing, with almost every country in the world seeing a population shift to older people as a larger proportion of the total population. The United Nations predicted that "the world's population is expected to grow by 2 billion persons in the next 30 years. With this increase, the world's population is growing older, with people aged 65 and older being the fastest growing [age bracket]" (International Organization for Standardization, 2020, p. 5). An increased population age requires planning on a systemic scale, as more individuals will require access to social protection systems, which include health-

care systems capable of providing safe, quality care in a timely manner. One way to address this challenge is for governments and healthcare-providing institutions to adopt values, goals, standards, and guidelines that result in cost-effective, high quality, people-centered care.

Climate Change

There is a visible and scientifically-proven link between the climate and population health. As the world continues to face increasing floods, drought, pollution, and rising temperatures, the impacts on both physical and mental health are notable. Climate change affects the most fundamental sources of health: clean air, safe drinking water, sufficient food, and secure shelter. As of October 2021, the WHO (2021b) predicts that "the direct damage costs to health (i.e., excluding costs in health-determining sectors such as agriculture and water and sanitation) is estimated to be between USD 2-4 billion/year by 2030" (para. 1).

In particular, pollution has significant negative impacts on health. The WHO (2018) estimates that

> exposure to air pollution causes 7 million deaths worldwide every year and costs an estimated US$ 5.11 trillion in welfare losses globally. In the 15 countries that emit the most greenhouse gas emissions, the health impacts of air pollution are estimated to cost more than 4% of their GDP. (para. 3)

Air pollution has disproportionally negative consequences for vulnerable populations such as the very young and the very old. Healthcare quality management should take this reality into consideration when planning not only the design and construction of facilities but also the design and offering of services.

Figure 7: Air Pollution From a Factory

Source: DWalker44 (n.d.).

Workforce Shortages

Even before the COVID-19 pandemic, many countries faced challenges with adequate healthcare staffing. The World Health Organization (n.d.) predicts a "shortfall of 10.2 million health workers by 2030, mostly in low- and lower-middle income countries." They further warn that "countries at all levels of socioeconomic development face, to varying degrees, difficulties in the education, employment, deployment, retention, and performance of their workforce" (para. 2). In the US, the American Hospital Association (2022) reports that "America will face a shortage of up to 124,000 physicians by 2033," and "will need to hire at least 200,000 nurses per year to meet the demand and replace retiring nurses" (Why? and The Issue sections). The OECD adds that the ageing healthcare workforce is a cause for concern. In a 2021 report, they offer Italy as an example, reporting that 56 percent of Italy's doctors are over the age of 55. They warn that healthcare workers will naturally retire, which will lead to even more staffing shortages (OECD, 2021) With these global shortages comes the need to explore new strategies for increasing the labor pool. Such strategies could include increasing medical school and nursing admissions, rethinking the educational paradigm for future healthcare providers, and task shifting (McCaskill, 2021). Quality management helps address this shortage through focused planning and design, risk and resource management, and creation of innovative approaches to workforce education.

Economic Impacts

Healthcare spending is of global concern, with the US and Switzerland having the highest out-of-pocket (patient) costs. In 2019, the WHO reported that the health sector "continues to expand faster than the economy. Between 2000 and 2017, global health spending in real terms grew by 3.9% a year while the economy grew 3.0% per year" (p. ix). Later, in 2021, they also stated that global spending on health has "doubled in real terms over the past two decades, reaching $8.5 trillion in 2019 and 9.8% of GDP (up from 8.5% in 2000)" (WHO, 2021a, p. ix). The direct care of patients and the administrative or "office" costs of doing business can add up and become costly. In the US, office costs amount to 34 percent of total healthcare expenditure, which is a lot more than the healthcare expenditure of the UK (16 percent) and the Netherlands (20 percent; Himmelstein et al., 2020).

There is no doubt that healthcare spending reform is needed to reduce costs and increase efficiency. A 2019 report from the international consulting firm Deloitte states that global healthcare "spending is projected to increase at an annual rate of 5.4 percent in 2017–2022, from USD $7.724 trillion to USD $10.059 trillion" (p. 7). An effective quality management system is instrumental in cost reduction, as detailed quality planning results in cost containment through prevention of rework, waste, and **risk mitigation**.

Risk mitigation refers to those strategies used to prepare for and lessen the effects of potential or actual threats

New Technologies

Digital healthcare is today's reality, and it promises an exciting tomorrow. A 2020 statistic predicts that "the global market size for telemedicine is projected to increase from around 50 billion U.S. dollars in 2019 up to nearly 280 billion dollars by 2025" (Statista Research Department, 2022, para. 4). In addition, the COVID-19 pandemic introduced unprecedented numbers of telemedicine appointments and forced the world to consider the

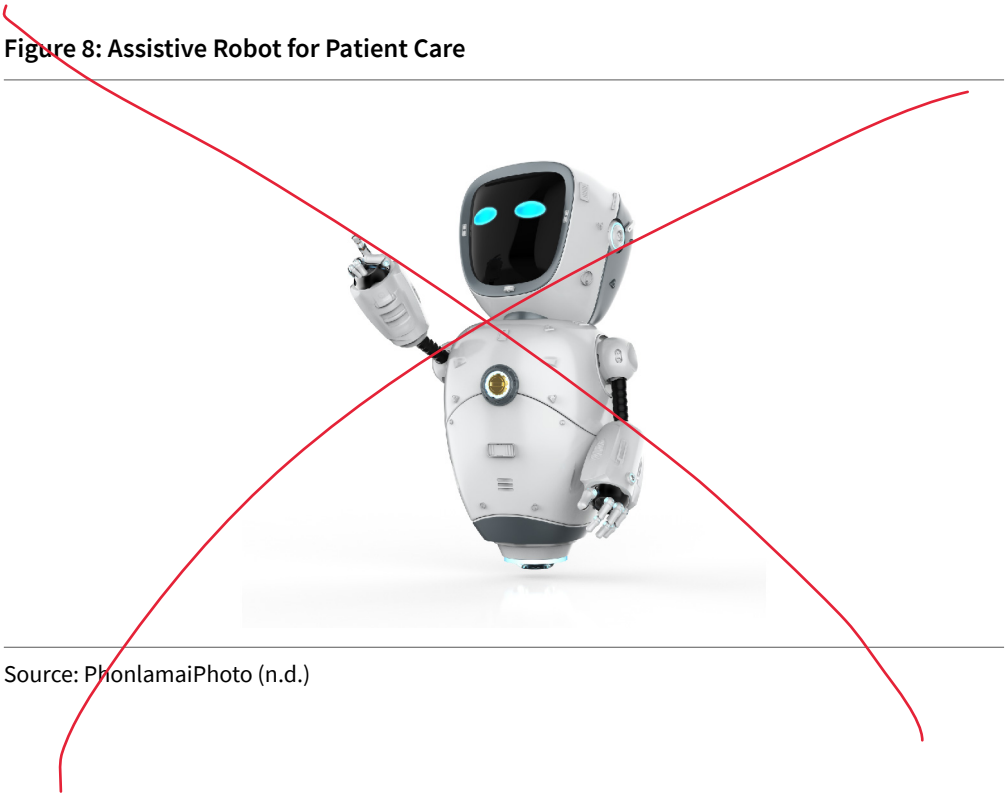
adoption of alternative technologies. While these scientific and technological advances are promising, it is important that quality management measures guide these processes to protect consumers from risks to health, safety, and privacy.

McKinsey & Company reports that venture capitalist investments in digital health and virtual care tripled between 2017 and 2020 (**Bestsennyy et al., 2021)**, and the use of telehealth has "stabilized at levels 38 times higher than before the pandemic" (Healthcare Standards Institute, n.d., Digital Health and Artificial Intelligence section).

> Uptake of telehealth continues to grow, with both patients and providers viewing it more favorably than they did prior to COVID-19. Deloitte's Global Healthcare Outlook 2022 emphasizes the need for healthcare leaders to balance the tremendous benefits of medical technology innovation with the practicalities of controlling healthcare spending. (Healthcare Standards Institute, n.d., Digital Health and Artificial Intelligence section)

Quality management plays a pivotal role in defining safe and effective telehealth processes, while controlling for costs. According to the third annual Optum Survey on AI in Healthcare, "83% of healthcare organizations have an AI strategy in place, and another 15% are planning on creating one" (Optum, 2020, p. 3), which emphasizes that AI is the future of healthcare. Frost & Sullivan, a market research and analysis firm, anticipate that sales of healthcare AI-enabled products will generate "more than $34.83 billion globally by 2025" (Doyle, 2020, para. 2). Many areas in healthcare can make use of AI, including "pharmaceutical AI, chatbots, Genomics AI, operations/supply chains, research of complex diseases, disease prediction, social AI such as contact tracing, and the use of robots" (Healthcare Standards Institute, n.d., Digital Health and Artificial Intelligence section) for surgeries and patient care. Quality management and quality standards can be used to ensure the efficacy and safety of many new technologies.

Figure 8: Assistive Robot for Patient Care



Source: PhonlamaiPhoto (n.d.)

The robot in the figure above could be used to remind a patient to take medication, change a wound dressing, or perform a rehabilitative exercise. Below are some questions to consider when planning for quality of care (remember, the user could be an elderly patient):

- Does the patient understand what the robot is saying?
- Can the patient control the volume?
- Is this robot user-friendly for all patient age groups?
- Does the robot reliably complete its tasks?
- Will the robot run out of charge? If so, how will the user be alerted before this happens?
- Can the robot overheat?
- What if the robot fails to alert a patient of low blood sugar or the need to take insulin?
- Does the robot make the patient feel observed? Is this a person-centered approach?
- Is patient care through the use of a robot humane? How do you ensure a favorable user experience? How do you measure this experience?

Asking these types of questions is not only necessary for risk management but also for ensuring that new technologies meet minimum quality measures for effectiveness, efficiency, people-centeredness, and safety.

1.2 Measuring Quality and Identifying Risks

According to W. Edwards Deming, "without data, you are just another person with an opinion" (Goodreads, n.d.-b, section 2). The imperative nature of objective evidence is well established. Throughout time, science has provided us with verifiable data that have led to significant advances in all sectors. Data, and even more "big data," are readily available electronically through our digitally-connected world. Opinions can be heard about any topic, from all viewpoints, from anywhere across the globe, but how do we know when opinions are simply opinions or actual facts? Now more than ever, the use of objective evidence is needed to protect consumers and advance responsible and sustainable practices. Measuring quality data is important for numerous reasons, including the following:

Downtime
This is time when a person or process is inactive. In manufacturing, this often refers to times when a machine is shut down due to maintenance, setup, and operator error.

- Rework or re-providing a service is expensive.
- **Downtime** is costly.
- There are multiple far-reaching costs associated with losing a customer, such as poor brand recognition, diminished trust, and actual lost income.
- Gaining a new customer has costs.
- You cannot control what you do not measure.
- Reliable data equip an organization to establish benchmarks, baselines, and goals from which to work upon and improve.
- Data allow for strategic design and planning.
- Data provide evidence to back up an argument and advocate for a cause.
- Data allow organizations to make strategic decisions about finances and resource allocation.

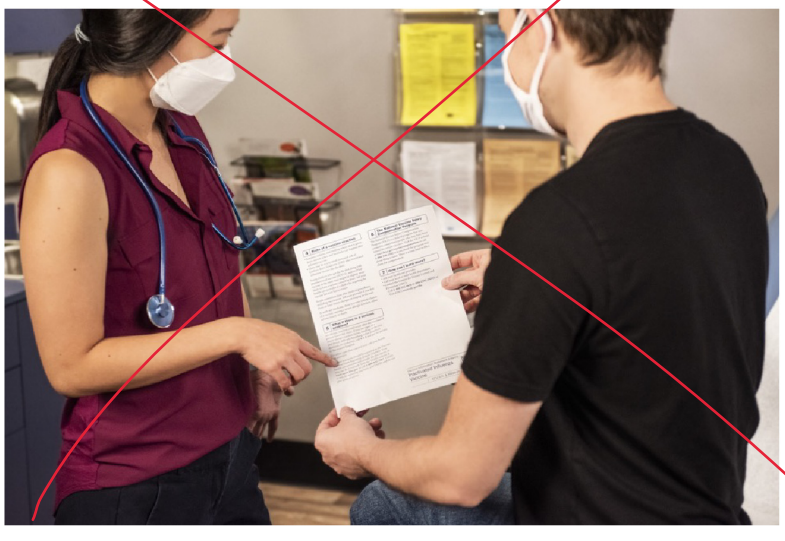
- Many customers and regulatory bodies require that organizations measure their performance.

Data are of particular importance because they help in the identification of risks. Big data can highlight trends at both high levels, such as industry trends, and more focused levels, such as a process trend. When process control statistics indicate that an error commonly occurs at a given point in a process, this signals that measures should be implemented to control for that error, thereby minimizing the risk that the error will occur.

A good example of data used to control risk in the healthcare setting is the use of indwelling urinary catheters in hospitalized patients and the prevalence of catheter-associated urinary tract infections (CAUTIs). Studies in the early 2000's led to a significant change in evidenced-based nursing practices concerning the use of long-term indwelling urinary catheters. Traditionally, hospitalized patients used catheters for many days to weeks. This was believed to give the patient comfort, increase safety, and provide solutions for patients with conditions that affected the functioning of their urinary systems. The catheter was also more convenient for hospital staff, as no one needed to help the patient to the bathroom or to use a bedpan. However, data from hospital studies showed that the catheters were a significant source of infection, which lead to increased morbidity and mortality. The Centers for Disease Control (CDC, 2015) estimated that "17% to 69% of CAUTI may be preventable with recommended infection control measures, which means that up to 380,000 infections and 9000 deaths related to CAUTI per year could be prevented" (para. 1).

The data in these studies led to signficant industry changes in guidelines regarding the need to use catheters, length of use, and infection control measures. It is evident that data are important in relation to increasing healthcare quality and control risks. Now, consider the following example: A patient is receiving discharge instructions after receiving a vaccine. What are topics that could be measured, and how could a hospital use these data to improve its services? You have freedom to interpret the photo as you would like. Be creative!

Figure 9: Patient Receiving Post-Vaccination Instructions



Source: CDC (2020). Public Domain.

1.3 Pay for Performance

Pay for performance
also referred to as "value-based" payment

Pay for performance (P4P) is a payment model that is increasing in popularity in some countries. It is an industry model that offers financial incentives to hospitals, physicians, medical groups, and other healthcare providers for meeting pre-defined performance goals and measures. Healthcare systems, organizations, and even providers are rewarded based on the quality of care provided, not just the quantity. Some examples of P4P measures are the number of hospital-acquired infections and conditions, readmission reduction, and the use of home health instead of in-hospital treatment.

