A Framework for Clinical Healthcare Process Design: Investigating Applicability to Lean

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A FRAMEWORK FOR CLINICAL HEALTHCARE PROCESS DESIGN: 
INVESTIGATING APPLICABILITY TO LEAN

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By 
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A FRAMEWORK FOR CLINICAL HEALTHCARE PROCESS DESIGN:
INVESTIGATING APPLICABILITY TO LEAN

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I dedicate this thesis to my mentor and friend Wes Page who has guided my work in performance improvement and process design transformation in healthcare. I wish to also thank my sweet wife Jodie and our wonderful boys William, Brendan, and Jaylen for making my life amazing each day.
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A FRAMEWORK FOR CLINICAL HEALTHCARE PROCESS DESIGN: INVESTIGATING APPLICABILITY TO LEAN

Sam Ellsworth May 2015 104 Pages

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Healthcare delivery is a process-driven sequence of patient care treatments and services. A prescribed method for process design is required in order for healthcare organizations of the future not just to innovate, but to safely provide highly-reliable patient care. Some healthcare organizations have established the utilization of lean methodologies as a tool for process improvement. Other philosophies and methods such as Six-Sigma have also been introduced into hospitals to guide quality. Many of these efforts have provided theories or perspectives of quality improvement without being firmly connected to a model of application relative to clinical process design, process formulation, or process readiness. Hospitals often fail to recognize this gap and subsequently roll out multiple overarching quality improvement initiatives. This research examines some of the methods and activities of continuous healthcare improvement that frame clinical process design. In addition to providing an overview of current activities and methods, this research will explore to what extent standardized models for process design were followed in the course of using lean or other quality improvement initiatives. The research will conclude with a recommended best practice discussion for a healthcare process design framework and future applicability to the work of code blue standardization.
Introduction

Healthcare operations have been plagued for years with throughput issues, patient delays, and generally fragmented performance execution. The existing process fragmentation and overall poorly planned healthcare environment creates a near constant demand for healthcare organizations to hire consultants and engineering experts to help hospitals figure out how they can improve operationally. Modern hospital operations management today enlists a variety of data analysis and performance improvement methodologies in an attempt to correct all of the waste inherent in healthcare operations. Some organizations select to analyze present-condition metrics on this journey and attempt to incrementally improve processes. The review of present-condition metrics may neither address operational gaps nor lead the organization to view healthcare operations horizontally as a stream of value to identify systemic improvement potential. The result is one in which the organization attempts to optimize a poor process.

Outside of the data-driven performance improvement methodology, a popular method currently existing in healthcare is the use of the “Toyota Production System” or lean manufacturing framework. The fundamentals of lean manufacturing invite the organization to more deeply consider how current state process design may result in wasteful conditions.

Unfortunately, the inconsistent application of lean tools often leaves the organization in a similar condition where systemic design and horizontal connectedness aren’t considered, and the patient experience deteriorates while in the hospital. Patients, for example, are often being asked the same questions multiple times about medical history; experiences long-delays before surgery, and occasionally encounter a variety of
medical errors. These process design failures have been long established in healthcare. The modern struggle in healthcare operations today is the ongoing journey of learning to develop sound operating processes first, and then use a robust data and metrics infrastructure to manage around that performance to see if the intended result is being delivered by the process itself. It is an unfortunate reality that organizations waste dramatic resources in accounting for these fragmented processes without first considering how to optimize the value-added patient experience or customer requirements. Healthcare for the better part of the last decade has inconsistently attempted to apply lean methods to healthcare operations with often mixed results. The healthcare business case for the application of lean methods is simple. Companies like Toyota have developed robust processes that help them to achieve almost zero defects in engine assembly for instance, while healthcare commits medical errors every year that result in the deaths of patients. Healthcare executives are attempting to learn from Toyota what makes them different when they apply lean methods.

What is it about a company like Southwest Airlines that allows them to execute operations in a way where airplanes rarely crash? How can these methods help improve what is needed healthcare? Many skeptics often immediately draw the line by saying that manufacturing experiences zero variability. Typically lean healthcare consultants hear the statement, “you are making cars, we are dealing with human life and that is not the same.” Competent lean consultants are aware that manufacturing is often subjected to greater degrees of variability than the healthcare industry itself, yet manufacturing has found ways to thrive and perform to six-sigma reliability. The main objective of lean fundamentals is the designing of waste-free, robust, interconnected processes for
healthcare delivery. Healthcare organizations however, often lack the expertise to help the hospital move toward a path of lean excellence. How do we integrate our healthcare systems fully around a stream of processes? What does it mean to eliminate waste from our work? How do we set up our work so that the patient truly comes first? This research evaluates the literature of those who have previously written on hospital operations design and operations improvement. The thesis investigates the field of new hospital construction, and how hospital clinicians engage with construction teams to design robust clinical processes. The research can be applied not only to new construction, but any hospital environment, as the theories discussed are helpful for planning hospital operations in many settings. At the conclusion of this thesis, the healthcare executive will gain a refreshing understanding of process design and process optimization in healthcare where the path forward starts with creating robust operating conditions first, and measuring secondly.

Healthcare operations take place in a world of variability. This may come as a surprise to the outsider who often has no choice but to trust in the healthcare system to deliver the desired result of patient treatment and recovery. The reality is that most hospitals today do not have tight operating controls in place around the sequence of patient care and how it is conducted. The end result is a tornadic dance where Registered Nurses are spun in variability and working conditions to heal a patient are largely unpredictable hour-to-hour and shift-to-shift. Most competent nurses will tell you that no day is ever the same in a hospital and they often have no control over much of the day-to-day business operations. The lack of healthcare commitment to sequencing healthcare delivery is fundamentally opposed to the ways in which manufacturing and industry
operate in modern plants today. Without the attention to detail and an absolute sequence of care to follow, lean manufacturing would be lost. This research is an investigation into the work of those who understand the critical importance of absolute sequencing of healthcare delivery. The structure of the well-sequenced healthcare delivery setting creates a very predictable set of working conditions for the nurse to follow. Nurses thrive in this condition and medical errors plummet while patient satisfaction soars.

This thesis uses the healthcare construction industry as a catalyst to understanding clinical operations design from a greenfield (startup) perspective. This condition leads to natural discussions about clinical operations process design, as hospitals are being conceived and ultimately built. The reality is that new hospital construction often exposes and magnifies many of the same healthcare challenges existing in current brownfield (previously developed) facilities. Construction however, requires hospital clinicians to think rapidly about process improvement.

Lean tools are a set of resources designed to guide the organization on the journey to robust process design. Among them, a more popular tool is 5S for organizing the workspace according to the process being conducted. Lean manufacturing also provides a framework for direct observation of processes where customer value is being added in order to identify waste present in the system for future improvements. A typical lean framework for waste identification includes defects, overproduction, waiting, confusion, transport, inventory, motion, and excess processing. The lean methodology contains a tool needed to sequence healthcare processes into a predictable routine called *standardized work instructions*. This tool is the literal creation of all of the previously fragmented conditions of healthcare into a cohesive, meaningful flow for all healthcare
practitioners to follow as they care for the patient. As this design is developed by those who complete the work at the *gemba*, it is also in a constant state of kaizen as healthcare regulatory practices shift, healthcare insurance requirements evolve, and the treatments for the patient condition improve through modern science. With this standard work, the day-to-day operation becomes predictable as healthcare becomes an operationally focused assembly line with reliable structure, but with the newfound capacity for patient compassion as the patient requires reassurance throughout the hospital stay. Some facilities in fact often elect to build compassion and empathy into customer service protocols of standard work to follow. This ensures the continuous result of always connecting and building trust with the patient during the hospital stay. Essentially, it becomes a culturally connected requirement to build revolutionary customer service into the healthcare sequence of care.

What is often the reality in healthcare is that clinicians, doctors, and healthcare administrators are not experienced in the process design and product development disciplines. These concepts serve healthcare well, but have only recently been included as a framework for planning deliverable sequences of healthcare interventions. The reason that these disciplines are so valuable in healthcare is that they help to bridge a previous innovation disconnect in evidence-based medicine. For example, consider evidence-based medicine software provider Lippincott. “Lippincott’s Nursing Solutions (*product*) makes evidence actionable for your clinical staff by taking all these evidence-based sources and synthesizing them into concise entries that clinicians use while directly caring for the patient.” (“Lippincott,” paragraph 2, 2013). While Lippincott is interested in providing best-practice recommendations for certain patient medical treatments and nursing
interventions, what it cannot consider is the individual hospital environment, hospital specific technology, or the overall systems and structures in which those treatments are received by the patient. This is where end-to-end operations sequencing via the process design and product development disciplines are critical. The end result is to connect the process design with standard work instruction writing to develop baseline systematic performance.

The more recent studies on healthcare process evaluation and process redesign frequently cite the work of author Allan Coletta (2012), *The Lean 3P Advantage: a Practitioners Guide to the Production Preparation Process*. The Coletta text is a body of work containing a set of tools and methods for healthcare process redesign. The Coletta (2012) text also contains a section that encourages process steps to be theorized and potentially formulated based on how certain activities and results “occur in nature,” as they are typically flawless (p. 140). Coletta’s work challenges the mind of the process formulator to think of different ways that a step in a process could be executed. Next, the team selects from the alternatives, the best possible solution from a framework largely grounded in the product development disciplines. At the heart of the Coletta theory on process redesign is a method for formulating each step in the sequence of a process.

Coletta (2012) states, “developing seven alternatives for each value-adding function in the process flow comes next. It is the most radical part of the process and is absolutely critical to event success. This is where you cast the big net to move people way out of their comfort zones and get them thinking differently. It tends to be very fast, very competitive, and usually very fun (p. 74).”
The critical to success factor here is that industrial and manufacturing leaders like Coletta are proposing prescript applications to guide the healthcare clinician and process improvement teams along the journey of process evaluation and ultimately process formulation. Some progressive hospitals understand the clinical benefits of process formulation methods and have become experts. However, other hospitals may have achieved limited success using the lean toolkit to identify variation and waste present within a process, but have no application framework for innovative process redesign with lean tools. What is even worse is that when the clinical director or executive takes the “figure it out when we get there” approach to designing healthcare clinical processes. Without a prescribed sequence of events or healthcare assembly to follow, the clinical work is doomed to treating sick patients in continuously variable conditions. Between the lean methodology framework and an application methodology proposed by Coletta, the majority of healthcare sequencing tools are present and functional when properly applied.

Clinical process formulation methodologies have been applied to the field of new hospital construction. It is frequently the case that new hospital construction so drastically alters clinical workflows, that the physical building design itself sometimes drives the need for innovative process redesign. The prescript application described by Coletta (2012) provides the framework that many project improvement teams in healthcare will require to achieve robust clinical systems design. Replacement hospitals also often take on an entirely different design structure and significantly alter the work processes that are conducted. Methods of process transition readiness evaluation deployed by various hospitals under construction will be a portion of this research.
Process transition readiness evaluation simply refers to the procedures, projects, and methods deployed by organizations in advance to plan how patient care will take place in a newly constructed hospital. The current state of healthcare in the majority of the patient care realm lacks the clinical patient care experts who also possess project management and process transition readiness evaluation skills to prepare the organization comprehensively to move from an existing facility to a new hospital. Some healthcare organizations don’t have a defined plan for process transition readiness evaluation. Because of these circumstances, some hospitals have been required to deploy outside experts and consultants to assist healthcare leaders with process transition planning. It is noteworthy that although a variety of external consultant companies exist for new hospital operations consulting, very few are experienced with the complete framework that this current research examines to properly formulate and completely sequence end-to-end healthcare operations processes. This research will evaluate how different hospitals have attempted process transition readiness evaluation for newly constructed hospitals and designed the new sequence of work.

“How does a hospital know when it is ready to move? What are the indicators that a hospital can safely relocate from one building to a new one, without compromising patient care?” (B. Grant, personal communication, June 8, 2012). The questions presented by Grant are difficult for many healthcare organizations to answer due to the states of variance, waste, and lack of standardized patient care processes present in existing hospitals. If no standard for completing a process exists now, then it becomes more difficult to formulate how a process should work in a new hospital with a design change. This inquiry is intended to explore how hospitals have attempted to prepare
processes tactically for relocation to a new facility.

Laguna and Marklund (2013) state, “understanding the process to be designed is a key element of any design effort. In terms of process understanding, only a subtle difference exists between redesigning an existing process in an organization and creating a design for a currently non-existing process. In both cases, we must understand what the new process is supposed to do and particularly in both cases what customers desire from it (p. 86).”

What has often proven difficult for healthcare administrators is how to do this. As the next section will describe, healthcare organizations need a certain theoretical construct or vision to guide and sponsor the organization on the process design journey. Constantly occurring medical errors coupled with government-induced reforms demand innovation from healthcare providers. It is now incumbent upon healthcare executives to sponsor these improvements. Failure to design robust healthcare sequences of care can result in core measure fallouts and Medicare payments being ultimately paid to competitors who execute better patient sequence models. Hospitals must find ways to separate themselves along competitive lines by creating processes, systems, structures, and standardized work that allow them to provide revolutionary patient care that excites and pleases customers. Measuring current condition data alone and attempting to optimize subpar processes will not be enough. This will require leaders to think of healthcare execution in a new, process-driven model that is grounded in best-practice sequences of waste-free care to the patient.

**Problem Statement**
Kohn, Corrigan, and Donaldson (2009) stated, “health care in the United States is not as safe as it should be--and can be. At least 44,000 people, and perhaps as many as 98,000 people, die in hospitals each year as a result of medical errors that could have been prevented, according to estimates from two major studies.” Many of the problems surrounding healthcare mortality from preventable errors arise from current state variation in healthcare practice. This research examines the framework of lean methods and its application to healthcare clinical process design in order to produce quality, reliable outcomes patients expect when hospitalized. The research examines the use of lean methods such as *standard work instruction* as a tool to bring baseline performance to facility clinical procedures.

**Significance of the Research**

This research will allow healthcare executives and clinicians a greater understanding of the field clinical process engineering. The healthcare executives will be able to deploy a sensible framework for clinical process design within the hospital setting based upon the review of literature in current practice and the recommendations provided in this thesis. The organization will gain a greater understanding of the use of lean tools and how the tools apply to clinical process design in both current state and newly constructed healthcare facilities.

**Purpose of the Research**

The purpose of this research is to analyze current state practices and frameworks of clinical healthcare process design in order to provide a recommendation for clinical and executive teams to utilize when establishing sequential clinical procedures in healthcare systems. The recommendation will be provided based on a survey research
conducted among the healthcare organizations about their practices of lean or other principles for process transition readiness. The intent of this research is to focus on those efforts that in the past have removed clinical variation from the healthcare setting in exchange for robust systems of clinical performance guided by frameworks for clinical design such as lean.

**Hypothesis**

The hypothesis of this research is that typical clinical areas are architecturally designed and the philosophy of execution is set in place before key clinical procedures that drive the day-to-day work have been completely formulated. Essentially, new hospitals for instance, may often be drafted for construction in advance of knowing exactly how the work will be executed inside of the new spaces clinically. This inattention to process establishment and avoidance of clinical standard work writing leads the newly defined space down an unwelcome path of clinical variability that may actually increase medical errors and patient mortality rates. This is greatly opposed to the methods in which procedures are defined in high reliability settings such as manufacturing and industry like Toyota or Alcoa Business Systems.

**Assumptions**

The assumptions of this research includes the concept that organizations in healthcare are relatively new to the journey of clinical process design using lean tools and that the firm foundation of this work historically has been tied to manufacturing and industry. Other assumptions include the notion that this topic of research is not well understood in healthcare and that executives often set the vision for healthcare.
improvement without understanding fundamentals of product design, process
development, and specifically the use of lean tools to drive clinical process design.

Limitations and Delimitations

No previous studies are available that address the clinical process design
frameworks comprehensively for healthcare. Most existing literature typically provides a
qualitative account of an individual hospital providing one framework to an individual
department or process design. No previous studies are available that address the specific
application of lean tools in healthcare across multiple organizations to establish a
framework for new hospital construction clinical design. This research is limited by the
notion that specific hospitals and specific individual participants were permitted to
submit data to the research anonymously in order to protect the legal interest of the
organization that may be faced with the knowledge that incomplete clinical process
design may have occurred. Other limitations include that the research questionnaire
was conducted electronically and thus, no specific qualitative investigation of individual
hospitals were conducted onsite with this research.

