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ROBUST SYSTEM FOR INFECTION CONTROL - AN INDUSTRIAL SYSTEMS ENGINEERING APPROACH

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ROBUST SYSTEM FOR INFECTION CONTROL
- AN INDUSTRIAL SYSTEMS ENGINEERING APPROACH

By

Sundaravel Achudhan

A THESIS

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The Graduate College at the University of Nebraska
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Health care delivery in the United States needs improvement. Each year about 98,000 people die as a result of medical errors and the United States is outranked by a number of developed countries in life expectancy, mortality and comorbidity. Healthcare quality is determined based on the quality of the service provided to the patient during their visit. Apart from the traditional problem solving design and development tools used to improve healthcare quality, The National Academy of Engineering and the Institute of Medicine recommend systems engineering principle and systems engineering tools to be used in health care to improve the industry. Systems engineering approach is a way to gain insight into a process by looking at the interactions of the various sub-processes within the whole system. It is a sequential approach which suggests that the performance of the components of a sub-system is essential to drive the performance of the entire system. On application of this approach to healthcare delivery system, the existing system of care for infection control is sub-divided into four broad subsystems based on the phases involved in healthcare delivery - pre-diagnosis, diagnosis, treatment and post-treatment. The attributes driving these subsystems were identified and failures of these attributes were tested for dependency on patient mortality. Upon analysis, the approach proved to be an efficient tool for developing an ideal patient centered healthcare delivery system, and attributes were suggested for improvement by adopting evidenced based care practices.
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CHAPTER 1 - INTRODUCTION

Industrial quality control ensures quality of a product or process through various steps and approaches. The quality control approach is a systematic approach to identify the defect in a product, or to identify the breakdown in the process through problem solving methodologies, which includes 8-dimensional problem solving methodology, cause and effects analysis, statistical quality control and quality function deployment (QFD). These approaches are designed to ensure the products’ or process performance. Healthcare is a complex network where every simple process involved in health care delivery is focused on improving the condition of the patient. The overall healthcare delivery process as a system should influence the people involved in the process, the care providing organization and the environment where the care is being provided. These factors in the overall system, as suggested by the Institute of Medicine, are essential to be considered in developing a system for care delivery. This was adopted as a result of a study conducted by Ferlie and Shortell (2001) under the supervision of Institute of Medicine (IOM). A similar study by IOM concluded that poor system design is the cause of death for over 98000 patients in the United States. The report also revealed that the care provided to the patients was not up to the expected standard given the advancements in 21st century science and technology. The system engineering approach, when used in designing a system for health care delivery will be a modernized approach for designing a care delivery. The approach keeps the patient and their family members the sole
responsible and beneficiary owners of the care delivery process. The systems design approach in the health care delivery process ensures that the patient and their family members are well informed about the care being provided to them. The approach increases the quality rating of the organization by providing best practiced care; also the approach adopts government healthcare reforms and insurance policies which are focused on providing cost effective care for the patient.

Systems engineering design, when applied in the healthcare delivery process, broadly categorizes the process into four phases: pre-diagnosis, diagnosis, treatment and post-treatment. The process begins at the time of the patient’s arrival to the hospital and ends with the patient discharge from the facility. The objective of this approach is to drive the performance of the attributes in the health care delivery system. The pre-diagnosis subsystem includes components at the beginning of the patient registration process, and flows up to the nurse’s initial assessment. Similarly, the diagnosis phase involves steps enabling the physicians to make the diagnosis process and treatment process much faster. This includes placing orders to the supportive services at the hospital – pathology, radiology and pharmacy. The approach ensures that the presence of a process to analyze and deliver the results to the physicians will result in faster diagnosis. The treatment phase is focused on delivering the best practiced care to the patients. This includes consulting specialized physicians for their expertise and comments on patient’s diagnosis. The final phase in the health care delivery is the post-treatment phase. The components at this phase are focused on educating the patient on activities to minimize the chances of re-admission. The systems engineering approach translates the
components of the subsystem into attributes that are critical to quality of health care delivery. The approach adopts practices to ensure that these identified components of each phase are functional and therefore make up a successful health care delivery system.

The health care delivery system designed on a systems approach adapts measures and best practiced care for the elements/attributes of the subsystem. Modernized treatment methods, sophisticated information systems, faster consultation time with the physicians, economic cost of health care, could potentially be a part of a system for health care delivery through systems engineering approach.

Chapter 2 of this research supports the study with literature involving applications of the systems engineering approach and its influence on health care delivery design. The literature also summarizes the systems engineering approach application in many fields: agriculture, aircrafts, etc. The literature provides results of validated studies which proved that systems engineering application improved the product and service quality.

Chapter 3 presents the rationale for this research on the application of systems engineering design on health care delivery. The section explains the need for a systems approach in health care delivery design and its influence on infection control and healthcare quality.

Chapter 4 provides a detailed description of the developed model for improving healthcare quality through the systems engineering approach. The model categorizes the health care system into four categories and describes the activities involved in the subsystem. The concept of the systems engineering approach is that the performance of
the attributes identified in a system is essential to drive quality for the entire system, and acts a potential failure mode.

Chapter 5 validates the developed model in a local facility in Nebraska and studies the behavior of the subsystems in the healthcare delivery process. Statistical analysis of data and pictorial representation of the identified data on the application of this model proves the model to be a significant tool in health care delivery.

Chapter 6 summarizes the results of testing this conceptual model for an ideal healthcare delivery process for infection control. The chapter also identified the attributes of the system that requires improvements and their influence on patient outcomes. The chapter concludes by providing evidence that the systems engineering approach is a tool for designing and developing a process that is complex and is required to meet quality demands.
CHAPTER 2 – BACKGROUND LITERATURE

2.1. QUALITY AND ITS DESCRIPTPION

2.1.1. Defining Quality

Quality is an important business factor. The term has been in casual and professional use without a rigid definition. It could be defined in many ways based on application and intended use. Some define quality as “degree of excellence”, ”fitness for use”, ”ability to satisfy needs”, etc. Quality has turned out to be a characteristic property in the current world. ISO 9000-2005 (quality standard) defines quality as “the degree to which a set of inherent characteristics fulfills requirements” (Krishnamoorthy 2012). To understand the importance of quality and its need to customers, it is required to state its dimensions. According to Garvin (1984), quality is dimensional and its definition is specific to its own purpose. The dimensions of quality are (i) performance – Product’s ability to do its required work; (ii) features – Characteristics that add convenience and comfort; (iii) reliability – ability to perform without failure over a period of time; (iv) conformance - degree to which the product meets its code or standards; (v) durability – length of time the product lasts before being discarded; (vi) serviceability – the ability to make repairs quickly at a reasonable cost; (vii) aesthetics – sensory appeal; and (viii) perceived quality – impression of the product on the customers’ mind. These dimensions of quality draw many definitions for quality.
2.1.2. Product quality and Service quality

Customer satisfaction is based on customers’ perception of quality or service. It is important for the survival of the organization in the market. Customer satisfaction is achievable when the dimensions of quality are met by an organization. Industrial quality assurance is a process that ensures the level of quality in a product, process or service. The quality assurance practice include actions that a business deems necessary to provide for the control and verification of characteristics of a product or service. Product quality is the organization's ability to produce low-cost products at a high volume, with the degree to which the product adheres to its specifications. These specifications include customer business requirements and performance, technical and regulatory requirements (Nordmeyer). The product quality is measured on the basis of the number of defects produced, number of customer complaints and claims over a period of time. It is measured through customer assessment of the product through surveys upon promising to meet certain requirements. In customers’ perception, service is a representation of product. Service is of two types: primary service and secondary service. When the service provided by the organization is the major ‘product’ for the organization, the service is considered to be primary service. Postal services, bank service, etc. are examples of primary service. On the other hand, services provided by product manufacturers to satisfy the customer requirements are called secondary services. Secondary service is important and is needed for creating customer satisfaction in the primary product or service (Krishnamoorthy 2012). Service quality is measured using qualitative tools like surveys and customer satisfaction scores. A customer's perception of service quality tends to be positive, if the manner in which a service is provided meets or exceeds customer
expectations in very specific ways that are intended to establish or reinforce an organization's relationship with a customer (Nordmeyer). There are five sets of dimensions to which the organization must adhere to meet customer needs, and to attain product or service quality. These dimensions are divided from the dimensions of quality (Garvin, 1984). The five dimensions of product-service quality (Strickland, 2004) are: (i) physical ability and capability to provide service; (ii) consistency and reliability of service; (iii) responsiveness and willingness to provide service; (iv) knowledge and competence of employees providing service; (v) empathetic concern for the customer. It is essential to understand the differences in the concepts of product quality and service quality to determine the classification of health care quality.

2.1.3. Healthcare Quality

Similar to the definition of quality, healthcare quality has multiple definitions: some view it as a high quality of care provided, and some view it as the satisfaction from the provided care. Both of these above perceptions are based on the care provided to the patient. The Agency for Healthcare Research and Quality (AHRQ) is a federal body formed by the US government, responsible for improving the healthcare quality in the United States. AHRQ defined health care quality as “doing the right thing for the right patient, at the right time, in the right way to achieve the best possible results” (O’Kane). Healthcare quality as defined by the Institute of Medicine (IOM) is “the degree to which health services for individuals and populations increase the likelihood of desired health outcomes and are consistent with current professional knowledge” (IOM 2004). Health care quality does not mean seeing the doctor right away, or being treated courteously by
the doctor’s staff, or just having the doctor spending a lot of time with patients. It is the effective quality of care delivered to an individual based on the right diagnosis.

Healthcare quality is determined based on the service provided to the patient. It is categorized as primary service as well as secondary service. Treatment received by the patients from care providers in clinics or hospitals for a health problem is primary service. Pre-treatment activities (reception, registration, etc.) and post-treatment activities (counseling, discharge education, etc.) are secondary services (Krishnamoorthy 2012).

The U.S is a world leader in medical sciences and technology and is on a mission to improve their healthcare quality. Their cutting edge technology in drugs and devices, resulting through research and innovations, has increase healthcare costs. The current American healthcare system provides highly specialized quality care to patients, but at very high cost. This is affecting the service quality of healthcare in the U.S. Through AHRQ and other medical organizations, the government now focuses more on the service quality in healthcare, by providing a specialized, patient centered care at a cheaper cost. This has paved way for further research and to seek help from other industries, who have achieved this success by adapting industrial quality assurance techniques.

A central goal of health care quality improvement is to focus on the areas that require improvement while sustaining the benefit of the existing health care system. The priority in the areas of research for AHRQ is improving the quality of care and reducing medical errors. There are 98,000 deaths in the U.S, annually due to Medical errors (NCQA, 2004). AHRQ is working to develop and test measures of quality, identify the best ways to collect, compare, and communicate data on quality, and widely disseminate information about the most effective strategies for improving the quality of care (AHRQ
The government agency AHRQ indentified that healthcare quality is affected due to the following:

(i) **Variation in services** - Wide variation in health care practice, including regional variations and small-area variations, is a clear indicator that health care practice has not kept pace with the evolving science of health care to ensure evidence-based practice in the United States.

(ii) **Underuse of services** - Millions of people in the U.S do not receive the required care and suffer from needless complications. This adds to increasing healthcare costs and hinders productivity (AHRQ 2002).

(iii) **Overuse of services** - Every year, people in the U.S receive healthcare services that are unnecessary. This will increase healthcare costs, and may even endanger their health. For example, in 1992, Colorado’s Medicaid program would have saved nearly $400,000 if they had used an equivalent antibiotic for treating ear infections in children. Amoxicillin was another antibiotic that was equivalent at that time and was comparatively cheaper (AHRQ 2002).

(iv) **Misuse of services** - Too many people are injured during the course of their treatment, and some die prematurely as a result of this injury. For example, a study of injuries to patients treated in hospitals in New York state found that 3.7 percent experienced adverse events; 13.6 percent of these events led to death, and 2.6 percent led to permanent disability. About one-fourth of these adverse events resulted from negligence. A national study found that over a
10-year period (1983 - 1993), deaths due to medication errors rose more than two-fold, with 7,391 deaths attributed to medication errors in 1993 alone (AHRQ 2002).

Disparities in Quality - Quality problems are common to any individual. A study by University of Alabama, Brimingham revealed that use of medicine for treating heart attacks were racially discriminated and using evidence based life saving treatment could have saved many lives. The disparities marked for the members of the ethnic and racial minority populations (AHRQ 2002).

It is now convincing based on the evidence that U.S. healthcare system requires improvement. Government agencies and other initiatives are considering numerous efforts to improve healthcare quality. As a result, there has been encouragement to adopt new means through which this improvement in healthcare quality can be achieved. The following section of this chapter describes the effect on quality through a systems engineering approach.
2.2 SYSTEMS DESIGN ENGINEERING IMPACT ON QUALITY

2.2.1. Systems design engineering approach on product and service quality

The quality of a product or service is measured by testing its performance. The primary objective of quality assurance is to ensure that the products or services that are provided to the customers are meeting specified requirements and characteristics (Krishnamoorthy 2012). These characteristics / requirements can vary between users. They have to be dependable, satisfactory, safe and fiscally sound. The goal of quality control is to identify products or services that do not meet specified standards of quality, and provide corrective actions to improve and sustain the performance of a product or process.

Customers’ current needs and requirements can be satisfied by creating a modernized quality system wherein the responsibilities for various aspects of meeting the customer needs are identified and assigned to various agencies in that system. The identified agencies then perform their specified functions in a coherent manner with an aim to achieve the common system’s goal. Creating such a system, which functions on a common goal, will produce quality products with efficient usage of resources (Evans et al, 2005). Quality control and quality assurance have a marginal difference based on their functions. Quality control is concerned with examining the end result of a product or process, whereas quality assurance is concerned with examining the process that leads to the required end result.
The systems engineering concept assures quality and enables the users to attain their quality needs. Studies on significance of systems design engineering concepts were done over the past 50 years. Most defined the objectives of systems engineering, and some stated its functions, but only few research studies have validated the impact of systems design engineering on quality and its effect on an organization. Since the approach focuses on improving the whole system, it is a unique approach to improve quality and performance of a process.

Systems engineering principles are used in improving the structure, processes, and outcomes of complex systems (Honour 1997). Systems engineering leverages information, science & technology, information systems and human resources and brings about system wide improvement. The technique was originally focused on manufacturing & industrial environments. Over time, the increasing research by a number of industrial and systems engineers has expanded to include numerous services such as transportation, hospitality, energy, and finance.

In healthcare, the systems approach is developed to capture all avenues, including those that would be difficult to capture by other quality tools such as statistical process control (SPC), etc. on care delivery. SPCs can monitor the ‘quality’ of patient care using two key clinical indicators: the patient’s length of stay (LOS) and occurrence of errors through infection rates or other complications. In hospitals, SPCs provide the care providers information on the three demons hindering healthcare quality: delay, defects and deviation. As a result, through SPCs, hospitals make sure that there is faster diagnosis, timely administration of antibiotics and means to capture deviations in care
delivery processes. SPC keeps track of processes, but the healthcare is a vast domain with various avenues like infection control, morbidity, length of stay, cost of health care, etc. This paved the way for application of system engineering principles in the health care domain. The systems engineering principle translates the healthcare delivery for an individual into four subsystems – pre-diagnosis, diagnosis, treatment and post-treatment. Further, the systems engineering principle identifies the attributes essential for the ideal health care delivery at the subsystem level, adopts changes and improvements to ensure that these attributes perform as per expectations, resulting in high quality health care delivery.

2.2.2. Systems design engineering approach applications

The systems engineering discipline was initially developed in the communications industry at Bell Laboratories in the United States to meet the networking challenges of the 1950. The discipline grew continuously in the field of space, defense, and computers from 1960 through 1990 in response to the rise in integration of hardware and software technologies. The DOD (Department of Defense) mandated the use of Military Standard for Systems Engineering 490 (MIL-STD-490) for the development of all military systems using a systems engineering approach. The National Aeronautics and Space Administration (NASA) and the Department of Energy (DOE) soon followed systems engineering guidelines for the civilian aerospace and energy program of the 1970s. From 1980 to 1990, there was an expansion of this discipline to many domains with growth in challenges, systems engineering tools, and expansion of industries (ANSI/EIA 632)
By the 21st century, the systems engineering discipline was applied to non-engineering disciplines – healthcare, agriculture, transportation, housing etc. The complexity of systems and the strict requirements on performance and reliability will challenge the development of a methodology or approach to efficiently balance users’ needs, technological capability, and limited resources. The recognition of systems engineering as a dynamic engineering discipline in various application domains is due to similar factors: increased system and product complexity, greater technological capability, more challenging customer requirements in terms of reliability and performance, and greater product interoperability with other products and systems (IEEE 1220-2005). This section of this thesis discuss the application of systems engineering discipline in various applications.

**Aircraft technologies**

The key systems engineering principle on aircraft is that commercial aircraft must be considered as a whole and not as a collection of parts that can be independently developed and integrated. The requirements for the subsystems and components of the aircraft are derived from a top-level set of functions, the requirements associated with these functions, and constraints on these requirements. The principle of the requirements flow is dependent on viewing the aircraft architecture as a hierarchy in which all elements are subordinate to higher-order elements, such as subsystems, the aircraft, and a higher-level system called the aircraft system, which includes the aircraft itself and all its supporting systems. Another principle is that traditional aircraft processes, such as certification, are to be considered to be part of the larger process of verification, in which
all requirements, either economic or regulatory, is verified by testing, demonstration, analysis, or inspection. Also of importance is systems engineering management in which a thorough review process is essential to ensure that all requirements are validated, that the design meets the requirements, and that the requirements are verified, both at the aircraft level and the subsystem level (Mackay, 1995).

Kehlet et al (1995) evaluated the capability of meeting the key design goals for modern aircraft, which are: reduced weight, noise and emissions, robust system for economic and safe operation, heads-up displays (HUDs), voice recognition, global positioning system (GPS) receivers, point-to-point inertial navigators, etc. and real-time computer fault detection and isolation for supersonic and subsonic aircraft, by experimenting with different kinds of composite materials and systems. The use of systems engineering approach narrowed the above factors to create a design which could cover most of the requirements.

Franz et al (1995) quantified systems engineering impact on a program by comparing three similar projects that ran in parallel at Boeing with various quality approaches. Their studies showed that project schedules can be reduced by a factor of two or three projects where systems engineering involvement was substantial.

Scott (1995) decomposed the major economic requirement for a commercial aircraft, from direct operating cost (DOC) to its constituents (navigation fees, insurance, landing fees, ground handling, fuel, etc.). The principle of allocation of systems
engineering derived the requirements for these subsystems of the aircraft from this parameter.

**Criminal justice system and legal services**

The systems engineering discipline can help by perceiving that the criminal justice system with its component hierarchy could be modeled just as any other probabilistic system might be. There are considerable opportunities existing for simulating the criminal justice system at any level for improvement or redesign. One could break down the criminal justice system using a systems approach.

When prosecution and defense are viewed as separate entities of the criminal justice system from the court, the system can be considered to have four parts: the police, the court prosecution, the defense, and corrections, each with its own distinct activities (Coffey 1974). The police are concerned with control, apprehension, and support for the criminal justice system. The court includes the roles of prosecutor and defense as two distinct interrelated phases of the administration of justice. The prosecutor is in the most favorable position to bring about the needed coordination among the various law enforcement and correctional agencies in the community. The prosecutor’s decisions significantly affect the arrest practices of the police, the volume of cases in courts, and the number of offenders cleared through the correctional system. The defense counsel provides clients with the right to be heard and achieves the most appropriate disposition of clients. Corrections involve implementing the orders that the court gives to probation departments or parole agencies and institutions.
Karlen, Shannon, et al (1994) designed an integrated farm management system to incorporate concerns from farmers, farm suppliers, environmentalists, consumers, etc. The study compared four approaches to design such an integrated system: establishment of ad hoc panels, awarding of grants, use of the existing Agricultural Research Service management structure, and writing of specific research contracts. Among the four, the systems engineering process suggested that use of contracts would provide the best performance and that using ad hoc panels would be less desirable, primarily because they lacked financial incentives for the scientists and provided minimal control over actual research efforts. Because of minimal cost associated with initiating and operating ad hoc panels, the anticipated return per dollar invested was higher for that approach than for the three other concepts. In addition to designing an integrated farm management systems research program, their study also demonstrated how systems engineering can be used for planning complex agricultural research projects.

Mackay (2000) studied the effect of systems engineering application and support on U.S. agriculture. Production mechanization, transportation, wholesale and retail distribution and sales were well supported by this discipline. Their analysis also suggested conducting tradeoff studies, which is an essential part of systems engineering practice. The challenge proposed as a result of their study is to use tradeoff study methods to identify costs, risks, and benefits of proposed technologies so that decisions to
use or reject technologies are made on the basis of accurate and complete information (Mackay 1995).