Research concerning P4P effectiveness has shown mixed results. The Lebanese Ministry of Public Health implemented a P4P policy in 2014. One study analyzed hospital performance from 2011–2016 to assess the impact of the new policy on hospital performance. Data showed that the policy increased healthcare effectiveness, and that it was mainly "attributed to decreased unnecessary hospitalizations and was accompanied by improved medical discharge coding practices" (Khalife et al., 2020, p. 19). In England and Wales in 2010, a P4P program was implemented to improve the quality of care provided to elderly patients with a hip fracture. This initiative – called the Best Practice Tariff (BPT) – financially rewarded hospitals who achieved six clinical standards of performance. The study showed that the initiative not only reduced mortality for elderly patients with a hip fracture, but it also decreased both waiting times for surgeries and readmissions (Metcalfe et al., 2019). While the aforementioned examples do show positive outcomes, debate remains around the design and evaluation of P4P programs. P4P schemes "require the collection of data to determine obtainment of goals and metrics. Healthcare management standards are a viable tool for the planning, management, monitoring, and improvement necessary for a value-based payment system" (Healthcare Standards Institute, n.d., Changes in Payer Systems section).

SUMMARY

Quality management began as statistical process control around the 1920s and has evolved into a wide-reaching, multifaceted discipline. Quality management is of particular relevance to the healthcare sector, as it deals with life and death, as well as patient safety and well-being, and it affects societal issues, such as equity and accessibility. More recent models of healthcare quality agree that high-quality care is efficient, effective, safe, timely, people-centered, and equitable. Today's healthcare industry faces significant challenges, including ageing and growing populations, workforce shortages, economic impacts, climate change, and new technologies.

Measuring quality using data is necessary for process control, improvement, and risk identification and management. Data are also considered when deciding how healthcare organizations and providers should be paid. One model called pay for performance requires the monitoring and tracking of predefined treatment outcomes. This is a pivotal time in history, as the healthcare sector faces great challenges, and even bigger opportunities. The discipline of quality management helps organizations avoid and overcome obstacles, reduce risk, improve patient outcomes, and best utilize limited resources.

UNIT 2

QUALITY ASSURANCE SYSTEMS

STUDY GOALS

On completion of this unit, you will be able to ...

- define key quality terms.
- describe total quality management.
- discuss both European and international norms for quality.
- understand the Six Sigma DMAIC process.

2. QUALITY ASSURANCE SYSTEMS

Introduction

Quality is a concept that has been studied since the 1920s, when quality management primarily focused on statistical process control. Today, the breadth and depth of quality management has expanded immensely. It has evolved to be a management system, a mindset, and an endeavor that requires organizational commitment at all levels. In the famous words attributed to W. Edwards Deming, “Quality is everyone’s responsibility” (BrainyQuote, n.d.). While every employee is responsible, experts agree that top management must be primarily responsible and accountable for the effective functioning of the quality management system. Effective functioning of systems and processes are of considerable importance in the healthcare industry, as it is often a matter of life or death. There may be no remake, redo, or return if a clinical process does not follow specified requirements. For this reason, healthcare organizations must have a “culture of quality” that is engrained at every level. This unit defines common industry terms, explores the importance of measurement and evaluation, introduces quality models in vigor today, and presents some of the most prevalent quality standards currently adopted in the healthcare sector.

2.1 Quality Management Models

Terms surrounding quality management can be confusing. Depending on the professional sector, or an organization’s understanding of quality, naming can be interchangeable and fluid. In general, the following are acceptable ways of defining common terms:

- quality management (QM): This is a management system made up of interlinking processes and procedures that are used to design and plan operations, identify risks, control processes, monitor and evaluate outcomes, continuously improve, and meet defined criteria. QM is an overarching mechanism that includes both quality assurance and quality control.
- quality assurance (QA): This refers to planning for a specific process. While QM is comprised of multiple processes, QA measures may be applied to a specific process and is aimed at preventing defects. It answers the following question: “What must be done to ensure that this meets the defined criteria?” Examples include creating instructions and checklists for prevention of errors in the operating theatre and creating a process to ensure that indwelling urinary catheters do not lead to urinary tract infections.
- quality control (QC): QC focuses on the final product or outcome. It aims to answer the following question: “Did established processes produce an outcome that meets the predetermined requirements?” QC should have a robust sampling method that is based on the severity of risk associated with the outcome of the product, process, or service. For example, sampling of **customer** satisfaction may be performed for 50 percent of dis-

charged patients; however, compliance review may take place for every hospital pharmacy transaction involving controlled substances. The higher the risk, the higher the sample size.

Customer
Depending on the sector, a customer may also be referred to as a client, user, end-user, or patient.

No matter which term is used, the goal is always the same: ensuring that the final product or service meets predefined requirements. In the special case of healthcare, risk management, patient and workforce safety, and ultimate health outcomes must always be included in these requirements.

Popular Quality Management Models in Use Today

Management system thinking evolves throughout time, and every few years, a new theory, technique, or style appears in the marketplace. Some of these are driven by desires to improve upon quality management and, at the same time, seek recognition for being the "latest and greatest" model of quality management. Aspects that almost all QM models have in common are the need for strong leadership, strategic planning, implementation of defined processes and procedures, monitoring and measurement, and a continuous improvement mechanism.

Total quality management (TQM)

TQM is a management system approach to "total quality" that includes all employees at all levels of the organization. While Deming has been credited with pioneering the TQM approach around the 1950s, it is based on the early teachings of numerous quality pioneers, such as Joseph Juran, Philip B. Crosby, Armand V. Feigenbaum, and Kaoru Ishikawa (American Society for Quality, n.d.-c) TQM is process based, with a focus on customer satisfaction and continual improvement. Data, monitoring, and measurement play key roles in preventing **nonconformances** and improving systems. TQM is a philosophy of quality management, but not a standard. An organization can adopt and practice the principles of TQM but cannot be accredited or certified in it. The eight principles of TQM are:

Nonconformances
the nonfulfillment of a requirement

1. **Customer-focused**: The customer decides what is important to them and, hence, what is considered quality. What is considered valuable to the organization may not always be the same as customer preferences.
2. **Continual improvement**: The organization should use all sources of information, analytical and social, qualitative and quantitative, to continuously improve in all areas.
3. **Total employee involvement**: A culture of quality starts with top management and flows horizontally and vertically to all employees. This requires recognition that everyone plays a role in quality. For example, the person in charge of general cleaning in a hospital has a vital role in the quality of services. A dirty room could lead to an increase in exposure to infectious pathogens that potentially affect patients, caregivers, and healthcare providers. Further, the patients might be unhappy if their rooms are not well cleaned, which leads to low patient satisfaction. A dirty floor that is slippery could cause an employee or patient accident. Additionally, if a worker has a poor attitude, this can spread throughout the organizational culture. As you can see in this example, every employee affects quality.

Customer-focused
In the healthcare industry, a customer may be the patient, patient's family, or an outside organization that subcontracts services from the hospital. For example, a private laboratory that pays the hospital to process certain blood tests would be a customer of the hospital.

4. **Strategic and systematic approach**: The organization should write a strategic plan that is in alignment with its mission, vision, values, and goals. Quality management strategies should be included in the plan.
5. **Process-centered**: Processes are a series of inputs that transform into outputs. The organization should take a process approach that starts at the very beginning of the process and define the procedures and quality assurance techniques along the way to ensure that outputs meet predefined customer requirements.
6. **Integrated system**: While most organizations have multiple departments with their own functions (i.e., sales and marketing, legal, human resources, clinical operations, maintenance, occupational safety), in the TQM model, it is important that all departments and functions focus on the shared mission, vision, goals, and communications amongst the departments. “An integrated system connects business improvement elements in an attempt to continually improve and exceed the expectations of customers, employees, and other stakeholders” (American Society for Quality, n.d.-c, Primary elements of TQM section).
7. **Communications**: Communication among employees and applicable stakeholders is essential to the effective functioning of an organization and its quality management system. Communication methods should be defined: who, what, when, where, why, and how communications will occur. This is particularly important when communicating changes.
8. **Fact-based decision-making**: Organizations should collect and analyze data throughout their processes and use those data to inform decisions and continuously improve.

Figure 10: Eight Principles of Total Quality Management

Source: Angela McCaskill (2023).

Soft and hard TQM

The eight principles can further be classified as "soft" or "hard" TQM. The soft principles are those that are "associated with management concepts and principles such as leadership, employee empowerment and culture," and focus on the social and behavioral aspects of organizations (Fotopoulos & Psomas, 2009, p. 151). The hard principles are technical, analytical, and related to process controls and quality improvement tools. Examples of soft strategies include management leadership; customer focus; training employees; and multifunctional teamwork, such as not working in **silos**. Hard strategies include fact-based decision-making and the use of techniques for monitoring, measuring, and obtaining quality data. Examples include statistical process control, benchmarking, failure mode and effects analysis (FMEA), cause and effect diagrams, run charts, just-in-time manufacturing, and preventive maintenance (Alkhaldi & Abdallah, 2022).

Silos
Working in silos means that departments or individuals work separately and do not share knowledge with other departments and coworkers within the organization.

Recently, Alkhaldi and Abdallah (2022) conducted some of the first research exploring the effects of hard and soft TQM quality performance and patient satisfaction. Results showed that "soft TQM has a significant and positive direct effect on patient satisfaction (β 5 0.163,

$p < 0.01$) … However, the direct effect of hard TQM on patient satisfaction was insignificant" (Alkhaldi & Abdallah, 2022, p. 378). They explain that this could be because patients do not always see or experience the hard practices that are technical in nature and control clinical processes. Since healthcare providers have direct contact with patients, the soft social aspects of care delivery have a more profound effect on patient satisfaction. Their results suggest that, while both soft and hard techniques are necessary, hospitals should focus on soft techniques when their aim is to improve patient satisfaction.

2.2 European Norms on Quality Assurance

Norms, also referred to as "standards" or "requirements", exist on country, regional, and international levels. The choice of which one(s) to use will depend upon the regulations of each country or region (e.g., the European Union [EU]). This choice may also be influenced by the organization itself and the type of recognition or status it seeks. While a state-funded entity may only adopt those norms required by the government, a private hospital might choose additional norms that give it a competitive advantage for attracting patients. The quality manager or responsible individual of an organization should know the applicable standards for each geographic area in which the organization operates. This section discusses both European and international standards for quality and healthcare.

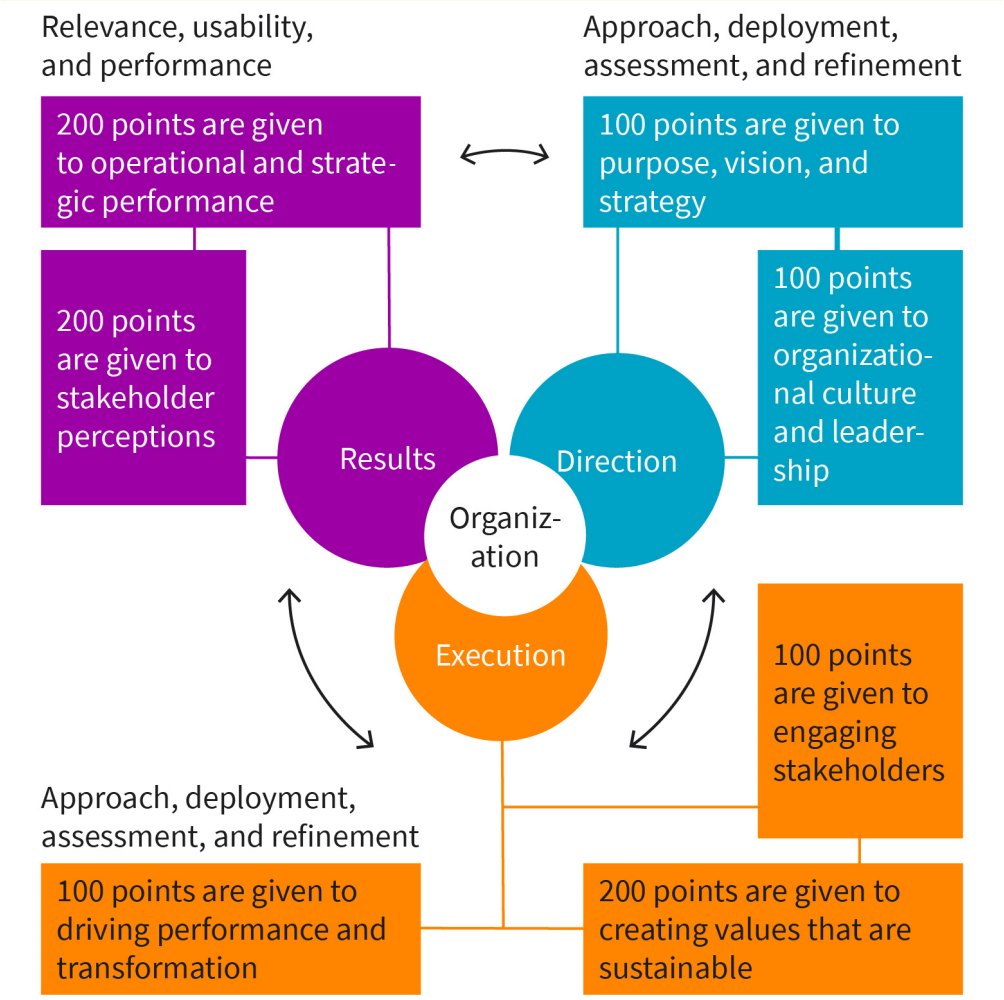
European Foundation for Quality Management (EFQM)

The European Foundation for Quality Management (EFQM) was founded in 1988 and promotes quality as the driver of continuous improvement in an organization. The EFQM Model, while recognized globally, is primarily used in Europe and embraces European values. It is based on TQM principles. The latest version of the model (2020) has three key areas: direction – why, execution – how, and results – what. EFQM uses a technique known as RADAR to assess an organization to the requirements of the scheme. The RADAR diagnostic tool allows assessors to award points to the organization based on how effectively the EFQM scheme is implemented (EFQM, 2019). RADAR stands for the following:

1. Results: The organization should define the results (aims and targets) it is working to achieve.
2. Approaches: The organization should define and develop the processes needed to achieve the defined results.
3. Deploy: Once results and approaches are defined, the processes should be implemented.
4. Assess and Refine: Processes should be monitored and evaluated to determine whether they are meeting the pre-defined results. If not, processes should be refined, and improvements should be made.

In the assessment scheme there are a total of 1,000 possible points. Based on the number of points awarded, recognition falls into one of the following categories: validated, qualified, or recognized EFQM. Within the recognized category, EFQM assigns a three-to-seven-star ranking based on performance (EFQM, n.d.). The EFQM mark can be instrumental in attracting new customers and winning bids for work contracts.

Figure 11: EFQM Model



Source: EFQM (2019, p. 4).

International Healthcare Standards

While each country may write its own set of healthcare-related policies, guidelines, and standards, there are some standards that are internationally recognized. It is not uncommon for a healthcare entity to comply with local and federal standards, while also seeking compliance with, or certification from, internationally recognized standards. Three popular international organizations providing healthcare quality standards are Joint Commission International (JCI), the International Society for Quality in Health Care (ISQua), and the International Organization for Standardization (ISO).