Definition of Terms

(PTRE) Process Transition Readiness Evaluation- PTRE in this context refers to the tools
and strategies deployed by various organizations in healthcare to clinically design
processes for use in a newly constructed hospital space. PTRE form was a tool used by
Grant (2012) to formulate clinical processes for a new hospital construction project.
Kaizen Event- Kaizen event is a cross-functional project and project team acting inside a
hospital collaborating specifically to bring continuous improvement to the processes of
clinical care within a given set of scope and objectives using lean tools.
Gemba- Japanese term which literally means “the real place” or workplace.

Andon- Is a system designed by the Toyota Production System for temporarily stopping work that may have some form of defect.

Standard Work Instruction- Is a performance workplace template used to define sequences of work for Registered Nurses and other clinical staff.

LEAN Methodology- is a framework of tools for clinical performance improvement and healthcare business models aimed at optimizing sequences of care through the elimination of waste inherent in the current state of work.

LEAN 3P Methodology-Lean 3P is a manufacturing related term similar to PTRE. Literally “production preparation process” Lean 3P is the specific application of lean tools in order to prepare processes and procedures for shop production.
Review of Literature

From the perspective of theoretical and vision-based frameworks for executives, Studer (2013) states, “consistent and sustained success with lean (methodology) depends on having a strong leadership infrastructure in place. Organizations need to have well-defined goals; well-trained leaders; a staff that uniformly practices proven behaviors; and, perhaps, most important, a mechanism for making sure people are held accountable for their performance” (p. 43). All of these behaviors, actions, and requirements are being described from the perspective of the gaining and the use of lean knowledge. Specifically, it is important to arrive at what is required in order to make standard work instruction utility effective in the hospital as an operations mechanism. Because the notion of process improvement and process design is fairly new to healthcare, it is often the case that the executive leaders of the organization do not have the previous experience of what it means to spread the vision of process improvement or understanding the requirements of sponsoring a process improvement and process redesign activity. For leaders at the highest levels of the organization, typically this involves the executive making the business case for change. The executive will be sponsoring / commanding the managers or staff workers of a clinical area to improve processes or redesign the current state of work so that it provides reliable, quality patient care every time. Without this executive vision in place, many hospitals today at the beginning of the process redesign or process improvement journey rely on healthcare consultants to make the initial rounds of improvement while equipping the leaders with the knowledge and skills to sponsor future process redesign activities.
An additional factor for administrators to consider prior to a process redesign effort arises from Robbins, Garman, Song, and McAlearney (2012) as they suggested in a study on high performance work systems that “an understanding of a health system’s existing work practices can assess the extent to which a given process improvement strategy is likely to yield greater relative success” (p. 190). For instance, some organizations may have functional processes with highly predictable outcomes that may lend themselves to a six-sigma methodology framework. Other organizations may have no process at all and the current state of work unfolds in a chaotic fashion. This organization may be better suited for the lean toolkit and lean 3P process design strategy. It is important to note that most healthcare organizations rarely execute clinical operational procedures to six-sigma reliability. However, the six-sigma toolkit contains a wealth of measures and problem-directed mathematical formulas that may assist an organization in determining the extent to which a problem exists.

When clinical procedures in healthcare are not delivered to six-sigma reliability, the lean methodology is often the toolkit that delivers many of the functions that process establishment or process redesign teams require. For the healthcare executive attempting to select between lean methods vs. six-sigma tools as an approach, generally if a healthcare executive cannot account for an absolute sequence of end-to-end patient care within a process clinically, the lean toolkit is often the first set of tools needed on the journey of process design. Six-sigma tools would be more appropriate when a process exists with well-defined process steps across the organization horizontally, ideal cycle time, and minimum variability with high customer satisfaction. Typically high performing metrics accompany a process suited for six-sigma application.
Clinical Application of Process Redesign Frameworks

Virginia Mason Medical Center in Seattle is one of the pioneers of lean healthcare improvement and 3P facilitation for process redesign. According to Kenny (2011 para 1), A lot of poor quality comes about through variation and a lack of standardization. If you go to most places, if there are six oncologists they can be treating breast cancer six different ways. Or if you go to a surgery department, there are people that are operating on gallbladders, and if you've got six surgeons, they're using six different sets of equipment and they're doing it six different ways, because they're all trained in different places, and, they will say this is the way I did it at Stanford, and, this is the way I did it at Harvard, and it's the best way.

Kenny describes the importance of having one process, which is typically the best practice in place to execute clinical patient care. The variance described and lack of a standard is one example of a condition in which a clinical process redesign effort may take place in a hospital setting in order to arrive at a standardized best practice. Although, Kenny (2011) does not describe a prescript framework by which process redesign is executed within the organization in the previous citation, the text does reinforce the notion that process redesign is of critical importance in healthcare and in the case of hospitals, specifically the use of the lean methodology from Toyota.

Henriksen, Battles, Marks, Lewin, Anthony, Chetty, and Jack (2005) describe the clinical application of hospital discharge process redesign. The Henriksen et al. (2005) research highlights a framework for process redesign of a specific clinical process conducted in all United States hospitals (discharging patients from care). According to
the Henriksen et al. (2005) research, the project team redesigned elements of the patient discharge process by utilizing the following framework:

1. “Formulate a project team.
2. Conduct probabilistic risk assessment.
3. Conduct process mapping.
4. Conduct qualitative analysis of patients and medical doctors.
5. Conduct failure mode and effect analysis.
6. Conduct root-cause analysis (p. 383-390).”

Henriksen et al. (2005) is describing in this framework, a partial set of lean methods tools typically used in the course of problem solving day-to-day operational failures. While these tools are quite efficient as a set of stand-alone problem solving tools, they do not describe all of the elements that would be required to arrive at robust process design. This work seems to suggest that healthcare would benefit from a more prescript framework for process redesign and process evaluation.

Varkey and Kollengode (2011) described the Deming PDSA model (Plan, Do, Study, Act) as the method by which “a group of physicians in our institution undertook QI project techniques to enhance patients’ understanding of diagnosis, management, and follow-up at the end of an office visit in an endocrinology clinic specialized in bone disease. This model was adapted to include three key questions: 1. What is the aim? 2. What will be measured to know the aim has been achieved? 3. What are the changes necessary? The project team worked through multiple PDSA cycles in the course of making improvements to the process. (pp. 239-240).”
As the foundational elements of lean and PDSA are somewhat new to the clinical operations of healthcare, organizations are learning how to make the tools and theories of process improvement fit into the work they do each day. This suggests that many healthcare facilitators are applying a mixed set of tools into the work of process redesign. Although the PDSA cycle described above may provide some discrete evaluation capabilities, in the larger healthcare operations arena, the above statement on PDSA demonstrates the overall lack of knowledge present in much of healthcare today about creating end-to-end sequences for executing clinical processes.

**Process Redesign Frameworks in New Hospital Construction Projects.**

Nicholas (2012) studied the process formulation efforts of the Loyola Hospital Emergency Department. According to Nicholas (2012),

The initial step in this approach is a kaizen event to map processes in the existing facility; this generates data on problems and wastes. Next are 5S and standard work events, which provide improvements in workplace organization and work procedures that establish guidelines for the redesigned facility. Finally, information on new procedures, facility reorganization, and standards generated from these events are combined with hospital census and voice of the customer (VOC) data as input for 3p events dedicated to the facility redesign. The result is a new design that minimizes waste, maximizes flow, focuses on the customer, and takes maximal advantage of clinicians’ knowledge of processes and the workplace (p. 49).
The method described here suggests the following application sequence for process formulation and process design activities:

1. Conduct a kaizen event.
2. Conduct a 5S event.
3. Conduct standard work writing.
4. Conduct a 3P event.

Nicholas (2012) describes this framework in the context of, *Integrated Lean Methods Approach to Facility Redesign*. As this execution presents a prescribed framework, there is no evidence that the sequence described above will achieve a well-formulated healthcare process. That is, there has never been a multi-site clinical test or trial to determine the effectiveness of this framework sequence beyond the present example. Rather in this example, Nicholas (2012) is communicating a qualitative instance of process and facility redesign. The next section will examine another new hospital facility process redesign approach from the perspective of a mechanical engineer designing from a healthcare clinical operations perspective.

“How does a hospital know when it is ready to move from an old location to a newly constructed one? What are the indicators that a hospital can safely relocate from one building to a new one, without compromising patient care?” (Grant, 2012). The questions presented by Mechanical Engineer Brian Grant are difficult for many healthcare organizations to answer due to the states of variance, waste, and lack of standardized patient care processes present in existing hospitals. To achieve revolutionary innovation, Grant (2012) suggested that, “hospitals will be confident and ready to move when all key processes have been evaluated, all identified gaps or issues have been resolved, processes
have been trialed, and work instructions have been finalized.” Grant (2012) additionally suggested the following, “7-step path to standardized processes as a key sequence of events leading to healthcare process redesign:

1. Identify the desired process to be improved.
2. Question each step in the process.
4. Answer the unresolved questions.
5. Write standardized work instructions.
6. Simulate or trial new processes to optimize.
7. Train employees and move into new facility.”

The Grant method proposed for clinical process formulation provides a sensible, sequential, and achievable process formulation methodology. The method was suggested as a project management application in conjunction with a stand-alone new hospital construction project. As such, this methodology also has no long-term clinical trial data connected to it and serves as a qualitative account from the perspective of a single-hospital tested process formulation methodology.

**Implications for Process Formulation in Healthcare Innovation.** While both Nicholas (2012) and Grant (2012) provided qualitative accounts of process formulation methods, it is clear that in the course of clinical innovation, healthcare would benefit from a prescript application for process formulation. Both Nicholas (2012) and Grant (2012) agree or include statements about the importance of two key processes: “1. Some degree of simulation or testing prior to full-scale implementation of new processes is
critical. 2. Standardized work instruction is a critical to success tool for any well sequenced clinical process.” Both Grant (2012) and Nicholas (2012) utilized mock-up based patient care areas for process simulation to validate how the preliminary process designs would be executed and make incremental improvements based on those outcomes. The simulation is the best-guess about clinical operational execution especially if a new hospital is designed before the operational processes inside the building are formulated. To that end, the processes according to lean methodologies should be in a state of Kaizen or continuous improvement, especially after moving into the new space to begin caring for patients. The standard work instruction is an important tool because it trains the employee new to the space on how to do work in addition to being an ongoing source of baseline performance. This typically leads to the formulation of metrics that can be audited to determine trends or determine if the process is delivering the intended result.

**Summary of last two sections.** The research provides an overview of the process redesign frameworks existing in two different categories: hospital clinical application and hospital construction. Both segments suggest a current state of non-prescript methods by which independent facilitators or project leads, guide teams down the path toward process excellence. While many hospitals are currently utilizing the tools of the lean methodology, the work of hospitals does not appear to follow a standardized framework for process redesign efforts. This research recognizes the variance in the course of process redesign efforts. This suggests that while in the course of innovation, the healthcare industry could potentially benefit from future studies and further development of a standardized model for process evaluation and process redesign.
Questioning and Experimenting in Process Redesign: The Problem Defined

Process redesign efforts are of critical importance when a healthcare organization is attempting to establish robust systems and structures to execute day-to-day operational requirements. Healthcare, hospital construction, industrial, and manufacturing organizations today heavily rely on lean 3P efforts for systems redesign. Critical elements of the lean 3P methodology include questioning and experimenting as processes are developed and refined. Questioning has replaced solutionist thinking as the behavior that helps innovators to arrive at desired robust processes. As questions about potential process development are answered, innovators launch into modes of simulation and experimentation to validate process designs and sequences. This section will explore the methodologies and outcomes of questioning and simulating in the health services sector leading to revolutionary innovation. The research will attempt to identify when in the course of innovation, what aspects of processes are important to question. The research will also highlight the methods and venues in which simulating is taking place for process redesign efforts.

Dyer, Gregersen, and Christensen (2011) stated that “(top executives) were extremely intelligent and talented individuals who were accomplished at delivering results, but they didn’t have much direct, personal experience with generating innovative business ideas” (p. 30). Many poorly formulated business processes contribute to the sufferings and misfortune of those who work within them. If top executives are key to delivery, often process engineers are key to process redesign and future innovation. Among the key problems that exist with this executive level disconnect is the issue of skill-task alignment. For example, administrative healthcare educational curriculums may
not contain educational segments on process redesign or product development. However, key executives are constantly required to engage in discussions and decision making about how processes should be improved, especially following periods of operational failures. This disconnect of skill-task alignment often requires the executive to rely heavily on the skills of the process engineer to question each step of an operational sequence and simulate proposed countermeasures to validate assumptions of redesign. This research will examine some of the current work of practitioners that are using questioning and simulating techniques in the course innovation to further assist the executive or other organizational stakeholders with revolutionary process redesign.

The Use of Questioning for Problem Solving and Innovative Process Design

It is an appropriate notion to consider jointly, questioning for problem solving and questioning for innovative process design. During process design some workflows are developed from a re-engineering perspective. Often, many of these processes require questioning to work toward the innovative future state. Other processes are formulated as new previously undeveloped work. In this sense, questioning takes a course more consistent with the product development disciplines. It is important to make this distinction here because questioning is the intuitive mechanism of problem solving whereas questioning in the course of product development or healthcare process design may contain unknowns for healthcare executives without prior experience leading the effort.

When in the course of problem solving, several current state tools exist that are important for healthcare administrators to be aware of that may assist them when questioning the current state workflow. Sarkar, Mukhopadhyay, and Ghosh (2012) state,
“With Apollo root-cause analysis (ARCA), the identification of potential cause is similar to a tree diagram. However, here each effect is related to at least two causes, one related to action and another related to condition (p. 175).”

What is interesting about the dynamic of the ARCA is that it may give rise to several operational conditions that may not have directly contributed to one specific effect in a particular instance. Rather than a result where one absolute root-cause may be produced, Apollo methodology brings several potential conditions to the forefront about the current state of a workflow which may all be important to consider for mitigation immediately. ARCA questioning may be a tool that isolates an absolute cause and effect relationship for one aspect of a problem while also providing the executive with additional information to prevent future repeat effects that may be driven from additional causes that arise during the ARCA evaluations session.

Sarkar et al., (2012) cites the use of a lean questioning process called “5 why’s” (literally asking why five times) to evaluate root causes of failures that may also give rise to a future state innovative process design (p. 174). In this system upon occurrence of failure, it is recognized that if the innovator asks why a problem occurs and connects that answer to the next questioning of why, eventually a root cause shall be recognized. Corrective actions or countermeasures should be recognized from asking the question of why five times and essentially providing the incremental improvement that solves the problem at hand. For the healthcare administrator, the promotion of “5 why’s” thinking should be encouraged because it is a low-cost method of simplistic questioning that if embedded culturally, will give many staff level workers a powerful framework for day-to-day operational problem solving needs. This method can be used to achieve what in
the next phases of process redesign may need to be written standard work drafts or potentially a simulation to test the assumptions of the 5 why’s questioning.

Chalice (2007) cites one tool that “Toyota uses to improve a lean value stream is called an A3 form. The A3 form is named after the large paper size (approximately 11 x 17 inches) that is typically used to draw it. Basically, the current condition or value stream is drawn on the left side of sheet. All of the issues, background, problems, and opportunities are listed. Then an improved future condition or value stream map is drawn on the right side, which contains all the target improvements. Also, list the implementation plan, that is, the steps needed to reach the target condition. The A3 form is a simple and concise high-level problem-solving approach that fits on a single sheet of paper (p. 48).”

While both methods are lean tools, when one compares the concept of 5 why’s questioning to the A3 problem solving process, it is rather apparent that the A3 process provides a more in-depth look at the process as it is analyzed. The key concept here for the healthcare administrator may be to understand that problems with higher levels of complexity may better lend themselves to the questioning processes of the A3 whereas, the 5 why’s form of questioning may for instance be best suited for an isolated, interdepartmental smaller scale problem. The result of the 5 why’s questioning may often contain a more immediately implemented countermeasure whereas the A3 form of problem solving may arrive at larger scale cross-departmental countermeasures that may require additional training and system redesign before they can be implemented within the organization. It is also important to note that the A3 may offer a more visual
representation of the problem at hand. It also offers a continuum from problem origination (left side) through problem resolution (right side).

As process formulation is also required for new or emergent processes that may not require initial problem solving, an evaluation of the product development disciplines provides some of the framework and context that clinical design may require. What is essentially different about this form of questioning is that it challenges design assumptions rather than failures or failure modes and effects. It is important to state here that healthcare professionals should liken healthcare process design to product design. Thus, if a cross-functional hospital team is developing the best sequence of patient care in a bed tower for general medical patients, they should consider what they are doing as a product development concept. As many hospitals today are focused on adding value to the patient experience as a component of the lean improvement framework, the product development disciplines follow a very similar trajectory toward identifying customer demands through a process of questioning as product concepts are identified and generated.