Other applications

Research and development in many fields have avoided application of structured processes, primarily due to a perception that structure inhibits the creative processes that are so crucial to the discovery and development of new technologies. A study proposed that systems engineering principles and creative discovery are not mutually exclusive environments, and that, in fact, appropriately tailored systems engineering processes can enable and enhance scientific discovery (Norman and Nolte). The study was validated with taking principles of Risk management to basic research, applied research and development and technology demonstrations.

The increasing number of sustainably designed high performance buildings provide numerous benefits to the owners and occupants to include improved indoor air quality, energy efficiency, and environmental site standards, and ultimately enhance productivity for the building occupants. The increasing demand for higher building energy efficiency and environmental standards led to application of a set of process models to support consistency and optimization during the design process. Systems engineering process models have proven effective in taking an integrated and comprehensive view of a system while allowing for clear stakeholder engagement, requirements definition, life cycle analysis, technology insertion, validation and verification. A research overlaid systems engineering on the sustainable design process by providing a framework for application of the Waterfall, Vee, and Spiral process
models to high performance buildings (F. Bersson, Mazzuchi, et al). Each process model is mapped to the sustainable design process and is evaluated for its applicability to projects and building types. The framework provided can be used in conjunction with Design Build, Design Bid Build CM At-Risk, and Integrated sustainable design to enhance research on Green building models.

NASA Langley Research Center carried out a study to identify the impact of systems engineering on quality and found that the outcome of a systems approach should reward or benefit the cost, technical performance and risks associated (Kludze 2004). The study found that the systems engineering approach reduced risks through various risk identification and management techniques, saved money to an organization by enabling cost effective solutions, reduced time for a process effectively, and satisfied expectations for a technical performance.

Khiabani et al discussed that the desired outcome of system engineering is to produce a quality product (INCOSE, 2010). Production is often referred to as a subset of quality (Howard & LeBlanc, 2003), and therefore improving quality can improve production goals subsequently.

**Systems engineering approach in Healthcare**

The systems engineering approach has the potential to address the challenges faced by the health care delivery system. The Agency for Healthcare Research and Quality (AHRQ) and the National Science Foundation (NSF) convened experts in both fields to explore the critical areas of research at the intersection of systems engineering
and health care. The study (Valdez 2010) found that the approach could articulate a vision for an ideal health care delivery system that would result in meaningful change on healthcare quality, and substantially contribute to the development of further initiatives to drive quality.

In the World Health Report 2000, ranking of health system attainment of 191 World Health Organization (WHO) member states was reported on; it found that the United States was ranked as the highest health care spending per capita of all 191 member states followed by Germany and France, but performance wise, the United States was in the 37th place. The cost factors were found to be medical malpractice, liability, litigation, liability insurance, quality, transparency, etc. After a series of research and studies, it was concluded that having an integrated health care delivery system would decrease the rising cost and take better control over the medical practices and public. The integrated healthcare system concluded from the research by Kaiser Permanente in 2002 was obtained using a systems approach (Carayon, Alvarado, Jenkinns, et al). This model paved way for the development of the ideal health care delivery system which is described in detail in Section 4.1.

Lynn et al (2004) worked on improving safety in outpatient surgery. They implemented a systems engineering intervention in their process to achieve their goal of improving the safety of outpatient surgery. The intervention process was carried out by SEIPS—Systems Engineering Initiative for Patient Safety, which is a step by step approach using systems engineering tools for process layout, data modelling and with solutions and validations.
In the handbook “Building a better healthcare delivery system”, INCOSE found that the systems engineering approach is a complex approach. Based on the complexity of health care delivery, which involves the coordination and management of large numbers of highly specialized, distributed personnel, multiple streams of information, and material and financial resources across multiple care settings, it is astounding that health care has not made better use of the design, analysis, and control tools of systems engineering (Compton 2005). The experiences of other major manufacturing and services industries, which have relied heavily on systems-engineering concepts and tools to understand, control/manage, and optimize the performance of complex production/distribution systems to meet quality, cost, safety, and other objectives, can provide valuable lessons for health care. It was also said that certain systems engineering tools are complex to use and require trained professionals and engineering to utilize the tools effectively.

The following section of this chapter explains the concept of systems engineering and the theory involved in developing a system model for driving performance and improving quality.
2.3 SYSTEMS DESIGN ENGINEERING APPROACH

Systems engineering is “an interdisciplinary approach and means to enable the realization of successful systems” (INCOSE 2012). It is an industrial quality assurance concept that has a holistic and a concurrent focus on understanding stakeholder needs; exploring opportunities; documenting requirements; synthesizing, verifying, validating, and evolving solutions while considering the complete problem, from system concept exploration through system disposal.

Systems engineering principles transform needs and requirements into a set of system product and process descriptions (SEF, 2001). This generates information for decision makers to provide input for processes’ or products’ next level of development for quality improvement. The decision makers mentioned could be users or stakeholders. The systems concept takes into account of the entire stream of processes which are required to function efficiently and effectively to ensure the quality of the product or process. Subsystems are sub-divisions of the system that contains attributes which determine the performance of the process (Misra et al, 2008). Systems engineering focusses on monitoring and controlling these attributes by identifying and improving its quality where applicable.

Systems engineering design is the process of designing a system whose attributes are the end users’ customer requirements. In the systems design phase, customer requirements are translated into a set of requirements that define the system performance and function (Kludze). The systems engineering design phase uses a V-model approach
developed by Forzberg et al (1991) and team to transform these customer requirements into quality attributes.

**V-Model**

The V-model is a graphical representation of the project’s life cycle phases in the systems design stage. The name is derived from the “V” shape of the model. This model is also called a ‘Verification and Validation model’ (Forzberg et al, 1991). The V-model represents the systems development life cycle and begins in the upper left of the “V” and proceeds down with decomposition and definition, it then goes up the right side of the “V” with integration and verification. This is illustrated in Figure 2.1.

![Figure 2.1. Systems design engineering “V” model, (Forzberg 1991).](image-url)
The V-Model was presented in the U.S. by Forsberg and Mooz at the National Council on Systems Engineering and American Society for Engineering Management conference in 1991 (Forsberg and Mooz, 1991). It was developed in Germany for project management use by the Federal Ministry of Defense. Forsberg in his research contended that many models for designing systems based on user requirements had a common deficiency downstream at the subsystem level that would hinder the development of design without upstream review (Mooz 1997). Forsberg made sure in his V-model that process developments will not begin until upstream review and control gates were satisfied (Forzberg 1991) This ensures that there is verification and validation from stakeholders and end users at every development stage of the system.

The V-model has applicability to complex projects that requires technology insertion, concurrent engineering, and incremental development. The steps flowing down the “V” are customer requirements, functional requirements, configuration/technical specification, and detailed design. The bottom of the “V” is system development. Following up to the right side of the “V” is unit integration testing, installation qualification (IQ), operations qualification (OQ), and performance qualification (PQ) (Forzberg 1991). Verification is applied to ensure that the development process meets the design and specification requirements for the customer. Additionally, the product development undergoes a validation traceability to ensure that it meets the users’ requirements. This function has a feedback loop tied to its process input variables. For each phase of the design engineering process, the output will be compared to the requirements (SEF 2001).
The systems engineering V-model provides guidance for the planning and realization of projects. Its objectives (SEF 2001) are:

(i) minimization of project risks- The V-Model improves project transparency and project control by specifying standardized approaches and describing the corresponding results and responsible roles. It permits an early recognition of planning deviations, and risks and improves process management, thus reducing the project risk.

(ii) Improvement and Guarantee of Quality- As a standardized process model, the V-Model ensures that the results to be provided are complete and have the desired quality. Defined interim results can be checked at an early stage. Uniform product contents will improve readability, understandability and verifiability.

(iii) Reduction of total cost over the entire project and system life cycle-the effort for the development, production, operation and maintenance of a system can be calculated, estimated and controlled in a transparent manner by applying a standardized process model. The results obtained are uniform and easily retraced. This reduces the acquirers dependency on the supplier and the effort for subsequent activities and projects.

(iv) Improvement of communication between all stakeholders-the standardized and uniform description of all relevant elements and terms is the basis for the mutual understanding between all stakeholders.
Thus, the frictional loss between the user, acquire, supplier and developer are reduced.

The systems engineering process provides a path for improving the cost effectiveness of complex systems. It includes early and comprehensive identification of goals. It is a concept based on operations that describes users’ needs and operating environment. It possesses thorough and testable system requirements, detailed design and implementation, and rigorous acceptance testing of the implemented system to ensure compliance of the stated requirements (system verification). On this process, the systems engineering approach measures its effectiveness in addressing goals (system validation), sustains ongoing operation and maintenance, enables system upgrades over time, and eventually paves way for further improvement.

The systems engineering “V” model has its pros and cons. The model takes into account of the deliverables at the subsystem level. The performances of the attributes are tracked down in the lowest level and routine quality control checks are to be established to ensure highest quality level in the process. The model does not involve the use of any complex statistical data analysis tools and it is relatively simple to use (SEF 2001). Since the system is designed based on the customer requirements, almost every possible attribute is taken into consideration and its performance is monitored. The systems approach could be labor resource intensive, and there is much less chance of having a prototype or a trial run to test for validation of the newly developed system.
2.4 INFECTION CONTROL AND ITS EFFECT ON HEALTHCARE QUALITY

Healthcare associated infections (HAIs) are a major public health concern throughout the United States. Healthcare associated infections are contributing to increased morbidity, mortality, and healthcare cost. Morbidity is the incidence of disease or rate of sickness (AMA); Mortality is the state or condition of being subjected to death (Kernan 1997). The occurrences of HAIs are still continuing to escalate at an alarming rate. HAIs were initially referred to as those infections associated with admission in an acute-care hospital, but the term now applies to infections acquired in the continuum of settings where people receive health care, e.g., long-term care, home care, ambulatory care (Collins). These unanticipated infections develop during the course of health care treatment and result in significant patient illnesses and deaths (morbidity and mortality), prolong the duration of hospital stays; and necessitate additional diagnostic and therapeutic interventions, which generate added costs to those already incurred by the patient’s underlying disease. HAIs are considered an undesirable outcome, and as some are preventable, they are considered an indicator of the quality of patient care, an adverse event, and a patient safety issue (Collins).

Patient safety studies published in 1991 reveal the most frequent types of adverse events affecting hospitalized patients are adverse drug events, nosocomial infections, and surgical complications (Brennan 1991) (Leape 1991) From these and other studies, the Institute of Medicine reported that adverse events affect approximately 2 million patients
each year in the United States, resulting in 90,000 deaths and an estimated $4.5–5.7 billion per year in additional costs for patient care (Kohn 2000).

Healthcare-associated infections, or HAIs, are infections that people acquire while they are receiving treatment for another condition in a health care setting. HAIs can be acquired in the place where care is delivered, including inpatient acute care hospitals, outpatient settings such as ambulatory surgical centers and end-stage facilities, and long-term care facilities such as nursing homes and rehabilitation centers. HAIs are caused by any infectious agent, including bacteria, fungi, and viruses, as well as other less common types of pathogens (Collins). These infections are associated with a variety of risk factors, including:

- Use of indwelling medical devices such as bloodstream, endotracheal, and urinary catheters
- Surgical procedures
- Injections
- Contamination of the health care environment
- Transmission of communicable diseases between patients and healthcare workers
- Overuse or improper use of antibiotics

The U.S. Department of Health and Human Services is committed to reducing the national rate of HAIs by demonstrating significant, quantitative, and measurable reductions in hospital-acquired central line-associated bloodstream infections, and catheter-associated urinary tract infections. These infections are constituents of a phenomenon called sepsis. This is a condition which arises due to a body’s inflammatory response to infection. The infection sources mentioned above are major causes of sepsis.
in the world. Sepsis is a complex set of signs, symptoms and causes, and even defining sepsis accurately can be difficult. Healthcare providers are aware of the condition of sepsis and related conditions, the processes involved and the common causes of sepsis. In identifying sepsis, a thorough scene size-up, history and assessment are all imperative to detecting sepsis. Sepsis is a disorder that affects individuals across all ages and general health conditions, and is one the prehospital provider should be ever-diligent in seeking and treating. This section of literature therefore concludes with information that infection control is a problem in the U.S; and government agencies are seeking alternative measures to improve healthcare quality through infection control.
CHAPTER 3 – RATIONALE FOR RESEARCH

3.1 LITERATURE SUMMARY

Quality Assurance is important and it is beneficial to the organization to meet customer needs and requirements. Quality assurance is classified as product quality and service quality, and furthermore, the service quality is sub-categorized as primary and secondary service based on the nature of business. Healthcare is a complex system and improvements to the system benefit both the product and service quality of healthcare. The literature on healthcare quality concludes with evidence that the nature of the current healthcare quality in U.S is a result of overuse, underuse and misuse of resources and available technology, and requires a method to effectively manage and use the resources to benefit healthcare quality. Systems engineering approach is a quality assurance method which on application would benefit both product and service quality. “V model” is a representation of the systems engineering process outlining the concept that every improvements adapted through redesign will be validated eventually to test for performance as a part of the process. The objective involved in this approach is that a system would be broken to its components, and the functions of these components determine the function of the system. In healthcare, the systems approach breakdown the system to four subsystems: pre-diagnosis, diagnosis, treatment and post-treatment. The healthcare quality is affected by spread of hospital acquired infection and identifying the infection on an individual is challenging, but also important.
3.2. RATIONALE FOR RESEARCH

Healthcare is a multi-dimensional field of study with multiple avenues of science. It is the practical application of the principles and skills on patient for health improvement, gained from multiple disciplines of science and engineering. Healthcare has always provided with challenges for research and development to improve the care delivery process, to achieve improvement in patient health and quality. Institute of medicine (IOM) with the Agency of Healthcare Research and Quality (AHRQ) collaboration identified significant differences between evidence and practice in the care delivery process. The difference between the two led to increase in healthcare costs, and decrease in patient safety. It was also identified that the current practice for healthcare delivery was not patient centered, but was a business practice of making money. This initiated the U.S government to focus on researches and development in multiple disciplines of science to improve the healthcare delivery process to make it entirely a patient centered process. The objective of these research studies funded by the U.S Government has to identify the factors that led to increasing healthcare costs, eliminate non-value added services in the healthcare system to decrease the burden on the end customers of the healthcare system.

Wu et al (2000) concluded that almost 45% of the population of the United States suffers with chronic conditions requiring care management. A concept through which clinical activities and practices are tailored to meet the needs of patient, by providing coordinated healthcare plan and services is termed as care management. Current care delivery
processes are not designed to support the activities that are involved in healthcare delivery system for the patients suffering from chronic illness. They will require a healthcare system that has the ability to accommodate input from multiple care providers and services to improve their chronic condition. Sepsis is one such chronic condition where a systematic inflammatory response of the body caused by the presence of infection spread. Sepsis results in organ system failure in a patient and causes patient death. The infection arises due to breakdown in the care delivery process and inefficient measures to identify the presence of infection in a patient. The healthcare quality is affected by phenomenon such as sepsis which would increase the mortality and length of stay of an individual in a hospital. As discussed in literature, the healthcare quality is determined by the mortality, morbidity and length of stay of an individual, and there is a need for a system which would identify infection on an individual and improve the care involved.

Institute of Medicine and National Academy of Engineering with the support from U.S government have encouraged research in the application of systems engineering principles in the field of healthcare. The objective of this research is to create a healthcare system model by understanding the application of systems engineering principle and its impact on the health care delivery system. The proposed model will break down the care delivery process to identify the attributes involved in the process of healthcare delivery. Systems engineering principle focuses on coordination, synchronization and integration of patient information, healthcare providing organization and financial resources. The conceptual model to be developed for ideal healthcare delivery system
through the system approach will be based on the identified drivers involved in the process. The concept involved in the creation of the model for healthcare delivery based on identifying drivers, is to understand the impact of the performance of the system drivers on the performance of the entire system. This concept when applied to healthcare delivery process suggests that the elements in the healthcare delivery systems need to be performing to conformance, to obtain a functional healthcare delivery system. This research identifies the attributes in the healthcare delivery system; understand its significance on the entire system, and ensures its performance. In the end, the concept will propose an idealized functional system for healthcare delivery process for infection control, which will be beneficial to the patient, healthcare providers and the government.

Objective of this research is to develop a model for healthcare delivery through systems engineering approach; the identified attributes drive the system for health care delivery to performance and consequently attains quality.
3.3. RATIONALE FOR METHOD

Systems engineering is a complex problem solving methodology. It is a field which includes all the combined efforts of Science and technology, and develops interactions between the elements within the system. The systems engineering is an interdisciplinary approach that encompasses the entire technical effort, and evolves into an integrated life cycle balanced set of system people, products, and process solutions that satisfy customer needs (EIA Standard IS-632, *Systems Engineering*, December 1994).

The methodology used in this research, is to create a model and test its performance in healthcare delivery process. A baseline model for healthcare delivery involves a diagnosis and treatment phase. The application of systems engineering discipline categorizes the processes involved to pre-diagnosis, diagnosis, treatment and post-treatment. An ideal model for healthcare delivery-infection control, is developed using this approach. The attributes in the subsystems of the healthcare delivery system are discussed upon identification, to understand the importance of these attributes in healthcare delivery process. The failure of the attributes is regarded as flaw in the system, thus resulting in improper system design. This is because, a failure in the function of the attributes will affect the subsystems’ performance and subsequently affect the performance of the system. Thus, attributes indentified using this approach is considered as failure modes of the process. Failure modes are used in systems design and development. Failure modes are used in systems operation to identify the component
which is critical to the overall function of the system. The model developed for healthcare delivery based on failure modes, is tested for conformance at a local facility in Nebraska. The hospital was on the process of improving its infection control process. The data used in our research is approved by the facility as this approach will suggest a different perspective on the infection control process using systems approach.
CHAPTER 4: SYSTEMS MODEL FOR IDEAL HEALTHCARE DELIVERY

4.1. DEVELOPMENT OF MODEL

4.1.1 Systems design

A system is an integrated composition of people, products and process that gives us a capability to satisfy a stated need or objective (system engineering fundamentals). A system can be defined as an aggregation of parts or elements, connected in some form of interaction or interdependence to form a complex or unitary whole. In other words, a system is a set of mutually related elements or parts assembled together in a specified order to perform an intended function. It is necessary to understand that a system is not a set of items, facts, methods or procedures. Also, a random collection of items or facts cannot be considered a system because of the absence of its purpose and the unit’s functional relationship.

Systems are broadly categorized into open system and closed system. A closed system is one that does not interact significantly with its environment and exhibits the characteristics of equilibrium resulting from internal rigidity, and controls the system in spite of influences from the environment. In contrast, an open system allows information, energy and matter to cross its boundaries and interact with the environment. In a dynamic interaction, the elements of the system adjust to the changes in the environment. Both closed and open systems exhibit the property of entropy, which may be defined as the degree of disorganization in a system and uses the analogous thermodynamics term.
The complexity of a system is determined by the number of interacting elements, and their physical dimensions, multiplicity of links or connections of the constituent elements within the system, multiple functions, etc. The complexity of a system can be best defined based on the nature of its structure and the functions performed by the system. The hierarchy of system is described below.

A system is a top-down approach and has three levels of hierarchy – systems, subsystems and components. A component is the lowest level of hierarchy in a system and is the basic functional unit of a system. Components, in the system are regarded as the basic unit of the system. They are indivisible in context of the problem being considered at hand. Components are also known as elements (fundamental units). The assembly of several components interlinked with a functional purpose is designated as a subsystem. It follows the next higher level of hierarchy in a system, above the component. Finally, an assembly of subsystems connected functionally to achieve an overall objective is called a system. It is the highest level of hierarchy in the concept of systems engineering. Figure 4.1.1 illustrates the hierarchy of systems engineering.
The system comprises items, attributes and relationships to accomplish a function. Items are the operational parts of a system consisting of input, process and output; attributes are the properties of the items or components of a system that are discernible, relationships are the links between items and attributes. Therefore, a system can be considered as a set of interrelated items or units working together to accomplish some common objective, purpose or goal.

Systems engineering is a flexible process which transforms the requirements into specifications and configures baselines. This is done at three levels (i) at a conceptual level – which is just a describing the functions of a process, (ii) at a system level – which gives a process description with its performance terms, and (iii) at subsystem level - which gives us a set of process description along with its detailed description of corresponding characteristics which are required for the process to transform requirements into specifications. The benefit of having a subsystem level problem solving approach is that there is a detailed description of information flow from one subsystem to
the following consecutive subsystem. Figure 4.1.2 below illustrates the systems engineering within its boundary containing its interactions with the subsystems.

