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On-Line Simulation in Clinical End User Training

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Comprehensive Project Report

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On-Line Simulation in Clinical End User Training

Abstract

In today's ever-changing, do more with less environment, nurses and clinicians must be thought of as adult learners who are self-motivated with a need to know and master the technology they are using. In busy hospital and clinical environments, training nurses and clinicians in the traditional classroom setting can be both difficult and costly. On-line simulation training provides access to all staff to gain hands on end-user experience before new equipment is implemented. As hospitals look to embrace new technologies in this complex healthcare environment, assuring staff training is a required part of the vendor selection process and incorporated into the purchase of complex technology is key in assuring end-user understanding. The purpose of this project is to understand how nurses and clinicians learn and align the training efforts provided for use of new complex technology to assure end-user satisfaction. This project is one part of a larger University offering.

Recent studies found in the publication Clinical Simulation in Nursing (Darragh et al., 2016; Zullosky, White, Price, & Pretz, 2016) suggest that simulation-based training is helpful in the mastery of complex clinical concepts. On-line simulation training provides access to all clinical end-users, so they can begin to understand and master complex medical equipment in advance of hands on clinical end-user training before the equipment arrives. Medical devices have become more interconnected and complex. The Association for the Advancement of Medical Instrumentation (AAMI) suggests that current training is based on past practices and has not evolved. This causes concern as the clinicians' focus is on the patient, coupled with the

understanding that technology is overwhelming and learning all facets of a device is not possible (AAMI, 2016).

Section II. Introduction

Problem Description

In today's busy hospital environment, training nurses and clinical end-users in the traditional classroom settings can be both difficult and costly. On-line simulation training provides access to all staff to gain hands on end-user experience before new equipment is implemented for actual patient care use. The Emergency Care Research Institute (ECRI) medical technology problem reporting system reveals that approximately 75% of reported problems are related to user error, specifically around the mastery of complex technology (ECRI, n.d.). In addition, when asked about required training, only 65% of hospitals surveyed by ECRI and American Association of Critical Care Nurses (AACN) require clinical training in regard to cardiac monitor use (Pelczarski, 1998).

As hospitals embrace new technologies in this complex healthcare environment, assuring appropriate staff training as part of the vendor selection process is key because many organizations do not factor in the cost of proper training as part of the entire purchasing process. The ECRI medical device reporting system relays that 75% of user error harkens back to lack of end user understanding (ECRI, n.d.). Available research indicates training has not improved since an ECRI study in 1998 (Pelczarski, 1998). Keller 2010, relays that today's medical devices are increasingly more computerized and more complex (Keller, 2010). As such; AAMI has commissioned a national coalition to understand the issues surrounding complex medical devices in the health care setting, make recommendations, and establish guidelines for healthcare technology training.

Industry has produced many useful medical devices. The number of new devices continues to grow (Doyle, Gruses, & Pronovost, 2016). ECRI attributes 70% of medical device accidents to error and use (ECRI, n.d.). The Joint Commission issued an alert in 2013 citing inadequate staff training for alarm related devices. (The Joint Commission [TJC], 2013). Safe training for the use medical devices is in crisis, and the formation of alliances to leverage experts to develop effective training is recommended (Doyle et al., 2016).

Doyle and Vockley (2018), suggest the characteristics of complex technology are as follows;

> difficulty to learn, hard to remember how to operate, hard to develop a mental map of how it works, has a large number of controls for operation, has a complicated menu-driven controls, does not easily communicate operational status, promotes use errors due to poor usability, difficult to troubleshoot or recover errors , Is computer based, and a high degree of operational variability across makes and models (Doyle & Vockley, 2018, p. 27).

Additionally, Doyle and Vockley 2018, report that over the last four years the number of non-disposable medical devices at Johns Hopkins Hospital in Baltimore Maryland have increased by 23% many of which are considered complex (Doyle & Vockley, 2018). As the number of complex medical devices increase in the healthcare setting, assuring clinical end-users have access to meaningful educational offerings tailored to their learning styles are the underpinning for assuring the successful integration of these devices into clinical practice.

Hospital, Industry, Regulatory and Patient Safety organizations must collaborate to assure clinical end-users have the necessary competency, training, and resources to safely use the tool sets organizations provide. Doyle and Vockley 2018, report; “not only do nurses feel overloaded on in training, but each requires another to be on the job which is an expense that institutions must bear” (Doyle and Vockley, 2018, p. 27). Given technology is a large part of the tool set that clinical care staff, healthcare providers and organizations depend on to provide care, as hospitals look to embrace new technologies in this complex healthcare environment, assuring

staff training is a required part of the vendor selection process and incorporated into the purchase of complex technology is key. AAMI (2016), relays that organizations should identify the need for training as part of the purchasing process. Devers (2018), suggests a combination of simulation and active participations can improve learning and mastery of complex skills and concepts. Integrating access to on-line simulation training into clinical end-user training was the first step for both the larger University, as well as for this project.

The larger University project had several key stakeholders. Key stakeholders were identified as customers, employees, and Global Subsidiaries. Market segments were defined as United States and global subsidiarity customers. Stakeholders for the larger University are divided into the following segments; Neurology and Patient Monitoring existing customers, new customers, and prospective customers. The stakeholder segments further divide by patient care areas; critical care, telemetry, medical surgical services, perioperative services, emergency services, interventional care areas, medical practice offices, clinics and long-term care facilities. Those segments separate into the type of clinical end-user, physicians, nurses, certified clinical technologists, and unlicensed care providers.

While all groups of stakeholders had common learning needs, the United States customer segment and employee segments were provided access to different types of printed clinical and marketing materials based on their segment and roles. Customers were provided access to marketing and specific clinical resources, whereas employees were provided access to materials based on their roles. Access to printed material were controlled via access and permissions granted when each person received a log-in credential.

When the University becomes global, each subsidiary campus will mirror the United States campus structure; however, they will have access to their content in English as well as in their preferred language.

Customer messaging began with a soft launch at The National Teaching Institute (NTI) for critical care nurses in May 2017. At the NTI, there were live demonstrations, the ability to interact with the simulation modules, communication cards for current customers, as well as free accredited course tokens given away via lottery each hour to allow clinicians free access the accredited clinical course offerings. An email notification was sent to all current customers, to the attention of their clinical leaders, notifying them of the launch of the larger university offering and explaining their access. New customers received a University Welcome with their clinical education roll out, as well as information regarding the University offerings.

Internal Customers received access to the University with their on-boarding and orientation. The University serves as the cooperate platform for education, training, clinical resources, and best practices. Internal Cooperate messaging began with a roll out and demonstration at the company national meeting in 2017 and continued with all new and current employee training and development. Messaging took place at the organizational weekly meetings, as well as via email, and easy to access links on the company intranet and in the sales management tool.

Global or subsidiary messaging utilized an electronic approach given the nature of the global reach. An email was sent to the international subsidiary leaders explaining the University's offerings. Embedded in the email was a link providing sample content across the platform as well as the entire University Catalog of offerings. When

requested the above communication will be followed by an in-person presentation, demonstration as the cooperate office with international leaders.

An overall Marketing and Public Relations plan was finalized for the University launch in May 2017 at the National Teaching Institute (NTI), with additional content launching quarterly such as, Augmented Reality Applications, additional course offerings, just in time video vignettes related to specific equipment questions as well as other offerings and content as it becomes available.

Each stakeholder message used multiple platforms to ensure messaging is received. Internal customer messaging was in the form of email communications, live organizational meetings which are audio and video recorded and posted on the employee intranet, live presentations at the company national meeting, as well as hands on use of the University offerings both from an employee and customer view. All messaging was tied back to the learning organization frame work, as well as the organizational guiding pillars. The use of multiple platforms with common ties and exposures assures communication on multiple levels that can be reviewed, revisited, and reinforced as the University will be woven into the fabric of the organization as well as that of clinical end user, internal employee and global subsidiary. The Message Map is located in Appendix A.

The Clinical Service was re-organized to support the University by creating a separate University cost center and providing a Director focused on Clinical Education. The focus of this project is EEG Simulation Training Modules which are housed within the larger University.

Available Knowledge

As a means to review the literature, a PICOT statement was developed. Is the addition of on-line simulation effective in educating clinical end-users when implementing complex medical technology as compared to traditional classroom in servicing three months post go-live? A literature search was conducted utilizing, the following Databases: Fusion, Business Source Complete, Science Direct, and Education Source. Subject heading terms as well as free text words and direct journal and website searches were also utilized. The terms used included: *knowledge, learning, medical devices, medical equipment, safety, key measures.* The subsequent review yielded twenty-seven articles including relative information from the TJC, AAMI and ECRI databases.

In an effort to assure the most relevant and recent findings, the publication date was set starting in 2010 and then references from literature obtained were searched and used if relevant to complex medical device training, adult learning, or education for complex technology. The searches produced several thousand articles each, most of which were irrelevant. Most of the relevant literature reviewed yielded non-research expert opinion articles, with a few studies that were applicable only after a direct journal search. Website searches of AAMI, Emergency Care Research Institute (ECRI) and The Joint Commission [TJC] were also utilized in the search strategy. In addition, articles that focused on learning theories and clinical staff in the healthcare setting were included.

Using the Johns Hopkins Nursing Evidence Based Practice (JHNEBP) appraisal tools (Melnyk & Fineout-Overholt, 2015), twenty-three of the twenty-seven were determined to be non-research expert opinion articles, most with extensive literature reviews.

The expert opinion articles proved invaluable as they laid the foundation for the use of adult learning principals, experiential learning, and simulation-based theories to form the basis of how to proceed with my intervention. It became clear that although many expert opinions and theories exist there seems have been a lack of integration of the body of evidence available to address the unique training needs for clinical end-users when implementing complex medical technology.

The following articles had a JHNEBP rating of Level 5, Expert Opinion – High Quality (A): (Clapper, 2010; Conlan et al.; 2015; Deronva, 2015; Devers, 2018; Doyle et al., 2016; Doyle &Vockley, 2018; ECRI, n.d.; Gewurtz et al., 2016; Groom, et al., 2014; Hallmark et al., 2014; Jeffries, 2015; Keller, 2010; Knowles, 1984; Kolb 2013; Kolb, 1984; Merrian, 2001; Poore, 2014; TJC, 2013).