“Ulrich (2012) provides the following framework for the identification of customer needs:

1. Ensure that the product is focused on customer needs.
2. Identify latent or hidden needs as well as explicit needs.
3. Provide a fact base for justifying the product specifications.
4. Create an archival record of the needs activity of the development process.
5. Ensure that no critical customer need is missed or forgotten.
6. Develop a common understanding of customer needs among members of the development team.

7. Gather raw data from customers.

8. Interpret the raw data in terms of customer needs.

9. Organize the needs into a hierarchy of primary, secondary, and tertiary.

10. Establish the relative importance of the needs.

11. Reflect on the results and the process (pp. 74-75).

The Ulrich (2012) framework provides a dynamic questioning process design scheme that is quite different than those historically created in healthcare disciplines while in clinical process design. Process design formerly was created from a physician, nurse, or clinician-centered perspective. The Ulrich (2012) framework creates a process that is driven from the customer perspective and eventually translates all of those requirements into a quantitative measurement system that makes the flow of the process sequence, and its design assumptions quite obvious to comprehend for those seeking to understand the rationale of development. The voice of the customer is often difficult to obtain in a healthcare setting where patients may be very ill and unable to engage in meaningful process discussions. Typically as process design events unfold in healthcare, it is the responsibility of the senior healthcare administrator to advocate for former patients of the system to be involved in determining process specifications from the customer value-added perspective. For the healthcare executive, the important concept to retain here is that methodical frameworks exist in the manufacturing and industrial disciplines that can greatly improve sequences of healthcare delivery when executed by a
project team with voice of the customer at the forefront. The skills of a competent process improvement facilitator or process engineer may be required to assist in the process redesign or formulation effort. It is noteworthy that as many consulting firms lack this expertise and often executives are challenged with finding the right people to lead these efforts, it becomes crucial for organizations beginning this journey to involve staff nurses, clinicians, managers, and executives of the hospital to interact and be mentored by mechanical engineers from companies like Alcoa or Toyota to assist with rapid acceleration of knowledge spread around the process improvement tools. The field of healthcare clinical process engineering has been around long enough now that it may even be possible to locate RN’s or other clinicians with previous kaizen or process design experience to help the organization accelerate the process of learning and training to these methods.

**Activities of simulation in the course of innovation.** Activities of simulation are seen as the next steps in the course of innovation after the powers of questioning for problem solving and process design are unleashed. It is important for healthcare organizations to have a framework and mechanism that allows for the testing of design assumptions so that incremental process design improvements can be made as the design team advances the process to finalized standard work instructions. Frameworks and methods ranging from computer-based models to physical prototypes exist for the testing and evaluation of design assumptions of patient care delivery sequences. This section of the research will explore some of the current state activity that is being used in the healthcare industry.
On the concept of electronic simulation methodologies Tobail, Egan, Ab-Hamad and Arisha (2013) stated “ExtendSim simulation modeling offers the opportunity to test process alternatives in a safe environment. The issue outlined (admission-discharge process) is a day-to-day problem which has implications for strategic planning. As the work involves processes at the patient level Discrete Event Simulation (DES) is suitable. The objective is to aid the bed administrator to allocate beds more efficiently, which will impact positively on the LOS of both the elective and ED admissions (both of which currently suffer delays due to the ad hoc discharge process) increasing patient satisfaction (p. 24).”

The concepts of discrete event simulation and computer-based modeling point to complex testing modes that require completion in an arena outside the hospital setting. Process engineers and healthcare administrators are required to make decisions about how certain processes or patient care activities should be sequenced or conducted in the simulation. It may also arise from the course of a technology-based simulation session, that unanswered questions are resolved and gaps are closed that help key leaders to understand what to do next. Marshall-Ponting, Kobbacy, Sapountzis, and Kagioglou (2013) also point to the notion of “visual analytics” as an emerging approach to the field of electronic simulation and modeling (p. 240). A prominent organization that produces this product is SAS Visual Analytics. It is clear, complex multi-system issues may be better understood by the use of electronic modeling. This methodology does require many inputs that often must be extracted from flat files or from project teams that need to tell the software what to do in order to make the model operate correctly. That is, the software must first learn the process to be analyzed. If the process is not optimized or
well formulated from the beginning, the organization may benefit from the initial application of lean tools prior to telling simulation software how to perform.

Many healthcare organizations that are currently utilizing the lean or lean 3P methodology use a simulation and experimentation model that involves physical mock-ups, human subjects, nurses, and doctors in the course of process design and process sequencing. Lean 3P is an extension of the use of lean tools in what is called production preparation process (3P) which is a design framework for process formulation. Coletta (2012) provided comprehensive research on the notion of prototype development in the context of project-team development using lean 3P. Essentially, the model was about combining the lean methodology framework with the product design development of 3P (production preparation process). While lean fundamentals may be better understood in hospitals today, healthcare administrators may desire the accompanying framework that 3P offers as a tool to guide teams through process and product design activities with lean methods. Lean tools provide the framework for how a process should be designed, while 3P provides the framework for the activity that will create the process. The perspective created by the work of Coletta (2012) introduces the notion of prototyping as a system that is ended by selection of the appropriate sequence or design, but started with defining customer requirements. The focus then becomes about building processes and / or value-streams that become the specifications of a prototype in the context of a project team lean 3P activity. During the steps prior to prototype development Coletta (2012) states, “The 3P participants should now have a very good understanding of each of the seven alternatives for value-adding functions. The process for selecting the better of the three
which will lead to a prototype for experimentation can be done in various ways but should incorporate the evaluation criteria selected in an earlier step (p. 154).

Coletta (2012) describes what are typically a series of specifications that lead to construction of a physical prototype. What is often the case in healthcare is that the outcome of a 3P event specific to process formulation becomes a simulation prototype where the process is being simulated to execute patient care as opposed to the physical manifestation of a product itself. Regardless, healthcare organizations utilizing the lean methodology as a business model for process improvement should follow the work of Coletta as a framework for conducting process design and process sequencing activities for clinical workflows. However, what should also be mentioned here is that often many healthcare 3P activities do at times result in a physical product requirement in which prototyping is the next stage, according to Coletta.

There are also numerous examples of process simulations in hospitals that have not specifically utilized the 3P framework to accompany the deployed lean method. Page (personal communication, 2013) provided simulations at Owensboro Health Regional Hospital to “test and validate” the design assumptions for medical drawers and medical supply nurse servers inside patient rooms by using nurses and electronic medical records in a mock-up patient room environment to simulate patient care for a newly constructed hospital. Using lean methods (value stream mapping and 8 wastes) to create the most value-added process sequences, a project team designed medication administration and patient care activities in a sequence and wrote standard work instructions to support these activities. These foundational lean elements created the requirements allowing the team to test and simulate the activities of patient care that were designed.
Summary of previous three sections. Within the natural progression of process design, it is important to question the elements of certain operational sequences. Often, problem solving mechanisms are deployed to create stability within a pre-existing process. If new processes are formulated, project teams often follow the pattern of questioning design assumptions and customer requirement matches. The next level of these outcomes is to validate the work by simulating or prototyping it so that incremental improvements can be made and the systems tested before they are placed into an actual environment of customer delivery. This research concludes that solutionist thinking and quick-fix deliverables are not the standard for organizations in healthcare that follow root-cause thinking, lean methods, and product design methods. As described previously, a behavior that accompanies solutionist thinking is the analysis of current state data alone in an attempt to optimize a subpar process, which may not always produce the desired result.

GE has had an influential role in shaping healthcare process design activities through the use of six-sigma techniques as it has been the historical benchmark for these efforts. However what is often the reality is that the lean methods toolkit should be applied before six-sigma application in order to first bring a process from chaos to stability. Big data or data rich organizations for instance may not always have functional processes. Typically if the big data is describing poor performance, it is a clear indicator that lean methods were not first applied to stabilize processes. The data rich organization is not above the tools of process design used in lean hospitals. Formulating ideal processes and system sequences result from staff-based project teams that use a framework for creating value-added functions. In the healthcare sector this will require
continuation on the current state trajectory of following lean facilitation efforts to create revolutionary innovation first.
Methodology

To further understand the methods by which hospitals are engaging in clinical process design, this research deployed a formalized questionnaire containing both quantitative and qualitative question types. These questions were utilized to gather information about the tools, methods, and activities of clinical process design currently in use at healthcare facilities with new construction projects. This questionnaire was distributed to healthcare facilities electronically under the guidance and support of a Chief Executive Officer, Chief Nursing Officer, or other clinical executive who explained the questionnaire to the staff participants. The survey results are anonymous in terms of not naming specific participants or participating hospitals. The rationale for anonymous study was also to protect the legal interest of the participating organizations as current healthcare operational gaps may be recognized by executives participating in the survey. The anonymity of the survey allowed the executive and organization to continue with involvement in the research questionnaire without the perception of threat or harm. The research also contains the personal communication / interviews of individuals who were willing to discuss specific clinical process design methods and projects. The typical structure for IRB approval was conducted via the Western Kentucky University Office of Research Integrity.

Population and Sample

The population for this questionnaire is that of American-based healthcare organizations. The specific purpose of this research is to learn about the methods, tools, and activities of healthcare clinical process design. According to the American Hospital Association (2014), “there are currently 5,723 registered United States Hospitals.
The population of these hospitals will contain the sample selected for clinical process design evaluation in conjunction with new hospital construction projects.

Many industry specific healthcare periodicals frequently list ongoing healthcare construction projects. This research also utilized Google search engine as a method by which to detect hospitals that are frequently undergoing healthcare construction projects. The participants of the healthcare process design questionnaire are those executives, nurses, doctors, medical directors, or other clinicians that have directly been involved in healthcare construction projects that required designing and formulating clinical process steps for patient care for future execution in the new healthcare setting. This required purposeful sampling in order to accurately question new hospital construction projects and new hospital construction clinical teams. The questionnaire participants were provided the purpose and nature of the research. They were each given an electronic informed consent document to read prior to conducting the questionnaire which states the potential respondent is not required by the organization (hospital) to participate. The participants were also informed that they may refuse to answer any questions or withdraw from participation at any point without harm or penalty of any type.

**Variables**

The variables that exist with this research include the amount of data supplied by each participant and the volume of participants from each hospital as neither is predictable. These variables are driven by the staffing models at the hospital, those who actually took part in process design activities still remaining with the organization, and the participants’ election to provide various levels of qualitative detail. To control these variables in research, full disclosure of results will be provided.
Instrumentation and Materials

The questionnaire instrument developed by the researcher contains a combination of multiple choice and open-ended questions related to healthcare process design activities. The questions attempt to extract knowledge of conditions that may signal a lack of healthcare sequencing standards, common tools deployed, activities conducted, and understanding of the types of staff members who participated in healthcare clinical process design activities. The central research question related to the understanding of conditions that may signal a lack of healthcare clinical process design sequencing standards is, “Were major architectural decisions about the design and layout of the new healthcare facility in place before key clinical / business processes had been completely planned?” The list of survey questions are provided in the appendix at the conclusion of this document.

Procedures

The data collection methodology was an electronic questionnaire via the survey website Survey Monkey. The Survey Monkey website is well-developed and frequently used by graduate students engaged in thesis writing activities. The Survey Monkey website has a built in electronic analytic tool to calculate results and compile manually written results to open-ended questions for analysis. The data collection tool automatically calculates YES / NO responses by cumulative percentages and the open-ended question result are available for cluster and common theme analysis.

Method of Data Analysis

The results will be listed for YES / NO responses by utilizing the Survey Monkey data tool for automatic calculation by cumulative responses. It is noteworthy that
although the respondents will answer these questions as YES / NO, the survey was
designed with a selection option to not answer a multiple choice question in the event that
a respondent did not have the proper information to answer a question or felt
uncomfortable answering a question. The open-ended questions can be analyzed for
common word clusters and like-minded approaches to clinical process design and listed
in the results section. The cumulative result of this work is to create a recommendation
for future studies or application at healthcare facilities as to some of the appropriate
methods or frameworks for properly sequencing healthcare clinical processes when they
are created in design sessions with cross-functional hospital teams.

Threats to Validity

The topic of this research, clinical process design in conjunction with new
hospital construction projects is poorly understood. One limitation of this study is that
hospitals elected not to participate in qualitative aspects of the project due to operational
and staff constraints. The questionnaire is the main vehicle for obtaining information
from hospitals in terms of specific mechanisms and strategies deployed in the course of
clinical process design activities.
Results

The questionnaire was presented to multiple hospital organizations, distributed by an executive within the organization who agreed to sponsor the questionnaire. The executive was requested to present the questionnaire to any individuals who had previously taken part in clinical process design activities in conjunction with new hospital construction projects. The identified facilities were approached at the executive level of the organization to explain the intent of the survey as a tool to identify methods by which clinical healthcare processes were designed in conjunction with new healthcare construction projects. All facility executives were given an introductory PowerPoint presentation and consent document to complete prior to moving forward with surveying individual hospital participants that had designed healthcare processes in conjunction with hospital construction projects. This document is included in the appendix section. This research represents a new field of study as there have never been previous publications surrounding the exact sequence by which healthcare processes are clinically designed in conjunction with new healthcare construction projects. In order to protect the legal interest of the individual participants and participating organizations, all questionnaire results and participation were submitted anonymously. The survey was submitted back by the participating hospital organizations from May 2014- December 2014 by a total of 27 participants.
Table 1.

Yes / No Survey Questions with 27 of 27 Participant Response Totals (Expressed as Percentage).

<table>
<thead>
<tr>
<th>Question</th>
<th>Yes</th>
<th>No</th>
<th>No Answer</th>
</tr>
</thead>
<tbody>
<tr>
<td>Question 1</td>
<td>100%</td>
<td>0%</td>
<td>0%</td>
</tr>
<tr>
<td>Question 2</td>
<td>85%</td>
<td>15%</td>
<td>0%</td>
</tr>
<tr>
<td>Question 3</td>
<td>78%</td>
<td>19%</td>
<td>3%</td>
</tr>
<tr>
<td>Question 9</td>
<td>63%</td>
<td>37%</td>
<td>0%</td>
</tr>
</tbody>
</table>

Question one confirmed that all surveyed facilities used some form of a project plan in the course of new facility design. Question two results confirmed that the majority of participants stated that key metrics regarding process readiness were routinely conveyed to the project teams. Question three confirmed that all facility project plans for the majority were standardized across departments in the hospital. Question nine which was the central research question for this investigation stated that 63% of survey responses answered that key clinical processes were formulated after the major architectural decisions about the design and layout of the new healthcare facility had been fully planned. This is important because the product development normal course in manufacturing would be to design first the product from the customer perspective and then formulate the tools, infrastructure, factories, etc. required to produce the product.
Table 2.

*Qualitative response common theme results from questionnaire.*

<table>
<thead>
<tr>
<th>Question</th>
<th>Common Cluster Result #1</th>
<th>Common Cluster Result#2</th>
<th>No Response by Participant or Skipped</th>
<th>Qualitative Participant Response</th>
</tr>
</thead>
<tbody>
<tr>
<td>Question 4</td>
<td>Simulation / Mock-Up</td>
<td>Lean Methods</td>
<td>10</td>
<td>17</td>
</tr>
<tr>
<td>Question 5</td>
<td>Executives / Leaders</td>
<td>Project Manager / Coordinator</td>
<td>11</td>
<td>16</td>
</tr>
<tr>
<td>Question 6</td>
<td>Lean / 3P</td>
<td>Budgets / Financial Return</td>
<td>15</td>
<td>12</td>
</tr>
<tr>
<td>Question 7</td>
<td>Day in Life / Simulation</td>
<td>Regulatory / Joint Commission</td>
<td>11</td>
<td>16</td>
</tr>
<tr>
<td>Question 8</td>
<td>Executives / Managers</td>
<td>Front-Line / All Hospital Employees</td>
<td>5</td>
<td>22</td>
</tr>
<tr>
<td>Question 10</td>
<td>Readiness / Testing</td>
<td>Activation / Simulation</td>
<td>14</td>
<td>13</td>
</tr>
</tbody>
</table>
Question four asked the participants to comment on activities, forms, and tools used in the course of clinical process readiness. The common theme responses confirmed that the use of lean tools and simulation were common activities conducted in the course of clinical process design. Question five asked the participants to comment on key roles involved in evaluating clinical process readiness. The common theme responses confirmed that executives, leaders, and managers were participants. The questionnaire respondents also confirmed that project managers or project coordinators were involved in the clinical process design planning. Question six asked the questionnaire participants to comment on any form of lean, six-sigma, or other strategic planning tools used. The common theme responses included the use of lean or lean 3P to guide clinical process teams during design activities. Participants also reported that financial and return on investment measures guided some of the decision making relative to process design. Question seven asked the questionnaire participants to comment on how they know when a key clinical process was deemed safe for use at the new hospital. The participants confirmed that simulation and day in the life scenarios were key aspects to making final determinations as to clinical process design safety for patient use. Participants also stated that they followed regulatory measures for fitness such as Joint Commission requirements. Question eight asked the questionnaire participants to comment on the types of employees typically involved in clinical process design planning. The questionnaire participants stated that hospital executives and managers were involved in clinical process design planning. The participants also stated that front-line staff and employees at all levels of the organization are important members of clinical design teams. Question ten discussed any routine events or activities completed during clinical
process design sessions. The participants stated that some form of readiness or testing was commonplace during the clinical process design meetings. Other common theme responses included concentration on activation or simulation in the course of clinical process design.
Discussion and Recommendations

The purpose of this research is to create a clinical process design sequencing methodology recommendation based upon literature review and a field-based hospital questionnaire. The literature review and questionnaire results demonstrated that the field of sequencing healthcare delivery into robust processes is not well researched. No comprehensive standards exist, and field-based consultants practice a variety of methods in an attempt to prepare clinical processes for utilization of patient care at a new healthcare facility. The field of healthcare consulting for hospital operations contains a variety of expert practitioners who have advanced knowledge of joint commission and regulatory requirements of new healthcare facilities. These consulting firms may also have project management professionals that may be able to prepare large scale plans to demonstrate from beginning to end what a new hospital construction clinical operations readiness project would entail. These consultants and the majority of United States hospitals do not have clinically enlisted experts that have the comprehensive knowledge to convert a Toyota Production System style of process design into the healthcare realm for clinical deployment of patient care.