![Figure 4.1.2. Systems framework](image)

Systems engineering can be applied to a wide range of applications with significant benefits. Fields where systems engineering disciplines are now used include

- Agriculture
- Commercial avionics
- Energy conservation and management
- Food services
- Healthcare
- Information systems
- Manufacturing
- Political and public interest systems
- Service industries and
- Telecommunication

Systems design is the method of creating a process which involves the collective work of interacting elements or sub processes satisfying the primary requirement of the process. International council on systems engineering (INCOSE), an organization formed by systems engineers to raise the systems approach among problem solving methodologies, guides the user to design a system to solve complex issues which arises in various platform. INCOSE provides specific guidelines and procedures that have to be followed in every platform on applying the systems design concept. These guidelines and methods on systems approach are prepared under the supervision of ISO and ANSI.

The attributes of the subsystem within a system determine the performance of the process in systems engineering. The attributes are a functional and an identifiable quality factor in the system. To better understand the role of attributes, it is required to understand the functionality and quality of the attributes. Functionality is the ability of the system to do the work for which it was intended. A process requires that many or most of the system's elements work in a coordinated manner to complete the process. If the elements have not been assigned the correct responsibilities or have not been endowed with the correct facilities for coordinating with other elements, the system will
be unable to offer the required functionality. But in some cases, the attributes will also be able to individually contribute to the completion of the process.

Therefore the system design phase is the essential initial step in understanding and specifying the needs of the customer or stakeholders. During systems design, all the interacting elements, user specifications and customer requirements are put together to create a system. The design should provide information on optimization, traceability, completeness, and the risk of the allocated requirements, while fulfilling the system/subsystem requirements. Section 4.1.2 describes the application of systems engineering principles in the healthcare field.

4.1.2 Healthcare systems design

First, it is essential to understand the need to use a systems engineering approach to improve healthcare delivery in the United States. The previous section describes the functions of the systems engineering concept. The section concludes that the attributes of the system drive the overall system for performance and quality. It portrays that failure of the attribute to fulfill its function will lead to breakdown in a process or improper systems design. In healthcare, on applying the systems approach, the care delivery process is categorized into four subsystems based on the phases of patient evolution.

In general, the main steps involved in healthcare delivery are admitting the patient and performing an initial assessment to identify illness; ordering lab work to make a diagnosis; providing the best treatment for the identified disease; and finally providing follow-up care and educating the patient to take better care of his health. Therefore, the
health care delivery process with a systems approach is divided into four subsystems.

They are:

- Pre diagnosis
- Diagnosis
- Treatment
- Post-treatment

Figure 4.1.3. Proposed subsystems in healthcare delivery

Each subsystem has several attributes performing a specific function. The components in the pre-diagnosis phase collectively gather information from the nurses and clinical staff to provide information to the physician. The diagnosis phase is where the actual illness is identified. The treatment phase includes activities which collectively cure the patient
from the illness and finally post-treatment activities includes those measures that are required to prevent re-occurrence and continue care. Figure 4.1.4 shows the components of each subsystem, and the baseline model for healthcare delivery developed through the systems engineering approach.

The components of the subsystem have a specific function. Their efficient performance drives the entire subsystem to function to its requirement. The approach describes that the attributes of the subsystem behave as the failure mode of the subsystem. This is because failure of an attribute in a subsystem will affect the quality of the subsystem, resulting in failure of the system. As a result, the indentified failure modes in the healthcare delivery system for infection control are:

Failure modes of the pre-diagnosis system:

- Failure to notify patient who requires immediate attention
- Severity patient not given importance
- Staff not using the right T sheet (triage sheet) for assessment based on initial complaint at admission
- Failure to change the T sheet upon misinterpretation after evaluation
- Failure to capture the critical information
- Failure to document the findings or observation to notify the physicians
- Not screening patients above 18 years of age to identify the spread of infection
- Failure to trigger the next step right away upon highly sick patients
Failure modes of the system for diagnosis:

- Delay in physicians seeing the patient
- Unclear evaluation – skipping steps and jumping to conclusions
- Improper documentation - decreases the clarity in communication between physicians
- Failure to administer antibiotics as fast as possible for highly sick patients
- Failure to place the right orders to the supportive services to help in diagnosis
- Delayed response to physician’s orders to the supportive services
- Labs, Radiology and Caths having a turnaround time of greater than 45 minutes
- Supportive services failing to process results for the highly sick patients faster
- Unclear documentation of results of the supportive services
- Presenting the results to the right patient at the right floor
- Failure to make an early diagnosis based on the initial complaint at the time of admission
- Improper communication between the physicians and staffs
- Lack of specificity in diagnosis
- Failure to monitor the patients to capture abnormalities
- Not keeping the patients well informed about the diagnosis made and the nature of care provided

Failure modes for the system of treatment:

- Breakdown in the communication between the physicians
• Failure to seek the admitting physician consent
• Delay in placing orders specific to the initial diagnosis
• Having a process with large variation in time of patient assessment
• Lack of uniformity among the staff in patient assessments
• Delay in informing physicians about the orders placed for treatment
• Delay in drawing blood cultures from the patient
• Intervention performed on the patient which resulted in an infection
• Delay in placing orders to pharmacy
• Medications being sent to the wrong patient
• Failure to monitor the patients
• Failure to capture the required information
• Failure to notify physicians immediately upon monitoring and capturing abnormalities

Similarly, the failure modes of the post-treatment system are:

• Ambiguity over who owns care of patients after discharge follow up appointment
• Patients having poor access to follow up care
• Inefficient patient education

These failure modes were obtained from the hospital from a 12 member team, consisting of pulmonary physicians, pharmaceutical service staffs, pathological service staffs and nurses. The members of the team insisted to use the mentioned failure modes on sepsis control for this study. The study provided a baseline capability of the quality of the sepsis care currently being provided at the facility. The failure modes were developed due to
possible breakdown in the observed healthcare delivery system. The team provided these failure modes after analyzing the history of patients infected with sepsis. It was obtained for this study through formal approval from the management. The detailed descriptions of these failure modes are explained in Section 4.1.4 of this chapter.
This healthcare model developed through systems engineering, must satisfy the requirements formed by the combined efforts of Institute of Medicine and INCOSE. According to the ideal healthcare delivery model, ‘Healthcare’ as defined in the article “Building a better healthcare delivery system” involves the interaction of four elements: Patients, Care team, Organization and Environment. This shows the complexity of the healthcare system and the opportunities it possesses for improving healthcare quality. The healthcare system has evolved considerably when compared to other industries, because of the involvement of Engineers in healthcare. As a result, healthcare is now viewed as an ‘industry’. It may encompass using insights to conceive, model and scale an appropriate solution to a problem or objective. This concludes that healthcare is more like an engineering field.

It is also important to understand that healthcare involves re-engineering. One of the primary objectives of systems engineering is re-engineering, which is described in the V-model in Section 2.3. In healthcare avenue, systems engineering helps in developing new metrics, identifying the tools, techniques, and methods of proven effectiveness that could be applied in hospitals and care delivery environments.

The ideal health care delivery model developed using a systems approach, must clearly show the interaction of the four levels: patients, care team, organization and environment. In an ideal health care delivery system the systems approach sees the stakeholders as patients and the care providers themselves. It is imperative for the current health care delivery to have a system focused on benefitting all the stakeholders, instead of being only on the patients.
The six aims of the ideal health care delivery system, as coined by the Institute of Medicine in 2001 are:

- **Safe** - Having a system of care which will cure the patient completely and will not bring about any infections and complications
- **Effective** - Providing care with scientific evidence to those who could be benefitted, and also making sure to use the right amount of resources (preventing over-use and under-use)
• Patient Centeredness - The delivery of care being entirely based on benefits to the patient and having satisfying their needs being the primary objective

• Timely - Delivering care at the right time without any sort of delay

• Efficient - Avoiding any waste (equipment, medicine, resources) in the care delivery process

• Equitable – Providing a standardized care to every individual, irrespective of their race, ethnicity and sex.

Patients

Patients no longer remain an individual seeking care, but have evolved to be a person with an eminent role in health care delivery. Changes in healthcare policy reflect an emphasis on “consumer-driven” healthcare. Availability of information, the establishment of private health care spending accounts, and other measures reflect an increasing expectation that patients will drive changes in the system for improved quality, efficiency, and effectiveness.

The developed system made it possible for the patients to be involved in the design, development, coordination and implementation of their care. Unfortunately, most people do not have access to the information, tools, and other resources they need to play their role effectively. As a result, there is a need for the patients to be well informed on the care provided. System engineering tools with applications in information communication technologies have helped us in keeping the patients informed and updated.
Patient centeredness in the healthcare delivery system is brought about by changing the impression of a patient in the minds of care providers. Clinicians consider patients and their family members as “partners” to incorporate their values and wishes into the care processes. Patients now want to be actively involved in the decision making process, or at least be a partner in the process to exchange information in the care delivery processes. The level of responsibility for a patient in this decision making process varies from patient to patient.

Patients in order to effectively participate in their health care delivery process, coordinate or be involved in the decision making process, must have the same information possessed by the physicians and care providers. This calls for patient accessible forms to be used in the organization providing care. These forms will have up to date patient physiological information, type of care, medical device used, drugs prescribed etc.

From the patient’s perspective, improving the timely recognition of diseases, effectiveness and efficiency of care improve the quality of care. Communication is another factor that has to be considered. In healthcare, communication between patients and physicians is synchronous and asynchronous. Synchronous communication is the real time communication between the patient and physicians. They are continuous and accelerate the diagnosis pace and reduces complications in the care provided. Asynchronous communication on the other hand, is the non-real time communication through internet and health portals. These methods improve the quality of care, as the internet involvement educates the patients and seeks feedback from care providers all
over the world. This tuned out to be the most effective mode of communication because, healthcare, being vast and flexible, provides information sharing, best practice technologies, etc from any part of the world. Figure 4.1.6 below illustrates the factors making patients an active participant in the health care delivery system.

![Diagram](image)

Figure 4.1.6. Patient as an active participant in the health care delivery system

**Care team**

The healthcare providers, physicians, nurses, supportive staffs and family members are members of the care team, whose collective efforts are required for an ideal healthcare delivery. The collective effort of all the members in the care team makes them
the “vitals” for the healthcare delivery system. Dr. Quinn in 1992 classified care team as the “clinical microsystem” or “essential building blocks of the healthcare delivery system”.

Ideally, the roles of the care team are to standardize care where possible, based on the best current evidence; to stratify patients based on medical needs and provide the best evidence based care within each stratum; and to customize care to meet individual needs of patients with complex health problems (Nelson et al., 1998).

Highly focused individual care, supportive tools and information technologies, and healthcare professionals are necessary to be a part of the care team. They are also considered to be the next level of the health care system. The main goal of the care team is tailoring the evidence based care to meet the needs and preferences of individual patients with complex health problems.

Due to increased medical specialties, chronic diseases have significantly cut the individuality of the physicians and have enabled them to work as teams. The adaptation of team based care has improved the quality of care and has gained expertise on possessing a culture void of many medical devices. The only drawback in following a team based care is that the chances of losing the patient confidentiality are greater in spite of their high training on patient privacy. Also, there is room for unwanted variations in the way the care could be provided. Physicians administering antibiotics to the patient before making a diagnosis is an example for this case. This is unacceptable or sometimes might not be advisable in the attending physicians stand point of view.
Adopting evidence based care, eliminates the variations in healthcare delivery. Accepting the value of ‘evidence-based medicine’ and recognizing that it is not possible for the physicians to deliver evidence-based care on their own, they are working to eliminate the barriers preventing this change. The guild structure of the health care professions; the absence of training in teamwork; the strong focus on the needs of individual patients as opposed to the needs of patient populations; and the lack of supporting information tools and infrastructure, are identified to be the barriers in adopting evidence based care. All of the above mentioned barriers can prevent systems thinking by clinicians, diffusion of evidence-based medicine, and clinical microsystems approach to healthcare delivery.

For the care team to be more patient centered, it is essential for the care providers to be responsive to meet the needs of the patients and involve the family members in the design and implementation of the new healthcare system. Care teams must provide patients with continuous, convenient, timely access to quality care. Members of the care team must also be responsible for ensuring effective communication and coordination between the patient and health care providers.

Figure 4.1.7 below illustrates the essential drivers for the care team to be a vital part of the healthcare delivery system.
Organization

Organization is the third level of the healthcare system that provides the infrastructure and resources to the care team. Organization in healthcare systems engineering as defined by Ferlie and Shortell (2001) is the continuum which provides an overall climate for change through decision making systems, information systems and human resource systems.

Organization systems encompasses the decision making systems, information systems, operating systems and financial, administrative, human resource and clerical processes to coordinate the activities of multiple care teams, supporting units and manage the allocation of flow of materials, human, financial resources and information in support
of care teams. The organization is the ‘business level’ of the health care system as investments are made through information systems, infrastructure, and project management systems tools.

The major threat to the organization system is the increasing cost of health care. The organization is focusing on developing new ways to provide care with minimum use of resources – care team, drugs, cost, etc. In order to minimize these effects, organization must be in a good position to battle this situation. One such way this could be achieved is by investing considerably in system engineering tools, information communication systems and associate knowledge. This will support the patient centeredness and also create a bridge between clinical microsystems.

**Environment**

The final level of the healthcare system is the political and economic environment. It includes the regulatory financial payment schemes and entities that influence the structure and performance of healthcare organizations directly and all the other systems along with them.

The Federal government has a vital role in this environment by implementing reimbursement reforms through Medicaid and related programs. The policies and reforms laid by the federal government through Medicaid/Medicare have been helpful to improve the patient diagnostics as it paved way to use therapeutic interventions (drugs, procedures, process, etc.). State government controls the administration of Medicaid reforms and influences other systems along with it. Private sectors such as insurers and
health plan companies are also a healthcare economic environment influencer, as they cover the remaining cost for health care delivery which is uncovered by the federal policies.

Federal regulations influence the structure, level, and nature of competition among providers and insurers. They affect the transparency of the health care system by setting requirements related to patient safety and other aspects of the quality of care. By exercising its responsibility to monitor, protect, and improve public health, the federal government shapes the market environment for health care. Federal agencies fund for biomedical research, and influence the research and technological trajectories of healthcare, and, with them, the education of health care professionals and professionals in other areas invested in the health care enterprise. Figure 4.1.8 below enlists the drivers for political and economic environment on health care delivery.

![Figure 4.1.8. Drivers for environment in the ideal health care delivery system](image_url)
4.1.3. Significance of proper healthcare systems design

As discussed in section 4.1.2, it is important for the subsystems to function effectively with efficient interactions to achieve an overall satisfying system. This section explains the systems approach in healthcare and significance of proper systems design.

The objective of the system design engineering process is to create a system with effective relationship between the subsystems, which does not sacrifice the benefits of the stakeholders. The concept looks at the system as a whole and works on achieving a favorable end result.

In healthcare, the primary objective of the systems approach is to control the process of health care delivery at the subsystem level to provide the best possible care to an individual. As per the discussion in section 4.1.2, the attributes or components of the subsystem are the functional quality blocks of the entire system. It is required that the information flows efficiently between components from the start of the health care delivery process through the end. A breakdown in this flow of information will primarily be due to poor interactions between components. This leads to system failure or improper system design. Therefore, in an ideal system, the interactions between the subsystems are frequently monitored and kept well checked to ensure proper functioning.

The rationale for this research is to study the effectiveness of the health care delivery system using a systems approach. It is important to realize the interactions of components within the subsystem and between the subsystems, and capture the flow of information between them to provide the right care for the patient. A patient during
his/her hospital visit, when diagnosed incorrectly due to improper initial assessment, will eventually be treated for his/her wrong diagnosis and might lose their life due to lack of specific care. This is a good example to explain the effect of a systems malfunction or improper systems design on systems engineering. Therefore, a good systems design will ensure proper diagnosis and early recognition of illness. Even in the case of wrong diagnosis, the presence of a feedback loop, i.e. frequent vitals monitoring, timely lab results or blood culture analysis will help us to rectify the mistake then and there and narrow the chance of mortality.

4.1.4. Failure modes in a health care delivery system

In order to identify the potential failure modes of the subsystems, we must understand the functions of each subsystem. Listed below are the step by step requirements to identify the failure modes of the subsystem.

(i) Understanding the functions of subsystems
(ii) Identifying the tasks-people, materials, method involved in every stage of the subsystems
(iii) Essential critical to quality (CTQs) of every subsystem
(iv) CTQs of subsystems that are vital in health care delivery in patients perspective
(v) Potential failure modes in every subsystem

Failure mode is a manner in which a system or process fails to perform its function. Some examples of failure modes are, i) premature operation, ii) failure to
function at its prescribed time, iii) failure to shut down the system or stop the process at the right time, iv) failure to perform its function, v) degraded capability.

CTQs – abbreviated for critical to quality, are characteristics of a product or process whose performance standards must be met in order to satisfy the customer. They are essential as they align the design of any system with the customer requirements. The attributes/components in our systems design function as CTQ for our system. Thus, considering CTQ as attributes for the healthcare delivery system will make sure that the process contains all the requirements to be of high quality and functions efficiently. The detailed description of CTQ at the subsystem level for health care delivery process is explained below.

**System for pre-diagnosis**

In the patient’s point of view, the pre-diagnosis system comprises of all activities right from the time the patient calls for an appointment, and continues until he/she gets a diagnosis. In order to make the diagnosis, the physician requires the initial assessment from the staffs, lab works and other supportive services. Figure 4.1.9 illustrates the proposed pre-diagnosis system.

The patient arrives at the hospital through the emergency services. It could be through an ambulance, a walk-in or a transfer from another facility. At the ER, the patient is first checked in by the registrar to create a patient ID, in order to keep track of patients’ records. Next the patient is triaged by the nurse based on the chief complaint present during registration. The nurse performs initial assessment, notes down the complaints
along with other findings and finally marks the severity of the patient based on their assessment. The patients requiring immediate attention, considered to be ‘highly severe’ are notified to the physician immediately. The physician does his part of the initial assessment and calls for the supportive services: Labs, x-rays and scans. Based on the combined information from the supportive services, physician’s assessments and patients’ responsiveness, the physician makes the initial diagnosis. It is understood that at this point of time, the physician might have numerous diagnoses, but he must draw it down to make his best diagnosis.

![Pre-diagnosis systems design](image)

Figure 4.1.9 Pre-diagnosis systems design

**Registration**

Registration is the first step in the pre-diagnosis subsystem. It is the process of gathering personal information about a patient, such as health data, demographics, nature of insurance, etc. The patient on arrival at the facility is first registered and given a
tracking number. The patient is kept track of at the facility through this tracking number till the day of his discharge. The figure 4.1.10 below illustrates the materials and people involved in the registration process.

T-sheets (Triage sheets) are the most widely used documentation system in the emergency room. It is a template which helps healthcare providers to chart and solve patients’ problems in a visual way. It contains necessary information to help the physicians make a diagnosis on the patient.

The essential attributes of the registration process which drives the pre-diagnosis system to attain high quality are listed below.

- Faster and accurate capture of demographic information
- Gathering insurance information at registration
- Collection of insurance copay within 30 minutes of registration
• Immediate notification of staff upon registering a patient whose conditions are severe

Among the above mentioned drivers of quality, notifying staff immediately upon registering a severe patient is the only important factor in the patient’s point of view. Since systems engineering is system based, equal importance is given to quality in the organization standpoint. The remaining three attributes mentioned above are not specifically designed to satisfy the patient, but are vital to the organization delivering the health care. Insurance and reimbursements are essential as they determine the cost of health care delivery. Therefore, in the proposed healthcare model, failure of any of the mentioned attributes will lead to system failure or poor health care delivery.

The potential failure mode of the registration process, in the healthcare delivery point of view would be:

• Failure to notify patient who requires immediate attention

The above mentioned attribute is considered a failure mode in care delivery system because, lack of immediate attention leads to delayed diagnosis on a patient. Subsequently the antibiotics administration or treatment process is delayed, resulting in poor healthcare delivery.

**Triage**

Triage is the process of determining the priority of patients' treatments based on the severity of their condition and nature of care. This enables the patients to receive
immediate specific attention based on their nature of complaint. Triage is most common in the emergency room of the hospital, as it determines the order and priority of treatment, and higher level destination for the patient, like ICU or other department or division. Figure 4.1.11 illustrates the documents and people involved in the triage process.

The task in triage involves, placing the patient from the emergency room (in case of an ER visit) or admissions to the care specific floor (pulmonary care, ortho-care, cardio care) based on the patient’s initial complaint.