The following articles had a JHNEBP rating of Level 5 Expert Opinion – Good Quality (B): (AAMI Foundation, 2016; Gewurtz et al., 2016; AAMI, 2016; McLeod, 2013; ECRI, n.d.). The following articles had a JHNEBP rating of Level 4- Systematic Review- High Quality (A): (Adamson, 2015)

Using the JHNEBP tool resulted in the remaining four articles being categorized as research. The articles were characterized as follows; (Darragh, et al., 2016) was appraised as a Level 3 Qualitative Study with a Quality Rating (B) or Good Quality; (Eisert, & Geers, 2016) categorized as a Level 3 Non-experimental Explorative Study with a Quality Rating of (B) or Good Quality. Pelczarski (1998), yielded an evidence Level 3 Non-Experimental Study with a Quality Rating of (B) or Good; and review of (Zullosky et al., 2016) resulted in an Evidence Level 2 Quasi -Experimental Study with a Quality Rating of (B) or Good.

A mixed method study (Darragh, et al., 2016) centered on gaming simulation to create a virtual environment to represent a virtual home-like environment containing hazards relevant multiple professional disciplines. Quantitative data from the Modified Home Healthcare Worker Questionnaire (MHHWQ) and Usefulness, Usability and Desirability (UUD) were analyzed via SPSS (version 21). The qualitative data from the study was analyzed descriptively. The study sample was a multidisciplinary group of sixty-eight home healthcare providers (HHP); nurses, home health aides, occupational therapists, administrators, and health and safety educators. The mixed method design included an interdisciplinary, participatory design methodology used to develop a Virtual Systematic Training System (VSTS) to train HHP to identify and manage health safety hazards in the home using gaming simulation. The study yielded positive results with the home health care workers, identifying over 350 hazards, as well as many other possible hazards. Examples of identified hazards included overloaded electrical outlets and slip/trip hazards. Hazards were identified in the top right corner of the screen as they were identified by HHP. No *p*-value was expressed in this study, as the review of data centered on the analysis of focus groups in which a pedagogical case-based design was used (Darragh et al., 2016). The study resulted in training that included electrical safety, fire hazards and environmental hazards such as slips, trips, and falls routinely encountered by HPP (Darragh et al., 2016).

A nonexperimental explorative study (Eisert, & Geers, 2016) used self-developed instruments including scenario descriptions and time log sections to understand the simulation process with a correlation to time, looking at patterns of activity usage and quantifying time commitments related to simulation (Eisert & Geers, 2016). Quality statistics were distributed via a Nursing Simulation Design Template distributed to both Healthcare and Academic institutions. The data was subjective as the study pulled from self-created tools. The participants documented

directly on paper copies of the tools. Response rates were between 80-100% and revealed the most important, best-spent time, was in the creation of the simulation. Currently, organizations budget the bulk of time to work with learners. This met the goal of the study, which was to identify the amount of time needed for simulation activities. Descriptive statistics were used to interpret data post simulation activities. The data was calculated using Microsoft Office Excel (Version 2010). In addition to the data being self-reported and having some fields left unanswered, the limitations included: the study was specific to a simulation consortium in Southeast Indiana, the timing for the study was limited due to the academic year as well as federal holidays. In addition, this study was limited to nursing. The author suggested that this topic be examined across other populations.

Pelczarski (1998) designed a survey collaborating between ECRI and AACN to explore the extent to which continuum of care monitoring had been implemented in hospitals, and to assess the impact of the continuum of care monitoring had on patient care, operations, patient mix, costs, staffing and training. Surveys were sent to 1278 Vice Presidents/Director of Nursing or Patient Care Services. A total of 141 responses were received from 38 states in the United States. Some of the data was “estimated” as not all responses were complete as some organizations did not collect some the data requested. The study concluded that 68.3% of hospitals provided continuum of care monitoring, 57.7% of hospitals did not provide continuum of care monitoring were discussing or planning for it, and 85.7% of hospitals indicated that implemented continuum of care monitoring reduced the demand for high-cost beds. It also determined that 65% of hospitals required clinical training regarding monitor use, 71% required clinical training regarding clinical alarm use, and 48.2% reported their nurses had “good acceptance and adaption” to monitoring system implementation. Observations from the data

collected by the survey included that continuum of care monitoring has come to the forefront in meeting the needs of the changing clinical needs of patients. The author recommended hospitals track and analyze the use of traditional monitored beds to determine how many patients could be moved to nontraditionally monitored areas if there were monitors. In addition, the author recommended, based on projected utilization, a determination of the appropriate number of telemetry beds hospitals require. Hospitals should also determine system configurations for the continuum of care and develop an implementation plan that incorporates operational and staffing adjustments. In addition, establishing alarm coverage protocols and providing sufficient training to all staff involved, as defined by their roles, should be part of a successful implementation. This study had limitations as there were only 141 survey respondents from 38 states out of 1278 total surveys sent. The response percentages were broken down by region with the Northeast region having the highest response rate at 34.6% and the Northwest having the lowest response rate at 3.7%. Not all responses were complete as some organization did not track all the data requested. In addition, this study was published in 1998. Despite the age of the study, it correlated with the current literature reviewed as required training and acceptance of new medical devices showed poor results.

Zullosky et al. (2016); was a quantitative mixed factorial design study with Clinical Decision Making (CDM) endpoints. The statistical significance for the study was set at $p < .05$. This study utilized a convenience sample of 120 fourth semester nursing students in an Associate Degree Program. Subjects were voluntarily recruited to participate in a rotating role-based simulation with endpoints for conditions and treatments they were familiar with. There were two CDM stopping points. The stopping points were shortness of breath (SOB), cardiac rhythm change, and atrial fibrillation, (AFib). Each CDM had a decision phase (cue acquisition,

diagnosis, and actions). The raw data from the forms was scored independently by two doctorally prepared, certified nurse educators, and study team members. Data was entered and analyzed by SPSS version 23. The study revealed age was negatively related to cue acquisition in the SOB situation ($p < .05$). Older students were less accurate with acquiring cues from the patient. Additionally, the study concluded that nurse educators should deliberately switch the roles of the participants, as some roles have more impact than others in learning. Although there were clear stopping points, limitations existed in the exact timing of the scenario and limited number of active roles, as well as vague answers in CDM questions. Review of Evidence Tables are available in Appendix B.

The Association for the Advancement of Medical Instrumentation (AAMI) suggests current training is based on past practices and has not evolved from traditional methods of class room in-services. This causes concern as the clinicians' focus is on the patient, coupled with the understanding that technology is overwhelming and learning all facets of a device is not possible (AAMI, 2016).

As the Vice President for Clinical Programs in a Medical Device organization, this author has the authority to move this intervention forward. After applying the review of the literature and the unmet needs of clinical end-users related to how they receive training when implementing new complex medical devices. The focus of this intervention was to provide on-line simulation modules to all healthcare organizations who purchase EEG systems prior to on-site Clinical Applications Training. This intervention is a smaller part of a larger strategic imperative, the creation of an on-line University to improve access to clinical training and resources across our organization and around the world, globally to those whom we serve.

Rationale

Clinicians are adult learners that are independent, self-directed, and goal-oriented. Adult learners are most effective when what they are learning is applicable to their practice as cognitive processes support learning, and active learning requires engagement (Kolb, 1984). Clinical staff are adult learners, as such, they rely on experiences. Although this project reviews Adult Learning in Simulation (Clapper, 2010) and Experiential Learning Principals (Kolb, 1984) in relation to simulation, no one theory explains how clinicians learn (Gewurtz, Coman, Dhillon, Jung, & Solomon, 2016).

Andragogy is the science of helping adults learn. It was originally described by Malcom Knowles, credited as the father of andragogy (Clapper, 2010). Clapper explains that according to Knowles, theory adults learn differently than children. Clapper proposes that adult learners are self-directed and have a wealth of prior experience that becomes a resource for learning. Adult learners are ready to learn and grow to fulfill their social roles related to learning. They apply their learning and leverage it toward problem solving. Clapper further states that adult learners are internally motivated and have a need to know what they are learning (Clapper, 2010). Adult learners are ready to learn and grow to fulfill their social roles related to learning. They apply their learning and leverage it towards problem solving.

Experiential learning is one of the foundations for adult learning. Dernova (2015) concluded that a key element of adult learning is experience; providing real world experiences that can be used in problem solving and knowledge transfer in an environment where the instructor facilitates, rather than instructs, ensuring a strong motivation to learn.

The National League for Nursing (NLN) and Dr. Pamela Jeffries simulation theory supports adding simulation as it encourages active learning (Hallmark, Thomas, & Gantt, 2014).

The theory states that learning is not a spectator sport, thus the active learning that takes place when adding simulation brings together multiple theories and frameworks to guide our approach in the education of clinicians.

Adult learning principles, NLN Jeffries simulation theory, as well as experiential learning guided a review of the evidence by providing a framework and insight into the way adults and in this case; the way that nurses and clinicians learn. Methods to teach adults how to use, understand, and master complex technology are different than commonly used methods to teach children.

Knowles used the following principles for designing and implementing adult learning programs:

- *Has an independent self-concept and who can direct his or her own learning*
- *Has accumulated a reservoir of life experiences that is a rich resource for learning*
- *Has learning needs closely related to changing social roles*
- *Is problem-centered and interested in immediate application of knowledge*
- *Is motivated to learn by internal rather than external factors* (Merriam, 2001, p. 5)

Merriam related that the development of the theory of adult learning illustrates that the designer of an educational offering "should involve learners in as many aspects of their education as possible and in the creation of a climate in which they can most fruitfully learn" (Merriam, 2001, p.7). Knowles' main focus with the development of andragogy was the notion of the “material being very learner centered and the learner being very self-directed” (Conlan et al., 2015, p. 2).

Adult learning principles, NLN Jeffries simulation theory, as well as experiential learning guided a review of the evidence by providing a framework to evaluate the literature related to the

way nurses and clinicians learn. These frameworks guided the development an on-line multi-media site with product simulation training modules to support clinical end user training.

Specific Aims

Improve education for clinical end-users by creating an on-line multi-media site with product simulation training modules to improve access to education and improve end–user satisfaction by March 2018.

Section III. Methods

Context

The purpose of this project was to provide simulation modules via an on-line delivery system to facilitate access to simulated product education and use prior to on-site training and education with an aim to improve clinical end user satisfaction, along with on-site clinical applications training. The data for this project was collected and reported by MD Buyline. MD Buyline is the leading provider of strategic sourcing information and research to hospitals. MD Buyline provides an exclusive satisfaction survey based on nationwide, direct-user feedback from hundreds of healthcare providers who rely on MD Buyline's research and analysis division to guide their critical decision-making in budgeting, planning, selecting, and acquiring medical equipment and technology (MD Buyline n.d.).