The Joint Commission International (JCI)

The Joint Commission International (JCI; named "The Joint Commission" in the US where it began), is an organization uniquely focused on improving healthcare quality and patient safety. Formed in 1951, The Joint Commission has a long, established history in the US, being one of the US's oldest and largest standards creator and accreditation agencies in the healthcare sector. Based on its national success, it expanded to create JCI in 1994–1995. The JCI's mission is "to continuously improve the safety and quality of care in the international community through education, advisory services, and international accreditation and certification" (JCI, n.d.-b, Our Mission section).

The JCI both creates standards and offers accreditation based on those standards. This is unique, as not all standard-creating bodies perform audits and accreditation, and not all audit bodies create standards. While some industries and organizations use the words accreditation and certification interchangeably, the JCI differentiates between the two and offers an array of standards against which organizations can be assessed and audited.

JCI has numerous accreditation standards, including those for home care, hospitals, primary care, long-term care, medical transport organizations, ambulatory care, and clinical care. The JCI also created guidelines and standards that address specific clinical functions and specialties. Examples include certified stroke centers, cardiac and orthopedic rehabilitation centers, primary heart attack centers, and thrombectomy-capable stroke centers (JCI, n.d.-a). Whether a healthcare organization is seeking accreditation or certification, or it simply desires to implement clinical best practices, the JCI offers many resources to improve healthcare quality.

International Society for Quality in Health Care (ISQua)

Surveyors
another word for auditor or assessor

ISQua is a non-profit, member-based, international organization whose mission is "to inspire and drive improvement in health, and the safety and quality of healthcare worldwide" (ISQua, n.d., Mission section). ISQua has a large networking and resource platform and provides education and fellowships. ISQua experts and **surveyors** are located throughout the world. ISQua does not write standards for hospitals, nor does it directly certify healthcare organizations. However, ISQua is worth mentioning because of the major role it plays internationally in the creation and dissemination of knowledge regarding high quality healthcare. In fact, ISQua has a liaison relationship with the WHO, and many of the major WHO publications contain significant contributions from ISQua experts.

In 2018, ISQua created the ISQua External Evaluation Association (EEA). It is through this mechanism that it "provides third-party external evaluation services to health and social care external evaluation organisations and standards-developing bodies around the globe" (ISQuaEEA, n.d., Home section). In other words, ISQua sets standards for the certification and accreditation bodies who will be auditing healthcare organizations. Their standards include the following:

- *Guidelines and standards for quality and patient safety training programs*
- *Guidelines and principles for the development of health and social care standards*
- *Guidelines and standards for external evaluation organizations*

- *Guidelines and standards for surveyor training programs*
- *Guidance on designing healthcare external evaluation programs, including accreditation*

The International Organization for Standardization (ISO)

Founded in 1946, the "ISO is an independent, non-governmental international organization that develops voluntary consensus standards" (McCaskill, 2021, p. 89). ISO boasts a membership consisting of 165 national standards bodies, which represent 165 countries. ISO reports that, as of 2021, its experts have developed over 24,115 International Standards that cover everything from manufactured products to the service sector, circular economies, information technology, and environmental management systems (ISO, n.d.-a). Most of the world is familiar with the ISO's most profitable and implemented standard, *ISO 9001: Quality Management Systems – Requirements*. ISO claims on its website that "there are over one million companies and organizations in over 170 countries certified to ISO 9001" (ISO, n.d.- b, Why ISO 9001? section).

While ISO 9001 is a generic quality management system standard, many hospitals have chosen it as the base for their quality management systems. Yousefinezhadi et al. (2015) performed a systematic review of literature regarding the effect of quality improvement strategies in healthcare (in particular, the effects of ISO 9001 and the European Foundation for Quality Management [EFQM] model in hospital performance). Findings suggest that implementation of an ISO 9001 quality system can lead to an increase in patient satisfaction, cost containment, and increased patient safety. A further study examined ISO 9001 certification in 45 Bulgarian hospitals. Hospital managers who were interviewed about the certification process stated advantages, including an increased focus on the patient, reduction in errors, and improved patient safety. They also felt that the standard's focus on identification of processes and the requirement to have performance indicators led to continuous improvement (Stoimenova et al., 2014).

Shaw et al. (2014) analyzed the relationships between ISO 9001 certification, hospital accreditation, and quality management in 73 European hospitals. They analyzed four measures of quality and safety related to the organization's accreditation and certification status. Findings suggest that both are positively related with "clinical leadership, systems for patient safety and clinical review" (Shaw et al., 2014, p. 100); however, they did not find a positive association with clinical practice.

A similar study looked at differences between hospitals that were either ISO certified, accredited by an outside agency, or neither. In the selected sample, they found hospitals that were either certified or accredited were better and safer than those who were neither. In particular, ISO-certified hospitals excelled in the dimension of patients' rights (Shaw et al., 2010). To sum up the benefits of ISO certification, a report from the Organization for Economic Cooperation and Development states that "conformity assessment has a number of important benefits: it provides consumers and other stakeholders with added confidence and helps regulators to ensure that health, safety or environmental conditions are met, especially when a standard is made mandatory through legislation" (Dupendant, 2016, p. 35).

ISO 7101

ISO has a new standard for healthcare quality, which is in the final stages of international voting: *ISO 7101: Healthcare Quality Management Systems – Requirements*. As of January 2023, the standard is in the Draft International Standard stage and is projected by ISO to be published in September 2023. IOS 7101 was written by a team of more than 60 global health experts representing all the WHO regions and all economic categories as defined by the World Bank. It is representative of the most current knowledge regarding healthcare quality on an international scale and, thus, achieved an important designation as a "high-impact" standard by ISO. The scope of ISO 7101 entails establishing requirements for organizations who aim to demonstrate their ability to consistently meet service user, stakeholder, and applicable statutory and regulatory requirements; enhance service user experience during the continuum of care; continually improve healthcare quality; and create and maintain processes that ensure timely, safe, effective, efficient, equitable, and people-centered care. All ISO standards are copyrighted and must be purchased; however, below is a sample of some of the innovative, core areas included in ISO 7101:

- leadership
- service user focus
- access to care
- planning
- risk culture
- risk management processes
- communication
- healthcare facilities management and maintenance
- contingency planning for facilities and services
- environmental responsibility
- emerging technologies
- service design in healthcare
- people-centered care
- service user experience
- compassionate care
- inclusivity and diversity
- health literacy
- co-production
- workforce well-being
- patient safety
- monitoring, measurement, analysis, and evaluation
- internal audit
- management review
- improvement
- nonconformity and corrective action

Upon the publication of ISO 7101, education, training, and promotion will be required to ensure that the standard is effectively implemented around the world. Follow-up research should be conducted to evaluate data concerning health systems outcomes post implementation of the standard.

EN 15224

EN 15224 Quality Management System is a “sector specific standard of quality management for healthcare organizations. It is based on the ISO 9001 standard, and it includes tangible requirements for patient safety and management of clinical risks in the planning, realization and management processes” (Technischer Überwachungsverein [TÜV], n.d., What is DIN EN 15224? section). EN 15224 is not an ISO standard, as it was not approved internationally through the ISO process. However, it was adopted as a European Norm (EN) through the European Committee for Standardization (CEN), European Committee for Electrotechnical Standardization (CENELEC) Members, and national standardization organizations in 34 countries. The implementation and use of EN 15524 has not been well documented.

2.3 Methods

There are numerous methods for assessing and controlling quality. One popular methodology that organizations use to improve their systems is Six Sigma; “the philosophical perspective of Six Sigma views all work as processes that can be defined, measured, analyzed, improved, and controlled” (American Society for Quality, n.d.-a, Differing Opinions section). Six Sigma focuses on specific tools to analyze, measure, and control processes. Some examples of these techniques include: the 5S (sort, set in order, shine, standardize, sustain), FMEA, seven wastes (transportation, inventory, motion, waiting, over production, over processing, defects), value stream mapping, Kaizen, Poka-Yoke, and Kanban. More detailed descriptions of these tools can be found on the American Society for Quality (ASQ) website. Many of these tools are highly statistical in nature, and their use requires a certain level of expertise in statistical methods. The Six Sigma name comes from the common bell-shaped curve used in statistics. One sigma is a single standard deviation from the mean: “If the process has six sigmas, three above and three below the mean, the defect rate is classified as ‘extremely low’” (Kumar, 2022, What is Six Sigma? section).

Six Sigma (abbreviated with the Greek symbol 6σ) methodology includes a series of tools and techniques, and individuals can earn professional recognition based on their level of knowledge regarding Six Sigma and its related tools. The certification levels for individuals in order of increasing expertise are white belt, yellow belt, green belt, black belt, and master black belt. There are various companies that offer these certifications, but there is no single official registry for certified individuals. The substance of the training and exam content varies from company to company. In the marketplace, having earned a Six Sigma designation is considered a significant value-added accomplishment and is also required for many jobs in the field of quality and risk management. Six Sigma follows a process improvement framework called DMAIC. Below, DMAIC is further explained in six steps:

1. **Define** the problem. Based on what needs to be accomplished, this might be a problem that has been identified internally, an external or internal customer requirement, an opportunity to improve processes, etc.
2. **Measure** the current process. At this step, it is important to collect data that allow you to analyze and evaluate current performance. As Six Sigma tools are highly data driven, it is essential that data are valid, accurate, reliable, relevant, timely, and complete.
3. **Analyze the cause of issues**. Once data are collected, analyze the data to discover trends, issues, deviations, and opportunities for improvement.
4. **Improve the process**. Update the process based on the objective evidence discovered.
5. **Decide** on solutions to fix issues. These amended or changed processes should improve statistical process control, reduce error, and lead to improvement. Implement the solutions identified.
6. **Control.** This is an ongoing step of monitoring and analyzing data from processes. Once a new process is in place, it should be controlled. Lessons learned should be shared with coworkers and stakeholders and implemented in existing or new processes if advantageous.

Figure 12: Six Sigma DMAIC process

Source: Angela McCaskill (2023).

The Six Sigma approach and tools are particularly useful to healthcare organizations that seek to streamline processes, reduce waste, and decrease spending. For example, patient scheduling that does not best utilize healthcare professionals' available time is costly. Performing a procedure more than once because of lack of information sharing between departments, or not performing the procedure right the first time, can be expensive.

A maternal-child hospital in Colombia sought to reduce appointment lead times, which would, in turn, decrease potential harm in high-risk pregnancies, while also increasing patient satisfaction. A team was created to implement Six Sigma methodology using various strategies. Once data were collected and analyzed, controls were put in place, and

“project results evidenced that average appointment lead-time reduced from 6.89 days to 4.08 days” (Ortiz Barrios & Felizzola, 2016, p. 12), suggesting that Six Sigma methodologies have the potential to be effective and advantageous in the healthcare setting.

SUMMARY

The understanding and practice of quality assurance has expanded exponentially since the early 1900s. Today, there are numerous models, methods, and standards that contribute to an entire sector of quality and risk management. Quality is of particular importance in healthcare, as it often deals with matters of morbidity, mortality, life, and death.

Total quality management is a philosophy based on eight principles: customer focus, continual improvement, total employee involvement, strategic and systematic approach, process-centered, integrated systems, communications, and fact-based decision-making. It has shown to be effective in the healthcare setting. Six Sigma is a quality assurance method used to measure and control processes. It employs the use of numerous statistical techniques and is based on a framework called DMAIC, which stands for define, measure, analyze, improve, decide, and control.

Standards and norms for quality in general, and quality in healthcare specifically, exist on local, regional, and international scales. The EFQM framework is popular in Europe, while standards such as the ISO series have an international appeal. Each healthcare organization is responsible for ensuring that it meets required minimum quality standards and pursuing those that will lead to continuous improvement in its operations and services.

UNIT 3

RISK IDENTIFICATION AND MANAGEMENT

STUDY GOALS

On completion of this unit, you will be able to ...

- describe a culture of patient safety, as well as strategies used to create this culture.
- create a critical incident reporting system.
- name steps in the risk management process.
- describe various actions to address risks.
- develop a risk register.

3. RISK IDENTIFICATION AND MANAGEMENT

Introduction

Risk is inherent in healthcare, so organizations must protect service users and healthcare workers through a delivery model that strongly manages risk. This should be an organizational-wide risk management approach that enables the organization to anticipate, recognize, and address the risks associated with healthcare both proactively and reactively. Creating and maintaining a culture that supports patient safety and risk management is crucial to the achievement of the organization's objectives. This unit discusses the need for a culture of patient safety, outlines steps in the risk management process, and highlights the importance of critical incident reporting systems (CIRS).

In 2005, Hurricane Katrina ravaged areas around the Gulf Coast of Mississippi. Katrina is reported to be the largest hurricane that has ever hit the US and resulted in approximately 1,800 deaths. Memorial Hospital in New Orleans faced an unforeseen situation after the levees broke, which resulted in massive flooding with dire consequences. It lost electricity, and both leaders and healthcare workers were forced to make critical, strategic decisions. Please listen to the Podcast *Playing God* from the reading list before continuing with this unit.

3.1 Patient Safety Culture

The World Health Organization (WHO, 2021c) defines patient safety as "a framework of organized activities that creates cultures, processes, procedures, behaviours, technologies and environments in health care that consistently and sustainably lower risks, reduce the occurrence of avoidable harm, make errors less likely and reduce the impact of harm when it does occur" (p. V). To ensure that patient safety efforts are successful, it is paramount that the organization creates a culture of patient safety. Creating this culture involves strong leadership and management commitment. It requires policies, training, the support of healthcare workers, and a **no-blame** culture. Only when healthcare workers feel safe in reporting a potential or actual safety incident will a patient safety program be effective. Below are some strategies for creating a patient safety culture:

No-blame
This accepts that errors occur and uses those errors as data for learning and improvement. It encourages open and honest incident reporting from employees.

- Conduct patient safety rounds. Safety rounds should be performed at the bedside to identify quality and safety concerns, and they should include a member of the management team.
- Provide safety training upon hire and on a yearly basis.
- Designate a "safety champion" for each work shift.
- Designate a "safety champion" for each unit/department. The designated person could change daily, weekly, or monthly.
- Encourage the use of the safety incident reporting system.

- Offer incentives for employees who come up with safety initiatives.
- Discuss safety concerns during shift changes.
- Conduct reenactments of possible risks to patient safety, and discuss preventive measures.

Patient safety events that affect the health and well-being of patients and their families are probably the most significant risks in healthcare. Nonetheless, risks can arise from other sources, such as natural disasters, terrorism, civil unrest, and climate change. Risks can result in financial loss, harm to facility workers, potential loss of a facility or service, and damage to reputation. Therefore, healthcare systems and organizations should have a comprehensive risk management program that considers and address all types of risks to healthcare service delivery. The following sections present a detailed explanation of the risk management process.