Figure 4.1.11 Relationship tree of Triage process
Essential attributes or CTQs of the triage process would be

- Triage: ranking patients on their condition based on severity
- Use of the correct assessment sheet (T-sheet) based on the patient’s initial complaint
- Immediate notification for nurse assessment

Every attribute mentioned here is considered a critical to quality characteristic because forgetting to place the patient on the right floor will lead to patient negligence, and using incorrect T-sheet leads to lack of specificity in assessment and will delay the correct diagnosis. All attributes are patient centered and are focused on providing quality care to the patient. Potential failure modes during triage will be due to the absence of the quality attributes, which are:

- Patient with severity not given importance
- Staffs not using the right T sheet for assessment based on initial complaint
- Failure to change the T sheet upon misinterpretation

**RN Assessment**

As the name suggest, RN assessment is the stage in pre-diagnosis subsystem (Figure 4.1.12) where the nurse or staff does an initial screening on the patient to capture the vitals, for the physician to make his diagnosis based on the patient’s complaint.
The assessment task involves capturing patient epidemiology and documenting this on a sheet (T-sheet) to conducting preliminary screening test to capture infection spread in the patient.

![RN assessment relationship tree](image)

**Figure 4.1.12. RN assessment relationship tree**

In order to have an efficient RN assessment subsystem, it is essential to provide the staffs with good tools for assessment and documentation procedure. This could be using a highly specific assessment tool or screening procedure to capture every abnormality in the patient. The essential attributes of this stage are listed below.

- RN, completing the information asked in the T sheet
- Possessing a highly specific assessment tool to get information on the chronic illness
- RN being up to date on the screening procedures and capturing information (Skilled staffs and education)
- Screening every patient above 18 years of age to capture the spread of infection
• Documenting the information precisely, in such a way that the key points are highlighted to make it easy for the physician to make his diagnosis

Among the above mentioned attributes for having an efficient RN assessment subsystem,

• RN completing the information on the sheet

• Screening every patient 18 years of age to capture infection spread,

are CTQ drivers for having a good pre-diagnosis subsystem. This information, in patient point of view, is important to get early diagnosis and faster treatment. Patients above 18 years of age require specific screening to identify the infection spread when compared to those below 18 years of age. The screening process includes capturing certain criteria (lactic acid levels, CO₂ perspiration levels, blood culture results, etc) which would imply the presence of an infection for those above 18 years of age.

Means of failure modes in the RN assessment could happen when there is a lack of information capture and failure to capture the right information. Incomplete assessment sheet leads results in lack of information for diagnosis. Sometimes, completing the assessment sheet also triggers the next step in the care delivery process i.e. RN staffs could administer certain types of drugs based on the information from evidenced based care to the patients before having a physician consult. This will enable them to receive critical care immediately to improve their condition. This is one of the important function of RN assessment. The potential failure modes here are:

• Failure to capture the critical information

• Failure to document the findings or observation to notify the physicians
- Not screening patients above 18 years of age to identify the infection spread
- Failure to trigger the next step right away upon highly sick patients.

This completes the pre-diagnosis subsystem in health care delivery. The end product of this phase is the T-sheet document from the RN assessment. This information will be the input for the diagnosis subsystem which mainly involves the functions and actions of physicians to make comments on illness found in the patient.

**System for Diagnosis**

The diagnosis subsystem in the system for healthcare delivery consists of all the activities that help the ER physician or the attending physician to make their diagnosis on the patient. The initial impression the physician had on the patient upon arrival, is confirmed at this stage after review of certain results. Results from support services like pathology, radiology and caths help the physician to make his diagnosis. Figure 4.1.13 below is a graphical representation of the diagnosis system.
It is important to do an early diagnosis after assessment mainly because (i) sometimes the symptoms might reverse and improve treatment, (ii) it will improve patient satisfaction, (iii) It is clinically proven that diagnoses is more accurate when done early in the process, (iv) early diagnosis decreases mortality, and (v) the patient could be discharged from the facility much sooner, decreasing the length of stay. As a result, it is essential to present the right information and tools to the physician to ease his work on early diagnosis. Lab results and analysis should be done right immediately and process the results faster to help the physicians on the diagnostic process.

Figure 4.1.13. Diagnosis subsystem design
Once the physician gets the required information and makes their diagnosis, the subsequent step will be to administer preliminary antibiotics or perform interventions like surgery depending on the capture of the complaint. The output of the diagnosis subsystem is having a patient with highly specific diagnosis void of any complications.

**Physician Assessment**

From a medical standpoint, physician assessment is the stage in the diagnosis subsystem where the physician, acknowledges the patients’ experience and assesses the care for illness. It involves listening to the patient’s complaint repeatedly and testing a hypothesis mentally. The physician conducts tests and screens to validate his findings on the patient and confirms his initial impression on the patient’s condition.

In order to make a preliminary hypothesis, the physician in the assessment phase gathers as much information as possible from the patient. The physician gets additional information – history of illness, current medications, recent surgery, allergies, etc.- from the nurses assessments which took in place in the pre-diagnosis phase. With all the required information in hand, the physician orders tests from supportive services like pathology, radiology, etc. The results produced by supportive services provide physicians, information on the patient at the component level. Hence, through medical orders, the physicians validate their observations. The documents obtained as a result at this phase is given in Figure 4.1.14.
The outcomes of the physician assessment phase are:

- An initial diagnosis in the physician’s mind (which is not produced on any paper, but sometimes documented as initial impression on the patient)
- An order sheet from the physician ordering lab works / scans / caths to validate his/her observations.

The essential attributes in the initial physician assessment stage of the diagnosis subsystem will include the following:

- Primarily, seeing the patient after RN assessment immediately, or within 10 -15 minutes.
- Making an initial hypothesis faster
- Early placement of orders to make faster diagnosis
- Sometimes, administering antibiotics before placing orders. 

Administering antibiotics before placing lab order is an arguable attribute currently. Antibiotics will nullify the illness and make the patient’s condition better upon administration. But, if provided up front, the time taken to identify the source of illness might be delayed.

Among the discussed attributes, some are significantly important in the patient point of view and could be termed as a critical to quality for an ideal health care delivery system. The CTQs are:

- Immediate evaluation of patients with severe conditions – as mentioned above, delay in seeing the patients will increase their chance of death due to improper diagnosis

- Making a clear evaluation – being as specific as possible in the findings and initial clinical impression. This will pave the way for faster healthcare delivery.

- Placing the orders for diagnosis faster

- Administering antibiotics before blood culture analysis for highly sick patients

- Documenting the findings and evaluation clearly

- Establishing a good relationship with the patients to minimize their fear, make them feel comfortable

The potential failure modes on the physician assessment includes:

- Delay in seeing the patient (making patient wait is a huge quality inhibitor, as it results in patient dissatisfaction)
- Unclear evaluation – skipping steps and jumping to conclusions are possible in case of similar symptoms
- Improper documentation will decrease the clarity in physician communication later on
- Failure to administer antibiotics as fast as possible for highly sick patients
- Failure to place the right orders for diagnosis

**Radiology/pathology/other services**

Pathology, radiology or other supportive services lie at the heart of health care services provided to patients and the community. They underpin the quality and cost effectiveness of health care. The supportive services confirm the diagnosis for valid inclusion of the patient. Among all, the pathological services in hospitals are widely used to make a diagnosis on a patient.

Supportive services provide diagnostic and consultative aide to physicians and patients in hospitals. This is done through the scientific analysis of specimens of blood, fluids, tissue, and visual analysis of x-rays and scans. Interpreting and reporting these results assists physicians to make the final diagnosis.

The tasks involved in this phase begin with a request from a physician or clinician upon evaluating the patient. Upon receiving the order, the phlebotomists report to the floor or ER to withdraw a sample from the patient to run the test. The phlebotomist is an integral member of the medical laboratory team whose primary function is the collection
of blood samples from patients by venipuncture or other micro techniques. The phlebotomist facilitates the collection and transportation of laboratory specimens, and is often the patient’s only contact with the medical laboratory. The need to assure quality and patient safety mandates strict professional behavior and standards of practice for Phlebotomists. The sample is now sent to the laboratory where equipment, instruments and trained staff process, analyze, interpret and report the results of the test. The report is provided back to the floor or ER through to the requesting physician though EMR (Electronic Medical Record) or fax, to help decisions about the patient’s diagnosis or treatment. Figure 4.1.15 illustrates the process, people and materials involved in the involvement of supportive services in the diagnosis subsystem.

![Figure 4.1.15. Relationship tree illustrating the materials and people involved in diagnosis subsystem](image-url)
The attributes of the supportive services in healthcare delivery are

- Prompt response to the orders
- Presenting the results faster, especially to those who are highly sick

The above mentioned attributes are among the CTQs of involvement of supportive services. In detail, their CTQs include:

- Quick response to the physicians orders
- Immediate processing of samples and producing results within 45 minutes
- Having clarity in results generated

Immediate response to the physician’s orders is considered to be a CTQ because faster analysis of specimen samples will result in faster diagnosis and treatment. AHRQ are working on standardizing the response time for lab results. The results produced from specimen analysis should be specific and must possess clarity in the result.

The potential failure modes of this subsystem would be:

- Delayed response to physician’s orders
- Having a turnaround time of greater than 45 minutes
- Failure to process results to those who are highly sick faster
- Unclear documentation of results
- Presenting the results to the correct patient at the right time and place
Diagnosis

The diagnostic process is a process that begins with the patient’s illness history and terminates in a result that can be postulated. In the medical dictionary, the diagnostic process is the act of determining a patient's health status and evaluating the factors influencing it, and diagnosis is the act or process of identifying or determining the nature and cause of a disease or injury through evaluation of patient history, examination, and review of laboratory data. The outcome of the process is regarded as important for effective treatment, by both the patient and the doctor.

The diagnosis phase has a little overlap with the physician’s evaluation. The results obtained from the lab analysis of the orders, mentioned in the physician evaluation phase are the base line for the diagnosis phase. Apart from analysis of cultures and obtaining results, the diagnosis steps involves the following three steps

- Neurological evaluation – The physician evaluates the patient to check for brain disorder
- Psychiatric test – This test is done on the patient to rule out depression, and
- Psychological test – Patient with the ailment is required to take a psychological test to test for cognitive functions

An early diagnosis allows the physician to implement a treatment plan and a follow up plan to track the patient’s response to the physician’s treatment. With the information on diagnosis, the patient now will be able to understand why they develop such symptoms. Early diagnosis allows the person to be involved in decisions about their
treatment and follow up care. It also helps the family members to understand the change in the patient’s behavior. This aspect of involvement of the patient in the decision making process and, keeping the patient and their family members well informed about the care, is essential in an ideal health care delivery system. This is therefore meeting the needs of the patient, as mentioned in the article building a better health care system.

The essential characteristics of the diagnosis system include:

- Making a complications-free diagnosis. Complications are secondary diseases that arise because of the prevailing or existing disease
- Performing an early diagnosis. Section 4.1.3 describes the benefits of early diagnosis in healthcare delivery
- Documenting each and every observation on a patient. This requirement will help the physicians to categorize abnormalities which could arise later on
- Providing antibiotics with no delay soon after diagnosis to improve the condition of the patient

The attributes which are required in the diagnosis phase to provide an ideal health care delivery system in the patient point of view are:

- Early diagnosis
- Keeping the patients well informed about the diagnosis
- Administering antibiotics as soon as diagnosis is made, enabling the physicians to begin the treatment process faster
- Frequently monitoring patients’ vitals to capture abnormalities
Failure to monitor the patients after diagnosis is one of the most common problems in the United States (AHRQ 2001). Monitoring patients often will help physicians catch sudden abnormalities, and complications which arise due to the care provided. Potential failure modes of the diagnosis subsystem are

- Failure to make an early diagnosis
- Improper communication between the physicians and staff, leading to improper diagnosis
- Unclear diagnosis—lack of specificity in the diagnosis made on the patient by the physicians
- Failure to monitor the patients frequently to capture abnormalities
- Not keeping the patients well informed about the diagnosis made and the nature of care provided.

**Systems for treatment**

Treatment is defined as the process of providing medical care for an illness or injury. It also involves the application of medicine, surgery, therapy, etc., depending on the nature and severity of the illness.

A patient is cured only upon treatment. The treatment subsystem has activities that will help the patient become healthy during his course of stay. This includes timely antibiotics, frequent monitoring to capture the vitals, etc. It is necessary to have simple process flow. Complex structures in the process flow will result in unwanted complications. The main motive in the treatment subsystem is to have a patient void of
any complications and free him from his diagnosis. Figure 4.1.16 below illustrates the characteristics of a good treatment subsystem.

Figure 4.1.16 Attributes for a good treatment system

The main tasks involved in the treatment system, begins with the notification from the attending physician to the admitting physician. The sequential list of activities in the treatment process are illustrated below in Figure 4.1.17
Admitting physician notification

The beginning of the treatment phase actually starts with the ER physician or attending physician. Administering drugs to the patient before admitting the patient is the first step in the treatment phase. Once the drugs are administered to the patient, then depending upon the severity and type of illness, the attending physician seeks the consent of the admitting physician and shares the patient’s information.

The decision for admission is decided upon the discussions from both the attending and admitting physician. Subsequently, the staff notifies the ward management to check rooms for availability and hence admits the patient to the floor.

The tasks taking place in this stage are listed below:

(i) Attending physician notifying the admitting physician
(ii) RN notifies the floor /ICU and checks for availability
(iii) Attending physician hand offs the documentation-patient evolution and evaluation to the admitting physician
The attributes which are critical in delivering good care to the patient at this phase are:

- Proper communication between the two physicians involved in the treatment phase – attending physician and admitting physician
- RN triggering next step- notifying the room and floor for admission
- Transferring the patient evolution and evaluation information from the attending physician to the admitting physician

A breakdown in any of the above mentioned characteristics will eventually be a failure mode for the treatment process. The two failure modes per the discussion are,

- Breakdown in the communication between the physicians
- Failure to seek the admitting physician consent

**Patient’s arrival to the room / ICU**

Once the patient is brought to the ICU/ floor, similar tasks as mentioned in the pre-diagnosis and diagnosis subsystem take place. These include activities such as

- Preparing progress notes charts and new documentation sheet for the patient, and
- Placing lab orders

The treatment phase should not have any complex process flow, which means there should not be any secondary interventions without seeking the attending physician’s consent. Moreover, the process calls for a ‘down-top’ sequential treatment approach.
Missing steps and moving ahead to before clarification of results will lead to unethical treatment processes. Attributes to this phase would be

- Placing initial orders immediately without delay to tighten the treatment phase
- Having a structured flow in patient assessment
- Keeping the physician well informed about the orders placed
- Keeping the patients well informed about the nature of care provided

The potential failure modes at this level are given below

- Delay in placing orders
- Having a process with much variation in time on patient assessment
- Lack of uniformity among the staffs in patient assessments
- Delay in informing the physician about the orders placed
- Delay in drawing blood cultures from the patient

**Drugs/therapy/care**

This phase of the treatment subsystem involves necessary surgical procedures, interventions, therapies and medications provided to the patient to improve their condition. The necessary attributes involved in this phase are a process for frequent monitoring, prompt response from the pharmacy and timely administration of drugs.

The attributes of this phase of treatment would be:

- Placing prescription orders to pharmacy immediately, right after physician consult
• Immediate administration of drugs upon receiving drugs from the pharmacy
• Staffs being well educated on the drugs administration of drugs, should possess enough experience to prioritize the order of administration
• Performing a successful intervention, which doesn’t leads to any spread in infection

The attributes, which turned out to be critical to quality for healthcare delivery system are essential to satisfy the needs of the patient, family members and even physicians. They are

• Performing a successful intervention – Hospital acquired infections are turning out to be occurring often in the society (NCQA 2004). Extra care must be taken to ensure such conditions do not tag along on performing interventions.

• Immediate administration of drugs to the patients

The failure modes in the this therapeutic phase are:

• Intervention resulting in a infection
• Delay in placing orders to pharmacy
• Medications being sent to the wrong patient – this happens when the staffs do not pay attention to the prescription number on the patient. The presence of numerous numbers on the patient’s tag are confusing and it requires extra attention and consciousness before administering drugs
Frequent vitals monitoring

The final phase in the treatment subsystem verifies and checks for improvement in the patient condition.

Staff capture essential information at least every 60 minutes to check for any signs of improvement from the patient. This phase is essential in treatment system as it keeps in track of:

- Vitals of the patient
- Captures abnormality and other signs of illness in the patient
- Gives information needed to discharge the patient from the facility, as a result of a successful healthcare delivery

These attributes are even essential from the healthcare delivery point of view. Failure to monitor the patients, failure to capture the information and failure to notify the physicians immediately are the potential failure modes to this phase and are likely to result in poor healthcare delivery system.

System for post-treatment

Post treatment activities are important as they are placed to ensure that the patient does not return back to the hospital immediately upon discharge. They make sure that the treatment provided at the facility, successfully cured the patient, and also makes sure that
the patient is free from any major complications. Importantly they are responsible for the prevention of re-occurrence of the disease.

Tasks involved in the post treatment phase include:

(i) Frequent and final patient monitoring
(ii) Discharge planning
(iii) Educating patient on “to dos” after discharge

AHRQ defines post treatment as a period or set of activities that happen after treatment which are essential for completing the care provided at the facility. This proves its importance. A good post treatment system will have an efficient documentation system which could give information on the patient’s evaluation and evolution. The communication between admitting and attending physicians is well documented as well.

Discharge planning prepares the patient to leave the hospital after their care, and it begins soon after treatment or at least several days before the patient is fit for discharge. The time available to a healthcare team to adequately prepare patients for discharge has virtually evaporated with decreasing lengths of hospital stay. After series of improvement and interventions, the hospital adopted a discharge team at the facility, whose primary responsibility is to discharge the patients from the facility with correct actions and education. Their functions include:

- Implementing a complete, timely, and accurate discharge planning evaluation process, including identification of high risk criteria
- Identifying the patient’s bio psychosocial needs
• Arranging necessary post-hospital services and care
• Educating the patient, family/caregivers, and community providers about the patient’s post-hospital care plans.

Failure modes on the post treatment discharge care includes

• Ambiguity over who owns care of patient after discharge follow up appointment
• Patients having poor access to follow up care
• Inefficient patient education

4.1.5. Proposed model - Proper systems design improves health care quality

Overall system design is a compilation of all the four subsystems as discussed above. Proper triage with efficient assessment and timely diagnosis, with help and support from supportive services will improve the diagnostic care. Similarly, frequent monitoring, physician promptness, and early antibiotics will enhance and improve the treatment care. All this calls for an efficient system to communicate and provide information with clarity and within a specified time. This paves way for a good information handling system, i.e. documentation system. A documented system eases the physicians to study the patients’ progress in the hospital. This improves the quality of care. The Figure.4.1.18 below represents the overall ideal system for health care delivery in a hospital.
Figure 4.1.18. Proposed system for Ideal Healthcare delivery
Per earlier discussion, the proposed system for ideal health care delivery is purely designed based on the drivers from the critical to quality for a healthcare delivery system. As a result, the patient will survive on discharge with a satisfactory outcome. In order to prove the proposed model’s applicability, it is essential to have the model tested on a healthcare platform. The test is a hypothetical test to test for dependency of occurrence of failure modes on healthcare delivery. Hospitals with the proposed healthcare delivery system will yield satisfactory results on the patient outcomes. The results from the statistical tests such as chi-square test for dependency, proportions test, etc provide information, as the failure modes are dependent on the healthcare delivery. This would indicate that the, unfavorable patient outcomes are primarily due to flaw in the system design.
4.2 SYSTEMS MODEL FOR INFECTION CONTROL

The model developed above is a robust model for infection control in healthcare delivery. The model is developed with an intention to capture the infection spread in the human body at various stages in the healthcare delivery system. Frequent monitoring of patients’ vital, timely antibiotic administration, and efficient screening for infection could highly prevent the spread of infection in a patient.