It is a dangerous notion to consider that healthcare facilities in the case of replacement hospitals enlist the fallacy that if a given process worked a certain way in a former hospital, it should work just the same way in a new hospital. If healthcare directors rather than direct resources toward robust process design, take the “figure it out when we get there” approach to new hospital operations functionality, the hospital will initially function in large-scale variability. The gap between high-reliability manufacturing and industry vs. healthcare is obvious. American healthcare was never
intended to exist beyond the silo. Those who work in healthcare and understand process sequencing are not only enlightened, but understand the difficult task of trying to bridge the healthcare variability of the past with the highly reliable process design methods of the future and how important they have become in the application of clinical process creation. The research conducted in this study demonstrated a result that stated that 63% of respondents claimed major architectural decisions about hospital design were in place before clinical procedures had been completely planned. This is fundamentally opposed to the way in which efficient healthcare processes should be designed and a new hospital built. Healthcare operations and clinical delivery should always be planned completely prior to designing the new hospital. It serves no purpose to design a hospital without knowing exactly how the clinical execution will take place inside the building. From an executive perspective it is highly advised based upon this research to have several years of research and development of clinical process execution completed prior to entering into discussion around architectural and construction needs of a healthcare organization. The research and development leading to clinical process execution should drive the design of the new hospital. If this careful attention to research and development is not completed, the organization will essentially be acting to “put up” a building and bring it to completion while later attempting to figure out how to make healthcare clinical processes “fit” into the building as it was established. The result of this poor planning will further contribute to the variation in clinical process and the fragmentation across departments as they attempt to comprehensively provide care for admitted hospital patients. The end result is poor patient satisfaction and the rise of a new facility with capacity and throughput issues from the start.
The general sentiment among some healthcare professionals is that the Toyota Production System method does not contain the compassion that humans require in a hospital. The association with an assembly line style of care is not humane and provides no condition for meeting patient needs while they are hospitalized. It is also believed that healthcare experiences more variability than manufacturing and that automobile assembly lines are easier to control than the unique conditions of operating equipment with ill humans inside a hospital. These are generally some of the conditions and psychological concerns that a healthcare organization must first overcome on the journey to achieving robust conditions for designing healthcare process sequences of care. For the executive to answer these questions and address these notions is to realize that healthcare is only currently experiencing the variability in operations that exist today because they have not elected to completely sequence the execution of healthcare. Literature is numerous on evidence based best practices for clinical treatment. Regulatory manuals describe the conditions of healthcare operating compliance. The large gap that exists in the current healthcare system is that nationally there is no direct mandate or regulation to completely time out and plan the work of nurses in the hospital from beginning to end of each shift by sequencing the activity of work based on clinical need, evidence-based best practices, voice of customer requirements, and ultimately a staff-driven determination as to the best possible sequence for the delivery of care. It is important to mention however that recent healthcare reform initiatives such as value-based purchasing lay out the quality effort needed to achieve optimum payments under those reforms. Without a well-defined sequence of care, results will suffer and hospital payments will be lost. The sequencing of healthcare activities creates a predictable pattern of performance that allows the hospital
to achieve consistent results. When value-based purchasing demands the best a hospital can offer, the sequencing of healthcare operations via the Toyota Production System will offer a majority of the solutions that hospitals will require when planning clinical operations to achieve profits. Well-developed assembly lines in manufacturing create optimum conditions for operations. Healthcare will be required to think in the future more along the lines of bringing the sequence of care together to achieve the best result for the patient and overall the best throughput flow to keep hospital operations at optimum levels of performance. The reality is that tremendous parallels exist between production system design and healthcare operations design. This requires building work not from the physician perspective or even the nurse, but in a patient-centric fashion through lean value-adding frameworks.

To connect the logic of the Toyota Production System to a scholarly nursing framework, it is worth mentioning the American Nurses Association American Nurses Association [ANA], 2015) as a similar approach to clinical care design. This framework according to the American Nurses Association (ANA, 2015) utilizes the framework of, “assessment, diagnosis, planning, implementation, and evaluation.” Grant (2012) utilizes a framework for a new hospital construction project that links up very similarly to the nursing process. Grant (2012), a former Toyota Production System Mechanical Engineer suggested, the following “7-step path to standardized processes as a key sequence of events leading to establishing a robust healthcare process:

1. Identify the desired process to be improved.

2. Question each step in the process.

4. Answer the unresolved questions.

5. Write standardized work instructions.

6. Simulate or trial new processes to optimize.

7. Train employees and move into new facility.”

The design of this framework is quite different compared to the other methods listed in the literature as the structure by which to design a healthcare process. While much of the literature review contained many industry popular buzzwords around lean thinking and lean methodology, Grant (2012) proposes a very simple and sequentially logical framework for hospitals to design work. While lean methods are vital to the success of a process design session and are highly encouraged in healthcare today, the Grant recommendation is one that is not explicitly stated in any of the lean methods or performance improvement literature. This framework arises from the logic of a Toyota engineer. When one analyzes the steps of the sequence, nothing is so largely manufacturing specific about the recommendation, that healthcare should be resistant to the application of the process on improving the overall sequence of care as it is being designed for new hospitals. The framework itself can actually be used to improve any healthcare process.

**Recommendation for Placing the Grant Framework into a Hospital Construction Clinical Process Design Project.**

With a general understanding of the Grant framework, this next section in the discussion will explore the recommendation for implementing the Grant framework into
a hospital construction clinical process design project. The elements explored will include recommendations for project management, process formulation activities / design, and overall clinical process design project tracking. A hospital journey on the path to creating a highly reliable network of hospital sequences of care requires the vision and sponsorship of the highest levels of the organization (CEO, COO, CNO, CFO), the tactical operations perspective of clinicians, and the support of project facilitators and process engineers to help the hospital to achieve the desired results. The questionnaire results abundantly stated that all levels of the organization are required to participate in achieving optimum clinical healthcare process design.

**Recommendations for clinical process design aspects of the Grant framework.** The Grant framework for clinical process design can be implemented within the lean methods framework through what is typically described as a “Kaizen” event. Kaizen (continuous improvement) is a largely accepted healthcare lean methodology for populating a cross-functional hospital team of clinicians to serve in the capacity of a process and performance improvement team. Typically these team members are given dedicated blocks of time or are taken out of the regular sequence of work completely in order to focus complete attention on the development or improvement of a process. Within the realm of team dynamics it may be an appropriate notion to populate this team with varied levels of clinical expertise in order to have a diverse set of perspectives leading to the best practice sequence of patient care. Kaizen events are typically led by a person with a lean or process engineering background. Registered Nurses may exist within the organization that have previously had this training or the organization may seek the outside resources of a lean consulting firm to guide them during Kaizen events.
The important factor here is that the facilitator of this activity understand the role of facilitation neutrality and not be overly expressive of personal opinions or philosophies to drive the project result. The populated cross-functional teams that are typically conducting the day-to-day operations will have the best ideas for how to tactically improve processes. The facilitator should merely create the conditions for making the project successful and guide the team to its completion. Typically these teams are created by senior sponsors or administrative healthcare executives who will be making the case for change and explaining the rationale for the project to front-line workers and department managers or directors. The project facilitator or lean engineer will be executing upon the various process steps of the Grant methodology as follows.

**Identify the desired process to be improved.** Typically at the beginning of a kaizen event, the process improvement team will define the scope and objectives of the activity. This usually involves a brief meeting with the senior sponsor on the first day of the meeting where front-line staff will provide input as to the deliverables under the guidance of the senior leader as expectations for improvement are set in the formal context of the kaizen event. Scope and objective definition are important in order to prevent scope creep (wandering off track) as the dynamics of process improvement or process definition can often create conditions that may lead the team down a path of discussing variation or process problems. This may prevent the team from making progress within the originally defined scope of the project. Generally, the Kaizen team should reach consensus on day one or prior as to the scope and objectives of the improvement event. The team from this point forward will be working on defining the sequence of patient care for the required scope and objectives. The Grant framework
suggested utilizing a custom template called a (PTRE) Process Transition Readiness Evaluation form from this point forward for defining the initially projected sequence of patient care. It is noteworthy that the lean method of value stream mapping may also be an appropriate tool at this stage so that the kaizen team has an opportunity to revisit the current state of work and identify task times, present waste inherent in the process, each step in the current sequence, who is conducting the work, and where the work is being completed. This is often a good brainstorming precursor to creating an innovative future state although some organizations view the current state of work as an obstacle to future innovation and elect not to spend ample time dwelling on current state problems.

*Question Each Step in the Process: Using the PTRE Form in the Grant Framework.*

The PTRE form is essentially a working draft or skeleton that eventually will become the standardized work instruction to be followed by front-line staff when completing day-to-day patient care. A recommended practice is to dedicate a Kaizen team member to fill out the PTRE form during the meeting as the process engineer is guiding the team through the initial establishment of the process sequence. The PTRE form sample will be provided here for review. The components of the PTRE form include listing the essential process steps of the sequence. It is often best to list these steps sequentially one step at a time. This method prevents the Kaizen team from jumping forward too fast and overlooking critical items that may be of importance when creating the most appropriate sequence of work. The next column of the PTRE form is for listing if the process step is a new way of doing the work or if it is the same way as work is currently completed. As Kaizen teams work through sequential processing many questions are certain to arise. Perhaps questions will arise that have never been answered.
before. Often Kaizen teams view these questions or lack of an answer as a stumbling block that could prevent the team from moving forward with the process sequence creation. The Grant framework addresses this problem in the PTRE form by creating a column for listing questions or concerns about the process step. Process sequencing for patient care is often cross-departmental in nature and as such, the PTRE form contains a column for listing any departments that may be affected by the process sequence step. The final column on the PTRE form is for listing either responsible staff, managers, or departments for bringing closure to a specific process step that may have unresolved questions. During the facilitation of the completion of the PTRE form, the facilitator will be asking the team to describe what is the most sensible first step, second step, third step, and so on while documenting major unresolved questions about the process. The process engineer will be documenting the accountability for who should help to resolve the open issues conveyed by the Kaizen team. In the case of new hospital design or new department design, it may also be an appropriate aide to use drafting printers in order to create large scale (enlarged) blueprints of the work area if they have already been created to help assist the team with clinical process design as they are able to visualize the space they will be completing the work in. Spaghetti diagramming, which is another lean tool, may also prove useful in helping the team to arrive at an appropriate sequence of patient care for a given process. If the hospital is greenfield and no facility architectural design exists, the kaizen team has the benefit of thinking of ideal scenarios and larger than life ideas that may deliver the best customer experience. It is noteworthy however that the kaizen team executive sponsor should outline from the beginning any constraints,
monuments, or limitations that the team may need to be aware of as they are attempting to formulate the most appropriate sequence of patient care.

**Document Process Steps and Unanswered Questions on a Process Transition**

**Readiness Evaluation (PTRE) Form**

The facilitation of process step sequencing is an important task in assisting the Kaizen team toward achieving the robust patient care design. What is often the difficult for Kaizen teams is the intense pressure of the unknown that comes with making decisions about future healthcare interventions and assurance that the team has selected the ideal path. The process engineer facilitating the team should help the team to understand that they have been called to the Kaizen event in order to think creatively and challenge the present ways of thinking by using the framework to come up with the best possible sequence of patient care. Often Kaizen teams can be reassured and redirected back to progress in completing the PTRE by explaining that the form is merely a skeleton or initial draft of ideally sequenced patient care. Essentially what is written on paper at this stage is not something that cannot be undone if the Kaizen team is ultimately displeased with the result. Often the act of simulating or developing patient mock up scenarios will expose any of the process inadequacies that the staff has designed. As these emotions and conditions are experienced by the Kaizen team, it is crucial to ultimately direct them back toward the task of completing the PTRE so that an initial draft of an ideal sequence of patient care can be completed. Another reassuring mechanism is to help the team understand the consequences of variability that will exist if the team cannot come to agreement on what is an appropriate sequence of patient care. The PTRE when complete, will give the team an initial baseline for conducting the new
process. This sequence once defined, may need to be followed up by a brief validation session with the senior sponsor of the activity in order to convey progress and inform the sponsor of appropriate next steps from the perspective of the lean engineer facilitating the project.

**Answer the unresolved questions**

The next step to bringing closure to the PTRE form will be getting answers to unresolved questions that arise during the process design session and defining sequence steps. What is often the case with the questions asked by the project team on a PTRE form is that by nature, the answer to the question lies outside of the scope, knowledge, or authority of the Kaizen team. When these types of questions are presented by the Kaizen team, it is often the responsibility of the process engineer, the senior sponsor of the engagement, and perhaps a Kaizen team representative to work with those who have the power to answer the question to help them understand the background and conditions that ultimately led the team to the point of needing answers to the questions asked. As this resolution typically involves people or departments outside of the scope of the Kaizen team, the question itself may cause the impacted department to undertake its own process evaluation session or complete a PTRE form of its own in order to answer the question the team has presented. It is not uncommon for the Kaizen team to approach a leader or healthcare director about a process design question only to initially find out that that leader also does not have all of the information needed to answer the question in the best interest of the patient or the process sequence. It may be the case that for a brief period of time, a specific sequence step may not have immediate resolution. A more in-depth analysis by the affected department may be required before closure to the existing
sequence step. This will lead to the question being answered. Ultimately in every case all unresolved questions need to be answered and plugged back into the PTRE for the team to validate that the sequential order is still the most sensible approach for delivering the patient care. The answer to the unresolved question may create conditions resulting in reversal of a process step sequence. It is vital for all process step unresolved questions to be closed and reevaluated by the team in order for the sequence to progress to the next step on the path to becoming the predictable standard. The PTRE form template is listed in the appendix.