3.2 Critical Incident Reporting Systems

A Critical Incident Reporting System (CIRS) is essential to a risk management program. As the name suggests, CIRS is a defined and documented process through which employees can report safety incidents. The WHO defines an incident as "any deviation from usual medical care that either causes an injury to the patient or poses a risk of harm, including errors, preventable adverse events and hazards" (WHO, 2020, p. xii). An incident can further be categorized as a near miss, no harm, or harmful. Data collected from incident reporting are indispensable for improving patient care and avoiding patient harm.

CIRS may take multiple forms and require differing data depending on how the system is designed. An organization may choose to create its own reporting structure, while others purchase preexisting software. After researching best reporting practices, the WHO (2020) defined the Minimal Information Model for Patient Safety (MIM PS). They created two options: the Basic MIM PS for organizations without a current reporting system and the Advanced MIM PS for organizations with already established reporting systems. The figure below shows the reporting criteria for each model.

Table 1: Minimal Information Model for Patient Safety

Basic MIM PS	Advanced MIM PS
a) Structured part Patient information (age, sex) Incident time Incident location Agent(s) involved • (Suspected) cause? • Contributing factor? • Mitigating factor? Incident type Incident outcome Resulting action Reporter's role	Patient information (age, sex) Incident time Incident location **Causes** **Contributing factors** **Mitigating factors** **Resulting actions** Incident type Incident outcome Resulting action Reporter's role

b) Free text part	b) Free text part

Source: WHO (2016, p. 10).

Since incident reporting takes place in multiple settings – hospitals, clinics, health outposts, and high- to low-income countries – resources available for reporting systems differ greatly. Reports may be made on paper, written on paper then later transferred to an electronic record by administration, or input directly into an electronic system.

It is imperative that the CIRS be embedded in the organization's culture and encouraged by top management. A "no-blame" culture will increase the odds of employees actually completing reports. Employees should be trained to ensure that they know how to access the form, how to complete each section of the report, and where to submit it. The reports are essential for gathering data that reduce risks, improve processes, and prevent patient harm.

3.3 Risk Management

A healthcare organization must develop the culture, organizational structure, and processes that support the identification, assessment, and treatment of risks in a timely manner. The program should be consistent with the organizational vision, mission, and values. Risk-based thinking is essential to achieve an effective quality management system throughout the organization and to establish criteria, assessment, treatment, and proposals for improvement. Below are some of the major steps in risk management.

Risk Criteria

The organization must define their risk criteria and consider how much risk it can or cannot accept in relation to meeting different types of clinical and non-clinical objectives. This includes defining the criteria for assessing the importance of each risk (e.g., a risk that can affect many people simultaneously is more important, or a risk that can cause irreversible damage to a patient is more important).

Risk Identification

Next, the organization should identify the risks that impede or assist the healthcare facility in meeting its objectives. To help identify the uncertainties that may affect the achievement of objectives, the following factors should be considered:

- tangible and intangible sources of risk
- causes and effects
- threats and opportunities
- changes in internal and external context
- limitations in knowledge
- reliability of information
- time-related factors

- personal beliefs and assumptions

Figure 13: SWOT Analysis Diagram

Source: Created by another author, based on Xhienne (2007). CC BY 2.5.

There are many tools available to help in the process of risk identification. Some of these include Failure Mode and Effects Analysis (FMEA); brainstorming; checklists; Delphi Technique; "What-if" questions; Hazard and Operability Study (HAZOP); Strengths, Weaknesses, Opportunities, and Threats (SWOT) analysis; and **5 Whys**. Some of the tools are more complex, such as the creation of a FMEA, while others are quite intuitive, such as brainstorming and **5 Whys**. Quality and risk leadership should familiarize themselves with various techniques.

5 Whys
This is a technique used to arrive at the root cause of a problem. It involves asking the question why five times, each time in response to the previous answer.

Risk Analysis

Once potential and actual risk have been identified, they should be analyzed. Such an analysis should consider the following factors:

- probability of occurrence of events
- consequences not only for patients or workers but for all the relevant stakeholders of an event occurring
- magnitude of the consequences
- complexity of the risk
- interconnectedness of the risk

Risk Assessment

To inform subsequent decision-making, the organization should assess the risk. This step endeavors to compare the results of the risk analysis with previously established risk criteria. The risk assessment may lead to a decision by the health organization to

- not address the risk,

- consider options to address the risk,
- initiate additional analysis to further study the risk, or
- consider rethinking or modifying objectives.

The risk assessment decision should be documented and used to plan further analysis, implement controls, and possibly reconsider objectives. It is important to communicate risk assessment outcomes to top leadership.

Addressing the Risk

Once risk criteria are defined and risks are identified, analyzed, and assessed, actions should be implemented to address the risk most effectively. Healthcare organizations may choose actions to address risks, including the following:

- avoid the risk
- assume the risk
- eliminate the source of risk
- mitigate the risk
- modify the likelihood of the risk
- modify the consequences of the risk
- **share the risk**
- maintain the risk
- transfer the risk

Share the risk
Risk sharing, also referred to as risk distribution, involves dividing the risk among multiple parties.

After the organization determines what it will do to address the risk, it must create and implement risk management plans, which address how the measure will be integrated with the quality management of the healthcare organization. Measures taken should be proportionate to the potential impact on healthcare delivery.

Many organizations create a “risk register” to document and quantify risks and outline mitigation measures. While there is not one common template for a risk register, some elements include the following:

- date
- description or name of risk
- likelihood of the risk occurring
- impact (or consequence) if the event occurs
- severity of the impact
- owner, or person responsible for managing that specific risk
- action taken to eliminate or lessen the impact

Figure 14: Example of a Risk Register

ID number	Date	Risk	Likelihood of risk occurring	Impact of risk	Severity	Responsible	Action
1	19/11/22	Patient taking a narcotic falling out of bed	Medium	High	High	Nurse manager/ Nurse	• Nurse will set bed alarm for all patients taking narcotics. • Nurse will remind patient to call before getting up. • Nurse will place fall risk sign on patient's door. • Nurse will communicate at shift change that patient is a fall risk.
2	10/12/22	Nurse forgetting to chart a patient safety assessment	Low	Medium	Medium	Nurse manager/ Nurse	• Planned chart reviews by nurse manager to verify that safety assessments are charted • Reminder signs posted at time clock and at medication dispensing time

Source: Angela McCaskill (2023).

The healthcare organization should conduct a periodic review to assess the effectiveness of its risk management framework and ensure that it continues to evolve and meet the needs of the care process. Reviews are planned as part of the risk management process, with clearly defined responsibilities. Results of risk monitoring and evaluation must be incorporated into all performance management, measurement, and reporting activities of the organization. Now, with a deeper understanding of the risk management process, use the below risk register to address at least four risks at Memorial Hospital that could have been identified before Hurricane Katrina (revisit the podcast if needed).

Figure 15: Risk Register

ID number	Date	Risk	Likelihood of risk occurring	Impact of risk	Severity	Responsible	Action

Source: Angela McCaskill (2023).

SUMMARY

Risk is inherent in healthcare, and a well-defined risk management program is an effective way to address potential and real risk. Patient safety is one type of risk, and it should be the first priority of healthcare delivery institutions. Creating a culture of patient safety, which encourages no-blame incident reporting, is a vital step in the risk management process.

A risk management program is multifaceted and includes steps for defining risk criteria, identification, analysis, assessment, addressing the risk, and a monitoring program to ensure that risk control and mitigation measures are effective. The use of a risk register is an effective way to document the type of risk, likelihood, impact, and severity of the risk, while assigning responsibilities and outlining actions to control the risk. The use of a critical incident reporting system is also a valuable tool for reporting patient safety incidents that are a near miss, no-harm, or harmful. Data collected from the reports are used for learning and the creation of processes and controls to prevent future safety incidents.

UNIT 4

AUDITS IN HEALTHCARE PROVIDING INSTITUTIONS

STUDY GOALS

On completion of this unit, you will be able to ...

- plan an internal audit.
- understand the external audit process.
- complete a nonconformance report.
- verbalize key concepts regarding certification and accreditation.

4. AUDITS IN HEALTHCARE PROVIDING INSTITUTIONS

Introduction

People often think of financial audits when they hear the word “audit”. However, both internal and external process audits are essential to the healthcare sector and an integral part of quality management. Healthcare audits may cover a wide range of scopes from the entire hospital; a specialty clinic; a stroke center; or specific departments, such as the laboratory, admissions, nursing staff, and the sterile processing department. Audits are beneficial for numerous reasons. In general, a well performed audit will

- identify lapses in operations;
- identify opportunities for improvement;
- identify areas where additional training may be necessary;
- provide valuable data that help an organization make strategic decisions, such as future spending, resource allocation, and service offerings;
- allow employees to share their experiences and knowledge; and
- provide objective evidence of compliance to internal and external standards.

Certification and accreditation schemes require audits. In this unit, you will learn about internal and external audits and gain knowledge about the accreditation and certification process.

4.1 Internal Audits

Internal audits are audits that an organization (facility, hospital, clinic, department, etc.) performs on itself. They are usually planned and executed by the quality management function but could be managed by another function if an organization does not have a specified quality department. While some audits are spontaneous and employees are not forewarned, the more common practice for an internal audit program is to have a yearly calendar that outlines when planned audits will occur. Audit frequency depends on numerous factors. Some organizations conduct audits year-round, while others prefer every six months or annually. Frequency should be tailored to each organization and will vary based on the complexity of operations, the maturity of operational systems, implementation of new processes or services, and past audit results. When planning for an internal audit, various factors should be considered:

- availability of trained internal auditors
- confidentiality requirements
- responsibilities of the **auditee**
- ensuring that audits do not interfere with patient care

Auditee
the individual or organization being audited

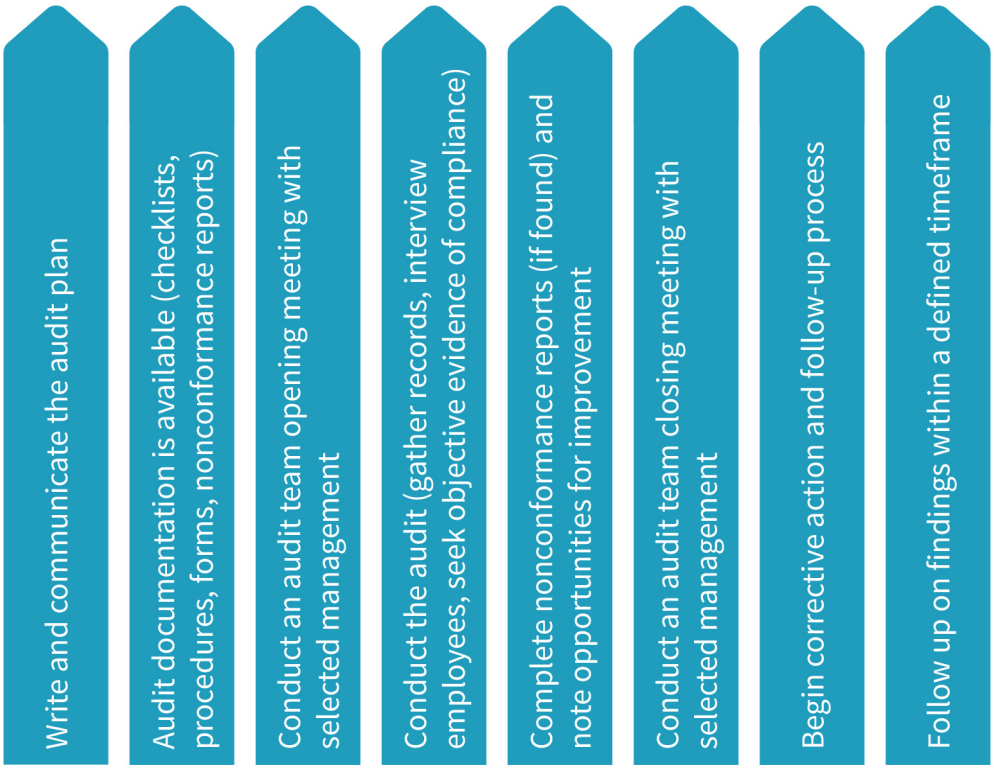
- selecting the hours of the day, days of the week, and times of the year that would best facilitate an audit
- resources needed to conduct the audit
- availability of senior leadership to review the audit results
- how results will be communicated to relevant stakeholders

Audit planning should consider higher usage times within a department when auditees might not be readily available. For example, emergency departments tend to be busier on Friday and Saturday evenings. Seasonal trends may also affect planning. Holidays, when employees often take vacation, may not be the best time to conduct an audit, as the workforce may be reduced or stressed.

Internal Audit Process

The internal audit process is defined, implemented, and improved upon as the audit mechanism matures. In most cases, the audit process can be visualized as in the figure below.

Figure 16: Internal Audit Process



Source: Angela McCaskill (2023).

Internal Audit Documentation

Numerous documents are required for a successful internal audit. Basic documentation includes the following:

- email or letter notifying the auditee that they will be audited
- annual audit schedule
- an audit plan for the specific audit being conducted
- an audit checklist or similar document that is used to guide the auditor (the checklist is also used for documenting objective evidence that proves requirements have or have not been met)
- nonconformance reports or similar documentation that describe the nature of the problem found, the responsible department or individual, and detailed notes about objective evidence to support the findings (see below report for an example)
- final audit report that gives an overall picture of the systems strengths, weakness, and opportunities for improvement
- letter or email to leadership establishing a meeting to review the audit results
- closed nonconformance reports that outline the corrective and/or preventive actions that were taken
- follow-up documentation that shows that all measures taken were effective and sustainable

Below is an example of a nonconformance report. Consider the following scenarios and determine how you might complete the form:

1. A family member calls you into a patient's room and states that the nurse has forgotten to turn on the bed alarm for two nights in a row.
2. The director of housekeeping tells you that they have found a needle mixed in with the dirty bed sheets.
3. An outside clinic uses your hospital's radiology services. The clinic supervisor calls you and informs you that radiology reports are being delivered about one week later than the agreed upon dates.

Figure 17: Example of a Nonconformance Report

NCR number:	**Date:**	
Department:	**Name of person submitting the report:**	
Source of nonconformity report:		
☐ Employee report of system failure	☐ Patient or family concern	
☐ Outside stakeholder	☐ Regulatory agency	
☐ Other complaint	☐ Internal audit	
Others, specify:		
Description of nonconformity or opportunity for improvement (by auditor or individual submitting the report):		
Investigation and root cause analysis (completed by auditee or quality manager):		
Action taken (by auditee, department head, or quality manager):		
Approved by quality manager:	Date:	Planned date for review of effectiveness:
Summary of document changes (if applicable):		
Review of effectiveness of CA taken (by auditor or quality manager) Date:		
Report reviewed, approved, and closed by:	Date	

Source: Angela McCaskill (2023).