Regular quarterly review of the existing Clinical Applications scores provided by MD Buyline suggested that clinical end-users using Electrical Encephalitogenic (EEG) systems required additional education as compared to clinical end-users using Patient Monitoring Systems. The overarching difference between the EEG and Patient Monitoring (PM) clinical applications training was, the PM clinical applications training included on-line simulation training as a standard, in advance of on-site hands in servicing. The EEG clinical applications

training model did not include on-line simulation training at all. Internal stakeholders to include clinical leaders, marketing, and clinical applications staff met to review enhancing the clinical curriculum for EEG customers. There was agreement among organizational stakeholders to enhance the current EEG clinical training curriculum with the addition of the on-line simulation modules and assess the clinical applications customer satisfaction scores once the on-line simulation modules were implemented.

The population for this project were customers who purchased (EEG) systems who received Clinical Applications Training. Prior to the intervention, this group only received on-site training by Clinical Applications Clinicians. Once development of on-line simulation modules for EEG were complete, customers were provided access to two on-line simulation modules via Healhtstream to complete simulation training for the EEG system they purchased. This training occurred prior to the Clinical Applications staff arriving on-site to configure the equipment and train the clinical staff.

Once the intervention was in place, I began to compare the Clinical Applications Training scores from MD Buyline post-intervention with the previous group of customers, pre-intervention who only received traditional training and not simulation. MD Buyline surveys its members with an on-line survey. In addition, they elicit and analyze direct customer feedback from Supply Chain Managers, Clinical Engineers, Clinical End-Users, and Clinical Leaders. MD Buyline also calls the above-mentioned group and completes over one hundred interviews daily in over three thousand hospitals with benchmark and user satisfaction surveys including 58 of top 100 Truven Hospitals (MD Buyline n.d.).

Intervention

The University of San Francisco Doctor of Nursing Practice Department (USF DNP) approved this project as a non-research project. Further agency support was given via a letter of agency support to provide simulation-based training in addition to the established training in place. Both the statement of determination and the agency letter of support are located in Appendix C and D respectively.

The purpose of this project was to provide simulation modules via an on-line delivery system to facilitate access to simulated product education and use prior to on-site training and education along with on-site clinical applications training with an aim to improve clinical end user satisfaction. The data for this project was collected and reported by MD Buyline. MD Buyline, is the leading provider of strategic sourcing information and research to hospitals. MD Buyline provides an exclusive satisfaction survey based on nationwide, direct-user feedback from hundreds of healthcare providers who rely on MD Buyline's research and analysis division to guide their critical decision-making in budgeting, planning, selecting and acquiring medical equipment and technology (MD Buyline n.d).

With the intervention in place, the Clinical Applications scores from MD Buyline post-intervention scores were reviewed and compared with the previous group of customers, pre-intervention who only received traditional training and not simulation.

After reviewing the available evidence, frameworks, as well as considering the pre-intervention data a gap analysis was performed. It became evident that, in the current state, customers received only on-site clinical applications training and did not receive on-line simulation training prior to on-site hands on training provided by clinical application staff. While each framework did not illuminate a specific gap related to adult learning principals or clinical

end-user training, the gap identified was a lack of standard use of simulation-based training as a tool when implementing complex medical devices. The future state filled the gap by adding on-line simulation to the current state which required a convergence of the following frameworks; Adult learning principles, NLN Jeffries simulation theory, as well as experiential learning as no one framework or method by itself fills the unmet need in brining actionable learning modalities to clinical end-user when implementing and deploying complex medical devices (Gewurtz, Coman, Dhillon, Jung, & Solomon, 2016).The Gap Analysis and convergence of the Adult learning principles, NLN Jeffries simulation theory, as well as experiential learning frameworks is depicted in Appendix E.

A pre-intervention Strengths, Weaknesses, Opportunities and Threats (SWOT) analysis was competed. The SWOT analysis was completed using all available cooperate data and information available via the literature search. One of the goals of the intervention is to fulfill an unmet need among clinical end users when implementing complex medical equipment. Additional goals to meeting the unmet need included; creating a convenient, easily accessible simulation-based training module that is included in the initial purchase of the equipment, broadening access and decreased complexity in operationalizing and coordinating the simulation training module. Opportunities existed in expanding the simulation and on-line content based both on market trends and direct clinical end user feedback. Simulation based training for complex medical devices is an emerging trend as such there is no real data to support this method of providing clinical end-user training. Given the threat of competitors creating this intervention and releasing it in advance, no real marketing efforts took place prior to the launch of the modules. As the modules as newly created and launched on the new platform, threats exist related to the newly launched site and its contents. As the site and its contents evolve the threat

of other in this space creating like content remain. A published manuscript emerged from the work related to this intervention, strengthening the acceptance of this emerging trend and bringing to light the unmet need and a viable modality in meeting the needs of the clinical end user. The SWOT analysis diagram is located in Appendix F.

The cost of creating the simulation modules totaled $80,875.00. Simulation modules costs included design and layout, programming, instructional design, project management fees on the part of the vendor, voice over recording as well as testing and quality control. The specific cost breakdown for each simulation module is located in Appendix G.

The creation and use of the Simulation Modules received corporate funding and included key stakeholder involvement. This intervention was a part of a larger on-line University project that required a much larger scale of resources. For the purposes of the simulation modules, an assumption of ten percent of the salaries was made for the following leaders; Director Clinical Education, Clinical Education Specialist, Corporate Training Director, VP Clinical Excellence Programs, and Director Neurology Services. Fifteen percent of the Learning Management Systems (LMS) hosting fees were also considered part of the requirements for the deployment of the EEG simulation modules at a total cost of $87,351.25.

There is no direct Return on Investment (ROI) for the organization. However, there are expected gains from a customer satisfaction perspective. The value of providing a best-in-class educational experience that is unique to our competitors is priceless. While no direct data is available related to the reduction of harm, given that, ECRI attributes 70% of medical device accidents to error and use (ECRI, n.d.) and The Joint Commission issued an alert in 2013 citing inadequate staff training for alarm related devices (The Joint Commission [TJC], 2013), it is reasonable to expect a decrease in user error as the clinical end-user experiences improved

satisfaction with medical device training. The larger University project has a break-even strategy once all subsidiary campuses purchase a campus site. Thereafter, there will be a yearly licensing fee equal to twenty-five percent of the initial campus fee. The Breakdown of Expenses is located in Appendix H.

Work began with a cross functional team of key stakeholders, each responsible for critical work for the overall university project. This project included multiple internal and external stakeholders as well as several vendors. Internal stakeholders included the executive team, CEO, Chairman of the corporation, department leaders, information technology team members, marketing, human resources, cooperate employees as well as global subsidiaries, clinical team members, sales team members and finance. Vendors included the Learning Management System (LMS) host, Interactive Module Developer, Web Designer and the Internal LMS provider. Several meetings to build consensus, gain buy in and develop our strategy were held. Contracts for all vendors were signed and executed for the development of the Website, development of Clinical Courses and Simulation Modules. A detailed Work Breakdown Structure to include the entire university scope is located in Appendix I.

Members from the clinical leadership team worked collaboratively with vendors to create and deploy the simulation modules. Based on their leadership roles and clinical area of expertise each leader work together along with the module developer to create the interactive simulation models. The Vice President Clinical Excellence Programs served as the Executive Sponsor and Program Provost. The Director Clinical Education served as the main contact and liaison simulation module developer and external LMS vendor. The Director of Neurology Services worked with module developer as the subject matter expert. The Neurology Clinical Education Specialist, worked with module developer as an additional subject matter expert and content

developer. The Director Cooperate Training and Development, interfaced with Web designer, internal LMS vendor, print vendor and the module developer creating the EEG Modules. Weekly, monthly and as needed meetings with module developer were held to review content and progress. The Clinical Excellence Program Team Charter Roles and Responsibilities are located in Appendix J.

This intervention began in April 2016 and was implemented in phases. The aforementioned neurology modules were the first phase. The simulation modules were completed in and launched in March 2017. Data collection began in June 2017 a full quarter after the launch and ended in March 2018, however, the data continues to be collected and analyzed moving forward to assure effectiveness, analyze trends, make improvements, and add additional on-line simulation modules and content. Additional details from this section are located in the Gantt Chart in Appendix K.

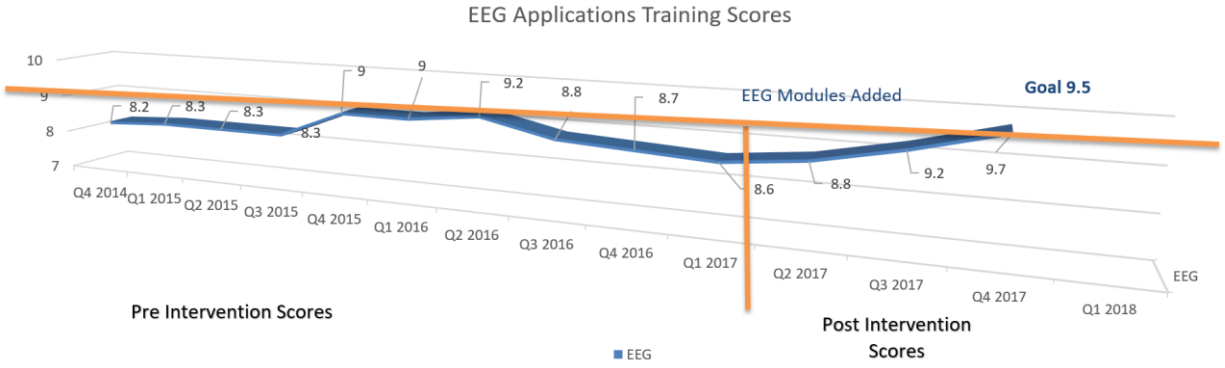
Study of Intervention

The outcome desired was to see an improvement in the Applications Training score for EEG customers and achieve and achieve a clinical application score of 9.5 after adding simulation modules for all customers who purchase EEG solutions, thus correlating to an improvement in end user satisfaction. MD Buyline surveys its' members who have purchased complex medical equipment. Members are made up of hospitals and healthcare providers that subscribe to MD Buyline. MD Buyline posts results quarterly and makes the report available to its members. Applications Training data, once available, was added to the Applications Training run chart. Data collection began in June 2017 a full quarter after the launch and ended in March 2018, however, the data continues to be collected and analyzed moving forward to assure effectiveness, analyze trends, make improvements, and add additional on-line simulation

modules and content. Currently, the data expressed in the run chart shows no astronomical outliers and shows no runs or trends as of the most recent data. The data has no control group and is expressed as a continuous variable looking at pre-and post-intervention clinical applications scores data.