**Write standardized work instructions.** Writing standard work instructions is the most important piece of the Kaizen team project. The best sequence of patient care that has been defined by the project team will be replicated and ultimately executed each business day to provide patient care. The work instruction document will help bring the predictable working conditions needed by nursing and other clinical areas of the hospital in order to produce the quality result patients require. The process ultimately when executed in a highly reliable system will be the standard that is measured on patient satisfaction calls, Press Ganey surveys, joint commission reviews, and other quality initiatives. Writing standard work has four critical design points. First, the standard work instruction must clearly define the sequence in the “step” portion of the document. The step in the sequence should describe the actionable item that the patient care provider should be completing. If the description of the process step is not actionable, it typically is not a process step. Second, the standard work instruction should contain any supporting details or additional background information that may be needed to clarify or support getting the sequence step complete. Third, the standard work document should explain
the reason that the sequence step is being completed. Finally, the standard work
instruction document should describe which position should conduct the work. For
example, the standard work instruction for admitting a patient to a med surg unit should
specifically delineate in the sequence which process steps are the responsibility of the
nurse assistant vs. the registered nurse. The standard work instruction document should
also include any major diagrams to bring visual clarity to the sequence of care. Nursing
standard work instructions typically include computer screenshots from an electronic
health record, pictures of a medical supply, or image of what an ideal patient room setup
would look like. The standard work in final form should be made available to all
employees who are involved in completing the execution of that process. The standard
work instruction should not be deviated from, and all employees should make every
effort to conduct patient care based on the Kaizen team developed best practice contained
within the document. Culturally as the notion of standard work becomes commonplace
within the organization, greater levels of variability begin to be removed from the
hospital. Nurses and doctors typically find that adhering to the standards in a well-defined
system of standard work yields simpler, organized conditions for conducting patient care.
In an environment where standard work is now the cultural norm, the role of the clinical
supervisor and charge nurse begin to shift dramatically. Typically sources of variation
from the past and healthcare complexities from fragmented healthcare silos (isolated,
disconnected clinical operations) required charge nurses to take a team of patients as an
assignment and manage the workload of the total business operation while at the same
time conducting patient care. In a well-defined system of patient care under a
standardized work model, silos are broken down, the work is now horizontal, and
everyone knows the sequence of care and who does each step in order. The role of the charge nurse and clinical supervisor begins to advance toward shift to shift observation and measurement of the process to see if the intended result is being delivered. The Toyota Production System deploys the method of Andon which is the standard for immediately bringing attention to any problem that arises in the day to day operation so that supervisors can immediately respond in order to rapidly problem solve and expose root causes in an effort to return the process back to the baseline of standard work. A revolutionary part of this “Andon” process is that clinical supervisors will then immediately audit recently completed work to evaluate the product or part for potential failures that may have previously been undetected. For some, the public sentiment is that Toyota produces too many failures and critics have even stated that the work they complete is unreliable. The truth however is that the problem detection capabilities of the organization are robust, and the culture of making problems obvious is a requirement. Other companies may try to hide from assembly failures and attempt not to publicly disclose the failure for legal reasons. In a culture of high reliability like Toyota, an organization recognizes the improvements that can be made when they do not feel threatened or intimidated by quickly making failures obvious and improving them. The reality is that “Andon” allows the Toyota culture to be honest and welcoming of failure whereas other companies may seek to hide from a defect. Healthcare cultures for decades in hospitals have been rooted in personal attacks, shame for failure, and short-sighted attempts to fix problems with deeper root causes. In an environment of standard work, the culture shifts to an environment of open disclosure of failures and Kaizen team development to solve problems rapidly in order to return the process as quickly as
possible to baseline. The role of the supervisor and charge nurse is to constantly monitor the delivery of the process to see if the intended result is being delivered. This is a dramatic shift from the culture of individual nurse competency, once a year skills lab, or “write ups” in the event of failure. In a culture of standard work, the requirement is for all staff members to execute the same process daily. When the variability is removed from the process, the standard work itself delivers the competency and the focus becomes less about blaming people and more about execution of a well-defined system of patient care.

It is also noteworthy that sequencing care and removing variability from work is a necessary first step for organizations that struggle with labor management issues. Organizations that are constantly chasing missed targets, making up for misses, and constantly trying to refine staffing models typically have not addressed an undefined sequence of patient care execution. Typically a horizontal, well-defined, lengthy value stream of standard work will by nature deliver the staffing model as the process itself will define for labor managers what resources are needed to make a predictable process work. The Stenzel (2007) text *Lean Accounting* is a tremendous resource for organizations that are transitioning from managing labor with lagging indicators into a lean accounting model where resource designation is set in place by the standard work for the process design of patient care. Failing to address process sequences on a clinical level will put the labor manager at a tremendous disadvantage as the work is multivariable, unstable, and unpredictable. Resources will be tremendously difficult to place as the process has no consistent baseline for nurses to execute from. Registered nursing culturally is one where best practices and protocols are commonplace. The connection of this knowledge across the organization into cohesive streams of well sequenced deliverables creates the best
circumstances for making labor resource management predictable. The constant demand for contract labor will diminish in a highly predictable system for nursing execution. For years, healthcare has operated in the silo and the result has been one in which the day to day work is never the same. From a retention perspective, highly predictable conditions that flourish under a standard work system keep experienced nurses engaged, and in the long term the comfort of variability dissolution reduces the contract labor demand. When organizations shift the standard work to an electronic healthcare record environment, the Kaizen team often finds that the hospital entity needs to ask more of its physicians when it comes to order entry, understanding of healthcare processes across the organization, and executing patient care as a team. The removal of barriers and creating more favorable conditions by inserting physician requirements into the standard work is also another powerful factor that can offset labor management challenges. This happens by making the work to be completed obvious and sequential for the nurse and physician in one comprehensive document. The standard work instruction template form is located in the appendix.

*Simulate or trial new processes to optimize.* Process simulation is a critical step within the validation of standard work sequences. Manufacturing and industry often spend 8-10 years in research, development, prototyping, and simulation prior to a major project launch. The power of the depth of simulation and planning is a critical call to action as healthcare rarely spends this length of time with research and development of a specific intervention delivery sequence. Hospitals often contend with splitting labor resources between maintaining the current state while pulling current state staff offline to focus on innovation. Culturally as organizations embrace innovation and process
sequencing for healthcare, the robust research and development components will become a normal part of the organization. The resource entity will no longer feel the pressure between perceptions of losing staff from the current state to innovate the future state. R&D, lean, process sequencing, or process improvement will become like any other department such as dialysis, surgery, or medical telemetry.

Registered Nurses often write a significant majority of healthcare sequences into standard work. The progressive organizations are often writing this standard work without a new hospital being completely built. As such, the nurse is focusing on what they believe is the best sequence that will provide a legendary patient experience while at the same time creating a stable environment for healthcare delivery. The hospital operation will require some validation framework for all of this standard work that is written. Much of the standard work sequences that are written by nurses cross over departmental and clinical boundaries and this requires many different clinical backgrounds to act within the sequence and complete the procedure in a predictable manner, in the same way, every time. This will not work well if it is not practiced, improved, and validated prior to opening the hospital. It is noteworthy that the Grant model is a much stronger call to the organization than simply writing standard work. A great deal of standard work has been written in hospitals that do not develop long sequences of assembly-style healthcare and create the modes for eliminating of cross-functional variability. The Grant model suggests full integration across the system and defining first from the patient value-added perspective, exactly how the process should function. The PTRE should be written this way. The PTRE then transfers to the standard work which leads to simulation and validation. Simply writing standard work because the
organization demands it, or attempting to write standard work to keep work the same does not address the larger needs of the patient. Sequencing healthcare delivery from the patient perspective means the organization no longer feels the pressure of individually having to be the highest achiever. Rather, the process itself as it is created through innovative nursing, creates the robust conditions for clinical excellence.

This section describes simulation recommendations for the Grant sequence development model. Full scale patient mock up rooms are an excellent resource for validating healthcare delivery sequences within standard work instructions. No cost should be spared in the development of a mock up patient room. In fact, the model should be built to scale with complete interior, mechanical, and technological integration once the vision for the innovative future state has been established. If the mock up patient room does not create the nearest to reality depiction, it will not serve the nurses well as they attempt to validate healthcare assessments, medication administration, ongoing patient care, daily room turnover, and patient discharge. The purpose of integrating the reality into the mock up is not just a venue for nurses to get these cross functional sequences of healthcare correct, but it also allows the organization to push to the limits of design and of the procurement that has been established for the hospital to see if the process will function as intended prior to the hospital being built. If a technology offering for instance claims to be a fully integrated clinical call system that interacts with an electronic health record, the simulation conducted in a mock up environment may shed light on technology gaps or perhaps even middleware needs. While pushing technology and infrastructure to the limits are some of the secondary benefits of a full scale patient mock up room, the primary purpose remains defining and improving patient care.
Simulation of the routine sequence of patient care standard work instruction on a medical unit is a highly recommended activity. This is critical because it is one of the most highly executed activities in the hospital by volume. It is the sequence of care that is prone to the most variation, delay, medical errors, and sources of frustration when things go wrong for the nurse and the patient as they exist within less than favorable operating conditions. If a patient room will be equipped with a computer for the nurse inside and outside of the patient room, medical supplies in a nurse server, and a nurse call system with an iPhone for instance, all of these items should be live and active for the nurse to simulate with while working in the mock up patient environment. The simulated version of the electronic health record should be active for the nurse to use. Pharmacy Directors should interact with the mock up director to provide guidance on how to simulate medication with empty medication boxes, pieces of candy (pills), or other items that can be made to look like a medication pass during simulation. All efforts should be exhausted on the front side to make the simulation of patient care as near as possible to the innovative future state. Healthcare providers for quite some time in annual training have been asked to “explain” how they would conduct a specific medical procedure. This is fundamentally opposed to the nature in which a mock up simulation functions. Healthcare workers simulating a routine patient care standard work sequence for a medical surgical unit should practice just as though the patient is actually in the mock up room laying in the patient bed. The purpose of the simulation of patient care standard work is twofold. First, the nurse needs to validate that the sequence of care is appropriate. Essentially, the nurse is working through the act of treating the patient to see if all human factors and operational factors in the prescribed to sequence are logical for thousands of
repetitions in the live environment. Second, the nurse working through the simulation may uncover elements of providing the patient care that could only be discovered by conducting the patient care in a mock up room. A Kaizen team working through this simulation may open the PTRE and standard work sequence back up for discussion and revision through the power of simulating these healthcare sequences. The simulated patient mock up room is such a powerful tool for kaizen teams generating these long sequences of patient care through standard work that improvements are sure to be gained each time a simulation is performed. One of the most often overlooked aspects of patient care delivery is hardwiring customer service standards into the standard work sequence. In some instances, the standard work may be most appropriately written to check with the patient first to address the customer needs and timing prior to beginning a routine sequence of patient care standard work. The standard work may include entering the patient room and conducting what Studer (2015) defines as the healthcare “Acknowledge, Introduction, Duration, Explanation, and Thank you (AIDET)” protocol while asking the patient if they have immediate needs. The most frustrating part of being hospitalized happens when patients are constantly bombarded, often late at night by healthcare staff knocking on doors to conduct patient care leading to sleep disruptions. Often this is happening to the patient simply because the most appropriate healthcare sequence and standard work has not been developed. The variation of the current state manifests itself in a poor patient experience as the patient is already sick and exhausted only to have the shortcomings of the healthcare delivery system make them feel worse than they already do. If checking with the patient is written into the standard work instruction, it is important to validate that the sequence of standard work as it is written addresses any
issues that would contribute to processing delays. For instance if the prep work of executing the standard work requires the nurse to walk to different parts of the hospital to gather medical supplies, the simulation may lead to the discussion of supply centralization which may need to become a process transition readiness evaluation (PTRE) discussion for supply chain. The point of the simulation is to mitigate these circumstances so that nothing takes the nurse off the clinical pathway of providing the standard work instruction sequence of healthcare delivery. Any opportunity the healthcare system introduces into the environment that disrupts the nurse from the standard work is another source of variation and delay that keeps the customer from being satisfied with the intervention provided. It is crucial for ancillary services to be involved with these simulations in order to get the standard work right, the supplies in the right place, and the staff human movement correct so that the clinical pathway is not disrupted while caring for the patient with built in waste from processes not being thought through. If the clinical pathway of standard work has to be disrupted, the standard work should also build in the Toyota Andon model so that the leadership have planned execution for problem solving when executing the standard work becomes problematic.

As the nurse works through the standard work sequence, gaps will be exposed around fundamental medical supply needs, linens, bathing the patient, responding to code blue, pain management, low blood sugars, etc. The Kaizen team should enlist a trained observer to validate the standard work and capture any problems that arise during the simulation so that they can be reviewed in the mock up room at the conclusion of the simulation. This may alter the future standard work and require it to be revised and
simulated again. The result of the simulation may require facilities directors or process improvement engineers to work with local contractors or industry for custom solutions to hospital design if a healthcare sequence uncovers mechanical issues that need to be resolved prior to opening the hospital.

**Train Employees and Move into New Facility.** Nursing educators are a critical to success factor for the broad launching of standard work instructions. Healthcare educators might express the frustration of variance and may not have standardized tools to teach from because healthcare for decades has failed to address the central issue of creating common operating conditions that are well understood by all staff. Once the nursing education staff is assured by the comfort of the common conditions created by standard work sequences, they have critical expertise in helping the entire hospital staff to learn to replicate the procedures. The education process has two fundamental phases. First, the education staff must be a part of the Kaizen team so that once the process is finalized; it can begin to be replicated within the current state. Replacement hospitals often drastically alter patient care operations. Attempting to insert innovation into a former state hospital prior to opening a new building is often the best way to begin to train staff on the how operations will be driven by the standard work. Second, when the new hospital is finally built, clinicians should move as quickly as possible to begin training in the new facility prior to the grand opening. Hospital construction deadlines are tight and rarely provide ample time in the new building before it opens. In fact, some hospitals are built and opened to the public before being entirely complete. With these tight construction timelines, it is even more important to use the mock up space and attempt to innovate in the old hospital prior to moving in. Once inside the new hospital,
staff should be working with educators to constantly execute the standard work documents written so that on the day the hospital opens, the patient is already receiving the best care possible. Educators need to develop competency tracking tools to monitor who has been educated to the standard work, trained in the standard work, and operating the standard work independently. Controlled knowledge spread is essential in the early life of a new hospital.

While moving into the new hospital on day one is one of the most intense and feared aspects of moving into a new building, it is beyond the scope of this research. It should be mentioned here that a well-executed project plan around day one move coupled with moving patients during weekend or off-peak hours creates the best conditions for getting patients out of an old building and into a new one. This patient transfer activity typically is not problematic.


Healthcare administrators are constantly concerned with the movement and management of knowledge within the organization. With a new hospital process design project, much information is passed through formal and informal channels. The administrative concern is that resources are maximized during the effort, project duplicate work is non-existent, and that all team members have the most current information about decisions that have and have not been made. While some healthcare project consulting firms might suggest a decisions log or a tracking log to control information dissemination, the majority of this information regarding decisions should rest within the standard work document itself and the sequences of care planned for operations, as this
document really will be that which drives performance. From a project management perspective, it is important to know which department in the new hospital will be heading up specific patient care sequences and where gaps exist between departments when a process may not have yet been fully developed. The project plan should be listed by hospital department, and contain each critical process that touches the patient directly. These processes should be established by a kaizen team first. All ancillary functions such as technology, medical records, etc. should be defined by the standard work of caring for the patient. In other words, the standard work should tell the hospital what ancillary services are needed when and where. Each process listed in the project plan should have a PTRE completed, and follow the Grant model for getting the patient care operational.

The project plan for tracking purposes should also list some measures that describe the newly created sequences status to completion i.e. process for patient medication administration by nursing is 75% complete or 75% formulated.

**Recommendations for project tracking aspects of the grant framework for clinical process design**

Project tracking is a critical aspect of keeping the standard work development in motion for all of the kaizen teams that will be working to define processes. It is suggested that kaizen teams have cross-functional status update meetings from time to time in order to spread knowledge about process design and clarify questions for other team members as they are in progress of writing standard work as well. A well-defined standard work project plan will provide metrics for the overall activity that will describe how much work is left to do, what processes have not been defined, and what key issues are the focuses of the Kaizen teams as they work. Kaizen teams may work together for extended
periods with very limited interaction with others. They may cross over boundaries to other areas of expertise only when the process definition or technology changes require it. These teams will be working very hard on the innovative future state. Putting these stakeholders together on occasion to provide an overall project status update and allowing the opportunity to ask clarifying questions will provide additional perspectives for teams to consider as they finalize the writing of these long standard sequences of patient care. The process engineer should create standard work for the project tracking and produce the same set of metrics for each meeting. As the hospital advances toward opening of the new building, the Kaizen teams should experience the same predictable conditions for the meeting without scope creep (wandering from the stated task).

**Summary of the Grant recommendations.** The Grant model for healthcare process sequencing provides a very logical, and easy to follow framework for hospitals to use as they design work for a newly constructed hospital. Toyota Production System is designed to create operating conditions that are free of variability, predictable for the worker to follow, with robust procedures for “Andon” when things go wrong and problem solving is needed. Grant (2012) adapted that model as a solution to help new hospitals develop a firm operations infrastructure. The framework does not leave the hospital to guess or wonder philosophically what it is about. Rather, the work is defined and the entire day of production is driven by the standard work that produces the result it was designed to achieve. Healthcare organizations in the future will learn to transition clinical supervisors and nurse managers into process observation and Andon experts with less emphasis on individual performance and more attention to systems performance.

Essentially a robust process design can have any Registered Nurse plugged into it, and
the result should always be the same if the standard work is delivering the intended result the hospital designed it for. Healthcare executives may ask how this is fundamentally different than what they are already doing. The answer lies in the Grant model suggestion that the organization be focused on robust process design, planning nearly every tactical piece of nursing and patient centered work, and delivering that same robust condition every day without deviating from it. Hospital day-to-day operations in the current state leave too much variability in the clinical pathway, which creates conditions that punish and destroy the art and science of nursing.