In summary, an internal audit is an audit that an organization performs of itself. These audits are a vital part of an effective quality management program and reveal valuable information. An internal audit system uses a variety of documents to facilitate the process and record results. Audit results may be used to identify training gaps, reveal needs to allocate or reallocate resources, identify lapses in verbal and written communication, improve record keeping, and outline opportunities for improvement.

4.2 External Audits

External audits
These are also referred to as second- or third-party audits. Internal audits are sometimes called first-party audits.

While an integral part of ensuring quality services, most organizations do not look forward to **external audits**. These audits are performed by outside entities that may be accreditation bodies, regulatory authorities, or customers (customer in the case an organization outsources a function, such as laboratory services or imaging). External audits may or may not be announced in advance; however, it is a frequent practice to give the auditee a general notice about an upcoming audit. For example, an accreditation agency might notify a hospital that they will audit in the last quarter of the year, or in the month of November. External audits are significant in the healthcare sector because they can be used to ensure adherence to regulatory and legal guidelines. Audits might be performed by the government, regulatory agencies, and even insurers that financially protect the hospital for the services it performs. An accredited or certified healthcare facility is audited by its external certifying or accrediting body, such as the Joint Commission International (JCI), or a national certification body (examples include Spain: AENOR, the UK: BSI, Germany: TÜV, Norway: DNV, France: AFNOR, and Sweden: SWEDAC).

The external audit process is similar to the internal audit process. There is an audit plan, an opening and closing meeting, a review of documentation and records, interviews with employees, written reports of nonconformance and opportunities for improvement, and a final audit report. Some auditing agencies will request access to documents and records before the onsite audit to better prepare and ensure that required documents exist. This is referred to as a "desktop audit."

Since the start of the COVID-19 pandemic, certification and accreditation bodies have become more innovative and flexible, often allowing virtual audits. In this scenario, a series of video calls are pre-arranged to interview management, employees, and even patients and service users. Required audit time and actual hours of the day that auditing occurs may vary with a virtual auditing approach. Even with this flexibility, certain audit activities continue to be performed onsite. Examples include processes that are not so easy to verify over a video call, such as adherence to sterile processing guidelines; storage of medications; treatment of biohazards; and employee behaviors, such as handwashing.

4.3 Certificates

Both certification and accreditation imply that an organization (the auditee) has proven to an external body (the auditor) that it meets defined criteria. These criteria, often called requirements, come from standards, policies, frameworks, guidelines, or a combination of them all. Organizations or industry groups that create these documents may use one term over the others. These same organizations may be public or private. Some certification/accreditation bodies have been granted authority from their national governments, while, in many countries, any company can be a certification body with no regulation at all. The certification and accreditation field can be confusing, as each country has its own laws and regulations as to which institutions are allowed to certify or accredit healthcare organizations. The quality manager or responsible function must be familiar with the certification and accreditation norms in their country or region.

Certification and Accreditation Further Explained

As discussed previously, the terms certification and accreditation may be used interchangeably, but there is also a common understanding of the following in many countries:

- The government grants an organization the power and rights to accredit a "certification body." This is called the "accreditation agency." International examples of accreditation agencies include DAkkS in Germany, UKAS in the UK, ENAC in Spain, NABCB in India, and JAB in Japan.
- The accreditation agency performs audits of a certification body and decides whether to grant the body accreditation status.
- The accredited certification body is the organization that performs audits on healthcare organizations (hospitals, clinics, laboratories, specialty functions, etc.). Based on this assessment, the certification body may grant a "certified" status to the healthcare organization. This is accompanied by an official certificate that can be shown to regulatory agencies and customers as evidence.
- Once certified, the organization can legally claim that they are certified, as long as they remain in compliance with the certification agreement guidelines. The organization must be careful not to mislead the public regarding the scope of the certification. For example, if only one hospital in a network is certified, it may not specifically or inadvertently advertise that all of its hospitals are certified.

There are additional models of healthcare certification and accreditation that do not follow the aforementioned government models. One of the oldest well-known examples is the JCI. This non-profit agency offers both accreditation and certification. Accreditation is offered for hospitals, home care, and laboratories, while certification is focused on specialized functions. Some certifications include perinatal care, healthcare staffing services, community-based palliative care, and advanced cardiac and stroke certifications (The Joint Commission, n.d.-a). The JCI is not regulated by the government, nor are they granted authority by the government or regulatory agencies to grant certifications. The JCI is a private enterprise.

Benefits of Accreditation and Certification

Many healthcare organizations chose to be certified because of the benefits, yet others may get certified because it is required. Some benefits of accreditation and certification include the following:

- evidence of compliance to legal and regulatory requirements
- a competitive differentiator in a healthcare market that has a large private provider industry
- external audits in addition to the already scheduled internal audits (more audits per year yielding more data for improvement)
- expert, outside auditor feedback to provide valuable information for process change and improvement
- price reductions based on certification status (from some hospital insurance companies), as this gives them confidence that risks are better managed
- employee pride and increased cohesion based on obtaining and maintaining certified status
- increased stakeholder confidence

There are multiple advantages to certification and accreditation; however, the process can be long and expensive, and it requires multiple resources. As an alternative, an organization may choose to claim they are "in compliance." Compliance means being in accordance with established guidelines or requirements. An organization may work hard to meet requirements of a standard, yet this compliance is not verified by an external accreditation or certification agency. Compliance is a self-declaration and still has multiple benefits.

External audits are conducted by second- or third-party organizations to verify conformance to standards, requirements, policies, and procedures. Some healthcare organizations will seek accreditation or certification by external agencies, which affords them benefits, including recognition in the marketplace and evidence of regulatory compliance. Others will choose to identify themselves as compliant with a specific standard. Whichever the case, a strong audit program is essential to the success of the quality management program.

Certificates

A certificate is the document that gives objective evidence of certification status. Depending on the certification or accreditation program, the length of validity of a certificate will vary. Some programs require yearly audits with a three-year recertification cycle. The certificate usually contains the following information:

- name of the certified organization
- address of the certified organization
- the name of the certifying or accrediting agency
- the name of the standard or norm (and date if the standard has a date)
- the scope of the certification (does it apply to one hospital, one department, etc.)
- the issue date and expiration date of the certificate
- a unique identifier, such as a number or number-letter combination

Most certifying and accreditation agencies now have online registers where one can validate the authenticity of a certificate. It is not uncommon to hear of falsified certificates, so agencies must provide a way to verify the validity of issued certificates.

SUMMARY

The practice of both internal and external auditing is essential to the healthcare sector and an integral part of quality management. An effective audit will identify lapses in operations, opportunities for improvement, and additional training needs; allow for knowledge sharing; and provide evidence of compliance to specified requirements. The audit process should be well planned and highly documented. Audit nonconformances are recorded, and corrective actions should be taken and verified for effectiveness and continued suitability.

External audits are performed by customers, regulatory agencies, and accreditation or certification bodies. During these audits, auditors seek objective evidence of conformance to predefined requirements. Healthcare organizations may seek certification or accreditation to demonstrate adherence to national and international standards. Once awarded certification or accreditation status, they are provided with a certificate that may be shown to stakeholders. Healthcare organizations must be careful not to imply that their certification covers areas outside of the audited scope. Finally, the certification or accreditation process can be costly and require many resources. Therefore, some organizations may prefer to self-declare as “in compliance” with a standard.

UNIT 5

PROCESS MANAGEMENT

STUDY GOALS

On completion of this unit, you will be able to ...

- define the concept of process management.
- describe tools for visualization.
- understand how to manage stakeholders.
- effectively manage process deviations.

5. PROCESS MANAGEMENT

Introduction

Process management is a significant subset of project management. While a project is likely to be a one-time "package" of a deliverable, such as building an emergency department entrance ramp or creating a digital prescription service, processes are ongoing activities that enable a project to work in the long term. A project usually comprises multiple processes. The goal of process management is to ensure that processes continue under controlled conditions with the goal of preventing deviations and achieving **lean**, low-risk outputs.

Lean
a "set of management practices to improve efficiency and effectiveness by eliminating waste" (American Society for Quality, n.d.-b, What is Lean? section)

One method that facilitates effective process management is visualization. The following section introduces the importance of visualization and various techniques that can be used. Another aspect of process planning and design is stakeholder analysis. Stakeholders play a significant role in the direction of projects; thus, they must be identified, considered, and managed. Finally, deviations, or errors, are part of any process. The overall goal is to prevent and reduce deviations. Numerous tools are available to help in this endeavor. This unit introduces some strategies for analyzing deviations and arriving at root causes.

5.1 Visualization

Process visualization is key to representing important steps that must be completed to achieve a deliverable or outcome. It is effective because it visualizes hierarchy and flow, which is often easier to understand than reading the information in a paragraph form. Visualization gives an "at a glance" view of the process or project. Another benefit is that visualization is an easy way to monitor, update, and communicate project progress to the project team. There are many ways to present a process graphically and just as many process management software options to do so. Perhaps the most well-known process mapping tool is the flow chart. Two other popular visualization tools are Work Breakdown Structure (WBS) and the Gantt chart. Process management software includes options for creating all of these types of graphics, while some basic charts can be created using tools such as Word and Excel.

Work Breakdown Structure (WBS)

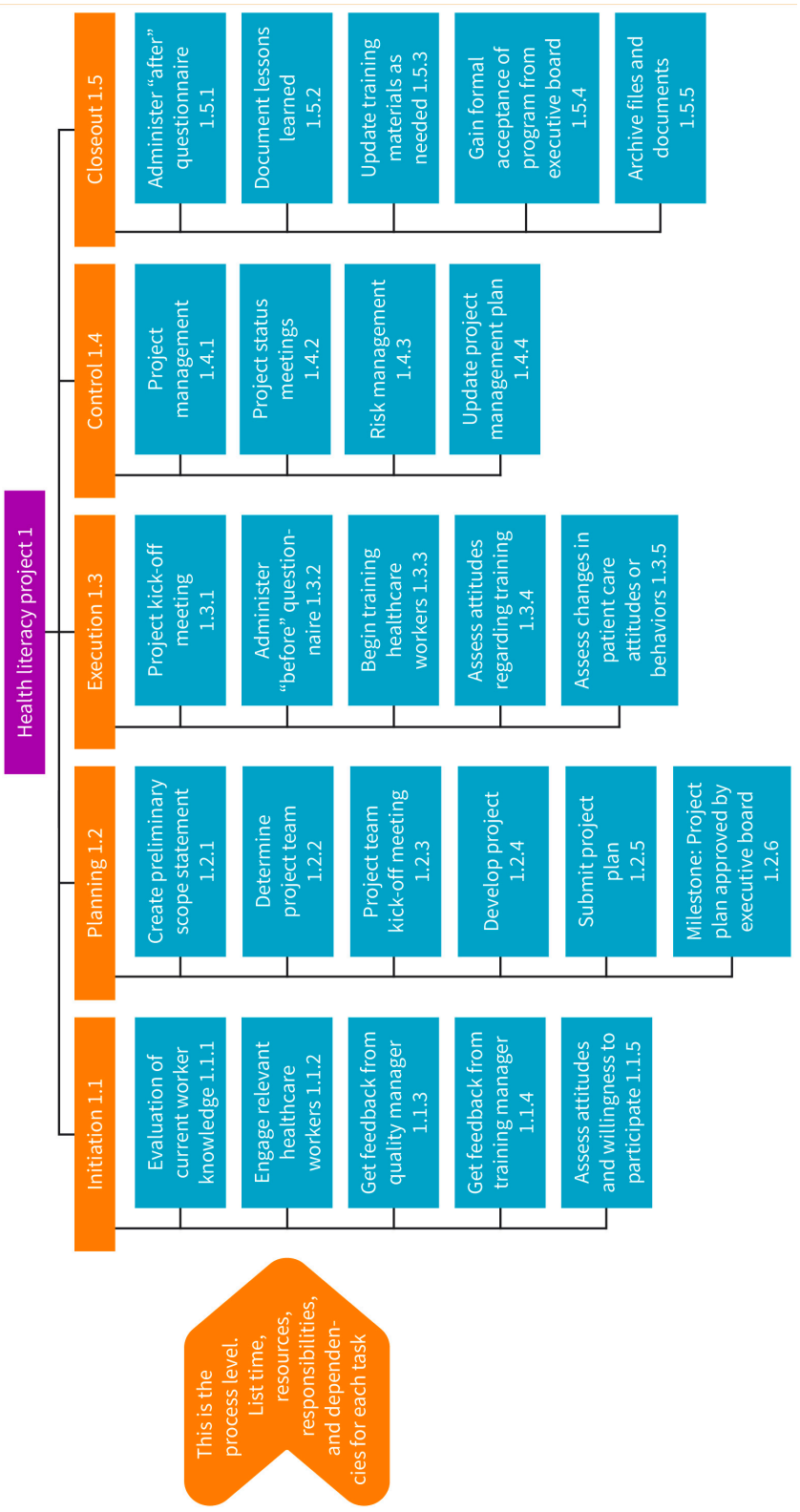
The Project Management Institute (PMI) defines WBS as a "hierarchical decomposition of the total scope of work to be carried out by the project team to accomplish the project objectives and create the required deliverables" (PMI, 2019, p. 12). The visual structure looks somewhat like an organizational chart and "subdivides the project work into smaller, shorter-duration, more manageable pieces of work, with each descending level of the WBS representing an increasingly detailed definition of the project work of the previous level" (PMI, 2019, p. 12).

The WBS is an effective way to highlight details, such as the project schedule, team meetings, resource requirements, and approval stages. It is also useful for estimating time and costs. A basic WBS can be created with the following steps:

1. The **top-level boxes** contain the major deliverables or milestones in a project. For example, if the project is to organize an appreciation party for the hospital volunteers, major deliverables could be seating, venue, food, drinks, entertainment, and gifts. Depending on the project, you may choose to divide the work structure by functions, such as project initiation, planning, execution, control, and closeout.
2. In the **sub-boxes** for each top-level box, you list the tasks needed to achieve the top-level deliverable. To help identify all tasks, ask the team "In order to produce this, what is the next smallest step that must be taken?" (Kearns, n.d., p. 4). Sub-boxes can be decomposed to even smaller and more detailed boxes.

Once top-level deliverables and tasks are identified, the timeframes, costs, dependencies, and responsibilities can be assigned. This should be done for each task. Once completed, the project manager can calculate an estimate of the cost, time, and resources need for each deliverable and sum them to create a budget for the entire project. Assigning these specifics to each task can be accomplished using a program such as Excel or one of the many project mapping software programs available today.

Figure 18: Example Work Breakdown Structure for a Health Literacy Campaign



Source: Angela McCaskill (2023).

Gantt Charts

The Gantt chart was named after American mechanical engineer Henry Gantt in the 1910s. He endeavored to create a scientific approach to management and focused on worker productivity and efficiency. While he made multiple significant contributions to process control and management, the Gantt chart is probably the most recognized and enduring.