Measures

Trending the data, as reported quarterly by MD Buyline on a run chart with annotations related to the intervention, provides a comparison pre-and post-intervention with a stable, non-biased, independent data source. Scores were averaged; mean scores were trended, as well as the percent change of the clinical applications score pre-and post-introduction of the simulation modules. The run chart below shows the clinical applications scores satisfaction data pre and post addition of the EEG simulation modules. The chart shows that the applications training scores improved post addition of the EEG simulation modules.



Data provided by MD Buyline and placed in to EEG Applications Training Scores Run Chart

The measure chosen was the EEG Clinical End-User satisfaction MD Buyline data for Clinical Applications Training. As previously reviewed; MD Buyline is the leading provider of strategic sourcing information and research to hospitals. MD Buyline provides an exclusive satisfaction survey based on nationwide, direct-user feedback from hundreds of healthcare providers who rely on MD Buyline's research and analysis division to guide their critical

decision-making in budgeting, planning, selecting, and acquiring medical equipment and technology (MD Buyline n.d.). MD Buyline's industry experts survey hundreds of end users to gain customer feedback and evaluate real-world experiences with capital equipment and vendors' service to develop quarterly user satisfaction trending reports. Based on user feedback, MD Buyline rates medical device suppliers on a scale from 1 to 10 in six categories: System Performance, System Reliability, Installation and Implementation, Application Training, Service Response Time, and Service repair quality. This projects data focused on EEG Applications Training.

MD Buyline conducts hundreds of medical equipment and healthcare IT product interviews daily. MD Buyline asks users to rate the technology they are using on a scale of 1-10, 10 being excellent and 5 being average. MD Buyline gathers these ratings on a quarterly basis, and they are valid for twelve months. New ratings are released on the first of each calendar quarter, generating a quarterly rolling average.

MD Buyline strives for thirty active interviews per vendor or technology at any given time. This may vary due to the installed base of the technology being surveyed. Due to the qualitative aspects of MD Buyline's interviews, analysts can validate or disprove any perceived trends with additional calls and subsequent interviews.

The style of the interview conducted with each user is informal and non-structured. The MD Buyline analyst uses the survey questions to engage in a conversation with the user. The information received in the interview, including direct statements by the user, is recorded. Each individual category rating is an average of the total responses for that category. The composite rating is the average of the category ratings (MD Buyline n.d.).

Analysis

Data collection began in June 2017 a full quarter after the launch and ended in March 2018. The data provided by MD Buyline was placed into an excel spreadsheet. A run chart with annotations was created related to the intervention. The run chart provides a comparison pre-and post-intervention. The data as previously mentioned was provided by MD Buyline, a stable, non-biased, independent data source. EEG Clinical Applications Scores were averaged; mean scores were trended, as well as the percent change of the clinical applications score pre-and post-introduction of the simulation modules. Currently, the data expressed in the run chart shows no astronomical outliers and shows no runs or trends as of the most recent data. The data has no control group and is expressed as a continuous variable looking at pre-and post-intervention data. The data continues to be collected and analyzed moving forward to assure effectiveness, analyze trends, make improvements, and add additional on-line simulation modules and content.

Ethical Considerations

There were no ethical concerns surrounding privacy or protection of participants or their physical and psychological well-being. No conflicts of interest were identified as the intervention simply added an additional educational resource, on-line simulation training, to an already established clinical education program to aide clinicians in mastering complex medical technology. In addition to the considerations above adding on-line simulation training, to an already established clinical education program to aide clinicians in mastering complex medical technology supports maintenance of competence which align with the American Nurses Association (ANA) ethical standards (ANA, 2015).

In considering the ethical aspects of implementing and studying this intervention consideration to Jesuit Values, the following values were relevant. Magis or meaning more

(Jesuit Values, n.d.). This value translates to striving for excellence. Providing a best in class clinical end-user training experience provides the clinical with the tools to excel as they learn how to envelop new complex medical devices into their practice. Additionally, Unity of Heart, Mind and Soul, exemplifies developing the whole person and integrating to all aspects of our lives, correlates to the convergence of adult learning principals, experiential learning and simulation frameworks as this projects' aim was to improve education for clinical end-users by creating an on-line multi-media site with product simulation training modules to improve access to education and improve end–user satisfaction. Finally, this intervention embodies the value of forming and educating agents of change by educating clinicians in a way that promotes critical thinking and increases awareness and growth (Jesuit Values, n.d.).

Section IV. Results

Pre – Implementation

The pre-implementation EEG Clinical Applications Satisfaction data revealed a mean score of 8.9 out of 10. Regular quarterly review of the existing Clinical Applications scores provided by MD Buyline suggested that clinical end-users using Electrical Encephalitogenic systems required additional education as the clinical applications scores did not reveal consistent improvement and in fact were decreasing. The only available bench marks were found in the Clinical Applications Scores for Patient Monitoring. The PM Clinical Applications training included online simulation training in advance of on-site hands on clinical end-user training. Based on the review of the data available; several members of the clinical leadership team worked collaboratively with vendors to create and deploy simulation modules.

Post - Implementation

The post-implementation EEG Clinical Applications data revealed a mean score of 9.2 out of 10. The Applications Training Scores rose after the intervention and met the overall goal of achieving an Applications Training Score of 9.5. Since the launch of on-line Simulation Training, EEG Clinical Applications Training scores have surpassed the competitor and remain consistently higher by .5.

Summative

The EEG Applications Training Scores rose after the intervention and met the overall goal of achieving an Applications Training Score of 9.5. Since the launch of Simulation Training Applications Training scores have surpassed the competitor and remain consistently higher by .5 points. The data related to the intervention as well as the competitor data are located in Appendix L.

The intervention was to add on-line simulation training to an already established clinical education program to aide clinicians in mastering complex medical technology. Contextually the elements that interacted with the intervention were the established on-site clinical applications training that was enhanced by the addition of the online simulation training prior to on-site clinical applications training. This provided the clinical end-user context and experience related to the new equipment prior to on-site education and could account for outcomes. There were no observed or reported unintended consequences or unexpected benefits, problems, failures, or costs associated with the intervention. Improvement in the clinical applications satisfaction scores were noted in the data provided by MD Buyline and improved each quarter as a result of the addition of the online simulation training as this was the only intervention added to the established clinical education program. The data demonstrates improvement in clinical end-sure

satisfaction after the addition of on-line simulation training. While no direct data is available related to the reduction of harm, given that, ECRI attributes 70% of medical device accidents to error and use (ECRI, n.d.) and The Joint Commission (TJC) issued an alert in 2013 citing inadequate staff training for alarm related devices ([TJC], 2013), it is reasonable to expect a decrease in user error as the clinical end-user experienced improved satisfaction with medical device training.

Section V. Discussion

Summary

Clinicians are adult learners in a complex environment that historically does not invest in training in a way that is conducive to adult learners (Doyle et al., 2016). The lack of well-planned and targeted end user training could lead to possible error and perhaps patient harm (Keller, 2010). A combination of simulation and active participation can improve learning and mastery of complex skills and concepts (Zullosky et al., 2016). The literature is not specific to implementing this approach for complex medical devices via simulation. Thirty-five percent of hospitals surveyed had not required end-user training for cardiac monitors (Keller, 2010). The AAMI foundation coalition on complex technology and alarm management supports there has been little to no improvement since the 1989 survey from ECRI (AAMI, 2016).

Interpretation

Leveraging adult learning principles and simulation in the clinical setting when implementing complex medical technology may improve mastery of complex concepts and improve end-user satisfaction as this is in keeping with the way this population learns. Recent studies in Clinical Simulation in Nursing (Darragh et al., 2016; Zullosky, White, Price, & Pretz, 2016) suggest simulation-based training is helpful in the mastery of complex clinical concepts.

On-line simulation training provides access to all staff along with hands on end-user experience before the equipment arrives. Medical devices have become more interconnected and complex. The AAMI foundation suggests current training is based on past practices and has not evolved. This causes concern as nursing's focus is on the patient, coupled with the understanding that technology is overwhelming and learning all facets of a device is not possible (AAMI, 2016). More specific studies are needed to answer this question and understand the benefits.

The purpose of this project was to provide online simulation in addition to on-site clinical end-user training in an effort to improve clinical end-user satisfaction with training. This project demonstrated the importance of aligning how the training of complex technology should be implemented to assure end-user satisfaction and adoption of newly purchased and implemented complex technology. The data illustrates the effect simulation training has on the clinical end-users when simulation is married with traditional on-site applications training. Trending the data, as reported quarterly by MD Buyline on a run chart, with annotations as well as understanding the statistical significance pre-and post-addition of on-line simulation modules provided a comparison pre-and post-intervention with a stable, non-biased, independent data source.

Limitations

Barriers or limitations to implementation were time and compliance. The time required to build the EEG modules and marketing materials took longer than initially projected. The EEG On-line Simulation modules and Marketing Materials were scheduled to be completed by March 31, 2017 and launched in August 2017. When the modules went live, customers received instructions to access the university's landing page for the training modules. Assuring customer buy-in and accountability to dedicate the time for their staff to complete the training, was identified as an additional potential barrier, however, this concern did not materialize

during the project. The reporting mechanism within customer facing LMS assisted in overcoming this barrier, as the LMS provided a record of completion for organizations to review and track for regulatory and complacence purposes.

Conclusion

As noted above and throughout this paper, this is a complex and multi-faceted issue that directly relates to caregiver competency and patient safety. ECRI notes that medical device reporting systems reports 75% of user error harkens back to lack of end user understanding (AAMI 2016). In addition, thirty-five percent of hospitals surveyed had not required end-user training for cardiac monitors (Keller, 2010). Hospital, Industry, Regulatory and Patient Safety organizations must collaborate to assure clinical end-users have the necessary competency, training, and resources to safely use the tool set organizations provide. Doyle and Vockley 2018, report; “not only do nurses feel overloaded on in training, but each requires another to be on the job which is an expense that institutions must bear” (Doyle and Vockley, 2018, p. 27). Given technology is a large part of the tool set that clinical care staff, healthcare providers and organizations depend on to provide care, as hospitals look to embrace new technologies in this complex healthcare environment, assuring staff training is a required part of the vendor selection process and incorporated into the purchase of complex technology is key. Devers, (2018), suggests a combination of simulation and active participations can improve learning and mastery of complex skills and concepts. Improvement in the clinical applications satisfaction scores were noted in the data provided by MD Buyline and improved each quarter as a result of the addition of the online simulation training as this was the only intervention added to the established clinical education program. The data demonstrates improvement in clinical end-sure satisfaction after the addition of on-line simulation training as well as a .5 numerical increase over the

competitors clinical applications scores as reported by MD Buyline. More research, collaboration, and partnerships are needed.