Recommendations for future clinical applicability as defined by the principal investigator: code blue response clinical process engineering

(researcher contribution)

Registered Nurses typically individually and jointly are assessed on Advanced Cardiac Life Support or ACLS protocols which are the cornerstone skills of providing Code Blue services to patients who become unresponsive and require lifesaving cardiopulmonary intervention. Medical Doctors are also trained in life saving cardiopulmonary skills in order to intervene in an emergent cardiopulmonary situation. While these skills are standardized from an accreditation perspective, the healthcare organization often fails to place a sequential set of best practices in place to regulate Code Blue response. It is possible to use the tools of lean standard work and lean 5S (sort, straighten, shine, standardize, and sustain) to bring role clarity and a predictable sequence of care to the hospital environment that houses the nurses and doctors with these lifesaving skills. In this section, recommendations will be provided specifically for the applicability of standard work during Code Blue response as well as 5S systems to
support the medical supplies of Code Blue response as a future potential benefit to healthcare using clinical process design methodologies.

**Clinical engineering of Code Blue response leading to standard work instruction**

The gap that exists in the current state of Code Blue is taking the ACLS standards of care and placing them within the elements of hospital design, location of supplies, technology, and other human factors that need to be considered in each individual facility in order for successful code blue management to take place. As most healthcare organizations have a code blue response team, the recommendation would be for these teams to collaborate in Kaizen in order to formulate the standard work instruction. This activity may begin be having the leader of the team discuss specific scope and objectives required for the meeting. The code blue team should be educated as to the lean observation framework “8 wastes” (GoLean 2015) which is essentially to seek out in observation what about the code blue response in the current state of work is defective, overproduced, or causes wait time. The team should also target identification through observation when the work seems confusing or unclear. Transport failures may also arise in the course of a code blue and should be identified. If excessive processing or excessive motion is contributing to quality issues of the code blue, those factors should be captured in observation. It is also possible that medical supply inventory failures may be observed and should be captured for mitigation in future work instructions.

When the code blue team has completed cycles of real time observation, they should be permitted to develop a current state value stream map of Code Blue procedures that clearly state each step in the process. Each process step should define who is assigned to complete the work if it is known. The value stream map should also define
where the work is being done and approximately how long it takes to complete process steps in the current state. The value stream map could also include a joint discussion of the 8 wastes where the team plugs the waste observed into the process map steps while also potentially listing waste issues that arise based on the personal experiences of the code blue team. While not all problems or identification of waste may be mitigated initially, it is important to capture all improvement potential and document it in an ongoing project plan for continuous improvement or Kaizen.

The code blue team now armed with a comprehensive view of the current state should be well positioned to begin formulating the future state of code blue in the facility. The future state of code blue should be created by maximizing value-added pieces of work and minimizing waste inherent in the current state of work through mitigation and problem solving. Some of the future improvements to code blue may include developing standard work around the clinical intervention specifically by perhaps assigning specific placement of code blue team members strategically in different positions around the patient bed based on the tasks delegated. The code blue team may also want to designate specific providers each shift to fulfill specific roles in the event of a code blue. ACLS protocols in the current state encourage delegation by a team leader for various roles in the moment of care for code blue. The future state of code blue may also include these specifics in advance for who potentially may respond and fulfill specific roles of the code blue. The future state of work may also require discussions around content of execution and where scope and objectives begin and end for each role. This discussion will further contribute to stable, predictable conditions for the code blue response. The team may also enter into discussion surrounding timing expectations for each step in the sequence and
what would be considered normal or required for saving the patient during the code blue response. All of these discussions can be managed by a competent lean engineer as standard work is being formulated. Based on the outcome of these discussions the standard work should begin to take place as steps are defined in the sequence, key points, and reasons for process steps are defined. Role clarity can be plugged into the standard work document and diagrams or supporting information may need to be applied to make the work more visual. It is likely that the code blue team will also need to address issues of standardization for code blue carts and code blue medical supplies during the Kaizen. It may be required to incorporate medical supply requirements of the code blue into the standard work instruction. The team should be encouraged to simulate the procedures and the standard work in a mock up environment to validate the assumptions of design. As the standard work is validated and the 5S of code blue supplies begin to yield a more stable working environment. The code blue team can transition toward further facility education of the changes and ultimately begin to implement the standard work in a live environment.

**Lean 5S (sort, straighten, shine, standardize, and sustain) for code blue medical supplies and supply carts.** Code blue carts are portable medical supply systems on wheels that can be moved to a code blue situation. The lean 5S method is a tool used to bring stability to the work of code blue supplies. The code blue team should work through the “sort” function by having a discussion about medical supplies in the code blue cart that are perhaps being underutilized or are potentially no longer necessary. This allows the code blue team to focus only on the supplies required to do the work. In the “straighten” function of 5S, the code blue team may wish to discuss location placement
of medical supplies as the future state of work may have liberated supply space that may result in an optimized configuration. As the decision is made regarding placement, the “shine” function of 5S is designed for the code blue team to clean and make ready, the supply cart for use. The shine function also allows the code blue team to inspect for mechanical failures with the cart itself or with medical supplies that may need to be replaced or have expired. The “standardize” function may be required for the code blue team to potentially write standard work instructions for the order and upkeep of the code blue cart itself. Standardization of medical supply locations within the cart can also be established through deployment of visual controls. The “sustain” function of 5S may result in the code blue team putting methods in place to ensure the long-term existence of the new procedures put in place. This can be accomplished by placing routine tasks connected to the processes of code blue maintenance in the workflow of nurses from shift to shift during off-peak hours. Task cards are often a good tool to list specific duties to see to the “housekeeping” of code blue equipment maintenance and functionality.

**Code blue conclusion.** The desired outcome of this work is that the code blue process delivers quality, reliable results each time that it is performed. While patient mortality rates may be an indirect indicator of success, the role of the charge nurse or clinical supervisor may be to observe the process as it is being conducted to see if the intended result is being delivered or if the code blue state of work should re-enter into Kaizen. The cultural expectation should be that leaders demand constant improvement of code blue systems of performance and execution as technology changes, regulations are imposed, or science changes to advance the survival of the patient.
Conclusion

The survey results for this research on clinical process design in newly constructed hospitals pointed clearly to the notion that hospitals are often set in place from a visionary perspective and drafted for construction prior to the formulation of clinical procedures and clearly defined sequences of care. By definition, this places the hospital prior to opening in a condition of discovering how to make the work of patient care fit into the previously defined spaces. This out of synch project progression may cause the hospital to have a suboptimal arrangement for providing the best patient care. If an organization is set on building a new hospital, the hope is that the patient will be receiving the best care possible from the point of opening the new building. If the creation of hospital architectural draft occurs first, the process of fitting care into that space may prove difficult. The more sensible approach is to first design the patient care in a way that delights and pleases patients and patient families. Based on this innovative approach to revolutionary patient care, the spaces should be created to augment the design of care that will take place in a new hospital. This reverse approach may also cause the organization to overlook key equipment needs, regulatory requirements, and drive the organization toward significantly high cost remodels of the new space after the fact.

The project management framework is also a vital aspect of hospital construction, as it was identified in the survey instrument that project plans were often communicated to clinical leaders as construction progressed and metrics regarding the state of process readiness were also conveyed to the organization. As processes are defined, these project plans are important to put in front of clinical leaders who are responsible for the
development of key procedures that touch the patient directly. Project plans for clinical process design and metrics to completion assist the leaders with establishing priorities and naming key resources to teams that will help with future clinical formulation work. It is also worth mentioning the importance of standardization of project plans across the organization helps to keep the organization grounded and reviewing the project plans in the same way. This may be of great benefit to the organization in the case of cross-functional project issues.

The survey results concluded that strategies, forms, and templates arising from the LEAN methods framework were utilized as resources to guide teams on clinical process design projects for newly constructed hospital spaces. These tools are important to hospitals on this journey because the framework itself is established to bring order to work systems and structures that previously existed in a state of chaos, confusion, and waste. Six-Sigma frameworks are designed to bring measures to work that have been in existence previously as defect free. When healthcare is operating in near constant conditions of variability, the lean tools continue to be the desired framework for first helping these hospitals establish clinical baselines and over the life of a new hospital as processes are culturally accepted and better understood, the transition can advance toward six sigma measures. Based on my interaction with lean hospitals and the literature described, at least 5-10 years of lean discipline is required before the organization may begin to think about the application of Six-Sigma reliability measurement in connection with clinical work.

As clinical work is defined, the survey results point to the need for simulations and mock-ups of patient care to validate the clinical operating environment as it has been
formulated. The benefit to the organization is that it will be better positioned to work out operational problems in advance of potentially causing clinical harm or damage to a patient. The survey also connected patient safety to the use of these mock-ups conditions to validate that patient care was fit for delivery to hospital patients in the system. Additionally, the organization that established proper simulation frameworks may also be able to test the limits of ancillary operations such as technology, supply chain, and pharmacy to see if it will be able to deliver the intended results of patient care established by creation of the clinical standard work. The survey results also pointed to all levels of the organization being required to invest in and be involved with the clinical design of patient care procedures. As a project of clinical process engineering advances, the creation of standard work magnifies the interconnectedness of a healthcare system and it requires all levels of the organization to collaborate regarding sequences of work in order to define the order in which the value-added patient care treatments and services will be delivered to patients.

Healthcare sequencing of processes is a revolutionary way of delivering healthcare. In most healthcare institutions the silo is the norm. Visionary work is required to convince leaders of healthcare organizations that it is possible to develop an assembly line-style of patient care delivery. Most executives have never been exposed to the rationale that assembly-line style of care should be conceived for the purposes of high reliability in patient care. The variables in healthcare are constant and nurses are rarely given the comfort of predictable working conditions and this state of work has been normalized in the industry. Process sequencing may seem at first without compassion, care, or comfort to those who are considering replicating lean manufacturing techniques.
into American hospitals. The application of lean techniques actually improves clinical stability to a future state where compassion, customer service, and on-time delivery of patient care are built-in components of standard work. Transitioning to this method of healthcare delivery requires the proper framework to help clinicians and executives to see comprehensively, the waste that is present in healthcare delivery silos. When value-adding patient perspectives define the healthcare sequence, silos surrounding healthcare operations move to horizontal interconnectedness.

The framework to this achievement lies in the manufacturing and industrial disciplines of process engineering and product design. Historically these improvement frameworks were not included in Registered Nursing or medical school curriculums. Innovative healthcare organizations of the future faced with government-induced reforms of Medicare, will be required to synergize with these process engineering concepts from manufacturing and industry. In the course of completing this work, it is often the habit of healthcare organizations to gravitate toward present condition metrics and attempt to optimize those processes which never had horizontal interconnectedness applied to them. Lean manufacturing methods contain the tools that healthcare organization of the future will require to yield horizontal interconnectedness of well-defined healthcare delivery sequences.

After an organization has developed cultural and operational excellence with process definition tools from the lean methodology, the robust process can then begin measurement with six-sigma tools. For healthcare operations new to the lean journey and process sequencing, the timeframe from transition of lean framework to lean six-sigma is 5-10 years at minimum. Essentially, if a process is not first performing in an optimum
state, it is reckless to attempt to measure its nearness to six-sigma reliability. This is the disconnect many healthcare executives today fail to recognize when deploying a six-sigma program before defining clinical process excellence through process sequencing with standard work instructions and other lean tools.

While many tools and methods exist in the quality realm where process sequencing of healthcare services is the topic, the framework defined by Grant and the tools that accompany that framework from the discipline of lean fundamentals are better prepared to establish the initial process stability most hospitals will require. For the healthcare executive these specialties are new to most organizations and require thinking of healthcare much more from the customer requirement perspective, and less from nurse or physician-centric desires in work shaping. All process sequencing activities should involve those clinicians who care for the patient and they should include former patients on the journey to defining how hospitals should conceive healthcare operations. These project teams should write standard work instructions to set a baseline for operating performance. These standard work instructions should be simulated in a test and trial environment.

Once optimized, these standard work instructions should be placed into the hands of healthcare educators to spread the knowledge and bring the sequence to full operations inside the hospital. Successful organizations in the past who have applied these techniques have the common characteristics of robust research and development bodies specific to lean fundamentals and healthcare performance improvement. These departments spend months to years understanding customer requirements and creating robust operational value streams, which contain the sequence of work and standardized
work instruction. The organization culturally transitions to a healthcare entity focused less on individual performance and more on measurement to see if the defined processes are delivering the intended results.

The role of nurse managers and clinical supervisors shifts dramatically from individual accountability management to systematic process delivery. Clinical supervisors are positioned to stop the process (Andon) when it is not delivering the intended result and quickly uses the high reliability infrastructure of lean tools to launch into modes of rapid problem solving to get the healthcare sequence back on track. This is different than the way in which healthcare operates today. Clinical supervisors to some extent stop the work when it is not delivering the intended result but they are really only stopping failures that arise from process fragmentation within a silo. As this happens daily in multiple silos throughout the organization, the patient experience is jeopardized within the hospital. The correction of this deficiency can be improved by using the tools discussed in the Grant model, lean tools, and the Toyota Production System to develop an absolute sequence of healthcare delivery that healthcare providers can work from each day as a well-understood baseline of performance. With healthcare reform for payment and transition to quality driving financial success, the opportunity has never been greater for organizations in healthcare to move to this model. Though few organizations have had limited success with this model of application as it is in healthcare infancy, manufacturing and industry contains decades of experience in deploying the framework required to create the most successful hospital organizations of the future.
Appendix A: Survey Instrument for Clinical Process Readiness Evaluation

1. During new healthcare facility construction, did your organization have a project plan for evaluating the feasibility or readiness of current patient care procedures or business practices for future use in the new facility?

2. Did your healthcare organization track and report on metrics related to process readiness for your patient care or business procedures as they were established for your new facility?

3. Was the project plan for clinical / business process evaluation or readiness standardized across all departments? (Was there a plan for doing it the same way across affected departments)?

4. What types of activities, forms, and tools were used to conduct process evaluations for business / clinical processes for the new healthcare facility?

5. What key roles were involved in evaluating business / clinical processes for readiness at the new healthcare facility?

6. Please describe any form of strategic planning or performance improvement (lean, six-sigma) used in the course of clinical & business operations process evaluation / readiness for the newly constructed healthcare facility.
Appendix A1: Continued Survey Instrument for Clinical Process Readiness Evaluation

7. How did you know when a business or clinical process was safe to start using at the new healthcare facility?

8. What types of employees were typically involved in evaluating clinical or business process readiness prior to moving into the new healthcare facility?

9. Were major architectural decisions about the design and layout of the new healthcare facility in place before key clinical / business processes had been completely planned?

10. Please describe any routine sequence of events that took place during process evaluation meetings or activities for clinical & business process readiness at the new healthcare facility.
Appendix B1: Survey Results for Clinical Process Readiness Evaluation

Q1. During new healthcare facility construction, did your organization have a project plan for evaluating the feasibility or readiness of current patient care procedures or business practices for future use in the new facility?

Answered: 27  Skipped: 0

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<tr>
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<td>0.00%</td>
</tr>
<tr>
<td>Prefer not to answer.</td>
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</table>
Appendix B2: Survey Results for Clinical Process Readiness Evaluation

Q2. Did your healthcare organization track and report on metrics related to process readiness for your patient care or business procedures as they were established for your new facility?

Answered: 27  Skipped: 0

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Appendix B3: Survey Results for Clinical Process Readiness Evaluation

Q3. Was the project plan for clinical / business process evaluation or readiness standardized across all departments? (Was there a plan for doing it the same way across affected departments)?

Answered: 27  Skipped: 0

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<td>NO</td>
<td>18.52%</td>
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<td>Prefer not to answer</td>
<td>3.76%</td>
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Appendix B4: Survey Results for Clinical Process Readiness Evaluation

Q4 4. What types of activities, forms, and tools were used to conduct process evaluations for business / clinical processes for the new healthcare facility? (Type "N/A" if you prefer not to answer this question.)