This model will be validated at a local hospital in Nebraska, to understand the application of a systems approach in a hospital for improving health care delivery. The model will test for dependency on the occurrence of failure modes on the patient outcomes. The hospital where the model will be tested is a multidimensional facility with a pre-established system for infection control. The existing system’s extremes will be tested through this proposed system in section 5.3 in the next chapter. This model is exclusive for infection control and to find the significance of failure modes occurrence in the health care delivery system.
CHAPTER 5: SYSTEMS DESIGN VALIDATION AND DATA ANALYSIS

5.1 ABOUT THE HOSPITAL

The hospital established in Nebraska in 1887, is a non-profit Catholic health initiative being highly patient centered. It is a 190 bed hospital, where 24,236 patients visited the ER alone last year (source: usnews.com). The hospital had 2134 admissions, and on a scale of 10, it had an overall patient satisfaction factor of 7; care outcome - 7.9; and communication -7 (source: unbiased data, besthospitals.com). On average the hospital has a 12.5% mortality rate and 18.2% readmission rate due to infection alone. The hospital creates wellness, cures illness and provides comfort and compassion utilizing best practices in medicine (Sfmc.gi.org) The hospital’s core values of reverence, integrity, compassion and excellence, define the organization and serve as the guiding principles from which all activities, decisions and behaviors follow.
5.2 SEPSIS

Sepsis is the tenth leading cause of death in the United States. With an estimated 750,000 cases annually and a nearly 40 percent mortality rate, severe sepsis is also one of the most common causes, and possibly the number one cause, of death in hospital critical care units. In addition to its high mortality rate, severe sepsis also bears a huge price tag, with a national estimate at $16.7 billion annually (STOP Sepsis campaign, 2010).

Sepsis is a clinical condition which arises due to the body’s systematic inflammatory response (SIRS) to an infection. Severe sepsis is the condition when sepsis leads to organ system dysfunction and would result in patient’s death when not treated within 24 hours. Having an effective infection control would decrease the transition of sepsis to severe sepsis in a patient. Therefore, sever sepsis or mortality due to sepsis could occur when there is improper infection control.
5.3 EXISTING SYSTEM FOR INFECTION CONTROL IN THE HOSPITAL

The hospital where the proposed healthcare delivery model is about to be validated is known for its quality and performance improvement initiatives. The existing system for infection control in place at the hospital begins from the patient’s visit to the ER and follows until discharge. The activities involved in the existing system for infection control are described under its respective phase below.

Pre-diagnosis

In the observed system for infection control, illustrated in Figure 5.3.1 the patient on arrival at the ER (Emergency Room), is registered by the registrar, and then triaged by the RNs or staffs in the emergency room based on their chief complaint. The RN screens the patient for possible infection, while also documents her observations to notify the physician for diagnosis.

The existing system in process lacks an efficient screening process for infection identification and control. Screening tool is a very powerful tool which is designed specifically to capture infection through the SIRS criterion in a patient. The patient is screened by monitoring patient vitals which could have changed due to the presence of infection. Screening tool were initially developed at various hospitals throughout the world when Sepsis became a factor hindering healthcare quality. Effective use of screening tools from infection control is clinically proven to decrease the spread of infection in a patient. There should be a secondary verification to check for completion of
the screening process. Another important attribute missing here would be to notify the physicians immediately upon arrival of a sick patient. The importance of this attribute is described in section 4.1.4

**Diagnosis**

At the diagnosis phase, the process begins with the arrival of the ER physician to the patient's room and continues until the physician makes a comment about the patient’s chief complaint. The physician examines the patient and also refers to the documents prepared by the clinical staffs to form a hypothesis about the illness of the patient. To validate his impression as diagnosis of a patient, the physician places orders for pathological analysis of cultures, scans and other supportive services. With the help of these results the physician makes the initial diagnosis on the patient. Sometimes antibiotics are given to the patient at this level based on their severity.

The attributes driving an effective diagnosis phase are procedures in place to make a faster diagnosis. Once the orders are placed to the supportive services, the standardized lab turnaround time to present the results to the physicians is 45 minutes. Clinical staffs must continuously monitor the conditions of patients and notify their observations to the physicians.

**Treatment**

The treatment system sometimes starts at the ER. In general, it is the phase which trails the diagnosis phase, and begins right at the time of initial administration of antibiotics. After the patient is being taken to the floor/ICU based on his severity from the
ER, they are tested frequently to capture abnormalities in the blood cultures. Abnormalities in blood cultures indicate the presence of infection in the patient. Meanwhile, interventions such as surgery and other procedures are done in the treatment phase to make the patient’s condition better. The attending physicians and the admitting physicians communicate with each other to prepare a plan to improve the condition of the patient. Patients are monitored to capture complications which might arise due to the presence of infection or an intervention that was performed earlier. Finally after thorough treatment, the patient is prepared for discharge.

**Post treatment**

The patient can only be discharged after seeking both the attending and admitting physicians’ consent. In the hospital, there is a need for patient education on things to do and not to do after successful healthcare delivery. There is a discharge team whose responsibility is to educate the patient and family members on activities, follow up visits, food habits etc. Physicians and clinical staffs take up these responsibilities in the absence of such discharge team. This should be done even when the patients are being transferred to a higher care facility for better treatment.
Figure 5.3.1. Observed infection control system in the hospital
5.4 DATA

5.4.1 Data summary

Table 5.4.1 gives the summary of data collected at random from July 2012 – June 2013 from the hospital. Information on 83 septic patients and 83 non-septic patients were analyzed to test for the flaw in the system for infection control in healthcare delivery.

<table>
<thead>
<tr>
<th>Type</th>
<th>Number of patients</th>
<th>Patients survived to discharge</th>
</tr>
</thead>
<tbody>
<tr>
<td>Septic patients</td>
<td>48</td>
<td>42</td>
</tr>
<tr>
<td>Severe septic patients</td>
<td>35</td>
<td>28</td>
</tr>
<tr>
<td>Non septic patients</td>
<td>83</td>
<td>82</td>
</tr>
<tr>
<td>Total patients</td>
<td>166</td>
<td>152</td>
</tr>
</tbody>
</table>

Table 5.4.1 Data summary of 166 patients collected from July 2012 – June 2013

The summary shows that among 166 randomly selected patients 152 patients survived to discharge and 13 patients died due to the result of infection or organ system dysfunction. For analysis purposes, a total of 83 patients from the sepsis list were randomly selected. The split of the data for septic patients is given below in Table 5.4.2.
<table>
<thead>
<tr>
<th>Type</th>
<th>Number of patients</th>
<th>Patients survived to discharge</th>
</tr>
</thead>
<tbody>
<tr>
<td>Septic patients</td>
<td>48</td>
<td>42</td>
</tr>
<tr>
<td>Severe septic patients</td>
<td>35</td>
<td>28</td>
</tr>
<tr>
<td><strong>Total patients</strong></td>
<td><strong>83</strong></td>
<td><strong>70</strong></td>
</tr>
</tbody>
</table>

Table 5.4.2. Data summary for 83 infected patients diagnosed as septic

The difference observed between the proposed system and existing system for infection control is that the existing system in place at the hospital lacks few attributes/elements which could drive the subsystem for better infection control.

5.4.2. Potential failure modes on the system for infection control

In the chapter 04, the ideal system for health care delivery was designed and its possible failure modes, obtained from practitioners and clinical staff were discussed. The health care delivery system was divided into four main subsystems (i) system for pre-diagnosis (ii) system for diagnosis (iii) system for treatment, and (iv) post treatment system.

Based on our discussion of the difference between the proposed model and existing model for infection control, it is evident that the failure modes are a result of the absence of the driving elements on the subsystem. Further, the infection spread in a patient is mainly because of flaws in system design. The tables in this section of the chapter identify the presence of the failure modes in the existing system in the hospital. A total of 166 patients were checked for the identified failure modes at the local hospital.
In the hospital’s fiscal year 2012, i.e., July 2012- June 2013, the hospital had about 461 patients diagnosed with sepsis, out of which 334 patients were diagnosed with sepsis and the remaining with severe sepsis. In order to validate or understand the impact of the systems approach on health care delivery, it should hold good for those patients with and without any infection. As a result, another set of 83 patients without any septic infection were randomly selected from the same fiscal year.

Table 5.4.3 summarizes the occurrences of failure modes in the pre-diagnosis phase of the existing infection control system in the hospital. The horizontal rows describe the four cases: (i) patients with infection who survived to discharge; (ii) patients with infection who did not survive to discharge; (iii) patients without infection who survived to discharge, and (iv) patients without infection who did not survive to discharge. The columns in the table show the possible failure modes in the pre-diagnosis phase.

Table 5.4.4 shows the failure modes occurrence in the diagnosis phase, against the four cases described above. Table 5.4.5 and Table 5.4.6 illustrate the failure modes occurrences against the four cases in the treatment and post-treatment sub systems respectively.
<table>
<thead>
<tr>
<th>Type</th>
<th>Registration</th>
<th>Triage</th>
<th>RN assessment</th>
<th>RN assessment</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td>Failure to notify patient who requires immediate attention</td>
<td>Failure to notify patient who requires immediate attention</td>
</tr>
<tr>
<td>Patients with infection survived</td>
<td>69/83</td>
<td>16</td>
<td>8</td>
<td>20</td>
</tr>
<tr>
<td>Patients with infection didn't survive</td>
<td>14/83</td>
<td>4</td>
<td>2</td>
<td>3</td>
</tr>
<tr>
<td>Patients without infection survived</td>
<td>82/83</td>
<td>7</td>
<td>7</td>
<td>33</td>
</tr>
<tr>
<td>Patients without infection didn't survive</td>
<td>1/83</td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
</tbody>
</table>

Table 5.4.3. Number of patients with failure modes in the pre-diagnosis system
<table>
<thead>
<tr>
<th>Type</th>
<th>total number of patients</th>
<th>Physician assessment</th>
<th>Radiology/pathology/services</th>
<th>Diagnosis</th>
</tr>
</thead>
<tbody>
<tr>
<td>Patients with infection survived</td>
<td>69.83</td>
<td>10 0 8 49 1</td>
<td>12 13 12 0 0</td>
<td>5 0 6 24 0</td>
</tr>
<tr>
<td>Patients with infection didn’t survive</td>
<td>14.83</td>
<td>2 0 0 0 0</td>
<td>4 3 0 0 0</td>
<td>0 0 2 4 0</td>
</tr>
<tr>
<td>Patients without infection survived</td>
<td>82.83</td>
<td>19 5 3 14 0</td>
<td>14 18 18 1 0</td>
<td>6 1 6 1 1</td>
</tr>
<tr>
<td>Patients without infection didn’t survive</td>
<td>1.83</td>
<td>0 0 0 0 0</td>
<td>0 0 0 0 0</td>
<td>0 0 1 0 0</td>
</tr>
</tbody>
</table>

Table 5.4.4 Number of patients with failure modes in the diagnosis system
<table>
<thead>
<tr>
<th>Type</th>
<th>Admitting physician</th>
<th>Patients arrival to the room/ICU</th>
<th>Drugs/therapy/care</th>
<th>Frequent vitals monitoring</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>total number of</td>
<td>Breakdown in</td>
<td>Failure to</td>
<td>Intervention</td>
</tr>
<tr>
<td></td>
<td>patients</td>
<td>communication between physicians</td>
<td>seek admitting</td>
<td>resulting in</td>
</tr>
<tr>
<td>Patients with infection</td>
<td>69/83</td>
<td>5</td>
<td>physician consent</td>
<td>an infection</td>
</tr>
<tr>
<td>survived</td>
<td></td>
<td></td>
<td>Delay in placing</td>
<td>Delay in placing</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>orders</td>
<td>orders to pharmacy</td>
</tr>
<tr>
<td>Patients with infection</td>
<td>14/83</td>
<td>2</td>
<td>variation in time</td>
<td>Delay in drawing</td>
</tr>
<tr>
<td>didn't survive</td>
<td></td>
<td></td>
<td>on patient</td>
<td>blood cultures from the</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>assessment</td>
<td>patient</td>
</tr>
<tr>
<td>Patients without infection</td>
<td>82/83</td>
<td>2</td>
<td>Lack of uniformity</td>
<td>Intervention</td>
</tr>
<tr>
<td>- survived</td>
<td></td>
<td></td>
<td>among the staff</td>
<td>resulting in</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>in patient</td>
<td>an infection</td>
</tr>
<tr>
<td>Patients without infection</td>
<td>1/83</td>
<td>0</td>
<td>Delay in informing</td>
<td>Delay in placing</td>
</tr>
<tr>
<td>- didn't survive</td>
<td></td>
<td></td>
<td>the physician about</td>
<td>orders to pharmacy</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>orders placed</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Delay in drawing</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>blood cultures</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>from the patient</td>
<td></td>
</tr>
</tbody>
</table>

Table 5.4.5 Number of patients with failure modes in the treatment system
Among 83 non septic patients, it is observed that only one patient who did not survive to discharge from the hospital. For calculation purpose, this one patient who did not survive to discharge will be neglected. This is because, only one non-infected patient did not survive to discharge. It is not a significant number when compared to other patient samples from the respective population. Analyzing the data will result in identifying the significance of the systems approach in the health care delivery. It will be easy to find the system with most recurring failure modes.

Table 5.4.6 Number of patients with failure modes in the post-treatment system
5.5 DATA ANALYSIS

5.5.1 Pictorial representation of the data and analysis

A bar chart is a tool to analyze a discrete set of data. 166 patients used in our analysis are discrete and are within a time frame of fiscal year 2012. The frequency of occurrence of these failure modes is investigated in this analysis. This shows the interdependency of the systems approach and infection control for the patient outcome in health care delivery. The vertical axis in the prescribed bar graphs is the frequency of failure modes and the horizontal axis represents the respective failure mode. A set of three cases is used in our analysis, (i) patients with infection who survived to discharge, (ii) patients with infection who did not survive to discharge, and (iii) patients without infection who survived to discharge.

The entire system for healthcare delivery

Figure 5.5.1 illustrates the occurrence of failure modes in the entire system for infection control in a hospital. The following inferences could be drawn from the pictorial representation of the data.

i. In this system of care delivery for infection control at the hospital, the pre-diagnosis subsystem has the highest number of recurring failure modes. This suggests that the pre-diagnosis subsystem has an effect on the patient outcome.

ii. The average occurrence of failure modes is high in two cases: patients with infection survived to discharge and patients without infection who survived to discharge.
iii. The occurrence of failure modes for patients with infection but did not survive to discharge is lower than the other two cases.

iv. Even though the highest peak was observed in the treatment subsystem, its average is almost the same as the average of occurrence of failure modes in the pre-diagnosis subsystem. The failure modes in the post-treatment subsystem are significantly lower in when compared to other subsystems.
Figure 5.5.1 Occurrence of failure modes in the system for infection control
Analysis of the proportional data

The 166 patients used in our analysis as discussed in Section 5.4.1, include 83 patients infected with sepsis and another 83 patients free from infection. The occurrence of failure modes discussed in this section takes into account of the failure modes occurring in all the three cases: patients with the infection who survived; patients with the infection who did not survive; and patients without infection who survived to discharge, in the entire subsystem. To study the rate of occurrence of failure mode accurately, it is important to make the data proportionate. This will provide information on proportion of patients with the occurrence of one of the failure mode across each subsystem. This is because, the number of failure modes across each system is not the same. This proportional analysis will help us to analyze the occurrence of failure mode with respect to the three cases in the subsystem level.
System for pre-diagnosis

<table>
<thead>
<tr>
<th>Type</th>
<th>Registration</th>
<th>Triage</th>
<th>RN assessment</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>Patients with infection - survived</td>
<td>69/83</td>
<td>0.232</td>
<td>0.116</td>
<td>1.507</td>
</tr>
<tr>
<td></td>
<td>14/83</td>
<td>0.286</td>
<td>0.143</td>
<td>1.429</td>
</tr>
<tr>
<td>Patients without infection - survived</td>
<td>82/83</td>
<td>0.085</td>
<td>0.085</td>
<td>1.488</td>
</tr>
<tr>
<td>Overall patients</td>
<td>166 patients</td>
<td>0.603</td>
<td>0.344</td>
<td>4.424</td>
</tr>
</tbody>
</table>

Table 5.5.1 Proportion data for failure modes in pre-diagnosis subsystem

Table 5.5.1 is obtained by calculating the data proportions with their respective sample size. Figure 5.5.2 below illustrates the respective proportional bar graph.
Figure 5.5.2. Occurrence of failure modes in the pre-diagnosis system proportional chart
Observations:

i. The use of triage sheets has a significant difference between the patients with infection and the patients without infection. This is mainly because of the absence of the Triage sheet on the floor. Patients admitted directly to the hospital without passing through the ER does not go through a triage process, and are directly brought to the floor. It is important to use a T-sheet as it identifies vital information which will ease the diagnostic process.

ii. The screening tool is used to identify the infection spread in patients. The data shows that the occurrence of failure mode ‘screening patients above 18 years of age’ for identifying infection control is 61 occurrences. This implies that out of 166 patients, only 100 patients were screened for infection. Without screening, identifying infection in a patient is a complex process and would result in delay of diagnosis.

iii. It is observed that the proportion of the patients not being screened for infection is very high for all patients seeking care in a hospital. As a result, there is a delay in recognizing the infection, or the patient is not recognized with any infection.

iv. Notifying the staff immediately upon arrival of a sick patient is much needed to have an early diagnosis. The data indicate that the occurrence of this failure mode is almost the same as the average number of occurrences of the failure mode, which is 31 times. Failure to notify a sick patient who requires immediate attention is higher for those infected with sepsis when compared to non-infected patients.
v. Capturing critical information by the RNs and staffs are almost the same with all kinds of patients.

vi. The system for documenting the findings and observation is functioning at every level.

System for diagnosis

The system for diagnosis involves processes that help in making the initial diagnosis on the patient. With (i) clear physician evaluation; (ii) timely recognition of diseases, (iii) timely order placement to the supportive services; and (iv) getting the results back on time with clear documentation, this makes the system for treatment completely functional. Failure modes are primarily time based in the diagnosis subsystem. The proportion data and bar graphs are given in Table.5.5.2 and Figure.5.5.3.
Figure 5.5.3 Occurrence of failure modes in the diagnosis system – proportion chart
<table>
<thead>
<tr>
<th>Type</th>
<th>Physician assessment</th>
<th>Radiology/pathology/services</th>
<th>Diagnosis</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>total number of patients</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Patients with infection - survived</td>
<td>69/83</td>
<td>0.145</td>
<td>0.000</td>
</tr>
<tr>
<td>Patients with infection - didn’t survive</td>
<td>14/83</td>
<td>0.143</td>
<td>0.000</td>
</tr>
<tr>
<td>Patients without infection -</td>
<td>82/83</td>
<td>0.232</td>
<td>0.061</td>
</tr>
<tr>
<td>Overall patients</td>
<td>165 patients</td>
<td>0.519</td>
<td>0.061</td>
</tr>
</tbody>
</table>

Table 5.5.2 proportion data for failure modes in diagnosis subsystem
Observations:

i. Failure to administer the antibiotics to the patient immediately upon recognition of the infection is the most frequently occurring failure mode in this phase. This is an important attribute in this subsystem because, if administered faster, the antibiotics are designed to suppress the pathogens before spreading in the body. The data indicates that almost 72 patients had this failure mode occurring in them, among which 9 patients could not survive to discharge.

ii. Antibiotics are administered significantly faster to those without the infection when compared to the former. This is proved because; the survival rate for the patients without infection is much greater than the patients with infection.

iii. Supportive services like radiology, pathology and caths have failed to respond immediately upon receiving an order. Their turn-around time is observed to be greater than 45 minutes. They are functioning at a constant rate, with the same number of failure modes in all three cases.

iv. The data shows that almost 29 patients were left without frequent monitoring. This process is done to capture immediate abnormalities or improvements in the care delivery process. In infection control, the surviving sepsis campaign recommends the hospitals to monitor the patients being treated for infection for every 6 hours. Patients with infection are left without thorough monitoring, as a result their failure rate is much higher when compared to the uninfected patients.
v. There is a delay in seeing the patient by the physician for those patients who are sicker with infection, than those patients without infection. This is mainly because of confusion and disorderliness in the ER.

vi. Lack of specificity in diagnosis has occurred almost 15 times, of which 3 patients did not survive to discharge. Clear initial diagnosis is the first step in the diagnosis stage and will subsequently help in providing the right treatment and care for the patient.

vii. For the patients who did not survive to discharge, failure to make a clear diagnosis is high comparatively.