Section VI. Other Information

Funding

Sources of funding that supported this work were provided by the medical device organization. The funding organization supported the design, creation, and implementation as well as access to MD Buyline as a data source. All time allotted by stakeholders involved in the intervention were incorporated into current stakeholders' roles to include development activities, retrieval, interpretation, and reporting of data. The budget for the larger University site is located in Appendix M. There was no grant funding associated with this intervention.

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Appendix A
Message Map

Appendix B
Review of Evidence

Citation	Conceptual Framework	Design/Method	Sample/Setting (population)	Major Variables Studied and their Definitions	Measurement	Data Analysis	Study Findings	Appraisal of Worth to practice Strength of Evidence (Level and Quality)
Adamson, K. (2015). A systematic review of the literature related to the NLN/Jefferies simulation framework. Nursing Education Perspectives, 36, 281-291. http://dx.doi.org/10.5480/15-1655	NLN/Jefferies	Systematic Literature Review via Cumulative Index of Nursing and Allies Health Literature (CINAHL) and Simulation in Healthcare and the Journal of the society in Simulation in Healthcare	153 studies	NLN commissioned review to understand best practices in simulation and priorities for research	Systematic Review and Data Synthesis	Theme 1 Simulation when compared with other types of instruction produces positive outcomes Theme 2 Fidelity Theme 3 Debriefing	Systematic review provides empirical support for the major components NLN/Jefferies Framework and Model	Level 4 – Systematic Review High Quality (A)
Clapper, T.C. (2010, January). Beyond Knowles: What those conducting simulation need to know about adult learning theory. *Clinical Simulation in Nursing, VOL* (6), e7-	Knowles	N/A	N/A	N/A	N/A	N/A	N/A	Level 5 Expert Opinion- High Quality (A)
Conlan, J., Grabowski, S., &Smith. (2015). Emerging Perspectives on Learning. Teaching and Technology, In *Department of Educational Pathology and Instructional Technology, University of Georgia.* Athens, Georgia: University of Georgia.	Knowles	N/A	N/A	N/A	N/A	N/A	N/A	Level 5 Expert Opinion- High Quality (A)

Appendix B
Review of Evidence

Citation	Conceptual Framework	Design/Method	Sample/Setting (population)	Major Variables Studied and their Definitions	Measurement	Data Analysis	Study Findings	Appraisal of Worth to practice Strength of Evidence (Level and Quality)
Darragh, A. R., Lavender, S., Polivka, B., Sommerich, C. M., Willis, C. E., Hittle, B. A., ... Stredney, D. L. (2016, August). Gaming Simulation as Health and Safety Training for Home Health Care Workers. Clinical Simulation in Nursing, 12(8), (328-335). http://dx.doi.org/10.1016/j.ecns.2016.03.006	None	Mixed method design that included an interdisciplinary, participatory design methodology used to develop a VSTS to train HHP to identify and manage health safety hazards in the home using gaming simulation.	Multidisciplinary group of 68 HHP, nurses, home health aides, occupational therapist, administrators, and health and safety educators.	Virtual Environments (VE) vs Interactive Training, Classroom Training. Multidisciplinary HHP with varying levels of education and job focus. female (95%) and white (71%). Approximately 67% worked in Ohio and Kentucky, with the remaining spread throughout the United States. Represented multiple professions, including registered nurses (31%), aides/homemakers (21%), administrators/educators (19%), and physical/occupational l therapists (19%).	Quantitative data analysis including two assessments Modified Home Health worker questionnaire UUD Survey includes ratings related to ease of use of the simulation and value and applicability to health and safety. Each were reviewed at focus groups and individual interviews. Qualitative review was embedded in focus and individual interview with embedded actives. All data and scenarios were reviewed until there was 100% agreement.	All statistical analyses were performed using the software package SPSS version 21.	HHP described 353 hazard management dilemmas with these hazard categories. They identified multiple, discrete hazards that were organized into three large categories: trip/slip/lift (e.g., clutter, throw rugs), environmental (e.g., bodily fluids, tobacco smoke), and electrical/fire (e.g., overloaded outlets, damaged electrical cords). Locations where these hazards were typically encountered	JHNEBP Level of Evidence Level 3 Qualitative Study Quality Rating B-
Deronva, M. M. (2015). Experiential *learning theoryas one of the foundations ofadult learning practiceworldwide. ComparativeProfessional Pedagogy , 5(2*),52-57. http://dx.doi.org/10.1515/rpp-2015-0040	Kolb	N/A	N/A	N/A	N/A	N/A	N/A	Level 5 Expert Opinion- High Quality (A)

Appendix B
Review of Evidence

Citation	Conceptual Framework	Design/Method	Sample/Setting (population)	Major Variables Studied and their Definitions	Measurement	Data Analysis	Study Findings	Appraisal of Worth to practice Strength of Evidence (Level and Quality)
Doyle, P. A., Gruses, A. P., & Pronovost, P. J. (2016). Mastering Medical Devices for Safe Use: Policy, Purchasing and Training. American Journal of Medical Quality. http://dx.doi.org/DOI:10,1|77|0628606|6645857	None	N/A	N/A	N/A	N/A	N/A	N/A	Level 5 Expert Opinion-High Quality (A)
ECRI. (n.d.). www.ecri.org/PatientSafety/Report A Problem/Pages/default.aspx	None	N/A	N/A	N/A	N/A	N/A	N/A	Level 5 Expert Opinion-High Quality (A)
Eisert, S., & Geers, J. (2016, September). Pilot-Study Exploring Time for Simulation in Academic and Hospital-Based Organizations. Clinical Simulation in Nursing, 12(9), 361-367. http://dx.doi.org/10.16/j.encs.2016.04.005	None	Nonexperimental explorative study Self developed instruments - *Previously developed instruments did not measure time for specific simulation activities.	Three simulation facilitators from two academic-based institutions (2-year colleges) and five simulation facilitators from two hospital-based institutions pilot study 80 % response rate	Time spent in simulation activated Hospital Based vs Academic Based environments	Self-developed instruments which included scenario description and time log sections were used for this study. Instruments were in the form of hard copies. Participants documented on the tools.	Descriptive statistics were used to interpret data post simulation activities were calculated using a Microsoft Office Excel Version 2010 (Microsoft Corporation Redmond, Washington, USA)	73.1%, was spent in other 29% of time spent with learner	JHNEBP Level of Evidence Level 3 Non-Experimental Study Quality Rating B - limitations-specific to a simulation consortium in southeast Indiana. Self-reporting was the means of data collection can be a subjective method for collecting data -???

Appendix B
Review of Evidence

Citation	Conceptual Framework	Design/Method	Sample/Setting (population)	Major Variables Studied and their Definitions	Measurement	Data Analysis	Study Findings	Appraisal of Worth to practice Strength of Evidence (Level and Quality)
Groom, J. A., Henderson, D., & Sittner, B. (2014). NLN/Jefferies simulation framework state of the science project: Simulation design characteristics. Clinical Simulation in Nursing, 10, 337-344. http://dx.doi.org/10.1016/j.ecns .2013.02.004	NLN/Jefferies	N/A	N/A	N/A	N/A	N/A	N/A	Level 5 Expert Opinion- High Quality (A)
Gewurtz, R. E., Coman, L., Dhillon, S., Jung, B., & Solomon, P. (2016). Problem-Based Learning and Theories of Teaching and Learning in Health Professional Education. Journal of Perspectives in Applied Academic Practice, 4(1), 59-70. Retrieved from http://0-web.a.ebscohost.com.ignacio.usfca.edu/	Problem Based Learning	N/A	N/A	N/A	N/A	N/A	N/A	Level 5 Expert Opinion- High Quality (A)
Hallmark, B. F., Thomas, C. M., & Gantt, L. (2014). The educational practices construct of the NLN/Jefferies simulation framework: State of the science. Clinical Simulation in Nursing, 10, 345-352. http://dx.doi.org/10.1016/j.ecns. 2013.04.006	NLN/Jefferies	N/A	N/A	N/A	N/A	N/A	N/A	Level 5 Expert Opinion- High Quality (A)
Industry, Nurses Address Barriers to Clinical Training on New Technologies. (2016) Retrieved from http://www.aami.org/news.newsdetail.aspx? Item Number=2994	None	N/A	N/A	N/A	N/A	N/A	N/A	Level 5 Expert Opinion- Good Quality (B)

Appendix B
Review of Evidence

Citation	Conceptual Framework	Design/Method	Sample/Setting (population)	Major Variables Studied and their Definitions	Measurement	Data Analysis	Study Findings	Appraisal of Worth to practice Strength of Evidence (Level and Quality)
Jefferies, P. R., Rogers, B., & A Anderson, K. (2015). NLN Jefferies simulation theory: Brief narrative description. Nursing Education Perspectives, 36, 292-293. Retrieved from http://www.nursingcenter.com/journal?Article_ID=3350601&Journal I3332683&Issue_ID335057	NLN/Jefferies	N/A	N/A	N/A	N/A	N/A	N/A	Level 5 Expert Opinion- High Quality (A)
Keller, J.P. (2010, April). Instructions Included? Make safety training part of medical device procurement process. Materials Management in Health Care,26-29.http://doi.org	None	N/A	N/A	N/A	N/A	N/A	N/A	Level 5 Expert Opinion- High Quality (A)
Knowles, M. (1984). Andragogy in action: Applying modern principals of adult learning. San Francisco: Jossey-Bass.	Knowles	N/A	N/A	N/A	N/A	N/A	N/A	››Level 5 Expert Opinion- High Quality (A)
Kolb - Learning Styles. (2013). Retrieved from www.simplypsychology.org/learning-kolb.html	Kolb	N/A	N/A	N/A	N/A	N/A	N/A	Level 5 Expert Opinion- High Quality (A)
Kolb, D. A. (1984). Experiential Learning: experience as the source of learning and development. Englewood Cliffs, NJ: Prentice Hall.	Kolb	N/A	N/A	N/A	N/A	N/A	N/A	Level 5 Expert Opinion- High Quality (A)