A Gantt chart is a graphic control plan of work, represented by a bar chart displaying activities, deliverables, or tasks against time. It is different than the WBS, as it shows a timeline that can be updated as the project evolves. Gantt charts are a good way to facilitate collaboration among stakeholders and identify tasks that are overdue. Some basic characteristics include the following:

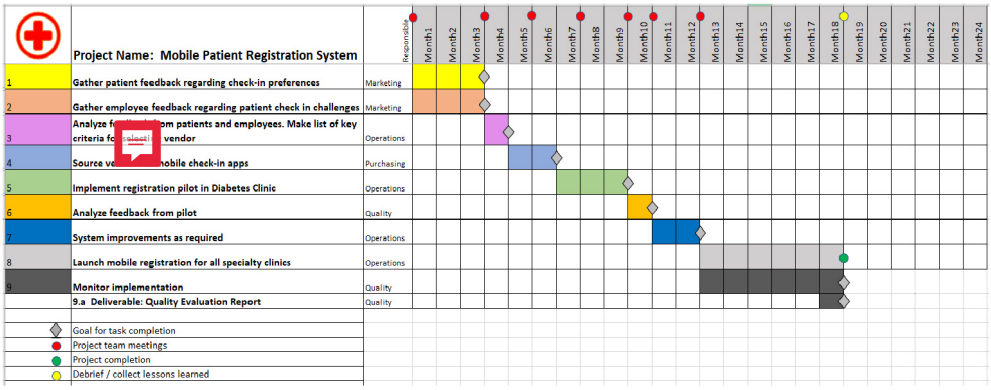
- Each activity is represented by a horizontal bar.
- The bar length reflects start date and end date of each task.
- Y axis lists each activity. X axis indicates time.
- Overlapping bars indicate two or more activities happening at the same time.
- The chart records progress towards goals and should be updated throughout the project's progress. This is usually done by the project manager.

Some factors to be considered when creating the chart are as follows:

- Do team members have other projects they are working on at the same time?
- Who ensures the chart is updated and at what frequency?
- Is "buffer" time allotted in the event that there are delays in a task?
- Is the chart too confusing, with too many tasks or subtasks specified?

Remember that bar length (time) does not necessarily represent the complexity of the task or the number of resources required. A task with a short bar might require significant resources.

Figure 19: Example of a Basic Gantt Chart for a Mobile Patient Registration System

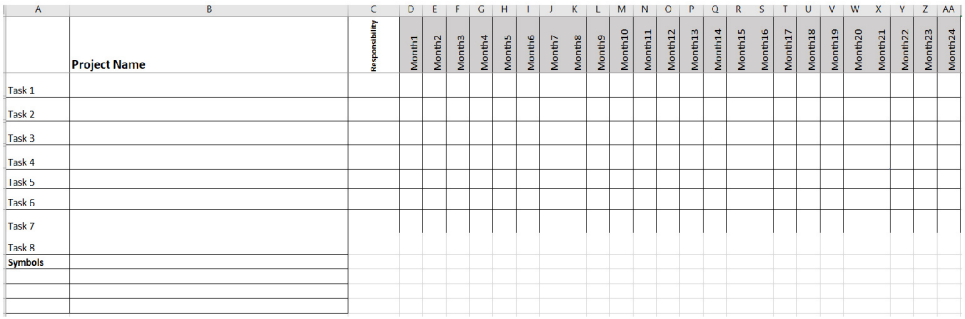


Source: Angela McCaskill (2023).

Below is an empty Gantt Chart. Think of at least seven tasks and time requirements for the following projects:

- sharps container upgrade: Your project team is assigned to select safer sharps containers and replace the old ones throughout the 400-room hospital.
- physician qualifying checklist: Your project team needs to create a checklist to ensure newly hired physicians meet minimum legal and hospital requirements before given permission to practice at your hospital.

Figure 20: Empty Gantt Chart



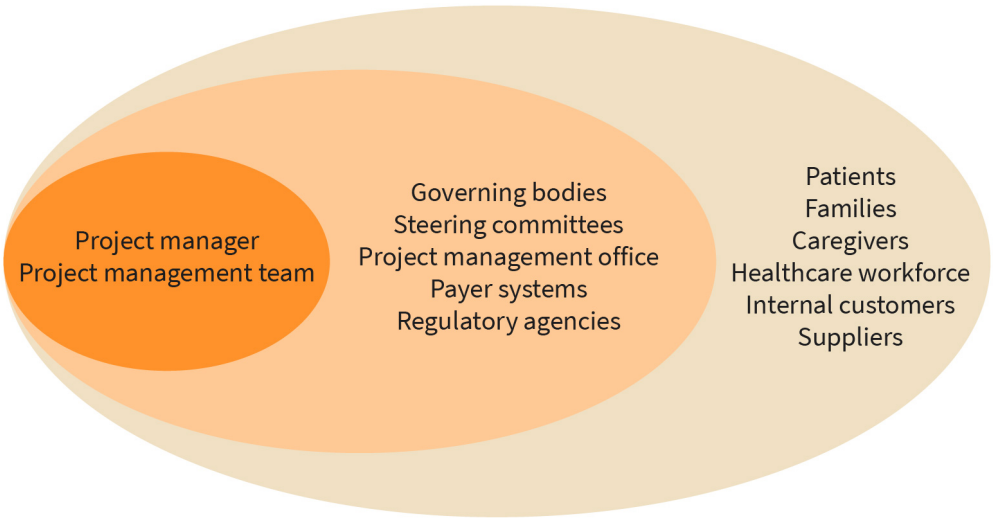
Source: Angela McCaskill (2023).

5.2 Stakeholder Analysis and Goals

Projects usually involve a number of stakeholders. **Stakeholder** relationships can be complex because end goals may differ among different types of stakeholders. Imagine that a hospital embarks on a project to build a new cancer treatment center within the existing facility. A patient is a stakeholder, and their priorities may include comfortable infusion chairs, access to smart televisions during long treatments, and toilets being conveniently located near the infusion room. Hospital management is another stakeholder. Their priorities might include patient safety, meeting financial goals and construction deadlines, and ensuring the correct storage and handling of expensive chemotherapy medications. A third stakeholder is a governmental regulatory agency. Their concerns revolve around the correct and safe disposal of hazardous materials, that the building and associated services meet safety guidelines, and that all required operating permits are obtained. As you can see, the project manager has to consider many stakeholder requirements and desires during project planning and design. See the figure below for examples of stakeholders.

Stakeholder
"an individual, group, or organization that may affect, be affected by, or perceive itself to be affected by a decision, activity, or outcome of a project, program, or portfolio" (Project Management Institute, 2021, p. 8)

Figure 21: Examples of Stakeholders



Source: Angela McCaskill (2023).

When embarking on a project, stakeholder analysis is key. It is important to know what expectations and requirements involved parties have before you design and implement a project. If these are not taken into consideration early, the project could be delayed or even suspended if it is later learned that a stakeholder is not in agreement with certain aspects of the project. Projects benefit from a variety of viewpoints; therefore, it is always a good idea to listen to stakeholders' voices. Additionally, when stakeholders have some involvement in a project, they tend to collaborate better and feel some "buy in" or responsibility for the outcome. The following six steps can assist in managing stakeholders:

1. Identify all stakeholders (this might involve brainstorming and asking for coworkers' opinions).
2. Rank their impact on the project. Are they a highly involved stakeholder? Are they necessary to make the project a success?
3. What level of influence does the stakeholder have over the project? Can they "make or break" the project? Can their feedback change the direction of the project? Does their opinion affect project funding?
4. What is important to the stakeholder? List all things that might be important. This will help the team make decisions about what must be included in the project inputs and outputs.
5. How can the stakeholder contribute to the project? Do they know reliable vendors? Do they have expertise or prior experience in the topic area?
6. What is your strategy for engaging the stakeholder? (Email, WhatsApp groups, formal or informal meetings, phone calls). Identify engagement techniques that are most meaningful to each stakeholder if possible.

Creating a table is a helpful visual tool to organize the above questions and answers, as well as specify any action items.

5.3 Management of Deviations

Even with comprehensive planning, expected results and actual results do not always align. Both human and machine are susceptible to error. These "errors" are also referred to as deviations, nonconformances, and even opportunities for improvement. Whatever the name, the goal is the same: to minimize variation and deliver a product or service that meets specified requirements. The healthcare setting is a unique one, in which a deviation could cause irreversible harm. This is why it is so important to do a detailed analysis when a deviation does occur.

The first step in the management of process deviations is to assess the impact. Some variances require immediate attention, such as a medication error or a leak of a patient's private medical records. However, others may not be as urgent, such as inadequate cleaning in the hospital's entrance and waiting areas. Therefore, a **corrective action** may be immediate or delayed; however, a broader analysis should always be done to get to the root of the problem.

Corrective action
a measure taken to correct a real or potential deviation

The next step is to collect and interpret data surrounding the problem. This could be in the form of data or verbal statements, such as a patient complaint. Objective information should be gathered before making decisions and changing processes. This evidence might include medication printouts, purchasing requisitions, employee training records, interviews with patients and staff, and data obtained from processes that are being controlled statistically.

Once the deviation is identified and immediate corrective action is taken when needed, a thorough root cause analysis must be performed. It is vital to get to the "root cause" and not just perform a quick fix. If a surgeon misuses costly medical equipment and breaks it

once, perhaps the immediate action is a verbal warning from hospital management. However, this measure does not necessarily address the root cause of the problem. There could be many reasons why the equipment is breaking. Was the surgeon adequately trained on how to carefully and correctly use the equipment? Maybe the equipment came with wrong or unclear instructions. It could even be that an important part of the device that keeps it from breaking is missing. The obvious first impression is not always the true cause. Various methods exist to assist in root cause analysis, such as brainstorming, the Fishbone Diagram, and 5 Whys. Fishbone Analysis and 5 Whys are explained in detail in the following sections. Some common causes of deviations in the healthcare setting that should be recognized are as follows:

- lack of training
- lack of communication (between teams; among teams; and between patients, families, and caregivers)
- equipment failures
- lack of time and resources
- fear of getting in trouble or being fired
- employee attitudes and beliefs
- supplier or vendor performance
- hand-off between one specialty to another
- incomplete or wrong information in medical records
- illegible records or instructions
- improper identification of critical activities
- insufficient patient identification
- inadequate risk identification and management
- the use of outdated forms and documents
- improper storage of medical supplies
- mislabeling
- billing and procedure coding errors

Once root cause analysis is complete, an evidence-based decision can be made as to the appropriate corrective action. When deciding on the corrective action, resources needed, timeframes, responsible parties, and sustainability of the action should be considered. If the action involves a process change, ensure that all affected stakeholders are aware and, if needed, receive training on the new process. If the correction involves a change in documentation, ensure that document control measures are followed: Who can authorize the change? How will you identify all employees who use the document? Are all employees using the new version? How are the document changes communicated to employees? Finally, remember that risk should always be identified, assessed, and managed with any new process.

The final step in handling deviations is to follow-up on the effectiveness of the corrective action taken. At the time of corrective action implementation, the responsible individual should establish a date to review the change to ensure that the process continues to function according to requirements. Some actions require only a few weeks to determine efficacy, while other, more substantial process changes need months of data collection before both sustainability and efficacy can be determined.

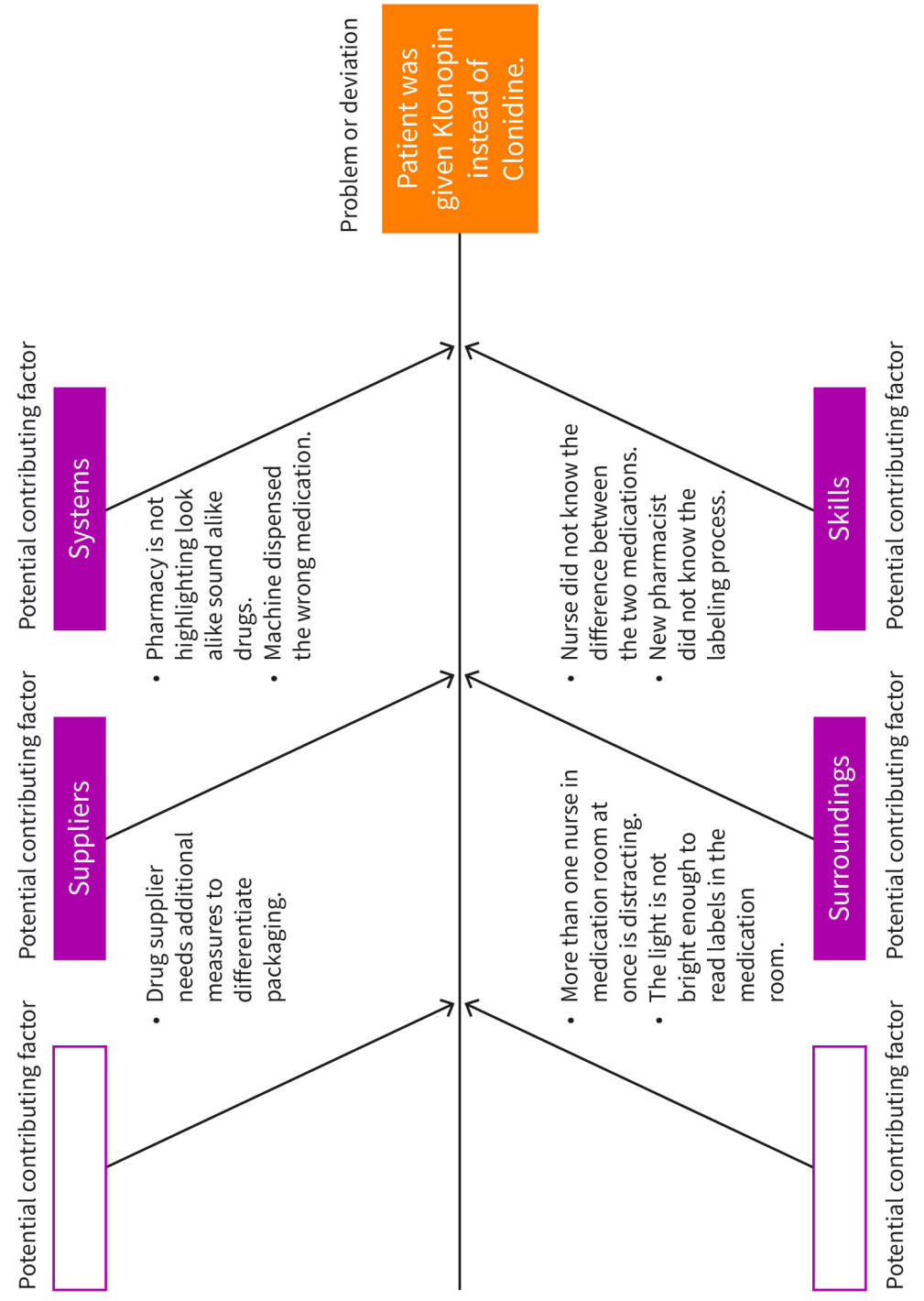
Fishbone Analysis

Creating a Fishbone diagram is a tool for arriving at the root cause of a deviation. With a fish-like appearance, it is also called a Herringbone diagram, Cause-effect diagram, or the Ishikawa diagram (named after its creator). This is a popular way to analyze a problem because of its simple, visual, and team-centered approach. The diagram is completed in the following fashion:

1. **Head section**: List the deviation as a statement or problem/question.
2. **Contributing factor boxes**: Identify the larger category sources of error. In the manufacturing environment, these are usually human, machine, method, material, and measurement. In the service sector, these are often surroundings, suppliers, systems, and skills. However, categories can be added or deleted with the identification of more possible causes.
3. **Angled bones**: List all likely causes of the deviation. Brainstorming is a helpful exercise to accomplish this.