**System for treatment**

The treatment subsystem is the actual care delivery phase in the system for infection control and healthcare. It is only in this phase the patient is treated for diagnosis and is kept on monitored to prevent any complications and infection spread. The patient is recovered from the disease in this phase to a healthy individual. Possible failure modes occur in this phase primarily because of late administration of drugs, late recognition of infection and primarily failure to monitor and to capture abnormalities. Table 5.5.3 and Figure 5.5.4 illustrates the failure mode occurrence in the treatment phase.
<table>
<thead>
<tr>
<th>Type</th>
<th>Admitting physician notification</th>
<th>Patients arrival to the room/ICU</th>
<th>Drugs/therapy/care</th>
<th>Frequent vitals monitoring</th>
</tr>
</thead>
<tbody>
<tr>
<td>Patients with infection-survived</td>
<td>0.072</td>
<td>0.058</td>
<td>0.072</td>
<td>0.014</td>
</tr>
<tr>
<td>Patients with infection-didn’t survive</td>
<td>0.000</td>
<td>0.000</td>
<td>0.143</td>
<td>0.071</td>
</tr>
<tr>
<td>Patients without infection-survived</td>
<td>0.024</td>
<td>0.061</td>
<td>0.037</td>
<td>0.049</td>
</tr>
<tr>
<td>Overall patients</td>
<td>0.097</td>
<td>0.119</td>
<td>0.252</td>
<td>0.135</td>
</tr>
</tbody>
</table>

Table 5.5.3 Proportion data for failure modes in treatment subsystem
Figure 5.5.4. Occurrence of failure modes in treatment system-proportion chart
Observations:

i. The occurrence of failure modes on seeking admitting physician's consent and break down in their communication appears to be about 10 times.

ii. The highest severity failure mode occurred after patients’ arrival to the floor/ICU. It is observed that there is a significant delay in placing orders with respect to the patient’s diagnosis. As a result, the drugs are not administered faster. The data indicate that order placement for drug administration was delayed in those patients who did not survive to discharge upon infection. The difference in time of order placement is significant.

iii. Monitoring the patients to capture abnormalities in the patients require experience. About 31 patients were not monitored effectively to capture vital information. Patients with infection were not thoroughly monitored when compared to the patients without infection.

iv. Patients requiring faster and improved care are the patients who are sick with an infection. But the observed data illustrate the possibility of delay in drawing blood cultures from the infected patients for faster recognition of pathogen.

v. The data also show us that the role of the pharmacy in treatment is very effective as there were no occurrences of failure modes respective to the pharmacy. There were no errors with the pharmacy subsystem in the selected sample of 166 patients.

vi. Primarily, there is a significant difference between capturing the critical information from the infected patients, when compared to the non-infected
patients. The margin of difference in failure rates is higher among the patients who survived with infection than those who could not survive to discharge.

System for post-treatment

Patients, family caregivers and healthcare providers play important roles in maintaining a patient's health after discharge. It is the most significant part of the overall care plan, and there should not be surprising lack of consistency in both the process and quality of discharge planning across the healthcare system. Effective discharge planning can decrease the chances that the patient is readmitted to the hospital, help in recovery, ensure medications are prescribed and given correctly, and adequately prepare the family caregivers to take over their family member's care.

In this subsystem, the failure modes are subjected to discharge planning and patient education. In general, it is mandatory that every patient who is to be discharged from the hospital goes through this system. But it is important that special care and instructions must be given to those patients who were sick with an infection. This will keep them informed and attentive, so that they take better care of them after discharge, thereby reducing the chance of re-admission. The following inferences could be drawn from the below chart and table
Table 5.5.4 Proportion data for failure modes in post-treatment subsystem

<table>
<thead>
<tr>
<th>Type</th>
<th>total number of patients</th>
<th>Ambiguity over who owns care of patients after discharge follow up appointment</th>
<th>Patients having poor access to follow up care</th>
<th>Inefficient patient education</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>Patients with infection - survived</td>
<td>69/83</td>
<td>0.058</td>
<td>0.116</td>
<td>0.101</td>
<td>0.275</td>
</tr>
<tr>
<td>Patients with infection - didn’t survive</td>
<td>14/83</td>
<td>0.000</td>
<td>0.143</td>
<td>0.071</td>
<td>0.214</td>
</tr>
<tr>
<td>Patients without infection - survived</td>
<td>82/83</td>
<td>0.085</td>
<td>0.098</td>
<td>0.232</td>
<td>0.415</td>
</tr>
<tr>
<td>Overall patients patients</td>
<td>166 patients</td>
<td>0.143</td>
<td>0.356</td>
<td>0.405</td>
<td>0.904</td>
</tr>
</tbody>
</table>

Figure 5.5.5 below illustrates the occurrence of failure modes on the post treatment subsystem in all the three cases.
Figure 5.5.5 Occurrence of failure modes in the post treatment system – proportion chart
Observations:

i. 27 patients were not given a proper discharge education. This implies that there is a high readmission probability.

ii. There was an ambiguity among the physicians over care ownership for the patients after discharge. This failure mode was higher for the patients at the hospital without infection because most of the times the physicians seek referral and aid from attending physicians. As a result, there is room for communication error between the physicians.

iii. 18 patients had poor access to follow up care. This happens when the patients are not informed on when they have their next appointment with the physicians. Having this follow up care, will increase the chances of finding any complications or infection in the patient due to any performed interventions.

iv. Patients with infection are found to have poor access to follow up care. When the patient is being discharged, it was observed that these patients were not given proper and clear information about the follow up appointment and care.

v. There is a significant difference in the occurrence of the inefficient patient education failure mode, between the patients without infection and patients with infection. Most of the time, patients on the floor are transferred to another facility for better treatment. But the failure rate for those patients with an infection also seems to be high. So, patient education on discharge needs to be improved in general at the hospital.
5.5.2. Cross tabulation analysis

In this section of the chapter, the dependency of occurrence of failure modes on patient survival is tested. The proportional values of occurrence of failure modes across all the system, for the three cases are used in our analysis. This is obtained by the sum total of the entire proportional failure mode occurrence in every subsystem. The table 5.5.5 shows the sum total of all the proportions of failure mode across all the system.

<table>
<thead>
<tr>
<th>System</th>
<th>$Y_1$</th>
<th>$Y_2$</th>
<th>$Y_3$</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pre-diagnosis</td>
<td>1.507246</td>
<td>1.428571</td>
<td>1.487805</td>
<td>4.423623</td>
</tr>
<tr>
<td>Diagnosis</td>
<td>2.028986</td>
<td>1.928571</td>
<td>1.307176</td>
<td>5.264733</td>
</tr>
<tr>
<td>Treatment</td>
<td>1.202899</td>
<td>0.928571</td>
<td>0.536585</td>
<td>2.668055</td>
</tr>
<tr>
<td>Post-treatment</td>
<td>0.275362</td>
<td>0.214286</td>
<td>0.414634</td>
<td>0.904282</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td>5.014493</td>
<td>4.5</td>
<td>3.7462</td>
<td>13.26069</td>
</tr>
</tbody>
</table>

Table 5.5.5. Data for Chi-square test of dependency

In this table, $Y_1$, $Y_2$, and $Y_3$ are the row totals, i.e. the occurrence of failure mode totals for patients with infection who survived to discharge, patients with the infection who did not survive, and patients without infection who survived to discharge.
Chi-square test

Hypothesis:

Null Hypothesis, $H_0$: The patient survival is independent of the occurrence of failure mode at each subsystem

Alternate Hypothesis, $H_1$: The patient survival is dependent on the occurrence of failure mode at each subsystem

Significance level:

$\alpha = 0.05$.

Degrees of freedom:

$$\text{df} = (# \text{ of Rows} - 1) \times (# \text{ of Columns} - 1)$$

$$= (4 - 1) \times (3 - 1)$$

$$\text{df} = 6$$

Decision rule:

From the Chi square table, for $\alpha=0.05$ and $\text{df} = 6$, the critical value is,$$
\chi^2,0.05 = 12.592
$$

Therefore, if the calculated $\chi^2$ is greater than 12.592, then reject $H_0$. 
Calculating test static:

\[ \chi^2 = \sum \frac{(f_o - f_e)^2}{f_e} \]

Where, \( f_o \) and \( f_e \) are the observed and expected frequency of occurrence

On calculation, the calculated \( \chi^2 = 0.339615 \)

Results and conclusion:

Our calculated test static is lesser than the critical value; therefore, we accept the null hypothesis.

As a result, the survival of a patient is independent of the occurrence of failure mode across the subsystem in health care delivery.

Cross tabulation analysis within the subsystem

Performing similar calculations as mentioned in Section 5.5.2 within the subsystem will test the dependence of failure mode occurrence on each other within the system. Please refer to Appendix B for detailed step by step calculation.
Pre-diagnosis subsystem:

The chi-square static was 23.685 and the calculated test static was 0.319.

As a result, the null hypothesis is accepted. This confirms that the failure mode occurrence within this subsystem are independent of each other. In the pre-diagnosis subsystem standpoint, the tabulation result infers that the failure mode occurrence in the pre-diagnosis subsystem are independent of each other. The occurrence of a failure mode in this phase does not influence the process for health care delivery.

Diagnosis subsystem:

The chi-square static was 41.337 and the calculated test static was 1.117.

Accepting the null hypothesis again proves that the failure mode occurrence on every step of this process is independent and does not influence the care delivery process.

Treatment subsystem:

The chi-square static was 36.415 and the calculated test static was 1.003.

The null hypothesis is accepted; therefore the failure in the treatment phase occurs at random and is not dependent on any phase of the process.

Post-treatment subsystem:

The chi-square static was 9.488 and the calculated test static was 0.133.

Accepting the null hypothesis, we can again conclude that the occurrence of failure mode in the care delivery process are random and are not related to each other.
Cross tabulation analysis – weighted failure modes

Weighted ranking criteria – severity:

In general, severity assesses how serious the effects would be should the potential risk occur. In the example of a manufacturing process for a drug substance, the severity score is rated against the impact of the effect caused by the failure mode on the batch quality. In healthcare delivery, severity ranking encompasses what is important to the patient mortality and healthcare delivery for infection control. The ranking criteria for the failure modes based on severity is explained below:

- 1–2: Failure is of such minor nature, that the patient / customer (internal or external) will probably not be affected by the failure
- 3–5: Failure will have a mild impact on the patient and/or slight deterioration of part or system performance
- 6–7: Failure will result in patient dissatisfaction and annoyance and/or deterioration of part or system performance
- 8–9: Failure will result in high degree of patient dissatisfaction and cause non-functionality of system, leading to infection spread
- 10: Failure will result in major patient dissatisfaction and cause nonsystemoperation or non-compliance with government healthcare regulations

The weighted failure modes are analyzed through cross tabulation to test for significant dependency of the healthcare delivery process’ failure modes on patient mortality.
<table>
<thead>
<tr>
<th>Failure modes</th>
<th>Rating</th>
</tr>
</thead>
<tbody>
<tr>
<td>Failure to notify patient who requires immediate attention</td>
<td>7</td>
</tr>
<tr>
<td>Severity patient not given importance</td>
<td>9</td>
</tr>
<tr>
<td>Staffs not using the right T sheet for assessment based on initial complaint</td>
<td>8</td>
</tr>
<tr>
<td>Failure to change the T sheet upon misinterpretation</td>
<td>4</td>
</tr>
<tr>
<td>Failure to capture the critical information</td>
<td>9</td>
</tr>
<tr>
<td>Failure to document the findings or observation to notify the physicians</td>
<td>3</td>
</tr>
<tr>
<td>Not screening patients above 18 years of age to identify the infection spread</td>
<td>8</td>
</tr>
<tr>
<td>Failure to trigger the next step right away upon highly sick patients</td>
<td>5</td>
</tr>
<tr>
<td>Delay in seeing the patient</td>
<td>8</td>
</tr>
<tr>
<td>Unclear evaluation</td>
<td>9</td>
</tr>
<tr>
<td>Improper documentation</td>
<td>6</td>
</tr>
<tr>
<td>Late administration of antibiotics</td>
<td>10</td>
</tr>
<tr>
<td>Failure to place the right orders for diagnosis</td>
<td>4</td>
</tr>
<tr>
<td>Delayed response to physicians orders</td>
<td>7</td>
</tr>
<tr>
<td>Turnaround time of greater than 45 minutes</td>
<td>6</td>
</tr>
<tr>
<td>Delay in processing results</td>
<td>5</td>
</tr>
<tr>
<td>Unclear documentation of results</td>
<td>5</td>
</tr>
<tr>
<td>Correct delivery of results</td>
<td>3</td>
</tr>
<tr>
<td>Failure to make an early diagnosis</td>
<td>7</td>
</tr>
<tr>
<td>Improper communication between the physicians and staffs</td>
<td>4</td>
</tr>
<tr>
<td>Lack of specificity in diagnosis</td>
<td>8</td>
</tr>
<tr>
<td>Failure to monitor the patients to capture abnormalities</td>
<td>7</td>
</tr>
<tr>
<td>Not keeping the patients well informed about the diagnosis made and the nature of care provided</td>
<td>2</td>
</tr>
</tbody>
</table>

Table 5.5.6.1 – Failure modes in healthcare delivery - Weighted
<table>
<thead>
<tr>
<th>Failure modes</th>
<th>Rating</th>
</tr>
</thead>
<tbody>
<tr>
<td>Breakdown in the communication between the physicians</td>
<td>6</td>
</tr>
<tr>
<td>Failure to seek the admitting physician consent</td>
<td>5</td>
</tr>
<tr>
<td>Delay in placing orders</td>
<td>9</td>
</tr>
<tr>
<td>Having a process with much variation in time on patient assessment</td>
<td>3</td>
</tr>
<tr>
<td>Lack of uniformity among the staffs in patient assessments</td>
<td>4</td>
</tr>
<tr>
<td>Delay in informing the physician about the orders placed</td>
<td>2</td>
</tr>
<tr>
<td>Delay in drawing blood cultures from the patient</td>
<td>10</td>
</tr>
<tr>
<td>Intervention resulting in an infection</td>
<td>10</td>
</tr>
<tr>
<td>Delay in placing orders to pharmacy</td>
<td>4</td>
</tr>
<tr>
<td>Medications being sent to the wrong patient</td>
<td>4</td>
</tr>
<tr>
<td>Failure to monitor the patients</td>
<td>9</td>
</tr>
<tr>
<td>Failure to capture the information</td>
<td>8</td>
</tr>
<tr>
<td>Failure to notify physicians immediately</td>
<td>7</td>
</tr>
<tr>
<td>Ambiguity over who owns care of patients after discharge follow up appointment</td>
<td>6</td>
</tr>
<tr>
<td>Patients having poor access to follow up care</td>
<td>9</td>
</tr>
<tr>
<td>Inefficient patient education</td>
<td>8</td>
</tr>
</tbody>
</table>

Table 5.5.6.2 – Failure modes in healthcare delivery – Weighted

For the weighted cross tabulation analysis in this section, the severity of the failure modes are multiplied by the occurring failure modes across each subsystem and the total failure modes for each subsystem is calculated. Refer Appendix B for failure modes based on severity. The combined total of weighted failure modes are given in Table 5.5.7.
Table 5.5.7 – Weighted failure modes total across the subsystem

The values $Y_1$, $Y_2$ and $Y_3$ are calculated by:

$$Y_i(subsystem) = \frac{\Sigma(rating \times Y_i)}{\Sigma rating}$$

Example,

For the pre-diagnosis subsystem, the weighted failure modes total for the patients with infection who survived to discharge (from Appendix B)

$$Y_1(pre - diagnosis) = \frac{\Sigma (rating \times Y_{pre-diagnosis \ failure \ modes})}{\Sigma rating}$$

$$Y_1(pre - diagnosis) = \frac{10.507}{53} = 0.1982$$

Repeating the same steps as mentioned in section 5.5.1, page 123, the obtained test static was 0.06188. The failure modes across each subsystem are significantly independent.
5.5.3 Correlation analysis

Correlation analysis is used to test the dependency between two or more random sets of data. The failure mode occurrence could be tested for the survival rate of the 166 patients through correlation analysis. Table 5.5.6 shows the total failure modes in a subsystem and its occurrence on the three cases.

<table>
<thead>
<tr>
<th>Type</th>
<th>total number of patients</th>
<th>Proportion of total number of patients (R)</th>
<th>Proportion of total number of failure modes in pre-diagnosis subsystem (Ta)</th>
<th>Proportion of total number of failure modes in diagnosis subsystem (Tb)</th>
<th>Proportion of total number of failure modes in treatment subsystem (Tc)</th>
<th>Proportion of total number of failure modes in post-treatment subsystem (Td)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Patients with infection - survived</td>
<td>69/83</td>
<td>0.831</td>
<td>1.507</td>
<td>2.029</td>
<td>1.203</td>
<td>0.275</td>
</tr>
<tr>
<td>Patients with infection - didn’t survive</td>
<td>14/83</td>
<td>0.169</td>
<td>1.429</td>
<td>1.929</td>
<td>0.929</td>
<td>0.214</td>
</tr>
<tr>
<td>Patients without infection - survived</td>
<td>82/83</td>
<td>0.988</td>
<td>1.488</td>
<td>1.307</td>
<td>0.537</td>
<td>0.415</td>
</tr>
<tr>
<td>Overall patients</td>
<td>166 patients</td>
<td>1.988</td>
<td>4.424</td>
<td>5.265</td>
<td>2.668</td>
<td>0.904</td>
</tr>
</tbody>
</table>

Table 5.5.8 Failure mode occurrence across subsystems

Correlation analysis for this data set was analyzed using Minitab version 16.
Minitab results:

**Correlations: R, Ta, Tb, Tc, Td**

<table>
<thead>
<tr>
<th></th>
<th>R</th>
<th>Ta</th>
<th>Tb</th>
<th>Tc</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ta</td>
<td>0.913</td>
<td></td>
<td>0.268</td>
<td></td>
</tr>
<tr>
<td>Tb</td>
<td>-0.545</td>
<td>-0.155</td>
<td>0.633</td>
<td>0.901</td>
</tr>
<tr>
<td>Tc</td>
<td>-0.279</td>
<td>0.137</td>
<td>0.957</td>
<td>0.820</td>
</tr>
<tr>
<td>Td</td>
<td>0.845</td>
<td>0.553</td>
<td>-0.909</td>
<td>-0.749</td>
</tr>
</tbody>
</table>

 **Cell Contents: Pearson correlation P-Value**

The Minitab results indicate that the failure modes occurring across the subsystems are not correlated to the patient’s survival across the entire system. There is no significant dependence of failure modes on the patient’s survival.

The correlation analysis could also infer the relation between each subsystems and patients’ survival rate. Appendix C shows the Minitab results in detail. The results are described below in Table 5.5.7. The rows describe the four subsystems in the system for healthcare delivery.
The cross tabulation and correlation analysis’ results concludes that the occurrences of failure modes have no significant impact on the patient’s survival. Thus, the observed failure modes are occurring at random, and the proposed system design is inadequate to be applicable for infection control to improve healthcare quality.

<table>
<thead>
<tr>
<th>SUBSYSTEM</th>
<th>CORRELATION RESULT (from Appendix C)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pre-diagnosis subsystem</td>
<td>The patient survival is not significantly correlated to the failure modes in pre-diagnosis system</td>
</tr>
<tr>
<td>Diagnosis subsystem</td>
<td>The patient survival is not significantly correlated to the failure modes in diagnosis system</td>
</tr>
<tr>
<td>Treatment subsystem</td>
<td>The patient survival is not significantly correlated to the failure modes in treatment system</td>
</tr>
<tr>
<td>Post-treatment subsystem</td>
<td>The patient survival is not significantly correlated to the failure modes in post-treatment system</td>
</tr>
</tbody>
</table>

Table 5.5.9 – Correlation analysis result - failure modes in the subsystem and patient survival rate
CHAPTER 6 : CONCLUSIONS AND DISCUSSIONS

6.1 SYSTEMS ENGINEERING IN HEALTHCARE DELIVERY

Systems engineering is an engineering industrial quality assurance approach with varied applications. It is a sequential problem solving approach which could be used under any circumstances. The approach encloses every attribute which affects the process, and in application the approach guarantees the process’s or the product’s performance. The systems engineering approach is primarily based on the functions of the attributes. The attributes are the essential elements that drive the processes’ performance to quality. The system engineering approach drills down a process to its subsystem level and further to its components or elements. The collective performance of the components determines the performance of the system. The approach was useful to identify, and understand the functionality of the attributes in the subsystem of the care delivery process. Section 6.2 summarizes the results of the data analysis, and application of system engineering principles to health care delivery process for infection control. A model for infection control was developed based on the systems concept described in Chapter 4. The ideal healthcare system is designed based on the framework developed by AHRQ and IOM. With the six aims of IOM (Safe, Effective, Patient centered, Timely, Efficient and Equitable) as a backbone for development, a healthcare delivery system focused on patient, care team, organization and environment was developed for infection control. The developed model was tested for its validity in a local hospital, where the attributes driving the healthcare system to quality & performance were identified, and tested for dependency on patient’s survival.
6.2 SYSTEMS ENGINEERING APPROACH ON INFECTION CONTROL

Sepsis is a problem in the World, and the quality metric obtained from the hospitals proved that sepsis has a significant effect on healthcare quality. It is observed that in general, the hospital’s quality index is dependent on length of stay, mortality and comorbidity. The hospital where the proposed model was validated had sepsis affected patients with an average length of stay of 7.5 days in the hospital (Appendix B). Healthcare specialists, researchers and industrial engineers are collectively working on alternative methods on improving the sepsis care delivery process.