Appendix B
Review of Evidence

Citation	Conceptual Framework	Design/Method	Sample/Setting (population)	Major Variables Studied and their Definitions	Measurement	Data Analysis	Study Findings	Appraisal of Worth to practice Strength of Evidence (Level and Quality)
McLeod, S. A. (2013). Kolb - Learning Styles. Retrieved from www.simplypsychology.org/learning-kolb.html	Kolb	N/A	N/A	N/A	N/A	N/A	N/A	Level 5 Expert Opinion-Good Quality (B)
Merriam, S. B. (2001). Andragogy and self-directed learning: pillars of adult learning theory. New Directions for Adult &Continuing Education, 89, 1-8. http://dx.doi.org/10.1002/ace.3	Knowles	N/A	N/A	N/A	N/A	N/A	N/A	Level 5 Expert Opinion-High Quality (A)
National Coalition: Hospital Preparation for Safe Use of Complex Healthcare Technology {Policy Brief}. (2016)Saami Foundationalism Foundation	None	N/A	N/A	N/A	N/A	N/A	N/A	Level 5 Expert Opinion-Good Quality (B)
Pelczarski, K. (1998). Continuum of Care Monitoring - Its Time Has Come. Retrieved from www.ecri.org	None	N/A	N/A	N/A	N/A	N/A	N/A	Level 5 Expert Opinion-High Quality (A)
Report A Problem Pages. Retrieved from www.ECRI.org/Patient Safety/Report a Problem/ Pages/default.aspx	None	N/A	N/A	N/A	N/A	N/A	N/A	Level 5 Expert Opinion-Good Quality (B)
The Joint Commission. (2013). Sentinel Event Alert. Retrieved from https://www.jointcommission.org/assets/1/6/SEA_50_alarms_4_26_16.pdf	None	N/A	N/A	N/A	N/A	N/A	N/A	Level 5 Expert Opinion-High Quality (A)

Appendix B
Review of Evidence

Citation	Conceptual Framework	Design/Method	Sample/Setting (population)	Major Variables Studied and their Definitions	Measurement	Data Analysis	Study Findings	Appraisal of Worth to practice Strength of Evidence (Level and Quality)
Zullosky, K. D., White, K. A., Price, A. L., & Pretz, J. E. (2016, March). Effect of Simulation Role on Clinical Decision Making- Accuracy. Clinical Simulation in Nursing, 12(3), 98-106. http://dx.doi.org/10.1016/j.ecns.2016.01.007	NESF Nursing Education Simulation Framework	This study utilized a mixed factorial design with decision point (shortness of breath [SOB] and rhythm change [atrial fibrillation, AFib]) and decision phase (cue acquisition, diagnosis, and action)	A convenience sampling strategy was used (Polit & Beck, 2012). All fourth-semester ASN students' weekday students were recruited to voluntarily participate in the study during their regularly scheduled simulation laboratory day.	Demographic Variables Age, gender ethnicity, native language, collage experience before nursing school, working in healthcare, direct pt care experience, Academic standing, GPA Role of the Nurse in Acute Care Scenarios, Stopping Points - Shortness of Breath- cue acquisition, diagnosis, action and Cardiac Arrhythmia (A-Fib)- cue acquisition, diagnosis, action	120 4th semester ASN students took on several roles and were stopped based on situation end points.	Age was negatively related to cue acquisition in the SOB situation ($p < .05$). Older students were less accurate with acquiring cues from the patient. Statistical significance for the study was set at $p < .05$. The two CDM stopping point forms were each scored by two doctoral prepared, certified nurse educator, study team members. Data analyzed by SPSS version 23	Provides evidence to determine the impact of roles within simulation and CDM accuracy. Observer role is valuable to enhance CDM accuracy when a situation is unfamiliar and relevant cues are few. Family member roles are less beneficial if the intent of the scenario is to learn and practice the phases of CDM. Nurse educators should intentionally rotate roles, consider what roles are necessary within each scenario, and ensure students experience	JHNEBP Level of Evidence Level 2 Quasi Experimental Study Quality Rating B -Good Quality -Limitations exact timing of scenario pause, limited number of active roles and vague answers in CDM questions

Appendix C
Statement of Determination

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DNP Statement of Non-Research Determination Form

Student Name: Genoveffa I. Devers

Title of Project:
The Development, implementation and evaluation an educational end-user training program with simulation and on-site education when implementing complex medical technology.

Brief Description of Project: Create an on-line multi-media site with simulation modules to improve clinical end-user satisfaction.

A) Aim Statement: Improve education for clinical end-users by creating an on-line multi-media site with simulation modules to improve access to education, and improve end–user satisfaction.

B) Description of Intervention: Collaborate with key stakeholders to amass content, to standardize, education via simulation for clinical end-users when implementing complex medical technology.

C) How will this intervention change practice? Improve access to education and training to assure clinical end-users are properly trained and can access for just in-time training, thereby improving end user satisfaction and quality.

D) Outcome measurements: Improve end-user satisfaction as evidenced by improvement of MD Byline scores for applications training. Reduce calls to technical support for EEG customers.

To qualify as an Evidence-based Change in Practice Project, rather than a Research Project, the criteria outlined in federal guidelines will be used: (http://answers.hhs.gov/ohrp/categories/1569)

☐ This project meets the guidelines for an Evidence-based Change in Practice Project as outlined in the Project Checklist (attached). Student may proceed with implementation.

☐This project involves research with human subjects and must be submitted for IRB

UNIVERSITY OF SAN FRANCISCO | School of Nursing and Health Professions

approval before project activity can commence.

Comments:

EVIDENCE-BASED CHANGE OF PRACTICE PROJECT CHECKLIST *

Instructions: Answer YES or NO to each of the following statements:

Project Title:	**YES**	**NO**
The aim of the project is to improve the process or delivery of care with established/ accepted standards, or to implement evidence-based change. There is no intention of using the data for research purposes.	**x**	
The specific aim is to improve performance on a specific service or program and **is a part of usual care**. ALL participants will receive standard of care.	**x**	
The project is **NOT** designed to follow a research design, e.g., hypothesis testing or group comparison, randomization, control groups, prospective comparison groups, cross-sectional, case control). The project does **NOT** follow a protocol that overrides clinical decision-making.	**x**	
The project involves implementation of established and tested quality standards and/or systematic monitoring, assessment or evaluation of the organization to ensure that existing quality standards are being met. The project does **NOT** develop paradigms or untested methods or new untested standards.	**x**	
The project involves implementation of care practices and interventions that are consensus-based or evidence-based. The project does **NOT** seek to test an intervention that is beyond current science and experience.	**x**	
The project is conducted by staff where the project will take place and involves staff who are working at an agency that has an agreement with USF SONHP.	**x**	
The project has **NO** funding from federal agencies or research-focused organizations and is not receiving funding for implementation research.	**x**	
The agency or clinical practice unit agrees that this is a project that will be implemented to improve the process or delivery of care, i.e., **not** a personal research project that is dependent upon the voluntary participation of colleagues, students and/ or patients.	**x**	
If there is an intent to, or possibility of publishing your work, you and supervising faculty and the agency oversight committee are comfortable with the following statement in your methods section: *"This project was undertaken as an Evidence-based change of practice project at X hospital or agency and as such was not formally supervised by the Institutional Review Board."*	**x**	

ANSWER KEY: If the answer to **ALL** of these items is yes, the project can be considered an Evidence-based activity that does NOT meet the definition of research. **IRB review is not required. Keep a copy of this checklist in your files.** If the answer to ANY of these questions is **NO**, you must submit for IRB approval.

*Adapted with permission of Elizabeth L. Hohmann, MD, Director and Chair, Partners Human Research Committee, Partners Health System, Boston, MA.

Appendix D
Letter of Agency Support

www.nkusa.com

Wilson Constantine
President & CEO
D: 949.268.7161
F: 949.266.8632
M: 415.606.8160
Wilson_constantine@nkusa.com

November 11, 2016

To Whom It May Concern

I am writing to acknowledge support for Genoveffa Devers in completion of her evidence based quality improvement DNP project *Does On-line Simulation Improve End-User Satisfaction when Implementing Complex Medical Equipment* in partial fulfillment of her Doctor of Nursing Practice degree in the Executive Leadership program at the University of San Francisco

This letter also verifies that Nihon Kohden has a memorandum of understanding with the School of Nursing and Health Professions at the University of Francisco for student clinical course work that is supervised by USF faculty.

Sincerely,

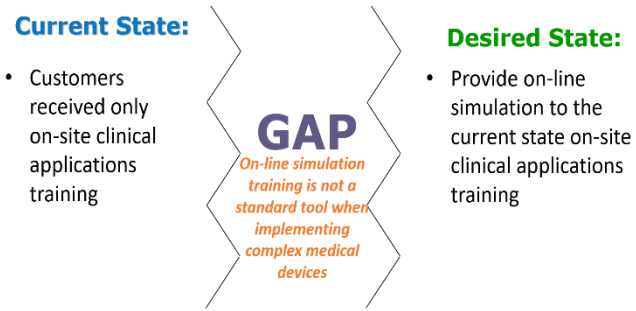
Wilson Constantine
President & CEO

Different Thinking for Better Healthcare.