Once the diagram is complete, study the possible causes to determine the most likely one. The diagram below depicts analysis for a medication error. What other possible causes might you identify on the angled bones? Is there another potential contributing factor you would list?

Figure 22: Fishbone Diagram Medication Error



Source: Angela McCaskill (2023).

5 Whys

The 5 Whys is a brainstorming technique that helps in identifying a root cause. It is simple, and a good way to facilitate a team approach to problem solving. 5 Whys was originally created by Sakichi Toyada, the founder of Toyota Industries. The steps in 5 Whys are as follows:

1. Write the problem statement at the top of the page. You can use any structure you choose, but for this example, a sentence is used with boxes beneath.
2. Below the problem, create five boxes or similar to record the next level of question. Ask "Why?" after each answer.
3. By the fifth question, the root cause should be identified; however, it could be revealed before question five.

Figure 23: Five Why Process

Source: Angela McCaskill (2023).

SUMMARY

Visualization is a valuable tool for communicating complex, multifaceted, or long processes in a user-friendly fashion. Visualization methods vary, and the creator of the tool should use the one that most simply and concisely outlines the process in a way that the target audience will understand. Both work structure breakdown and Gantt charts are effective visualization tools.

Process management requires the inclusion of stakeholder interests, expectations, and requirements. In the healthcare industry, there is a wide range of stakeholders, including hospital management, healthcare workforce, regulatory agencies, payer systems, medical equipment suppliers, pharmaceutical companies, patients, families, and caregivers. Identification and analysis of stakeholders allows for the proper planning and control of processes that are deemed most important. It can also reduce time and money wasted on rework or repeat services that did not meet stakeholder requirements.

Despite the fact that we can plan to control processes, deviations or errors still occur. A comprehensive correct action system is invaluable to risk reduction, compliance, patient safety, and continuous improvement. Root cause analysis should be performed to identify the fundamental cause of a deviation, and not just a quick fix. Fishbone analysis and 5 Whys are useful tools for identifying the root cause(s) of a deviation. Once corrective actions are implemented, follow up on the effectiveness of the action must be performed. To close the loop, lessons learned from the deviation and correction should be translated into action and continuous improvement.

UNIT 6

PROJECT MANAGEMENT

STUDY GOALS

On completion of this unit, you will be able to ...

- define project management.
- name characteristics of an effective project manager.
- list and describe the five stages of the project life cycle.
- explain the basics of Scrum.
- understand how to communicate with the project team and stakeholders.

6. PROJECT MANAGEMENT

Introduction

Throughout life we are confronted with new projects on both a personal and professional level. Projects may be simple and straightforward or complex and multifaceted. When faced with the role of leading or managing a new project, knowing where to begin can be challenging. Questions such as what, when, why, where, and how must be effectively addressed in an organized, sensical, and timely manner. Additionally, there may be multiple stakeholders with divergent views involved in the same project. This is exactly why the practice of project management (PM) is so helpful. The Project Management Institute (PMI) defines PM as "the application of knowledge, skills, tools, and techniques to project activities to meet project requirements" (PMI, 2021, p. 4). As the definition suggests, there are multiple resources available to assist in meeting project requirements. This section introduces fundamentals of project management, a popular method of PM called Scrum, and essential project communication strategies.

6.1 Project Management Basics

In the words of Benjamin Franklin, "If you fail to plan, you are planning to fail!" (Goodreads, n.d.-a, para. 1). To best understand PM, it is useful to know what a project is. Projects are made up of actions to achieve goals through the use of products, services, and processes. Some projects can be achieved rather quickly, while others require a lot of time. For example, a project for building a new outpatient clinic might take a number of years, while a project to implement a new patient check-in system might require a few months. For a project to be successful, tasks, activities, and deliverables must be structured and executed carefully (PMI, n.d.).

It could be argued that effective PM is even more important in healthcare, as many of the decisions made are matters of life and death. Examples of projects include improvement of an isolation room so that mental health patients cannot hurt themselves, creating a system for receiving mothers who require emergency caesarean sections, construction of a new helicopter landing pad for the emergency department, and projects to improve medication reconciliation to reduce risks associated with polypharmacy.

Healthcare organizations face an ever-growing patient population; limited resources; changing payer systems; and unprecedented challenges, as seen with COVID-19. Therefore, it is vital that projects are highly managed to make the most out of the available resources while safeguarding human health and well-being.

Projects are implemented and achieved through a project management team, which is led by a project manager. Project teams are usually temporary and may be disbanded once the project is complete. Teams achieve project goals utilizing a broad range of PM approaches. The **project manager** is a key member of the team and should possess the following characteristics:

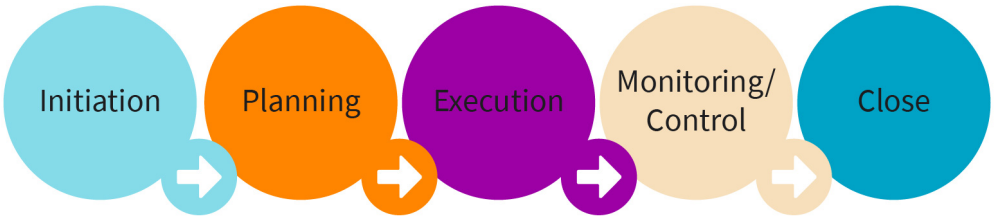
Project manager
The project manager is responsible for achieving the project objectives. They perform a variety of functions, such as facilitating the project team, managing process, and achieving milestones and predefined outcomes.

- honesty and integrity
- focused on stakeholders
- gives credit to others
- excellent written and verbal communicator
- respected leader
- flexible and able to pivot quickly when challenges arise
- ability to delegate work
- empathetic and motivational
- strong time management skills
- conflict resolutions skills
- stays calm under pressure

Project Management Life Cycle

It is generally agreed upon that the PM life cycle is made up of five stages. While some literature says it can be made of up to eight, the content is basically the same, only broken down into smaller stages. The five stages are shown in the following figure and explained below.

Figure 24: Five Stages of PM Life Cycle



Source: Angela McCaskill (2023).

1. Initiation

In the initiation stage, the team should start to define the purpose and goals of the project. This includes documenting the scope of the project, deliverables, risks, estimated costs, and resource requirements. Management may even want to perform a feasibility study before embarking on a costly project. At this point, stakeholders should be consulted to ensure that project goals are in alignment with their expectations.

2. Planning

This is the time to clearly define the steps necessary to achieve the project goals. Costs, timeframes, responsibilities, the communication plan, risk management plan or risk register, and stakeholder relationship strategies should all be defined. Project visualization tools, such as Gantt charts, work breakdown structures, the waterfall method, Kanban boards, and **mind maps**, are helpful techniques. There are also multiple project management software options that can be used. Useful questions to ask during the planning stage include the following:

Mind map
A mind map is a brainstorming organizational tool used to visualize the entire scope of an idea or project on one page. It must have a central theme, topics on main branches, and sub-topics protruding off the main branches.

- Have the cost, budget and resources been identified?
- Have stakeholders been identified, and are their views taken into account as appropriate?

This is also the stage where quality controls and measurement criteria should be established.

3. Execution

This stage is also referred to as implementation or project launch. At this time, all the planning is put into action. The team begins to execute the project plan, working toward achieving predetermined deliverables at specified times. The project manager plays a vital role by managing backlogs, keeping the team focused and moving forward, as well as facilitating both internal and external communications.

4. Monitoring and control

The fourth stage of the project life cycle often overlaps with the prior stage because many of the activities are occurring simultaneously. Monitoring and control of the project performance and deliverables should be in accordance with previously defined quality metrics and key performance indicators. Monitoring could be on a broad scale, such as “is the project progressing as planned on the Gantt chart?” to very specific details, such as statistical parameters surrounding a product. If project outputs are not as planned, then this is the time to adjust, rethink, redesign, or implement further controls.

5. Close

As the project comes to a close, work deliverables are presented. Throughout the project, new processes and work requirements will undoubtedly emerge. Therefore, it is necessary to identify any new training needs and ensure that changes are implemented through a controlled change management process. Be aware that process changes often result in documentation changes. Verify that documents are updated in a controlled manner and that obsolete documents are no longer in use.

Lessons learned are an essential part of any project, and these lessons should be translated into future action. Ensure that this new knowledge is recorded and communicated to management. During the close, contractual relationships with suppliers may end, and team members may be released from their project duties as appropriate. Always remember to thank the team!

6.2 Scrum Framework

Scrum is “a lightweight framework that helps people, teams and organizations generate value through adaptive solutions for complex problems” (Schwaber & Sutherland, 2020, p. 3). As with many PM methods, its goal is to move toward project completion while controlling risk. There is much mystification around Scrum, as it is both a philosophy and method of PM that is based on explicit values and pillars. Therefore, it is not just about the steps of completing a project but also about the culture of the team and the environment in which work is completed. The team approach is evidenced by its name: Scrum. In rugby, the scrum is a strategic, circular formation, which provides the opportunity for players to mount an attack (World Rugby, n.d.). Similarly, Scrum PM involves a strategic team approach.

Figure 25: Rugby Scrum

Source: Skynesher (n.d.).

Scrum was created in the early 1990s by Ken Schwaber and Jeff Sutherland (2020), who worked in the information technology (IT) industry. The earliest applications of Scrum were in software development, but since its inception, it has evolved and is now used in all sectors. Scrum has also become an economic endeavor, as classes on how to implement Scrum and how to become an official “Scrum Master” are offered by numerous compa-

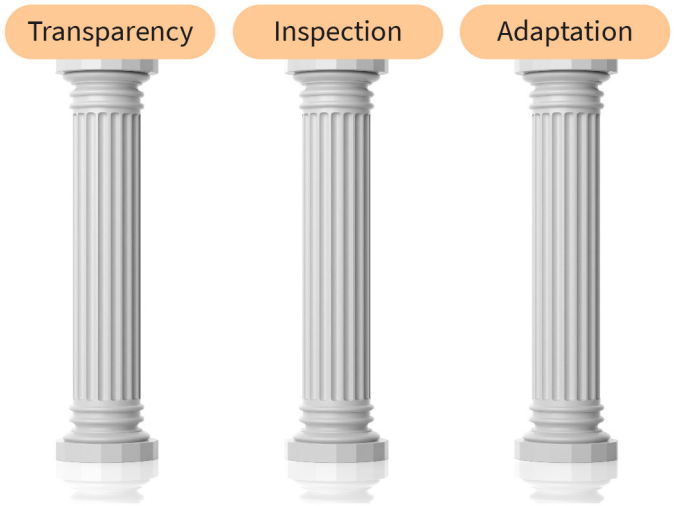
nies. Many job postings in quality and project management advertise the requirement for a Scrum Master, while some companies send their employees to receive the training. Scrum Master training is essential because the framework does not work without a trained and equipped Scrum Master.

Scrum Pillars

Scrum is based on three pillars that lead to an empirical discovery process:

1. **Transparency**: Everyone is aware of the work that is being done. This includes setbacks and challenges.
2. **Inspection**: Products, processes, and each individual's work are frequently inspected to identify the need to adapt and improve.
3. **Adaptation**: In response to the findings of inspection, the product or process should be changed or adapted. This leads to changes in real-time before more time-consuming and costly changes are needed at the end of the process.

Figure 26: Scrum Pillars

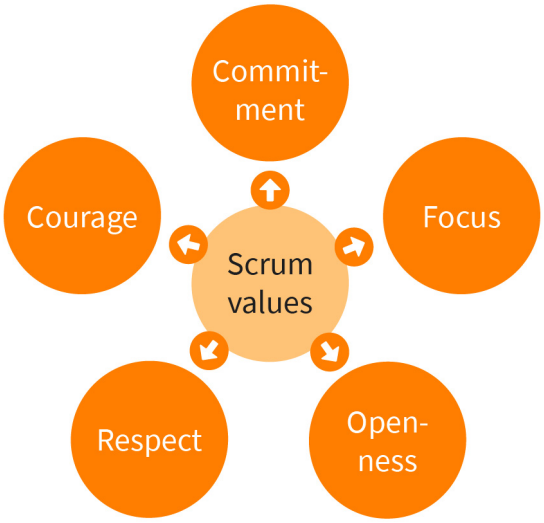


Source: Angela McCaskill (2023).

Scrum Values

Along with the Scrum pillars, certain values must be upheld by the Scrum team. The values are important because they create a team culture, shared vision, group cohesion and understanding, and a safe community for expressing ideas and embracing change. The five values are pictured in the figure below.

Figure 27: Scrum Values



Source: Angela McCaskill (2023).

Scrum Team

The Scrum team is the engine of the Scrum process. The ideal number of team members is debated, but consensus is that it should not exceed ten individuals. The minimum number is three, as there are three key positions that every team must have. These individuals are the Scrum Master, Product Owner, and Developer(s).

Scrum Master

The Scrum Master leads the team and facilitates adherence to the Scrum Guide. They manage the team in accordance with Scrum values and should practice servant leadership. The Scrum Master is ultimately accountable for the success of the team. As mentioned previously, numerous courses exist to become a Scrum Master, and some companies offer a Scrum Master certification.

Product Owner

The Product Owner and the Scrum Master work closely together; however, the role of the Product Owner focuses more on the product or service and less on team dynamics. Main responsibilities of the Product Owner include managing the product backlog, communications between project managers and project development (design, engineering), and ensuring that the product or service meets stakeholders and customers' needs and requirements.