The systems engineering approach broke down the healthcare delivery process to its subsystem level based on four phases in healthcare delivery – pre-diagnosis, diagnosis, treatment and post-treatment. Further, the ideal system for infection control was designed based on the components which drive the performance of the subsystem.

6.2.1 Inferences from the data analysis

(i) The cross tabulation analysis in section 5.5 shows that the patient survival is independent of the occurrences of failure modes in the healthcare delivery process. There is no significant influence on the failure modes between subsystems and it occurs at random.

(ii) The correlation analysis in section 5.6 implies that the failure modes between subsystem and failure mode occurrence on the patient’s survival are not significantly correlated.
The failure modes chosen for this study are approved and validated by clinical practitioners. They are provided in clinical context and are not per observation of a systems engineer. The reason the cross tabulation analysis and the correlation analysis disapproved the dependency of failure mode occurrence on patient survival could be because; (i) the chosen failure modes are inadequate for the study, (ii) the failure modes are not clearly defined, (iii) there is a flaw in the proposed systems design for infection control, (iv) the data used for this analysis are inadequate, or (v) the data are not entirely random.

The proposed system for infection control was not validated by a clinical practitioner before application. The conceptual model was developed with capturing the failure modes occurring during healthcare delivery. Defining and choosing the failure modes is crucial to system design and development. The failure modes are dependent on the effectiveness of the design. The chosen failure modes address the system at the attribute level, and it is recommended to be extended further to its lowest level possible. As an example, the failure mode – failure to monitor the patients is generic and is not defined completely. The failure mode should be specific and needs to address the critical information that is required to monitor the patients in the hospital.

Data used for analysis and study must be random and sufficient. One of the reason, the analysis disproved the dependency is because, the data are inadequate. It is also observed that the sample data used is specific to older people. The average age of the patients collected for the study is 67 years. Older people are more prone to infection (AHA 2004) and controlling the infection spread is challenging. A study with sufficient
data and defined failure modes could validate the systems approach on quality of healthcare delivery. The power of the test is calculated in Appendix E. The test results indicate that the power of the test to be 5%. This supports the point that the sample used for systems design is inadequate. The power analysis results concludes that, (i) the test is hypothetica – the system designed in our study is not designed to improve the infection control care, but expected to improve the care for infection control, (ii) The power of the test is small, which supports the point that the sample used in our analysis is very small. The ability for the designed system to detect an improvement in the failure mode occurrence is very low.

6.2.2 Discussions

Pre-diagnosis subsystem

The systems approach identified the major components which influenced the pre-diagnosis subsystem’s performance. Activities such as registration, triage and initial assessment by RNs might not have a direct influence on the care delivery process, but the systems approach validates its importance in the pre-diagnosis subsystem. The data representation in section.5.5.1 illustrates that the occurrence of failure modes in the pre-diagnosis subsystem is almost the same as the occurrences of failure modes across the entire system. This implies that a breakdown in the registration and triage process could potentially affect the healthcare delivery system. This infers that an ideal healthcare delivery must have measures to drive performance of the efficient pre-diagnosis system. The efficient usage of triage sheet and screening tool increases the specificity in the diagnosis made on the patient. The notes prepared by the RNs on initial assessment must
capture as much information as possible on the patient’s complaint. Incomplete screening tools and assessment forms lack information required to make diagnosis and delays the diagnostic process. The screening tool must be up to date accommodating the latest information on identifying the infection spread in the patient. Once the patients are screened, the information provided by the screening tool will automatically trigger the next step in the care delivery process. These steps could be administering medicines, performing interventions, etc. This proves that an efficient pre-diagnosis system will initiate the initial treatment process, increasing patients’ survival.

**Diagnosis subsystem**

The systems approach identified the attributes driving the performance of the diagnosis system. It was observed that the performance was hindered by the delay in: physicians seeing the patients during their time of admission; time taken to administer initial drugs; and the time taken to process lab results. Time turns out to be a governing factor in the healthcare delivery. Physicians require time to make a clear accurate diagnosis on the patient, but too much time delays the treatment process, causing patient death. In the context of diagnosis, there should not be any delay in the process associated with patient wait time, administering medicines and processing lab results. These need to be fast to initiate the treatment for the diagnosis. The proposed system recommends a time limit of 10 minutes for the physicians to see the patients upon admission. AHRQ sets a standardized time for processing lab results (turnaround time) to be no later than 45 minutes, and this processing time should be faster for the patients identified with infection. The attributes in the diagnosis phase are correlated to each other in way. In
order to make a diagnosis with high specificity on the patient, accurate lab orders are
required to be placed, based on the results from initial assessment. Their results need to
be processed accurately and faster and be brought to the physician to diagnose the
patient. Based on the observed statistics, 15 infected patients lacked specificity in their
diagnosis, among which 3 patients did not survive to discharge. Specificity in the
diagnosis is an important attribute in the diagnosis subsystem, and the attributes affecting
it should be performing accurately to have a good diagnosis system in healthcare
delivery. A diagnosis when being specific to the complaint initiates a good treatment
process on the patient. This would reduce the time taken to draw blood cultures from the
patient. Blood cultures are required to study the micro-organisms causing the infection on
the patient.

The role of supportive services is crucial to the diagnostic process. Pathology
processes the blood cultures and prepares hematological information of the patient for the
physicians. Their results are to be documented clearly. An unclear documentation of
results leads to misinterpretation, thus increasing the probability to provide inefficient
treatment. The clarity in the results could be ensured by enforcing a secondary
verification process for processing blood cultures. Communication between the RNs and
physicians needs to be effective to transfer information and observations between them to
make a better healthcare delivery system.
Treatment subsystem

The observed treatment system had an average occurrence of failure mode lesser than the diagnosis and pre-diagnosis subsystem. The most recurring failure mode in the treatment subsystem is infrequent monitoring of the patients. The observed process justifies that about 31 patients were not monitored frequently to capture abnormalities in their health. When not being monitored, the infected patients are prone to comorbidity. Co-morbidity is the phenomenon in which a secondary disease is developed due the effect of the prevailing disease. Research by Kaiser Permanente suggests that the infected patients are to be monitored at least every two hours. About one-third of the observed infected patients did not survive to discharge. Monitoring the patients frequently can be accomplished by placing the patients in an intensive care unit or skilled care unit where, each patient will be monitored by an RN frequently. An individualized care provides more attention on the patient and the chance to capture sudden changes in a patient’s care increases. Therefore, it is important to either transfer the highly sick patients to a skilled care facility or provide individualized care to the patients.

Another important attribute of the treatment subsystem is the role of the pharmacy. The observed pharmacy service is well performed in the facility. But it is essential to understand the role of the pharmacy service while designing a healthcare system. In 1999, healthcare statistics of the world by Institute of Medicine, in their article “to err is to human” pointed out that 98000 people died in a year due to medical mistakes, out of which 7000 were due to medication errors. The staff involved in healthcare delivery process should make sure that the medication provided to the patient
is correct and conforms to physicians’ prescription. The RNs should also check and verify for the quantity to be administered to the patient. This does not apply just to hospital staff, but also to family members involved in the healthcare delivery. This phase of the care delivery process requires monitoring to understand the progress of the treatment process on the patient. If patients are not monitored in the treatment subsystem, there will be no means to measure the progress of the patient in the hospital. Per discussion in Chapter 02, the systems approach includes a feedback loop, which is the verification and validation of the V-model. In the health care delivery system, the verification and validation of the treatment process will be the continuous patient monitoring process.

**Post treatment subsystem**

The post treatment system includes activities that prevent the patient from being re-admitted to the hospital. The hospital re-admission index is one of the many indices that influence healthcare quality. The activities are to educate the patients on the things ‘to do’ and ‘to not do’ after the treatment process. The patients along with the family members are to be educated on the post-treatment activities.

The most occurring failure mode in this phase is the patient education. Per the analysis in section 5.5.1, 27 patients did not receive any education on post-treatment activities. The post-treatment activities include education on consumption of the right food, regular chiropractices, exercises, etc. depending on the treatment provided. Patient education is emphasized in every healthcare delivery process. Article *Annals of Internal*
*Medicine* (AHRQ 2009), it states that the hospital re-admission reduces by 30% due to patient education on discharge process. Patients are educated on procedures to take medicines, the right activities to do, the correct food to consume and the follow up date for consultation.

Patients need to be provided with the follow up care date during discharge. In infection control especially, the patients are prone to get infected again within 45 days after treatment. The pathogens are believed to be dormant in their blood for a period of time. As a result, there is a need to provide a follow up date to the patients by the physicians, to check for infection spread. The observed data shows that 18 patients did not have access to follow up care, out of which 2 patients did not survive to discharge.

**Conclusion**

This study demonstrated that systems engineering is a quality assurance tool that could be applied on a process to identify the system of interest. It served as an efficient tool to breakdown a process to its subsystem and then into its components, and also track its performance using appropriate quality control tools. The approach helped in understanding the properties of the subsystems involved in a system for healthcare delivery processes. The overall behavior of the system is dependent on the performance of the components in the subsystem. The care process for infection control (Sepsis) was complex, and the approach broke down the process into its component by categorizing into four main phases of the healthcare delivery process – pre-diagnosis, diagnosis, treatment and post-treatment. The attribute that are critical to quality for the infection
control care delivery process could be identified through the test for dependency. The approach could be used as a significant method to design a real life system for infection control that is completely patient centered, and could also satisfy IOM’s six aims to attain healthcare quality.
CHAPTER 07 : REFERENCES


27. Kludze, 2004, “*The importance of systems engineering on complex systems*” Conference on systems engineering research, University of Southern California, Los Angeles, CA


33. Journal of American medical association (AMA), morbidity, Web

34. Random House Kernesman Webster's College Dictionary, © 2010 K Dictionaries Ltd. Copyright 2005, 1997, 1991 by Random House, Inc. All rights reserved


APPENDIX

Appendix A – Demographics of Sepsis infected patients

Appendix B – Cross tabulation analysis within the subsystem

Appendix C – Correlation analysis within the subsystem

Appendix D – Failure mode occurrences across the system

Appendix E – Statistical power
### APPENDIX A - DEMOGRAPHICS OF SEPSIS INFECTED PATIENTS (continued)

<table>
<thead>
<tr>
<th>Patient Number</th>
<th>Age</th>
<th>Sex</th>
<th>Discharge date</th>
<th>Admission date</th>
<th>LOS</th>
<th>Time of Recognition</th>
<th>Time of First Antibiotic</th>
<th>Time to antibiotic</th>
<th>ER time IN</th>
<th>ER time OUT</th>
<th>Total time in ER</th>
<th>Floor admitted time</th>
<th>screening tool</th>
<th>Readmitted 30 days</th>
<th>ER vs dir admit</th>
<th>Unit admitted to</th>
<th>Transf to higher care</th>
<th>survived to discharge</th>
</tr>
</thead>
<tbody>
<tr>
<td>F**********</td>
<td>M</td>
<td>2/20/2012</td>
<td>3/9/2011</td>
<td>3/9/2011</td>
<td>1:10:00</td>
<td>15</td>
<td>2/20/2012 13:00</td>
<td>2/20/2012 13:54</td>
<td>0:54:00</td>
<td>2/20/2012 11:18</td>
<td>2:52:00</td>
<td>2:52:00</td>
<td>no</td>
<td>ER ICU no no</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>F**********</td>
<td>M</td>
<td>5/18/2012</td>
<td>3/9/2011</td>
<td>3/9/2011</td>
<td>1:10:00</td>
<td>15</td>
<td>5/18/2012 7:30</td>
<td>5/18/2012 11:45</td>
<td>4:15:00</td>
<td>5/18/2012 15:00</td>
<td>7:45:00</td>
<td>5/18/2012 19:00</td>
<td>yes</td>
<td>ER ICU no yes</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>F**********</td>
<td>F</td>
<td>6/21/2012</td>
<td>3/9/2011</td>
<td>3/9/2011</td>
<td>1:10:00</td>
<td>15</td>
<td>6/21/2012 16:00</td>
<td>6/21/2012 17:30</td>
<td>1:30:00</td>
<td>6/21/2012 18:00</td>
<td>9:00:00</td>
<td>6/21/2012 21:00</td>
<td>yes</td>
<td>ER ICU no yes</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>F**********</td>
<td>M</td>
<td>8/14/2011</td>
<td>3/9/2011</td>
<td>3/9/2011</td>
<td>1:10:00</td>
<td>15</td>
<td>8/14/2011 4:00</td>
<td>8/14/2011 2:25</td>
<td>1:40:00</td>
<td>8/14/2011 1:00</td>
<td>4:00:00</td>
<td>8/14/2011 3:00</td>
<td>no</td>
<td>ER ICU no no</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

APPENDIX – A: Patient demographics on Sepsis infected patients
<table>
<thead>
<tr>
<th>Patient Number</th>
<th>Age</th>
<th>Sex</th>
<th>Discharge date</th>
<th>Admission date</th>
<th>LOS</th>
<th>Time of Recognition</th>
<th>Time of First Antibiotic</th>
<th>ER time IN</th>
<th>ER time OUT</th>
<th>Total time in ER</th>
<th>Floor admitted time</th>
<th>screening tool</th>
<th>Readmitted 30 days</th>
<th>ER vs dir admit</th>
<th>Unit admitted to</th>
<th>Transf to higher care</th>
<th>Survived to discharge</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>1</td>
<td>12/28/2011 14:00</td>
<td>12/28/2011 16:30</td>
<td>5:01:00</td>
<td>5:03:00</td>
<td>2:02:00</td>
<td>1/29/2012 15:15</td>
<td>yes</td>
<td>Yes</td>
<td>Yes</td>
<td>ICU</td>
<td>No</td>
<td>Yes</td>
</tr>
<tr>
<td>2</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>2</td>
<td>5/18/2012 10:45</td>
<td>5/18/2012 13:20</td>
<td>3:50:00</td>
<td>3:52:00</td>
<td>2:02:00</td>
<td>5/18/2012 18:30</td>
<td>yes</td>
<td>Yes</td>
<td>No</td>
<td>ER</td>
<td>No</td>
<td>Yes</td>
</tr>
<tr>
<td>3</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>3</td>
<td>10/10/2011 01:49</td>
<td>10/10/2011 02:15</td>
<td>1:55:00</td>
<td>2:00:00</td>
<td>0:55:00</td>
<td>10/10/2011 03:00</td>
<td>yes</td>
<td>Yes</td>
<td>Yes</td>
<td>ICU</td>
<td>No</td>
<td>Yes</td>
</tr>
<tr>
<td>4</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>4</td>
<td>11/16/2011 13:40</td>
<td>11/16/2011 16:15</td>
<td>3:15:00</td>
<td>3:17:00</td>
<td>2:02:00</td>
<td>11/16/2011 18:15</td>
<td>yes</td>
<td>No</td>
<td>No</td>
<td>ER</td>
<td>No</td>
<td>Yes</td>
</tr>
<tr>
<td>5</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>5</td>
<td>2/15/2012 23:00</td>
<td>2/15/2012 23:45</td>
<td>0:45:00</td>
<td>0:47:00</td>
<td>0:02:00</td>
<td>2/15/2012 24:00</td>
<td>yes</td>
<td>Yes</td>
<td>No</td>
<td>ICU</td>
<td>No</td>
<td>Yes</td>
</tr>
</tbody>
</table>

Sepsis infected patients – Demographics
APPENDIX B: Cross tabulation analysis within the subsystem

System for pre-diagnosis

<table>
<thead>
<tr>
<th>Type</th>
<th>Registration</th>
<th>Triage</th>
<th>RN assessment</th>
<th>Not screening patients above 18 years of age to identify the infection spread</th>
<th>Failure to trigger the next step right away upon highly sick patients</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>Patients with infection -</td>
<td>69/83</td>
<td>0.232</td>
<td>0.116</td>
<td>0.290</td>
<td>0.072</td>
<td>0.391</td>
</tr>
<tr>
<td>survived</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Patients with infection -</td>
<td>14/83</td>
<td>0.286</td>
<td>0.143</td>
<td>0.214</td>
<td>0.143</td>
<td>0.000</td>
</tr>
<tr>
<td>didn’t survive</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Patients without infection</td>
<td>82/83</td>
<td>0.085</td>
<td>0.085</td>
<td>0.402</td>
<td>0.098</td>
<td>0.012</td>
</tr>
<tr>
<td>- survived</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Overall patients</td>
<td>166 patients</td>
<td>0.603</td>
<td>0.344</td>
<td>0.907</td>
<td>0.313</td>
<td>0.012</td>
</tr>
</tbody>
</table>

Hypothesis:

Null Hypothesis, $H_0$: The occurrence of failure mode at the pre-diagnosis subsystem is independent of each other

Alternate Hypothesis, $H_1$: The failure mode occurrence is dependent on the occurrence of failure mode within the pre-diagnosis system

Significance level:

$\alpha = 0.05$. 

**Degrees of freedom:**

\[ df = (# \text{ of Rows} - 1) \times (# \text{ of Columns} - 1) \]

\[ = (3 - 1) \times (8 - 1) \]

\[ df = 14 \]

**Decision rule:**

From the Chi square table, for \( \alpha=0.05 \) and \( df = 14 \), the critical value is,

\[ \chi^2_{0.05} = 23.685 \]

Therefore, if the calculated \( \chi^2 \) is greater than 23.685, then reject \( H_0 \).

**Calculating test static:**

\[ \chi^2 = \sum \frac{(f_o - f_e)^2}{f_e} \]

Where, \( f_o \) and \( f_e \) are the observed and expected frequency of occurrence.

On calculation, the calculated \( \chi^2 = 0.31865 \). Therefore, reject \( H_1 \).

**Results and conclusion:**

Accepting the null hypothesis, the tabulation analysis shows that occurrence of failure mode across the pre-diagnosis subsystem in health care delivery is independent of each other.
## System for diagnosis

<table>
<thead>
<tr>
<th></th>
<th>Physician assessment</th>
<th>Radiology/pathology/services</th>
<th>Diagnosis</th>
<th>System for diagnosis</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Type</strong></td>
<td><strong>total number of patients</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Delay in seeing the patient</td>
<td>Unclear evaluation</td>
<td>Improper documentation</td>
<td>Late administration of antibiotics</td>
</tr>
<tr>
<td>Patients with infection - survived</td>
<td>69/83</td>
<td>0.145</td>
<td>0.000</td>
<td>0.116</td>
</tr>
<tr>
<td>Patients with infection - didn’t survive</td>
<td>14/83</td>
<td>0.143</td>
<td>0.000</td>
<td>0.000</td>
</tr>
<tr>
<td>Patients without infection - survived</td>
<td>82/83</td>
<td>0.232</td>
<td>0.061</td>
<td>0.037</td>
</tr>
<tr>
<td>Overall patients</td>
<td>166 patients</td>
<td>0.519</td>
<td>0.061</td>
<td>0.153</td>
</tr>
</tbody>
</table>

**failure modes – diagnosis subsystem**
Hypothesis:

Null Hypothesis, $H_0$: The occurrence of failure mode at the diagnosis subsystem is independent of each other

Alternate Hypothesis, $H_1$: The failure mode occurrence is dependent on the occurrence of failure mode within the diagnosis system

Significance level:

$\alpha = 0.05$.

Degrees of freedom:

$$df = (# \text{ of Rows} - 1) \times (# \text{ of Columns} - 1)$$

$$= (3 - 1) \times (15 - 1)$$

$$df = 28$$

Decision rule:

From the Chi square table, for $\alpha=0.05$ and $df = 28$, the critical value is,

$$\chi^2_{0.05} = 41.337$$

Therefore, If the calculated $\chi^2$ is greater than 41.337, then reject $H_0$.

Calculating test static:

$$X^2 = \sum \frac{(f_o - f_e)^2}{f_e}$$
Where, \( f_o \) and \( f_e \) are the observed and expected frequency of occurrence.

On calculation, the calculated \( \chi^2 = 1.1177 \). Therefore, reject \( H_1 \).

**Results and conclusion:**

Accepting the null hypothesis, the tabulation analysis shows that occurrence of failure mode across the diagnosis subsystem in health care delivery is independent of each other.

**System for treatment**

**Hypothesis:**

Null Hypothesis, \( H_0 \): The occurrence of failure mode at the treatment subsystem is independent of each other

Alternate Hypothesis, \( H_1 \): The failure mode occurrence is dependent on the occurrence of failure mode within the treatment system

**Significance level:**

\( \alpha = 0.05 \).