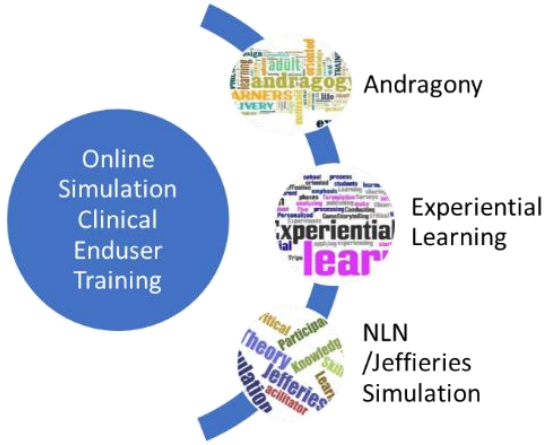
Appendix E

Gap Analysis & Convergence of Frameworks to Include Online Simulation in Clinical End-user Training

Gap Analysis



Convergence of Frameworks to Include Online Simulation in Clinical End-user Training



Appendix F
SWOT Analysis

SWOT ANALYSIS

On-Line Simulation in Clinical End-User Training

Appendix G
Neurology Training Module Cost Breakdown

Neurology Training Module Cost Breakdown adapted from original vendor quotation

Neurology Training Modules Level 2 *One 30 Minute Module - 30 Screens Each* Excludes: any customization of screen records, medical illustration or animation (these are separate lines items dependent on client requests)	HOURS	COST
Design & Layout	30	$ 3,750
Front-end Programing	80	$11,600
Back-end Programing	30	$ 4,950
Instructional Design	30	$ 4,350
Project Management	21	$ 3,885
Voiceover Recording	#	$ 2,000
Testing & QC	24	$ 2,400
Total:		**$32,935**

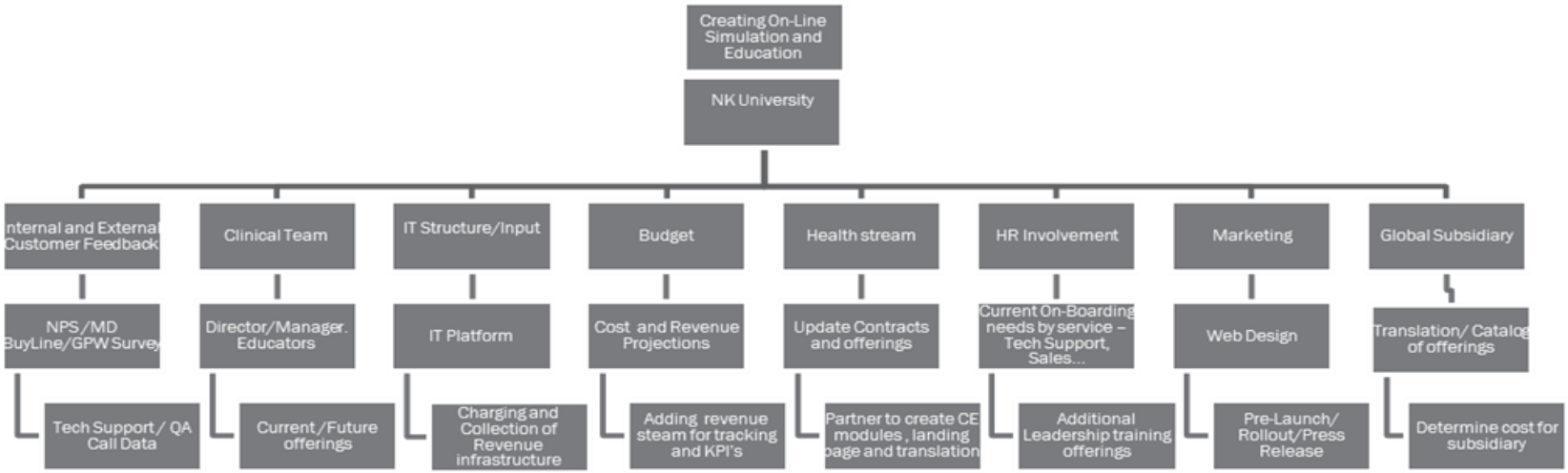
Neurology Training Modules Level 2 *One 45 Minute Module - 45 Screens Each* Excludes: any customization of screen records, medical illustration, or animation (these are separate lines items dependent on client requests)	HOURS	COST
Design & Layout	45	$ 5,625
Front-end Programing	120	$17,400
Back-end Programing	45	$ 7,425
Instructional Design	45	$ 6,525
Project Management	29	$ 5,365
Voiceover Recording	#	$ 2,000
Testing & QC	36	$ 3,600
Total:		**$47,940**

Appendix H
Proforma

A breakdown of expenses for the creation of the Neurology Product Simulation are as follows:
Financial Assumptions and Break-Even

Line Item	Expense	Attributed Expense	Notes / Assumptions
Tipping Point Media			
Neurology Training Module	$47,940	$47,940	Total cost noted
Neurology Training Module	$32,935	$32,935	Total cost noted
Healhtstream Hosting Cost	$43,175	$6,476.25	Assumes Fifteen percent of the total hosting fee for this project.
Director Clinical Education, Clinical Education Specialist, Corporate Training Director, VP Clinical Excellence Programs, Director Neurology Services	$695,000	$69,500	Assumes Ten Percent of the position listed.
Total	$819,050	$156,851.25	
Subsidiary Pricing for Global Campuses (Revenue)	$1,000,000	$160,000	Cost for Global Campus Builds – Assumes all subsidiaries purchase a campus - 10% attributed to neurology
Breakeven expected by end of 2018	$180,950	$3,149	Rollout for International Campus Build is in process

Appendix I
Work Breakdown Structure

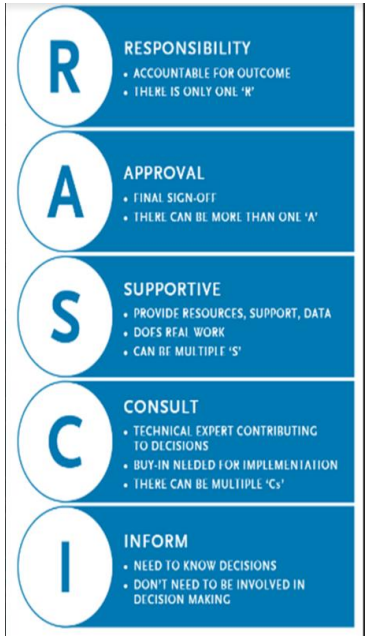


Appendix J
Responsibility/Communication Matrix

Responsibility /Communication Matrix (Adapted from Nihon Kohden Clinical Leadership Team Charter)

Project: Creation and Deployment of Simulation Modules

Project Start: April 2016 - Project End: March 2018



Team Member Role	Functional Group	RACI	Activity	Activity Reporting	Data Reporting
Vice President Clinical Excellence Programs	Executive Sponsor	RA	Executive Sponsor and Program Provost	Weekly	Quarterly **
Director Clinical Education	Clinical Excellence Programs Leader	SAC	Main Contact and liaison module developer	Weekly	Quarterly**
Director of Neurology Services	Clinical Excellence Programs Leader	SAC	Working with module developer as the Subject Matter Expert	Weekly	Quarterly *
Clinical Education Specialist	Clinical Excellence Programs Educator	SC	Working with module developer as the Subject Matter Expert	Weekly	Monthly *
Director Cooperate Training and Development	Human Resources and Clinical Excellence Programs Leader	SC	Interfacing with Web designer, Internal Learning Managing System and Print Vendor	Weekly	Monthly **
Module Developer	Vendor	SI	Creating of the Simulations Modules	Bi-weekly	As needed **
Learning Management System Host	Vendor	SI	Hosting of the Simulation Modules	Weekly/Monthly	Monthly **

Appendix K
Gantt Chart Page 1

Task Name	Duration	Start	Finish
GANTT Chart - Devers N749E			
DNP Program Start	60d	05/23/16	08/12/16
Semester 1			
N734 Scholarly Inquiry and Evidence Based Practice	60d	05/23/16	08/12/16
N738 Project Management for the Executive Leader	60d	05/23/16	08/12/16
N790 2 units - Practicum Micro- Systems 90 hrs	60d	05/23/16	08/12/16
Review Healthstream Proposal	1d	05/27/16	05/27/16
Call with Dr. Waxman to review project scope	1d	06/03/16	06/03/16
AAMI Complex medical Device Coalition Meeting	1d	06/14/16	06/14/16
In-Person Interview Cooperate Training Manager	1d	06/14/16	06/14/16
Key Stakeholders Meeting - NK University	1d	06/17/16	06/17/16
Review of Evidence N734-E	1d	06/19/16	06/19/16
GANTT Chart	1d	06/26/16	06/26/16
Framework Paper N734-E	1d	06/27/16	06/27/16
NK University Road Map Meeting	1d	07/01/16	07/01/16
Healthstream Matting - Review Agreements	1d	07/06/16	07/06/16
Meeting of the Americas - NKU Subsidiary Plans	2d	07/07/16	07/08/16
Literature Fulfillment Vendor Meeting	1d	07/14/16	07/14/16
Healthstream Follow Up Meeting	1d	07/18/16	07/18/16
Literature Fulfillment Vendor Meeting	1d	07/19/16	07/19/16
NK University Meeting	1d	07/27/16	07/27/16
Review of Evidence Paper N734-E	1d	07/27/16	07/27/16
Marketing Meeting NK Uinversity	1d	07/29/16	07/29/16
NK University Meeting	1d	08/01/16	08/01/16
Final Paper and Work Breakdown Structure	1d	08/06/16	08/06/16
NK University meeting with Web Design Vnedor	1d	08/08/16	08/08/16
Meeting with Tipping Point Media re quotes	1d	08/19/16	08/19/16
Review Progress re Modules and NK University	1d	08/12/16	08/12/16
Final Paper - Evidence and Framework N734-E	1d	08/13/16	08/13/16
Healthstream Contracts Signed	1d	08/19/16	08/19/16
Healthstream Kick off meeting - Landing Page	1d	08/22/16	08/22/16