Answered: 25  Skipped: 2

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<td>12/2/2014 8:58 AM</td>
</tr>
<tr>
<td>2</td>
<td>n/a</td>
<td>12/2/2014 8:39 AM</td>
</tr>
<tr>
<td>3</td>
<td>System planning, department planning that included assumptions and issues. Tracking tools and team rooms were used.</td>
<td>11/5/2014 10:15 PM</td>
</tr>
<tr>
<td>4</td>
<td>Mediated group discussion</td>
<td>10/30/2014 9:21 AM</td>
</tr>
<tr>
<td>5</td>
<td>Concept of Operations meetings and documenting</td>
<td>10/29/2014 11:30 AM</td>
</tr>
<tr>
<td>6</td>
<td>N/A</td>
<td>10/22/2014 10:11 PM</td>
</tr>
<tr>
<td>7</td>
<td>Multidisciplinary meetings and phone calls process deadline spreadsheets</td>
<td>10/8/2014 1:14 PM</td>
</tr>
<tr>
<td>8</td>
<td>N/A</td>
<td>9/30/2014 11:24 PM</td>
</tr>
<tr>
<td>9</td>
<td>Cient sheets, minutes of meetings, equipment inventory lists, outstanding issues lists, etc.</td>
<td>9/30/2014 2:11 PM</td>
</tr>
<tr>
<td>10</td>
<td>We conducted activities that used 'mock' patients on several different days to move them through all of our processes and procedures. Very effective.</td>
<td>9/30/2014 12:19 PM</td>
</tr>
<tr>
<td>11</td>
<td>Day in the life scenarios - reenacted all possible situations we would have in the hospital.</td>
<td>9/30/2014 11:44 AM</td>
</tr>
<tr>
<td>12</td>
<td>n/a</td>
<td>9/30/2014 11:34 AM</td>
</tr>
<tr>
<td>13</td>
<td>We developed our own spread Sheet to track activity and established a team room site for all the share</td>
<td>9/30/2014 11:33 AM</td>
</tr>
<tr>
<td>14</td>
<td>n/a</td>
<td>9/21/2014 4:39 PM</td>
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Appendix B4: Continued Survey Results for Clinical Process Readiness Evaluation

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<tr>
<td>15</td>
<td>N/A</td>
<td>8/5/2014 7:29 PM</td>
</tr>
<tr>
<td>16</td>
<td>Standard project plan forms used; all day, half day, and weekly meetings were held over a two year period to develop and implement the plan prior to opening the new hospital.</td>
<td>8/1/2014 2:27 PM</td>
</tr>
<tr>
<td>17</td>
<td>We completed readiness testing but run patient scenarios from admission to discharge.</td>
<td>8/12/2014 1:30 PM</td>
</tr>
<tr>
<td>18</td>
<td>Lean 3P methodology, value stream mapping, standard work</td>
<td>7/10/2014 7:21 AM</td>
</tr>
<tr>
<td>19</td>
<td>Lean foundation with std work for evaluation and process for cradle to grave of project</td>
<td>7/10/2014 12:04 PM</td>
</tr>
<tr>
<td>20</td>
<td>Break out design sessions Voting session Voice of the customer</td>
<td>7/6/2014 3:06 PM</td>
</tr>
<tr>
<td>21</td>
<td>Utilization studies, Collaborative design using 3P process, full scale mock-up simulation and computer simulation, standard work Kanban events to implement the new process, and weekly project team meetings</td>
<td>7/6/2014 2:22 PM</td>
</tr>
<tr>
<td>22</td>
<td>n/a</td>
<td>9/22/2014 1:49 PM</td>
</tr>
<tr>
<td>23</td>
<td>Activation Plan, Departmental operation plans, Activation Committee structure (Steering Committee, Physician Committee, Operations Committee, Patient Experience Team, Occupancy Planning Committee, Education &amp; Orientation Committee)</td>
<td>9/22/2014 1:39 PM</td>
</tr>
<tr>
<td>24</td>
<td>n/a</td>
<td>9/22/2014 1:26 PM</td>
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</table>
Appendix B5: Survey Results for Clinical Process Readiness Evaluation

Q5. What key roles were involved in evaluating business / clinical processes for readiness at the new healthcare facility? (Type "N/A" if you prefer not to answer this question.)

Answered: 25  Skipped: 2

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<th>#</th>
<th>Responses</th>
<th>Date</th>
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<tbody>
<tr>
<td>1</td>
<td>CNO, CEO, Risk Manager and all Directors</td>
<td>12/2/2014 6:58 AM</td>
</tr>
<tr>
<td>2</td>
<td>n/a</td>
<td>12/2/2014 8:30 AM</td>
</tr>
<tr>
<td>3</td>
<td>All department clinical, nursing, and ancillary. Directors and leaders from each area.</td>
<td>11/5/2014 10:15 PM</td>
</tr>
<tr>
<td>4</td>
<td>Leadership representing hospitals throughout the division</td>
<td>10/8/2014 9:21 AM</td>
</tr>
<tr>
<td>5</td>
<td>N/A</td>
<td>10/25/2014 11:20 AM</td>
</tr>
<tr>
<td>6</td>
<td>N/A</td>
<td>10/22/2014 10:11 PM</td>
</tr>
<tr>
<td>7</td>
<td>CEO, CNO, MEC, Department Directors</td>
<td>10/8/2014 1:14 PM</td>
</tr>
<tr>
<td>8</td>
<td>n/a</td>
<td>9/30/2014 11:24 PM</td>
</tr>
<tr>
<td>9</td>
<td>NA</td>
<td>9/30/2014 2:11 PM</td>
</tr>
<tr>
<td>10</td>
<td>All staff were involved in evaluating processes, as well as outside observers.</td>
<td>9/30/2014 12:19 PM</td>
</tr>
<tr>
<td>11</td>
<td>administration, management, employees</td>
<td>9/30/2014 11:44 AM</td>
</tr>
<tr>
<td>12</td>
<td>n/a</td>
<td>9/30/2014 11:34 AM</td>
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<tr>
<td>13</td>
<td>This was the role of department leadership and executive leadership</td>
<td>9/30/2014 11:30 AM</td>
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<tr>
<td>14</td>
<td>Director of Clinical Transformation</td>
<td>6/21/2014 4:50 PM</td>
</tr>
<tr>
<td>15</td>
<td>Process redesign coordinator for clinical processes. Other departments addressed using existing staff in their departments.</td>
<td>8/5/2014 7:25 PM</td>
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## Appendix B6: Survey Results for Clinical Process Readiness Evaluation

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<tr>
<td>16</td>
<td>Director of Transformation; Director of Clinical Transformation; Project managers, performance engineers, clinical directors, front-line staff and physicians</td>
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</tr>
<tr>
<td>17</td>
<td>Education department with all other departments at teh new facility</td>
<td>8/1/2014 1:35 PM</td>
</tr>
<tr>
<td>18</td>
<td>Process participants, process owners, medical staff, administrative leaders</td>
<td>7/19/2014 7:21 AM</td>
</tr>
<tr>
<td>19</td>
<td>N/A</td>
<td>7/10/2014 12:04 PM</td>
</tr>
<tr>
<td>20</td>
<td>NA</td>
<td>7/9/2014 3:06 PM</td>
</tr>
<tr>
<td>21</td>
<td>Senior executives Clinicians Support Staff Process Improvement Staff Space Planning Staff Project Manager Staff Process Owners Staff Architect partners Construction Partners Equipment Vendors Patients</td>
<td>7/9/2014 2:22 PM</td>
</tr>
<tr>
<td>22</td>
<td>Current managers of parallel services at existing facility</td>
<td>5/22/2014 1:48 PM</td>
</tr>
<tr>
<td>23</td>
<td>Steering Committee which was made up of CEO, CMO, CNO, Operation directors, Activation Coordinator, Facility Mgr VP, CFO</td>
<td>5/22/2014 1:35 PM</td>
</tr>
<tr>
<td>24</td>
<td>n/a</td>
<td>5/22/2014 1:26 PM</td>
</tr>
<tr>
<td>25</td>
<td>See Process Interviews listed above. There was one designated Project Manager.</td>
<td>5/22/2014 10:03 AM</td>
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Q6 6. Please describe any form of strategic planning or performance improvement (lean, six-sigma) used in the course of clinical & business operations process evaluation / readiness for the newly constructed healthcare facility. (Type "N/A" if you prefer not to answer this question.)

Answered: 25  Skipped: 2

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<td>2</td>
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<td>12/2/2014 8:39 AM</td>
</tr>
<tr>
<td>3</td>
<td>Both lean and six-sigma</td>
<td>12/2/2014 8:33 AM</td>
</tr>
<tr>
<td>4</td>
<td>Equipment list and budgeting provided by corporate for us to stay within budget</td>
<td>11/5/2014 10:16 PM</td>
</tr>
<tr>
<td>5</td>
<td>N/A</td>
<td>10/30/2014 9:21 AM</td>
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<td>6</td>
<td>N/A</td>
<td>10/29/2014 11:30 AM</td>
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<td>10/9/2014 9:14 PM</td>
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<td>9</td>
<td>n/a</td>
<td>9/30/2014 9:24 PM</td>
</tr>
<tr>
<td>10</td>
<td>Looked mostly at volumes, financial return. Once with the NICU expansion, we measured staffing productivity if all nurses were in one location vs 5.</td>
<td>9/30/2014 2:11 PM</td>
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<tr>
<td>11</td>
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<td>12</td>
<td>N/A</td>
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Appendix B6: Continued Survey Results for Clinical Process Readiness
## Evaluation

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<tr>
<td>14</td>
<td>we were a combination of all the above. With a new facility what was more important in the beginning was to develop a culture. We used &quot;If Disney Ran your Hospital&quot;</td>
<td>3/30/2014 11:33 AM</td>
</tr>
<tr>
<td>15</td>
<td>n/a</td>
<td>8/21/2014 4:50 PM</td>
</tr>
<tr>
<td>16</td>
<td>N/A</td>
<td>8/5/2014 7:25 PM</td>
</tr>
<tr>
<td>17</td>
<td>Adaptive Design which is similar to lean; PDCA methodology</td>
<td>9/1/2014 2:27 PM</td>
</tr>
<tr>
<td>18</td>
<td>Applied lean principles</td>
<td>7/16/2014 7:21 AM</td>
</tr>
<tr>
<td>19</td>
<td>Lean VSM for service line flows and tie back to higher level enterprise VSM. 3-P for design of Facility and Detail to support programmatic decisions Volume analysis and</td>
<td>7/18/2014 12:04 PM</td>
</tr>
<tr>
<td>20</td>
<td>Inviting key stakeholders, staff, and support services in the process involving the architects, construction company and an estimator from the start of design to the completion of the detailed designs. Ensuring you stay within budget. Staying within the footprint of the construction Utilizing 3P Tool Utilizing 7 Flows</td>
<td>7/9/2014 3:06 PM</td>
</tr>
<tr>
<td>21</td>
<td>Utilization studies, Collaborative design using 3P process, full scale mock-up simulation and computer simulation, standard work Kanzen events, go live simulation</td>
<td>7/8/2014 2:22 PM</td>
</tr>
<tr>
<td>22</td>
<td>n/a</td>
<td>5/22/2014 1:48 PM</td>
</tr>
<tr>
<td>23</td>
<td>N/A</td>
<td>5/22/2014 1:35 PM</td>
</tr>
<tr>
<td>24</td>
<td>n/a</td>
<td>5/22/2014 1:28 PM</td>
</tr>
</tbody>
</table>


<table>
<thead>
<tr>
<th>ID</th>
<th>Description</th>
<th>Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>25</td>
<td>Lean</td>
<td>5/22/2014 10:03 AM</td>
</tr>
</tbody>
</table>
Appendix B7: Survey Results for Clinical Process Readiness Evaluation

Q7 7. How did you know when a business or clinical process was safe to start using at the new healthcare facility? (Type "N/A" if you prefer not to answer this question.)

Answered: 26  Skipped: 1

<table>
<thead>
<tr>
<th>#</th>
<th>Responses</th>
<th>Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Day In the Life drills</td>
<td>12/2/2014 8:58 AM</td>
</tr>
<tr>
<td>2</td>
<td>n/a</td>
<td>12/2/2014 8:39 AM</td>
</tr>
<tr>
<td>3</td>
<td>Once all processes have been tested with day in the life scenarios which have not yet occurred. There will be two of these scenarios to see where we need to make changes or if our processes are functioning as designed</td>
<td>12/2/2014 6:33 AM</td>
</tr>
<tr>
<td>4</td>
<td>Once Senior leader and corporate approved and the vendor demonstrated via clinical trial.</td>
<td>11/5/2014 10:15 PM</td>
</tr>
<tr>
<td>5</td>
<td>N/A</td>
<td>10/30/2014 9:21 AM</td>
</tr>
<tr>
<td>6</td>
<td>N/A</td>
<td>10/29/2014 11:30 AM</td>
</tr>
<tr>
<td>7</td>
<td>After testing in a mock environment and truly analyzing what all the failures could be.</td>
<td>10/22/2014 10:11 PM</td>
</tr>
<tr>
<td>8</td>
<td>All State and CMS and Joint Commission standards had been met and State Inspection was completed</td>
<td>10/8/2014 1:14 PM</td>
</tr>
<tr>
<td>9</td>
<td>n/a</td>
<td>9/30/2014 11:24 PM</td>
</tr>
<tr>
<td>10</td>
<td>We used the HCA CAMS model</td>
<td>9/30/2014 2:11 PM</td>
</tr>
<tr>
<td>11</td>
<td>Trained and tested through mock patients: Every process was trained at least a few times or until there were no errors/concerns.</td>
<td>9/30/2014 12:19 PM</td>
</tr>
<tr>
<td>12</td>
<td>After we conducted 2 days of day in the life scenarios we were able to resolve any issues and plan for patients.</td>
<td>9/30/2014 11:44 AM</td>
</tr>
<tr>
<td>13</td>
<td>N/A</td>
<td>9/30/2014 11:34 AM</td>
</tr>
<tr>
<td>14</td>
<td>We tested our process at least 3 times before going live</td>
<td>9/30/2014 11:33 AM</td>
</tr>
<tr>
<td>15</td>
<td>n/a</td>
<td>6/2/2014 14:26 PM</td>
</tr>
<tr>
<td>16</td>
<td>Staff training and verification of competence.</td>
<td>8/5/2014 7:25 PM</td>
</tr>
<tr>
<td>17</td>
<td>All high risk processes were tested over a 4 day period prior to the move; all staff received a minimum of 8 hours orientation to a maximum of 96 hours prior to opening the new hospital.</td>
<td>8/1/2014 2:27 PM</td>
</tr>
<tr>
<td>18</td>
<td>We had a checklist that was used for readiness testing. Anything that did not work correctly was follow up and remedied</td>
<td>8/1/2014 1:35 PM</td>
</tr>
<tr>
<td>19</td>
<td>Process participants were involved in process design. Regulatory and infection control personnel also involved.</td>
<td>7/19/2014 7:21 AM</td>
</tr>
<tr>
<td>20</td>
<td>N/A</td>
<td>7/19/2014 12:04 PM</td>
</tr>
<tr>
<td>21</td>
<td>Having weekly meetings to update, issues concerns, opportunities Reviewing all safety measures prior to opening Having a &quot;day in the life&quot; test to ensure safety and proper use of all equipment</td>
<td>7/9/2014 3:06 PM</td>
</tr>
<tr>
<td>22</td>
<td>Multiple go live simulations to stress the system and test for operational readiness</td>
<td>7/9/2014 2:22 PM</td>
</tr>
<tr>
<td>23</td>
<td>n/a</td>
<td>5/22/2014 1:48 PM</td>
</tr>
<tr>
<td>24</td>
<td>N/A</td>
<td>5/22/2014 1:35 PM</td>
</tr>
<tr>
<td>25</td>
<td>n/a</td>
<td>5/22/2014 1:28 PM</td>
</tr>
<tr>
<td>26</td>
<td>Steering Committee review of work group process plans.</td>
<td>5/22/2014 10:03 AM</td>
</tr>
</tbody>
</table>
Appendix B8: Survey Results for Clinical Process Readiness Evaluation

Q8. What types of employees were typically involved in evaluating clinical or business process readiness prior to moving into the new healthcare facility? (Type "N/A" if you prefer not to answer this question.)