**Degrees of freedom:**

\[
\text{df} = (\# \text{ of Rows} - 1) \times (\# \text{ of Columns} - 1)
\]

\[
= (3 - 1) \times (13 - 1)
\]

\[
\text{df} = 24
\]
### Systems for treatment

<table>
<thead>
<tr>
<th>Type</th>
<th>Admitting physician notification</th>
<th>Patients arrival to the room/ICU</th>
<th>Drugs/therapy/care</th>
<th>Frequent vitals monitoring</th>
<th>Patients with infection - survived</th>
<th>Patients with infection - didn’t survive</th>
<th>Patients without infection - survived</th>
<th>Overall patients</th>
</tr>
</thead>
<tbody>
<tr>
<td>Breakdown in the communica-tion between the physicians</td>
<td>0.072</td>
<td>0.072</td>
<td>0.029</td>
<td>0.174</td>
<td>0.159</td>
<td>0.000</td>
<td>0.246</td>
<td>1.203</td>
</tr>
<tr>
<td>Failure to seek the admitting physician consent</td>
<td>0.058</td>
<td>0.014</td>
<td>0.000</td>
<td>0.000</td>
<td>0.357</td>
<td>0.000</td>
<td>0.071</td>
<td>0.929</td>
</tr>
<tr>
<td>Delay in placing orders</td>
<td>0.072</td>
<td>0.014</td>
<td>0.029</td>
<td>0.174</td>
<td>0.159</td>
<td>0.000</td>
<td>0.246</td>
<td>1.203</td>
</tr>
<tr>
<td>Having a process with much variation in time on patient assessment</td>
<td>0.029</td>
<td>0.000</td>
<td>0.000</td>
<td>0.000</td>
<td>0.000</td>
<td>0.000</td>
<td>0.071</td>
<td>0.929</td>
</tr>
<tr>
<td>Lack of uniformity among the staffs in patient assessments</td>
<td>0.174</td>
<td>0.000</td>
<td>0.000</td>
<td>0.000</td>
<td>0.000</td>
<td>0.000</td>
<td>0.286</td>
<td>0.537</td>
</tr>
<tr>
<td>Delay in informing the physician about the orders placed</td>
<td>0.159</td>
<td>0.000</td>
<td>0.000</td>
<td>0.000</td>
<td>0.000</td>
<td>0.000</td>
<td>0.024</td>
<td>0.537</td>
</tr>
<tr>
<td>Delay in drawing blood cultures from the patient</td>
<td>0.122</td>
<td>0.000</td>
<td>0.000</td>
<td>0.000</td>
<td>0.000</td>
<td>0.000</td>
<td>0.012</td>
<td>0.537</td>
</tr>
<tr>
<td>Intervention resulting in an infection</td>
<td>0.159</td>
<td>0.000</td>
<td>0.000</td>
<td>0.000</td>
<td>0.000</td>
<td>0.000</td>
<td>0.024</td>
<td>0.537</td>
</tr>
<tr>
<td>Delay in placing orders to pharmacy</td>
<td>0.000</td>
<td>0.000</td>
<td>0.000</td>
<td>0.000</td>
<td>0.000</td>
<td>0.000</td>
<td>0.000</td>
<td>0.537</td>
</tr>
<tr>
<td>Medications being sent to the wrong patient</td>
<td>0.000</td>
<td>0.000</td>
<td>0.000</td>
<td>0.000</td>
<td>0.000</td>
<td>0.000</td>
<td>0.000</td>
<td>0.537</td>
</tr>
<tr>
<td>Failure to monitor the patients</td>
<td>0.000</td>
<td>0.000</td>
<td>0.000</td>
<td>0.000</td>
<td>0.000</td>
<td>0.000</td>
<td>0.000</td>
<td>0.537</td>
</tr>
<tr>
<td>Failure to notify physicians immediately</td>
<td>0.000</td>
<td>0.000</td>
<td>0.000</td>
<td>0.000</td>
<td>0.000</td>
<td>0.000</td>
<td>0.000</td>
<td>0.537</td>
</tr>
</tbody>
</table>

**Total**

- **Patients with infection - survived:** 69/83
- **Patients with infection - didn’t survive:** 14/83
- **Patients without infection - survived:** 82/83
- **Overall patients:** 166

**failure modes – treatment subsystem**
**Decision rule:**

From the Chi square table, for $\alpha=0.05$ and df = 24, the critical value is,

$$\chi^2_{0.05} = 36.415$$

Therefore, If the calculated $\chi^2$ is greater than 36.415, then reject $H_0$.

**Calculating test static:**

$$\chi^2 = \sum \frac{(f_o - f_e)^2}{f_e}$$

Where, $f_o$ and $f_e$ are the observed and expected frequency of occurrence.

On calculation, the calculated $\chi^2 = 1.0031$. Therefore, reject $H_1$.

**Results and conclusion:**

Accepting the null hypothesis, the tabulation analysis shows that occurrence of failure mode across the treatment subsystem in health care delivery is independent of each other.
System for post-treatment

<table>
<thead>
<tr>
<th>Systems for post-treatment</th>
</tr>
</thead>
<tbody>
<tr>
<td>Type</td>
</tr>
<tr>
<td>Patients with infection - survived</td>
</tr>
<tr>
<td>Patients with infection - didn’t survive</td>
</tr>
<tr>
<td>Patients without infection - survived</td>
</tr>
<tr>
<td>Overall patients</td>
</tr>
</tbody>
</table>

**Hypothesis:**

Null Hypothesis, $H_0$: The occurrence of failure mode at the post-treatment subsystem is independent of each other

Alternate Hypothesis, $H_1$: The failure mode occurrence is dependent on the occurrence of failure mode within the post-treatment system

**Significance level:**

$\alpha = 0.05$. 
**Degrees of freedom:**

\[ df = (# \text{ of Rows} - 1) \times (# \text{ of Columns} - 1) \]

\[ = (3 - 1) \times (3 - 1) \]

\[ df = 4 \]

**Decision rule:**

From the Chi square table, for \( \alpha=0.05 \) and \( df = 4 \), the critical value is,

\[ \chi^2,0.05 = 9.488 \]

Therefore, If the calculated \( \chi^2 \) is greater than 9.488, then reject \( H_0 \).

**Calculating test static:**

\[ \chi^2 = \sum \frac{(f_o - f_e)^2}{f_e} \]

Where, \( f_o \) and \( f_e \) are the observed and expected frequency of occurrence

On calculation, the calculated \( \chi^2 = 0.1336 \). Therefore, reject \( H_1 \).

**Results and conclusion:**

Accepting the null hypothesis, the tabulation analysis shows that occurrence of failure mode across the post-treatment subsystem in health care delivery is independent of each other.
### WEIGHTED FAILURE MODES

<table>
<thead>
<tr>
<th>System for pre-diagnosis</th>
<th>Registration</th>
<th>Triage</th>
<th>RN assessment</th>
<th>Severity of the failure modes (1-10)</th>
<th>Patients with infection - survived (Y1)</th>
<th>Patients with infection - didn’t survive (Y2)</th>
<th>Patients without infection - survived (Y3)</th>
<th>Overall patients</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Type</strong></td>
<td><strong>total number of patients</strong></td>
<td>Failure to notify patient who requires immediate attention</td>
<td>Severity patient not given importance</td>
<td>Staffs not using the right T sheet for assessment based on initial complaint</td>
<td>Failure to change the T sheet upon misinterpretation</td>
<td>Failure to document the findings or observation to notify the physicians</td>
<td>Not screening patients above 18 years of age to identify the infection spread</td>
<td>Failure to trigger the next step right away upon highly sick patients</td>
</tr>
<tr>
<td><strong>Patients with infection - survived (Y1)</strong></td>
<td>69/83</td>
<td>0.232</td>
<td>0.116</td>
<td>0.290</td>
<td>0.290</td>
<td>0.072</td>
<td>0.000</td>
<td>0.391</td>
</tr>
<tr>
<td>Rating * y1</td>
<td>1.623</td>
<td>1.043</td>
<td>2.319</td>
<td>1.159</td>
<td>0.652</td>
<td>0.000</td>
<td>3.130</td>
<td>0.580</td>
</tr>
<tr>
<td><strong>Patients with infection - didn’t survive (Y2)</strong></td>
<td>14/83</td>
<td>0.286</td>
<td>0.143</td>
<td>0.214</td>
<td>0.214</td>
<td>0.143</td>
<td>0.000</td>
<td>0.357</td>
</tr>
<tr>
<td>Rating * y2</td>
<td>2.000</td>
<td>1.286</td>
<td>1.714</td>
<td>0.857</td>
<td>1.286</td>
<td>0.000</td>
<td>2.857</td>
<td>0.357</td>
</tr>
<tr>
<td><strong>Patients without infection - survived (Y3)</strong></td>
<td>82/83</td>
<td>0.085</td>
<td>0.085</td>
<td>0.402</td>
<td>0.402</td>
<td>0.098</td>
<td>0.012</td>
<td>0.354</td>
</tr>
<tr>
<td>Rating * y3</td>
<td>0.598</td>
<td>0.768</td>
<td>3.220</td>
<td>1.610</td>
<td>0.878</td>
<td>0.037</td>
<td>2.829</td>
<td>0.244</td>
</tr>
<tr>
<td><strong>Overall patients</strong></td>
<td>166 patients</td>
<td><strong>0.603</strong></td>
<td><strong>0.344</strong></td>
<td><strong>0.907</strong></td>
<td><strong>0.907</strong></td>
<td><strong>0.313</strong></td>
<td><strong>0.012</strong></td>
<td><strong>1.102</strong></td>
</tr>
</tbody>
</table>

Weighted failure modes – pre-diagnosis subsystem
WEIGHTED FAILURE MODES

<table>
<thead>
<tr>
<th>System for diagnosis</th>
<th>Physician assessment</th>
<th>Radiology/pathology/services</th>
<th>Diagnosis</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Type</strong></td>
<td><strong>total number of patients</strong></td>
<td><strong>Delay in seeing the patient</strong></td>
<td><strong>Unclear evaluation</strong></td>
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<tr>
<td><strong>Severity of the failure modes (1-10)</strong></td>
<td>-</td>
<td>8</td>
<td>9</td>
</tr>
<tr>
<td><strong>Patients with infection - survived (Y1)</strong></td>
<td>69/83</td>
<td>0.145</td>
<td>0.000</td>
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<tr>
<td></td>
<td>r*y1</td>
<td>1.159</td>
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<td><strong>Patients with infection - didn’t survive (Y2)</strong></td>
<td>14/83</td>
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<tr>
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<td>r*y2</td>
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<td><strong>Patients without infection - survived (Y3)</strong></td>
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<td>0.061</td>
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<tr>
<td></td>
<td>r*y3</td>
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<tr>
<td><strong>Overall patients</strong></td>
<td>166</td>
<td>0.519</td>
<td>0.061</td>
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</table>

Weighted failure modes – diagnosis subsystem
# WEIGHTED FAILURE MODES

## Systems for treatment

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<tr>
<th>Type</th>
<th>Admitting physician notification</th>
<th>Patients arrival to the room/ICU</th>
<th>Drugs/therapy/care</th>
<th>Frequent vitals monitoring</th>
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<tr>
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<td>Breakdown in the commuina-</td>
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<td>communication between the</td>
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<td>physicians</td>
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<td>Failure to seek the</td>
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<tr>
<td>admitting physician</td>
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<td></td>
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</tr>
<tr>
<td>consent</td>
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<td>Delay in placing orders</td>
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<td>Having a process with</td>
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<td>much variation in time on</td>
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<td>the staffs in patient</td>
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<td>69/83</td>
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<td>0.058</td>
<td>0.072</td>
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<td>-</td>
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</tr>
<tr>
<td><strong>Didn't survive (Y2)</strong></td>
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<tr>
<td>14/83</td>
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<td>0.000</td>
<td>0.143</td>
<td>0.071</td>
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<tr>
<td>r * y2</td>
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<td>1.286</td>
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<td>-</td>
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<tr>
<td><strong>Survived (Y3)</strong></td>
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<tr>
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<td>0.061</td>
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<td>0.305</td>
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<td>166 patients</td>
<td>0.119</td>
<td>0.252</td>
<td>0.135</td>
<td>0.078</td>
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</table>

**Weighted failure modes – treatment subsystem**
### WEIGHTED FAILURE MODES

#### Systems for post-treatment

<table>
<thead>
<tr>
<th>Type</th>
<th>total number of patients</th>
<th>Ambiguity over who owns care of patients after discharge</th>
<th>Patients having poor access to follow up care</th>
<th>Inefficient patient education</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>Severity of the failure modes (1-10)</td>
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<td>6</td>
<td>9</td>
<td>8</td>
<td>23</td>
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<tr>
<td>Patients with infection - survived (Y1)</td>
<td>69/83</td>
<td>0.058</td>
<td>0.116</td>
<td>0.101</td>
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<td>r * y1</td>
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<td>Patients with infection - didn’t survive (Y2)</td>
<td>14/83</td>
<td>0.000</td>
<td>0.143</td>
<td>0.071</td>
<td>0.214</td>
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<tr>
<td>r * y2</td>
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<td>1.286</td>
<td>0.571</td>
<td>1.857</td>
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<td>Patients without infection - survived (Y3)</td>
<td>82/83</td>
<td>0.085</td>
<td>0.098</td>
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<td>0.415</td>
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<td>y * y3</td>
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<td><strong>0.143</strong></td>
<td><strong>0.356</strong></td>
<td><strong>0.405</strong></td>
<td><strong>0.904</strong></td>
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</table>

Weighted failure modes – post treatment subsystem
APPENDIX C: Correlation analysis within the subsystems

Please refer to the following table for data

Table 5.5.1. Proportion data for failure modes in pre-diagnosis subsystem.................107
Table 5.5.2. Proportion data for failure modes in diagnosis subsystem.................112
Table 5.5.3. Proportion data for failure modes in treatment subsystem.................115
Table 5.5.4. Proportion data for failure modes in post-treatment subsystem.................119

Pre-diagnosis subsystem

The actual minitab results are given below

**Correlations: R, Ia, II a, IIIa, IVa, Va, VI a, VII a, VIII a**

<table>
<thead>
<tr>
<th></th>
<th>R</th>
<th>Ia</th>
<th>II a</th>
<th>IIIa</th>
<th>IVa</th>
<th>Va</th>
<th>VI a</th>
<th>VII a</th>
<th>VIII a</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ia</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>-0.823</td>
<td>0.384</td>
<td></td>
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<tr>
<td>II a</td>
<td>-0.929</td>
<td>0.975</td>
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<td>0.143</td>
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<tr>
<td>IIIa</td>
<td>0.898</td>
<td>-0.989</td>
<td>-0.997</td>
<td>0.290</td>
<td>0.094</td>
<td>0.049</td>
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<tr>
<td>IVa</td>
<td>0.898</td>
<td>-0.989</td>
<td>-0.997</td>
<td>1.000</td>
<td>0.290</td>
<td>0.094</td>
<td>0.049</td>
<td>*</td>
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</tr>
<tr>
<td>Va</td>
<td>-0.857</td>
<td>0.414</td>
<td>0.606</td>
<td>-0.544</td>
<td>-0.544</td>
<td></td>
<td></td>
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<td></td>
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<tr>
<td></td>
<td>0.344</td>
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<td>0.634</td>
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<tr>
<td>VI a</td>
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<td>0.917</td>
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<td>0.551</td>
<td>0.167</td>
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<td>0.997</td>
<td>0.619</td>
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<td>0.713</td>
<td>0.653</td>
<td>0.452</td>
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</tbody>
</table>

Cell Contents: Pearson correlation

P-Value
Where R is the total across patients with infection who survived; patients with infection who did not survive to discharge; and patients with out infection who survived on discharge.

Alphabet ‘a’ denotes pre-diagnosis subsystem and I, II, thru VIII are the eight failure modes across the pre-diagnosis system.

The results show that the failure modes are not correlated to each other.

Diagnosis subsystem

The actual minitab results are given below

Correlations: R, Ib, II b, III b, IV b, V b, VI b, VII b, ...

<table>
<thead>
<tr>
<th></th>
<th>R</th>
<th>Ib</th>
<th>II b</th>
<th>III b</th>
<th>IV b</th>
<th>V b</th>
<th>VI b</th>
<th>VII b</th>
<th>VIII b</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ib</td>
<td>0.663</td>
<td>0.538</td>
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</tr>
<tr>
<td>II b</td>
<td>0.648</td>
<td>1.000</td>
<td>0.551</td>
<td>0.013</td>
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</tr>
<tr>
<td>III b</td>
<td>0.610</td>
<td>-0.188</td>
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<tr>
<td>IV b</td>
<td>-0.556</td>
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<td>0.319</td>
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<tr>
<td>V b</td>
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<td>-0.482</td>
<td>-0.500</td>
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<td>0.596</td>
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<tr>
<td>VI b</td>
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<td>VII b</td>
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<td>-0.995</td>
<td>0.384</td>
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<td>IX b</td>
<td>0.648</td>
<td>1.000</td>
<td>1.000</td>
<td>-0.208</td>
<td>-0.993</td>
<td>-0.500</td>
<td>0.630</td>
<td>0.588</td>
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<tr>
<td>X b</td>
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</table>

* denotes significance at the 0.05 level.
Where R is the total across patients with infection who survived; patients with infection who did not survive to discharge; and patients with no infection who survived on discharge.

Alphabet ‘b’ denotes diagnosis subsystem and I, II, thru XV are the fifteen failure modes across the diagnosis system.

The results show that the failure modes are not correlated to each other.
Treatment subsystem

The actual minitab results are given below

**Correlations: R, Ic, II c, III c, IV c, V c, VI c, VII c, ...**

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<th>III c</th>
<th>IV c</th>
<th>V c</th>
<th>VI c</th>
<th>VII c</th>
<th>VIII c</th>
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<tr>
<td>II c</td>
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Cell Contents: Pearson correlation

P-Value

Where R is the total across patients with infection who survived; patients with infection who did not survive to discharge; and patients with out infection who survived on discharge.

Alphabet ‘c’ denotes treatment subsystem and I, II, thru XIII are the thirteen failure modes across the treatment system.

The results show that the failure modes are not correlated to each other.
Post-treatment subsystem

The actual minitab results are given below

**Correlations: R, Id, II d, III d**

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<th>Id</th>
<th>II d</th>
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</table>

Cell Contents: Pearson correlation
P-Value

Where R is the total across patients with infection who survived; patients with infection who did not survive to discharge; and patients with out infection who survived on discharge.

Alphabet ‘d’ denotes post-treatment subsystem and I, II, thru III are the three failure modes across the post-treatment system.

The results show that the failure modes are not correlated to each other.
APPENDIX D : Failure mode occurrence across the system

Appendix D-1. Occurrence of failure modes in pre-diagnosis system

Appendix D-2. Occurrence of failure modes in diagnosis system

Appendix D-3. Occurrence of failure modes in treatment system

Appendix D-4. Occurrence of failure modes in post-treatment system
Appendix D-1. Occurrence of failure modes in pre-diagnosis system
Appendix D. Occurrence of failure modes in diagnosis system

- Delay in seeing the patient: 31
- Improper documentation: 11
- Failure to place the right orders for diagnosis: 72
- Turnaround time of greater than 45 minutes: 30
- Unclear documentation of results: 34
- Failure to make an early diagnosis: 33
- Lack of specificity in diagnosis: 11
- Not keeping the patient well informed about the diagnosis made and the nature of care provided: 29
Appendix D-3. Occurrence of failure modes in the treatment system
Appendix D-4. Occurrence of failure modes in post-treatment system
APPENDIX E: Statistical power

Number of failure modes = 39
Sample size (total number of patients observed) = 166
Potential failure modes for the patients observed = 39 x 166
= 6474
Total failure modes observed in 166 patients = 716 failure modes
By the application of this approach, the expected failure modes should decrease
Let us assume the expected failure modes to be 600.

Therefore, $\mu_0 = 0.11059$; $\mu_1 = 0.09267$

$$\delta = \frac{\mu_0 - \mu_1}{\sigma}$$

Analyzing the 1-sample t-test using Minitab 16 to detect the difference in mean failure mode:

**Power and Sample Size**

1-Sample t Test

Testing mean = null (versus not = null)
Calculating power for mean = null + difference
Alpha = 0.05  Assumed standard deviation = 18.46

<table>
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<th>Sample Difference</th>
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</thead>
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For the given test, the power is observed to be 5%.

The test hypothesis is based on the hypothesis is that the proposed system design is expected to improve the healthcare delivery for infection control. There is no alternate hypothesis for this test. The test was performed to analyze the power of the test to detect the change in mean failure modes occurrence with the given sample size.