Developer

The Scrum Developer is responsible for actual product or service deliverables. The Scrum team may have more than one developer; therefore, there may be a "development team." It is important that Scrum Developers understand the requirements as specified by the

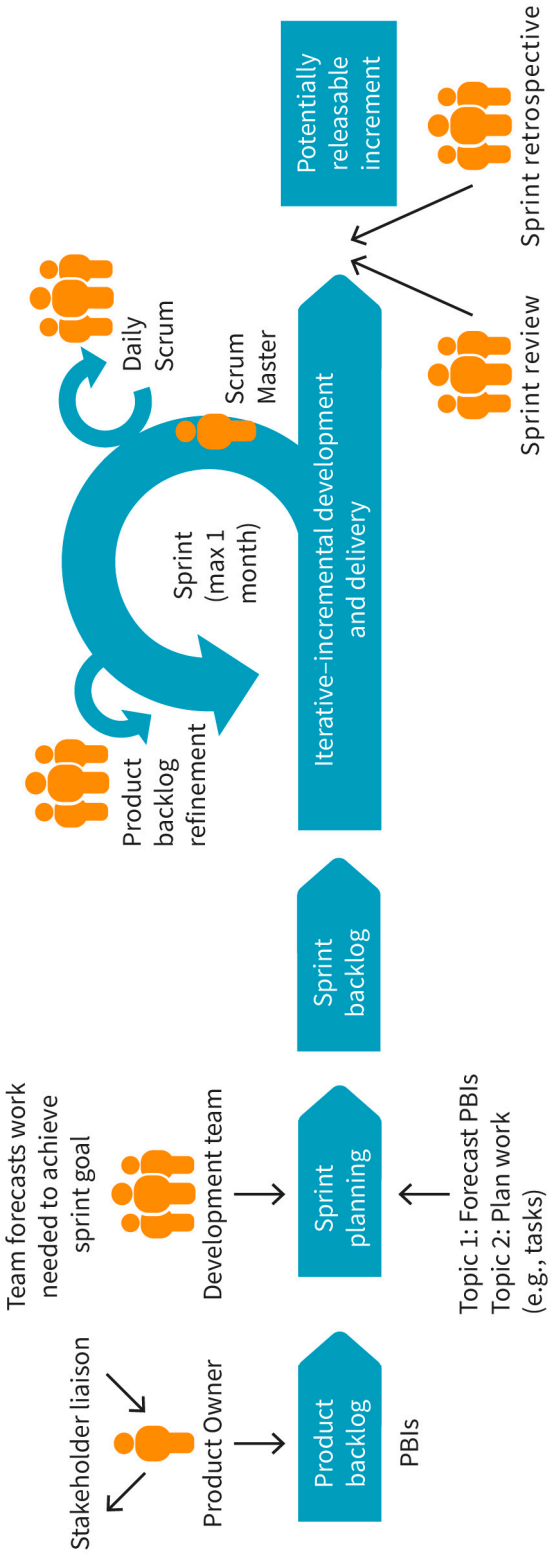
Product Owner because, as mentioned above, the Product Owner is responsible for knowing and meeting the needs of stakeholders, customers, and end users. The Developer(s) play a key role in the sprint, choosing items from the product backlog and planning the needed steps to meet the **Definition of Done**. The sprint is described in the following.

Definition of Done
This is the formal statement of what the deliverable looks like when it meets the quality criteria for the product/service. All features have been tested and meet all predefined acceptance requirements.

Scrum events

The official Scrum Guide describes a sprint as “the heartbeat of Scrum, where ideas are turned into value” (Schwaber & Sutherland, 2020, p. 7). Each sprint should last no more than a month. Before delving into specific events of a sprint, it is helpful to see an overall visual. The following image shows the Scrum framework, along with the sprint events.

Figure 28: Scrum Framework



Source: Mitchell (2015). CC BY 4.0.

The visual flows from left to right and will be explained as such. Per the diagram, the Product Owner liaises with stakeholders and creates a product backlog.

Product Backlog Items (PBI)

This is the “to-do” list that prioritizes task-level details and requirements. It may contain multiple projects needed to achieve the final product or service. It is the ultimate responsibility of the Product Owner to organize, update, and maintain the backlog. Once the backlog is created, the development team begins to plan the sprint.

Sprint planning

During this event, the team works collaboratively to define the sprint goal and tasks to be accomplished. They select PBIs and create the Definition of Done for each one. These PBIs are recorded on the sprint backlog.

Sprint backlog

This contains the sprint goal, the selected PBIs for that specific sprint, and action items to achieve the PBIs. This log contains the “why, what, and how.” Once the sprint backlog is finalized, the team can begin to work on the deliverables. Each day the team will analyze progress toward the sprint goal during a Daily Scrum meeting.

Daily Scrum

This is a mandatory 15-minute meeting attended by the team Developers. The Scrum Master and Product Owner may attend if desired. At this time, any challenges or obstacles in achieving the sprint goal are discussed. Changes or adjustments are made as necessary, and the sprint and product backlogs are updated as appropriate. The Daily Scrum is held at the same time and location each day of the sprint.

As the sprint comes to an end, there should be a releasable increment.

Releasable increment

An increment is a deliverable that contributes to the final product or service goal. Increments are considered additive, meaning that they work along with other increments to achieve the goal. A releasable increment must meet the Definition of Done.

At the close of each sprint, there will be a sprint review and a sprint retrospective. These meetings facilitate analysis and overall sprint improvement.

Sprint review

This is an important part of Scrum, as the team gathers to evaluate their work and decide if adaptations are needed. Each PBI that was planned for the sprint should be completed. The review may be attended by various parties, such as the Scrum Master; Product Owner; Developers; and other stakeholders, such as management or customers. These meetings

should be informal and include feedback from team members and stakeholders. As an output of the meeting, any identified revisions or opportunities for improvement should be made to the product backlog in order to best plan the next sprint.

The length of the meeting depends on the length of the sprint. For a month-long sprint, the meeting should not exceed four hours. For shorter sprints, a generally agreed upon length is one hour per week of sprint.

Sprint retrospective

This is the final step to conclude the sprint. This meeting is attended by the Scrum team and is focused on improving the quality and effectiveness of the sprint process. It should address the following questions:

- What went well?
- What could be improved?
- What is the focus of the next sprint?

Asking why something did not work, or why a team member preferred a certain strategy, is also a great way to obtain valuable information. The retrospective is an opportunity to discuss the team dynamics and tools or techniques that were or were not useful. Meeting length is limited to three hours maximum per month-long sprint, and 30-45 minutes per each week of sprint is recommended.

While Scrum is a popular PM framework, it may not be the preferred choice for all companies. As the format is highly dependent on team dynamics, poorly-functioning teams that lack cohesion or do not have the sprint values may not perform well. For large organizations, teams usually require more members. Large teams are more challenging to manage within the Scrum framework. Additionally, some individuals do not appreciate daily meetings as required in the sprint, which can cause resentment toward the process. Finally, Scrum works best with leaders who are experienced in the Scrum methodology. This is not always feasible, and trained employees can and do change jobs.

6.3 Project Communication

There is a popular childhood game called “telephone.” It is a message game involving about 5–10 people, and begins with one person whispering a short message into the ear of the person next to them. The listener then repeats what they heard to the next person. This process repeats until the last person who receives the message states the message out loud. This is usually followed by surprise and laughter as the message changed in strange ways as it traveled through the chain of ears, minds, and lips. This happens because what each person hears may vary depending on their sense of hearing, how their mind interprets messages, preconceived notions or ideas, and even whether or not the message is in their native language. The game is a fun and impactful demonstration of the volatility of communication.

Communication is how humans create a co-reality with one another. Whether in the personal or professional realm, the influence of communication cannot be overstated. It is multifactorial, complex, and highly culturally dependent. Paul Watzlawick said that "one cannot not communicate" (Creative Bureaucracy Festival, n.d.). While studies disagree on the exact number, it is estimated that 70–90 percent of communication is nonverbal. Therefore, it is also important to understand social and cultural differences of nonverbal communication. Being a complex function already, one can imagine that communication among a team during a multistage project might be even more challenging.

Communication in PM can be divided into two major categories: team and stakeholder communication. Team communication is essential because it helps avoid conflict, aligns the team, and allows members to know what is expected of them. Effective team communication saves projects from delays and costly wastes of resources. This section explains best practices for creating a healthy and productive environment for team communication.

Figure 29: Team Communication

Source: Eva-Katalin (n.d.).

Team Communication

Know your audience

Individuals interpret messages differently based on a variety of factors, such as age, race, gender, education level, culture, personality, values, and preconceived notions and biases. Therefore, to best package a message so that it is received and understood as intended, ask yourself some deeper questions about the individual:

- Why is this person interested in the project?
- What do they know about the project?
- Do they prefer direct, strong communication or a more passive and gentle approach?
- Is this a newer employee, or do they have years of experience with the company?

Answers to questions such as these will allow the sender of the message to most effectively connect with the message receiver in a constructive manner.

Trust

Open, honest, and transparent communication is built on trust. Remind the team of any confidentiality requirements, and make a group commitment to transparent and respectful communications.

Be positive

Be honest about setbacks, but focus on solutions.

Word choice

Whenever possible, choose words that evoke hope and synergy. Instead of words such as "problem" or "obstacle," try using words such as "opportunities" and "chances."

Respect time

Each team member has competing responsibilities and assignments. Try to schedule meetings as much in advance as possible. Consider having standing meetings at the same time each week.

Communication platforms and file sharing apps

The use of platforms and apps is essential for team communication, sharing documents, and ensuring that everyone has access to the same, timely information. Examples of popular options include Slack, Microsoft Teams, Google Chat, Huddle, and SharePoint; however, there are many more options.

Vision and purpose

Remind team members of the vision, values, and goals at each major meeting. This can be done briefly and is an excellent way to remind the team of the bigger picture and that "we are in this together."

Celebrate

Both big and small accomplishments are worth recognition. This might take the form of an email, certificate of appreciation, a short message in the company bulletin or newsletter, a team coffee, or a shared celebratory lunch.

Define roles

Consider creating a responsible, accountable, consulted, and informed (RACI) matrix. This is an effective way for everyone to see what is expected of them and others. See the figure below of a RACI matrix.

Online approval tools

Frequently, projects require multiple approvals at ongoing stages. The ability to approve electronically facilitates rapid, standardized communication.

Start strong

Have a project kickoff meeting that is well-organized, well-rehearsed, and sets the stage for a positive, motivating experience.

Close strong

Have a well-planned closing meeting that ties up any loose ends. Consider allowing team members time to debrief and share lessons learned. Always remember to thank the team!

Figure 30: Example of a RACI Matrix

Activity	Project manager	Quality manager	Purchasing representative	Patient advocacy	Nurse manager
Identify data sources	A	R	C	I	C
Select data collection methods	A	R	R	I	C
Map evaluation questions and data collection methods	A	R	I	I	I
Finalize data collection tools	A	R	–	–	–
Pre-test and pilot-test data collection tools	A	R	I	I	I
Confirm ethics and confidentiality in data collection	R	R	–	–	–
Conduct data and respondent sampling	A	R	R	R	I
Effort to improve response rates	A	R	C	C	C

Source: Angela McCaskill (2023).

Stakeholder Communication

It has been established that communication among project team members can be complex. Now, add a diverse set of stakeholders into that mix. These stakeholders maybe be from highly diverse sectors with varied interests; for example, investors, patients, healthcare works, and government institutions can have highly different needs and expectations. During the planning stages of project initiation, it is helpful to spend time creating a stakeholder communication plan. This plan will help ensure that the necessary and vital details concerning communication are planned and implemented throughout the project life cycle. When identifying stakeholders for communication, it is useful to seek feedback from project members.

Pictured below is an example of a project communication plan. The column titles can be changed, and more columns can be added to reflect the information needed for each specific project. However, basic items should always be included, such as communication methods, timing, and the responsible individual or department.

Figure 31: Example Project Communication Plan

Project Name: New Vendor Selection Process

Initiation Date: 10 August 2022

Project Manager: Dr. Kathryn Spuehler

Project Communication Plan

Harris Smith Hospital

Stakeholder	Information	Communication method(s)	Frequency	Responsible	Useful information	List all dates of communication
Purchasing Supervisor	Provide detailed information on vendor requirements in writing	Email and verbally during project meetings	Email project update weekly. Attend project meetings as scheduled	Project Manager	Best to contact via email on Tuesday-Wed. Fridays they work half day.	12/09/22, 19/09/22, 26/09/22
Quality Manager	Collaborate to create quality checklist for vendor qualification	Email and verbally during project meetings	Email weekly at a minimum, more often if needed. Attend project meetings as scheduled	Project Assistant	Prefers to be contacted in the afternoon.	05/09/22, 12/09/22, 20/09/22
Dr. Smith	Is serving as an expert for establishing new vendor criteria	In person verbally	As needed, but at least 3 times during the project duration for primary assessment, talk during implementation, and final discussion	Project Manager	He prefers to have short, personal meetings. He conducts hospital rounds M-W from 07:30 - 09:30. Does not readily read emails. Plan for a 30 minute time slot when you see him.	01/09/22, 28/09/22
Purchasing Agents	Provide with information regarding upcoming training once new process is finalized	Notice via email and on SharePoint	Contact once for training notice. Then update as needed	Project Assistant	Agents are busiest in the mornings. Best time to plan training is on a Wed and/or Thursday afternoon	To be determined

Source: Angela McCaskill (2023).

SUMMARY

Project management is a vast field of study that encompasses numerous models, methods, frameworks, tools, and techniques. No matter which resources are chosen, the goals are the same: to plan, implement, execute, monitor, and improve upon deliverables in a timely manner and within budget. PM occurs in a multifaceted work environment and requires collaboration between coworkers and departments. A project team is often lead by a project manager, who should possess some of the following characteristics: honesty, integrity, stakeholder focus, excel-

lent written and verbal communication skills, ability to delegate work, flexibility, strong time management skills, able to motivate the team, and a respected leader.

The PM life cycle is made up of five stages: initiation, planning, execution, monitoring and control, and project closure. Upon the project's close, the project manager should document and communicate lessons learned to enhance organizational effectiveness, reduce risk, and improve future product and service quality.

One popular PM framework is Scrum. It began as a software development tool in the early 1990s and has since grown and flourished as a PM tool for diverse industries and organizations. Scrum is based on the pillars of transparency, inspection, and adaption. Team members should abide by the values of commitment, focus, openness, respect, and courage. Three necessary Scrum team members are the Scrum Master, Product Owner, and Developer. Each plays a defined role in the framework. Scrum includes a series of events, with the sprint being the heart of it all. A sprint begins with the creation of a product backlog. Next, planning occurs, during which the sprint backlog is generated. The process then moves forward with Daily Scrum meetings that continue until the sprint goal has been achieved. Two meetings wrap up the sprint cycle: sprint review and sprint retrospective. While Scrum has proven to be an effective PM tool, it may not be suitable for all organizations.

A carefully planned and executed communication plan is a vital part of PM. Communication occurs both internally among team members and externally with stakeholders. Individuals receive, interpret, and respond to messages differently based on complex and sometimes controversial notions, such as race, gender, sex, religion, and socioeconomic status. A person's upbringing, life experience, biases, and preconceived ideas also affect how messages are received and understood. These factors must be studied and considered when planning communication strategies. A beneficial tool for communication with stakeholders is the creation of a project communication plan. The plan identifies key stakeholders, what will be communicated, method, frequency, and the responsible person, then documents the dates of actual communications.