<table>
<thead>
<tr>
<th>#</th>
<th>Responses</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Directors, Administrators, and Managers</td>
</tr>
<tr>
<td>2</td>
<td>n/a</td>
</tr>
<tr>
<td>3</td>
<td>Physicians, nurses, administrators, front-line staff from women’s services and emergency department, ancillary staff such as therapy</td>
</tr>
<tr>
<td>4</td>
<td>Directors, managers, educators, Lab, pharmacy, HR, Administration</td>
</tr>
<tr>
<td>5</td>
<td>Members ranged from staff positions to senior leadership</td>
</tr>
<tr>
<td>6</td>
<td>CEO, CNO, directors and executive support</td>
</tr>
<tr>
<td>7</td>
<td>All employees that would be involved in the process.</td>
</tr>
<tr>
<td>8</td>
<td>Department directors in all clinical areas</td>
</tr>
<tr>
<td>9</td>
<td>Medical Staff Coordinator, Hospital Administration</td>
</tr>
<tr>
<td>10</td>
<td>Leadership group/directors/management/Advisors</td>
</tr>
<tr>
<td>11</td>
<td>Directors, key staff members, administrative, third party opinions from state licensure and Joint Commission</td>
</tr>
<tr>
<td>12</td>
<td>All hospital employees, i.e. Housekeeping, Nurses, Imaging, Administration, etc.</td>
</tr>
<tr>
<td>13</td>
<td>N/A</td>
</tr>
<tr>
<td>14</td>
<td>All employees were involved.</td>
</tr>
<tr>
<td>15</td>
<td>Staff and leaders were involved.</td>
</tr>
<tr>
<td>16</td>
<td>N/A</td>
</tr>
<tr>
<td>17</td>
<td>Executives to frontline staff and physicians</td>
</tr>
<tr>
<td>18</td>
<td>Management from all areas as well as staff that volunteered to help. We also used community volunteers to act as &quot;patients&quot; during our readiness testing</td>
</tr>
<tr>
<td>19</td>
<td>Same people as Question 5</td>
</tr>
<tr>
<td>20</td>
<td>All levels from front-line to CEO were involved.</td>
</tr>
<tr>
<td>21</td>
<td>Front line staff Senior leadership, including managers, directors, support staff, security, IT, Risk management</td>
</tr>
<tr>
<td>22</td>
<td>Senior executives clinicians, nurses, technicians, Staff Process Improvement Staff Space Planning Staff Project Manager.</td>
</tr>
<tr>
<td>23</td>
<td>Management level only - no frontline staff</td>
</tr>
<tr>
<td>24</td>
<td>Representation from all areas of the facility from front-line staff to senior level leadership</td>
</tr>
<tr>
<td>25</td>
<td>n/a</td>
</tr>
<tr>
<td>26</td>
<td>Front line employees and their managers were interviewed for the creation of system assumptions. They were also active members of the work group committees.</td>
</tr>
</tbody>
</table>

Answered: 26  Skipped: 1
Appendix B9: Survey Results for Clinical Process Readiness Evaluation

Q9 9. Were major architectural decisions about the design and layout of the new healthcare facility in place before key clinical/business processes had been completely planned?

Answered: 27  Skipped: 9

<table>
<thead>
<tr>
<th>Answer Choices</th>
<th>Responses</th>
</tr>
</thead>
<tbody>
<tr>
<td>YES</td>
<td>62.96%</td>
</tr>
<tr>
<td>NO</td>
<td>37.04%</td>
</tr>
<tr>
<td>Prefer not to answer</td>
<td>0.00%</td>
</tr>
<tr>
<td>Total</td>
<td></td>
</tr>
</tbody>
</table>
Appendix B10: Survey Results for Clinical Process Readiness Evaluation

<table>
<thead>
<tr>
<th>#</th>
<th>Responses</th>
<th>Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>N/A</td>
<td>1/2/2014 8:58 AM</td>
</tr>
<tr>
<td>2</td>
<td>n/a</td>
<td>1/2/2014 8:39 AM</td>
</tr>
<tr>
<td>3</td>
<td>Blue prints already laid and then decisions were made regarding care flow. Issue was that corporate didn't realize how much interest this demographic would have and built a smaller facility and quickly had to make changes to accommodate growth. We have limited meeting space or education training areas and will need expansions shortly after opening.</td>
<td>1/8/2014 10:15 PM</td>
</tr>
<tr>
<td>4</td>
<td>N/A</td>
<td>1/30/2014 9:21 AM</td>
</tr>
<tr>
<td>5</td>
<td>N/A</td>
<td>1/29/2014 11:30 AM</td>
</tr>
<tr>
<td>6</td>
<td>N/A</td>
<td>1/22/2014 10:11 PM</td>
</tr>
<tr>
<td>7</td>
<td>Timeline review Met and un-met goals Needs assessment Action item assignments</td>
<td>1/30/2014 1:14 PM</td>
</tr>
<tr>
<td>8</td>
<td>Met frequently to determine our &quot;assignments&quot; performed &quot;Day in the Life&quot; prior to opening (role playing of events in the hospital to ensure processes created would work. Hiring for employees, developing policies and procedures Job descriptions for staff, Competencies for staff, Equipment availability)</td>
<td>9/30/2014 11:24 PM</td>
</tr>
<tr>
<td>9</td>
<td>We discussed staging of construction, when to hire, etc.</td>
<td>9/30/2014 2:11 PM</td>
</tr>
<tr>
<td>10</td>
<td>Weekly meetings</td>
<td>9/30/2014 12:19 PM</td>
</tr>
<tr>
<td>11</td>
<td>We had many meetings where we had to come up with all possible patient scenarios, and then construct from beginning to end how those patients would be moved through our processes.</td>
<td>9/30/2014 11:44 AM</td>
</tr>
<tr>
<td>12</td>
<td>N/A</td>
<td>9/30/2014 11:34 AM</td>
</tr>
</tbody>
</table>
Appendix B10: Continued Survey Results for Clinical Process Readiness Evaluation

<table>
<thead>
<tr>
<th>#</th>
<th>Description</th>
<th>Date/Time</th>
</tr>
</thead>
<tbody>
<tr>
<td>13</td>
<td>Many group meeting - plan reviews - but for the most part corporate has a design that they like to us which decreases input.</td>
<td>9/3/2014 11:33 AM</td>
</tr>
<tr>
<td>14</td>
<td>n/a</td>
<td>8/21/2014 4:59 PM</td>
</tr>
<tr>
<td>15</td>
<td>Our project was a replacement facility. The design incorporated planned changes in process to improve efficiency and effectiveness. Not all changes could be tested in advance of moving into the facility. We did build mock-up spaces but learned after opening that issues experienced were a result of the interaction between processes and not within a particular process itself.</td>
<td>5/5/2014 7:25 PM</td>
</tr>
<tr>
<td>16</td>
<td>N/A</td>
<td>8/1/2014 2:27 PM</td>
</tr>
<tr>
<td>17</td>
<td>planning, implementation, testing, revision then reimplementation; PDCA cycle</td>
<td>8/1/2014 1:35 PM</td>
</tr>
<tr>
<td>18</td>
<td>N/A</td>
<td>7/10/2014 7:21 AM</td>
</tr>
<tr>
<td>19</td>
<td>Standard process used for all with cadence developed in standard work and rollout for projects.</td>
<td>7/1/2014 12:06 PM</td>
</tr>
<tr>
<td>20</td>
<td>NA</td>
<td>7/9/2014 3:06 PM</td>
</tr>
<tr>
<td>21</td>
<td>Our facility design process is understanding of the current process state; understanding of the current patient experience state; future state process and overall facility design (3P): simulation using full scale mock-up; computer simulation; detail design of each room; final design; architectural drawings; permitting; building activation; simulation testing; go live.</td>
<td>7/9/2014 2:22 PM</td>
</tr>
</tbody>
</table>


<table>
<thead>
<tr>
<th>#</th>
<th>Description</th>
<th>Date/Time</th>
</tr>
</thead>
<tbody>
<tr>
<td>22</td>
<td>State of readiness summits held quarterly, review of activation plan daily.</td>
<td>5/22/2014 1:35 PM</td>
</tr>
<tr>
<td>23</td>
<td>n/a</td>
<td>5/22/2014 1:26 PM</td>
</tr>
<tr>
<td>24</td>
<td>Regular committee meetings, timelines and documentation tools.</td>
<td>5/22/2014 10:03 AM</td>
</tr>
</tbody>
</table>
Appendix C: Hospital Participant Packet

- The thesis team for this project is interested in learning about your organizational journey as you have recently built a new hospital or are in the process of building a new hospital.

- We want to know how your staff or project teams evaluated and designed all of the workflows for your new hospital.

- To obtain this information, we need anyone who was involved in the process evaluation work to complete an anonymous online survey or phone interview which will take about 10-minutes to complete. The survey results when published will not identify the employee or the hospital name.

Clinical or Business Trial: After completion of the survey, your organization also has the opportunity to utilize a standardized tool in a clinical trial for process evaluation on a low-risk, low-visibility project at the new hospital at no cost to you.

- We would also like to obtain your feedback and work with the team to explain the use of the standardized tool for process evaluation.

- Risks and Benefits: The risk to your organization is minimal as all published results will not identify the hospital organization or staff member. Each hospital will sign a participation letter and each employee of the hospital will sign an informed consent letter for voluntary participation and at-will withdrawal. The research survey will not involve hospital patients or direct patient treatments. The benefit of participation in this survey is that your organization will be provided a standardized tool for future process evaluation activities at no cost.
Appendix C1: Hospital Participant Packet

How do I give consent?

- Each hospital will be provided a letter of participation consent form to be signed by a hospital administrator.

- Each employee conducting the survey and participating in the trial toolkit will also be provided a voluntary consent form along with an at-will withdrawal statement. This means the employee volunteers to participate, and can also stop participation at any time without fear of harm or penalty. The electronic consent form is attached to the online 10-question survey.

How do I take the survey?

The survey and online consent form is available now at:

https://www.surveymonkey.com/s/9J3T2YY
Appendix D: Hospital Letter of Approval

Hospital Letter of Approval

1. (Hospital Name) ______________________ agrees to participation in this anonymous multisite case study by Sam Ellsworth, RN (Principal Investigator) on process readiness evaluation practices for clinical or business activities for newly constructed hospitals.

2. Agrees to allow Sam Ellsworth, RN (Principal Investigator) to discuss questions in a survey instrument or directly administer a survey instrument to any hospital staff member previously involved in new hospital operations strategic planning activities regarding clinical and business process design.

3. Agrees to allow Sam Ellsworth, RN (Principal Investigator) to provide a trial toolkit for a standardized process evaluation method for use on a low-risk clinical or business project for the purposes of strategic planning and process readiness. Principal investigator will also be permitted to obtain feedback from project team regarding the use of the trial toolkit.

4. Hospital acknowledges that all organizational names and employee participants will be kept anonymous and will not be named in the final publication of this research.

5. Agrees to allow Sam Ellsworth, RN (Principal Investigator) to provide participating hospital employees with an informed consent document which essentially states that participation in the research project is voluntary and can be terminated by that employee at any time without fear of harm or disclosure.

__________________________________________  ______________________________
Signature of Hospital Administrator                                                        Date___/___/___

__________________________________________  ______________________________
Signature of Sam Ellsworth, RN (Principal Investigator)  Date___/___/___
Appendix E: Informed Consent Document

INFORMED CONSENT DOCUMENT

Principal Investigator: Samuel Blake Ellisworth, RN, Department of Architectural & Manufacturing Sciences - Western Kentucky University. 270-492-1322 she237@gmail.com

You are being asked to participate in a project conducted through Western Kentucky University. The University requires that you give your agreement to participate in this project.

The investigator will explain to you in detail the purpose of the project, the procedures to be used, and the potential benefits and possible risks of participation. You may ask any questions you have to help you understand the project. A basic explanation of the project is written below. Please read this explanation and discuss with the researcher any questions you may have. You should keep this form for your records.

1. **Nature and Purpose of the Project:** The nature and purpose of this project is a multisite case study of hospital staff and administration to gather data related to the methods of process readiness evaluation for clinical, business, and new hospital construction. Participants will be asked a series of questions in an interview or survey to explain the organizational system of process evaluation methods. The participating organization will be offered to participate in a trial of the standardized use of a process evaluation tool.

2. **Explanation of Procedures:** Participants are asked to complete a survey or interview regarding various hospital projects and how process evaluation methods were deployed. Participating organizations will be given a standardized toolkit for process evaluation and be requested to use it on a low-risk project to evaluate and provide feedback regarding its use.

3. **Discomfort and Risks:** Discomfort and Risks: The discomfort and risks of this research are minimal as the activity will consist of an interview, survey, and trial of a standardized process evaluation tool for a low-risk business-type of project which should not harm the individual in any way.

4. **Benefits:** The benefit of this research is to develop a comprehensive body of work that describes the various methods of hospital process readiness or process evaluation. The participants in the research will also be given the opportunity to test a standardized methodology for hospital process evaluation project needs.

5. **Confidentiality:** The research **WILL NOT** collect the names of any participating hospital organization or employee.

6. **Refusal/Withdrawal:** Refusal to participate in this study will have no effect on any future services you may be entitled to from the University. Anyone who agrees to participate in this study is free to withdraw from the study at any time with no penalty.

You understand also that it is not possible to identify all potential risks in an experimental procedure, and you believe that reasonable safeguards have been taken to minimize both the known and potential but unknown risks.

**Your continued cooperation with the following research implies your consent.**

---

THIS PROJECT HAS BEEN REVIEWED AND APPROVED BY THE WESTERN KENTUCKY UNIVERSITY INSTITUTIONAL REVIEW BOARD
Paul Mooney, Human Protections Administrator
TELEPHONE: (270) 745-2129

[Stamp: Institutional Review Board Approved]
Appendix F: IRB Approval Letter

DATE: May 6, 2014
TO: Samuel Ellsworth
FROM: Western Kentucky University (WKU) IRB
REFERENCE #: IRB 14-456
SUBMISSION TYPE: New Project
ACTION: APPROVED
APPROVAL DATE: May 6, 2014
REVIEW TYPE: Exempt from Full Board Review

Thank you for your submission of New Project materials for this project. The Western Kentucky University (WKU) IRB has APPROVED your submission. This approval is based on an appropriate risk/benefit ratio and a project design wherein the risks have been minimized. All research must be conducted in accordance with this approved submission.

This submission has received Exempt from Full Board Review based on the applicable federal regulation.

Please remember that informed consent is a process beginning with a description of the project and insurance of participant understanding followed by an implied consent form. Informed consent must continue throughout the project via a dialogue between the researcher and research participant. Federal regulations require each participant receive a copy of the consent document.

Please note that any revision to previously approved materials must be approved by this office prior to initiation. Please use the appropriate revision forms for this procedure.

All UNANTICIPATED PROBLEMS involving risks to subjects or others and SERIOUS and UNEXPECTED adverse events must be reported promptly to this office. Please use the appropriate reporting forms for this procedure. All FDA and sponsor reporting requirements should also be followed.

All NON-COMPLIANCE issues or COMPLAINTS regarding this project must be reported promptly to this office.

This project has been determined to be a Minimal Risk project.

Please note that all research records must be retained for a minimum of three years after the completion of the project.

If you have any questions, please contact Paul Mooney at (270) 745-2129 or irb@wklu.edu. Please include your project title and reference number in all correspondence with this committee.
# Appendix G: Grant PTRE Form

## Process Transition Readiness Evaluation Form

<table>
<thead>
<tr>
<th>N.</th>
<th>Process Being Evaluated</th>
<th>Team Members</th>
<th>Department</th>
<th>Questions or Concerns with New/Modified Process</th>
<th>List Affected Department</th>
<th>Transition Team Responsible for Resolution [if necessary]</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Nurse draw blood per order</td>
<td>Same</td>
<td>Lab</td>
<td>How to ensure pneumatic tubes are always available for sending</td>
<td>Lab</td>
<td>Lab/Pathology Team</td>
</tr>
<tr>
<td>2</td>
<td>Nurse TUBE blood to lab for testing</td>
<td>New</td>
<td>Lab/ED</td>
<td>How to ensure results are not delayed for urgent labs</td>
<td>Lab/ED</td>
<td>Lab/Pathology Team</td>
</tr>
</tbody>
</table>

---

*latest PTRE form*
Appendix H: Standard Work Instruction Form

<table>
<thead>
<tr>
<th>NO</th>
<th>STEP</th>
<th>KEY POINT</th>
<th>REASON</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>OMHS staff measure patient intake and output data</td>
<td>Measure data according to CNA, RN role clarity sheet</td>
<td>Accurate I&amp;O information is needed by clinical staff to monitor changes in patient condition and make decisions for patient care.</td>
</tr>
</tbody>
</table>
| 2  | OMHS staff write and initial ALL measured intake & output data on intake & output flow sheet | - I&O flow sheet is on the outside of the patient’s bathroom door  
- Write value in appropriate column and row, based on time and type of intake or output  
- Initial beside each value that you write  
- Sign bottom of sheet once for each I&O flow sheet | - Rows and Columns organize information so that it can be correctly charted in Centricity  
- Initialing allows others to see who collected the data |
| 3  | CNA chart 4-hour intake & output totals in Centricity | Chart totals in room every four hours during vital - I&O rounding | Marking with single line identifies when value has been charted while still allowing staff members to see old values. |
| 4  | CNA draw single line through each value after charting in Centricity | Use single line only | Write measured value in correct row, column and format. |

1 2 3 4
References

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