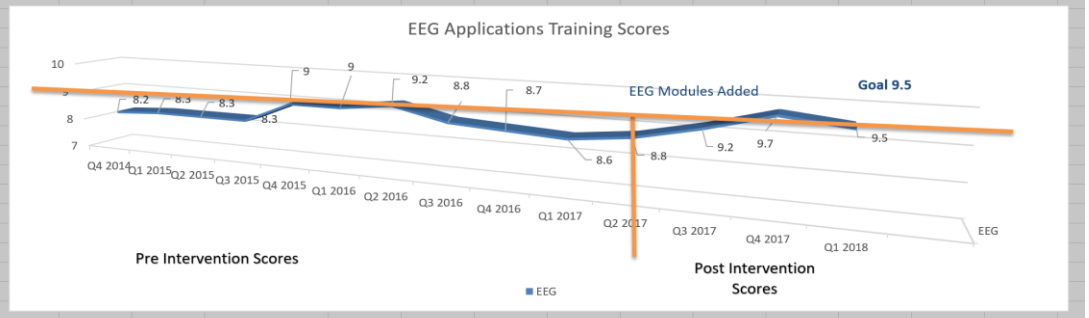
32	Semester 2			
33	N739E Quality and Patient Safety	77d	08/23/16	12/07/16
34	N72E Epidemiology and Data Anaylsis	77d	08/23/16	12/07/16
35	N791E Practicum II Micro-Systems 5 Units -225hrs	77d	08/23/16	12/07/16
36	CE Course Meeting NK University	1d	08/26/16	08/26/16
37	NK University Planning Web Design Vendor	5d	08/29/16	09/02/16
38	NK University Planning Meeting	1d	09/07/16	09/07/16
39	Check in with Tipping Point Media	1d	09/12/16	09/12/16
40	Subsidiary Planning Meeting	1d	09/26/16	09/26/16
41	Meet with NKU final Web Design Vendor to create site map	1d	10/03/16	10/03/16
42	Scope Clarification with Healtstream	1d	10/12/17	10/12/17
43	Update with Tipping Point Media	1d	10/19/16	10/19/16
44	Call with CEO - Updates on NK University	2d	12/01/16	12/02/16
45	Review Site Map NK University	2d	12/01/16	12/02/16
46	Data Collection and Analysis Plan Paper	1d	12/09/16	12/09/16
47	Draft Manuscript for PublicationCompleted	1d	12/10/16	12/10/16
48	Review Data for Clinical Applications with MD BUyline	1d	12/12/16	12/12/16
49	Litrature Fullfillment Meeting	1d	12/15/16	12/15/16
50	Quality and Patient Safety Analysis Paper	1d	12/18/16	12/18/16
51	Review Website Design and E Commerce	5d	12/19/16	12/23/16
52	Review Project Scope and Progress	1d	12/21/16	12/21/16
53	Review marketing needs	4d	01/05/17	01/10/17
54	Semester 3			
55	N721 Legal and Risk Management	86d	01/23/17	05/22/17
56	N749E Qualifiyng Project	86d	01/23/17	05/22/17
57	N792E Practicum III Meso Systems- 4 units 180 hrs	86d	01/23/17	05/22/17
58	Meet with MD Buyline Review Data Collection Methods	1d	01/27/17	01/27/17
59	Online #1 Risk and Legal Interview	1d	02/06/17	02/06/17
60	Meet with Tipping Point Media re module progress	1d	02/06/17	02/06/17
61	Zoom with Dr. Waxman	1d	02/10/17	02/10/17
62	Manuscript for Publication Submitted	1d	02/19/17	02/19/17
63	Begin to train Project Manager on Process to Assign Modules	1d	02/20/17	02/20/17
64	Pull MD Buyline Data	1d	03/01/17	03/01/17
65	First Draft Marketing Materials	1d	03/08/17	03/08/17
66	View final version EEG Modules	1d	03/24/17	03/24/17

Appenxix K
Gantt Chart Page 2

	Task Name	Duration	Start	Finish
67	Final updates EEG module offering in quoting tool	1d	03/27/17	03/27/17
68	Marketing Release for EEG Modules	1d	04/03/17	04/03/17
69	Final Paper Legal and Risk	1d	05/11/17	05/11/17
70	Semester 4			
71	N764E Advanced Finance Management	65d	05/22/17	08/18/17
72	N742E Strategic Leadership, Innovation and Entrepreneurship	65d	05/22/17	08/18/17
73	N793E Practicum IV Macro Systems 4 units 180 hrs	65d	05/22/17	08/18/17
74	File for NKU Trade mark	1d	06/01/17	06/01/17
75	Pull MD Buyline Data	1d	06/01/17	06/01/17
76	Review Training Strategy	1d	06/08/17	06/08/17
77	Work with Marketing for Augmented Reality (AR) Ap branding	1d	06/14/17	06/14/17
78	Training Council Meeting	1d	06/29/17	06/29/17
79	Meet with Legal Counsel re NKU Disclaimer Language	1d	06/30/17	06/30/17
80	Review Baseman current status with printed materials	1d	07/10/17	07/10/17
81	Meet with Legal Counsel re NKU Disclaimer Language	1d	07/14/17	07/14/17
82	NKU Team Sync	1d	07/18/17	07/18/17
83	Finalize Press Release	1d	07/19/17	07/19/17
84	File for CARE App Trademark	1d	07/24/17	07/24/17
85	FInalize Post Cards	1d	07/25/17	07/25/17
86	Finalize Customer Email Blast	1d	07/26/17	07/26/17
87	Review CARE AP Logo	1d	07/28/17	07/28/17
88	Launch NKU	1d	08/01/17	08/01/17
89	Semester 5			
90	N754 Healthcare Policy and Ethics	77d	08/22/17	12/06/17
91	N*** Healthcare Informatics	77d	08/22/17	12/06/17
92	N793E Practicum Synthesis and Complex Organizations 5 units 225 hrs	77d	08/22/17	12/06/17
93				
94				
95	Pull MD Buyline Data	1d	09/01/17	09/01/17
96				
97				
98	Pull MD Buyline Data	1d	12/01/17	12/01/17
99				
100	Semester 6			
101	N789E DNP Project	93d	01/02/18	05/10/18
102	N795E DNP Residency 3 units 135 hrs	93d	01/02/18	05/10/18
103	Write project and presentation	93d	01/02/18	05/10/18
104				
105				
106	Pull MD Buyline Data	1d	03/01/18	03/01/18
107				
108				
109	DNP Presentation and Graduation	3d	05/16/18	05/18/18

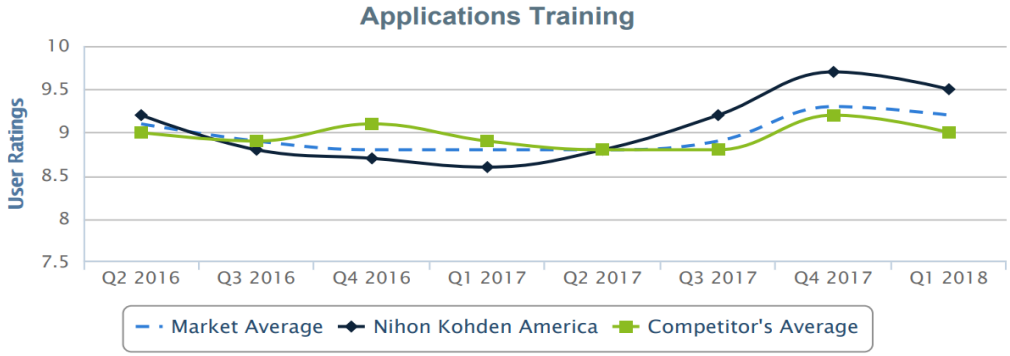
Appendix L
Data

Applications Training	Q4 2014	Q1 2015	Q2 2015	Q3 2015	Q4 2015	Q1 2016	Q2 2016	Q3 2016	Q4 2016	Q1 2017	Q2 2017	Q3 2017	Q4 2017	Q1 2018
EEG	8.2	8.3	8.3	8.3	9	9	9.2	8.8	8.7	8.6	8.8	9.2	9.7	9.5



	Data Post Launch AT2		Pre-Launch Historical Data AT 1		Pre/Post Launch Difference
Q1 2017	8.6	Q4 2015	9		(0.40)
Q2 2017	8.8	Q1 2016	9		(0.20)
Q3 2017	9.2	Q2 2016	9.2		0.00
Q4 2017	9.7	Q3 2016	8.8		0.90
Q1 2018	9.5	Q4 2016	8.7		0.80
AT2 Mean	9.2	AT 1 Mean	8.9	Mean Difference	0.22

Run Chart showing Pre and Post Intervention Clinical Applications Training Scores



Competitive Data provided by MD Buyline Showing .5 increase over competitors Clinical Application Scores since the addition of Simulation Training

https://members.mdbuyline.com/Members/RatingsReport#

Appendix M
3 Year Budget Plan

University Budget Planning

University Budget	2016	2017	2018	
Learning Management System				
Contract Cost				
Custom A&P Course	$ 23,524.00			
CE Courses	$ 161,509.00			
Landing Page	$ 2,134.00	$ 448.00	$ 448.00	* New
CE Course Landing Page External Customers				
Vendor Credantuialing RepDirect Subscription: 200 Enrollments of OR Protocol ($65) and HIPAA ($20). 200 Enrollments of Bloodborne Pathogens ($15); 200 Enrollments of Fire Safety (Free); Electrical Safety (Free); National Patient Safety Goals (Free); and Sexual Harassment in the Workplace (Free)	$ 20,000.00	$ 20,000.00	$ 20,000.00	
Simulation Module Hosting	$ 43,175.00	$ 43,175.00	$ 43,175.00	* Continued Servie
On-Line Healthcare Reform and Industry Series $50.00 per user	$ 5,000.00	$ 5,000.00	$ 5,000.00	* New 100 users
Anit Kick Back Safe Harbors $30.00 per user	$ 6,000.00	$ 6,000.00	$ 6,000.00	*New 200 Users
On-Line Complaince Courses Business Ethics $9.15 per user	$ 1,830.00	$ 1,830.00	$ 1,830.00	*New 200 Users

NKU Web Design				
Web Designer	$ 47,000.00	$ 20,000.00	$ 20,000.00	* New
* $28,000 Per Campus Translation		$ 140,000.00	$ 140,000.00	* Assumes 5 additional campusus / yr 2017 & 2018
*$5,000 Per Landing Page per campus		$ 25,000.00	$ 25,000.00	* Assumes 5 additional campusus / yr 2017 & 2018
Marketing				
Marketing Dollars	$ 9,874.00	$ 10,000.00	$ 10,000.00	
Internal Learning Manamgent System				
Learning Manamgne System	$ 72,510.00	$ 62,000.00	$ 62,000.00	* New
Additional Subsiderery Uers		$ 20,000.00	$ 20,000.00	*Projected
Tipping point Media				
EEG Moduels	$ 110,435.00			
Neurology Augmented Reality Apps		$ 70,000.00		* New
Additional Neurology Moduels		$ 45,000.00		*New
MEB Modules		$ 60,000.00		*New
Sleep Modules		$ 45,000.00		*New
Augmnted Reality Apps and Posters	$ 118,910.00			
GZ		$ 60,000.00		*New
BSM 3500		$ 60,000.00		*New
BSM 1700		$ 6,000.00		*New
AEEG AE 918	$ 32,935.00			*New

Additional Translations per Module				
IEC Changes	$ 3,015.00			*New
Translation based on 6,000 words G9 Course voice over front end and back end programming - Per Language per module * 15 possible modules = per module cahrge		$ 74,375.00	$ 74,375.00	* Assumes 5 additional campusus / yr 2017 & 2018
Other				
12 Lead EKG App	$ 3,500.00			
G9 App		$ 10,000.00		* New
BSM App		$ 10,000.00		*New
CNS/RNS App		$ 10,000.00		*New
Universtiy Coordiator 1.0 FTE	$12,000	$61,800.00	$ 63,654.00	
Total Expected Cost	$ 673,351.00	$ 865,628.00	$ 491,482.00	