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14. ABSTRACT The advent of the Internet followed by the transformative diffusion of Web 2.0 has the potential to revolutionize the delivery of clinical training in healthcare in both remote and urban clinical environments [1-4]. This is of significant interest and relevance to the military given the shortage of healthcare providers and the remote locations in which the military has to operate. The objective of this proposal is to design, develop and evaluate a socially relevant knowledge driven collaborative training network. The scope of the project would include geographically distributed clinical teams solving medical decision making problems with the help of Web 3.0 tools that include virtual social networks. During this period of the project we have established the core informatics architecture, the virtual world necessary for the project. We have also developed phased multi-participant clinical case studies that will be employed in a persuasive computing framework to engage users, build shared mental models and vocabularies. Further we have developed an evaluation framework for the proposed efforts that will measure transfer from VR to actual dynamics on the floor.				
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Introduction

The advent of the Internet followed by the transformative diffusion of Web 2.0 has the potential to revolutionize the delivery of clinical training in healthcare in both remote and urban clinical environments [1-4]. This is of significant interest and relevance to the military given the shortage of healthcare providers and the remote locations in which the military has to operate. However, the vision of adequately training teams across disparate locations and experience levels requires a theoretical framework that employs principles from cognitive psychology and decision making sciences to ensure the maximal integration of Web 2.0 tools to deliver effective pedagogic knowledge [4-6]. As healthcare today moves to a more networked, grid-supported, and conjoined infrastructure, while increasingly using shared developed applications and shared simulated environments for training healthcare professionals, these networks need to be more socially relevant, connected and focused on formal methodologies to increase cooperative clinical behaviors and collaborative teamwork outcomes. The objective of this proposal is to design, develop and evaluate a socially relevant knowledge driven collaborative training network. The scope of the project would include geographically distributed clinical teams solving medical decision making problems with the help of Web 3.0 tools that include virtual social networks. This project presents a controlled scientific methodology towards the development of next generation social networks to deliver distributed clinical training. It employs principles of persuasive technology, computer supported collaborative work and cognitive psychology to ensure team training is grounded in the affective core of the clinical practitioners thereby facilitating a more natural progression toward working in teams.

Body

Background. The project commenced in October 2008. From a financial perspective, many original quotes for equipment were no longer valid due to significant price increases of the equipment since the original proposal was submitted. This limited the ability to complete the proposed project for developing physical telemedicine connections across the western region of Banner. More importantly, the project did not have a clinical champion as the Principle Investigator and that would have been a major roadblock in accomplishing the goals of collaborative telemedicine. These factors were recognized within the first three months of the project, and at which stage TATRC was informed about the difficulties that had arisen. Arizona State University (ASU) continued to develop the web 2.0 backbone for the project, but the project was halted at that point. At this stage, we contacted TATRC to better define a new project within the lines of military relevance and of importance to our organization.

Banner Health presented a new plan to TATRC and it was approved on June 12, 2009. The actual project started in July 2009. The overall scope of the project and the tasks are presented in summary below.

This project focuses on developing cognitively grounded theories for delivering distributed education and developing models for delivering team training and team interaction over the web 2.0. We are developing sound methodologies that aim to not only develop a web 2.0 solution but also to focus on persuasive technology [7] for motivating users to use such technology in their daily interactions. Persuasive technology refers to systems and scientific paradigms designed to motivate users and change their behavior. Influenced by the early Technology Adoption Models pioneered in the telemedicine arena, this type of technology is designed to ensure maximum adoption and maximum usage. With web 2.0 technologies that is a major issue. Many of the web 2.0 initiatives are plagued by unsustainable models of usage. They often generate interest but due to lack of familiarity and no possible rewards, they end being unsuccessful ventures.

We employ a generic framework of training that combines contextual sensitization, patient simulations and computer supported collaborative work in order to provide a sustainable method for delivering team training in remote locations for cognitive decision making. These training sessions are being developed using collaborative work and software engineering methodologies that use socially relevant techniques. Contextual sensitization sets the necessary atmosphere for group decision making. Using theories of cognitive psychology and social sciences, we are developing a cohort of techniques and tools for contextual sensitization. Computer supported collaborative work architecture enable a multi-tiered collaboration between involved parties who, based on contextual sensitization, are motivated to collaborate and use the variety of tools Web 2.0 offers. The simulation models will allow users to see the effect of their decisions on patients and hospitals. This will allow users to develop an affective bond with their decision making process and both ensure and maximize robust learning. This framework is designed to offer a sustainable model for the usage of computer supported collaborative work and the delivery of quality patient care. We plan to employ this framework to deliver tabletop exercises for decision

making for clinical teams involving physicians, nurses and other clinical team members. We will test the validity of these tabletop exercises through practice on simulation tasks and qualitative observations in hospitals and quantitative impact on patient care. This type of evaluation will provide us with a detailed view of how the given model works, how the given model influences workflow, impacts patient safety and how it can be improved.

In the past three months, we have made significant advances in furthering our research goals. We will refer to the original timeline in some of our discussions. We will also assume that we are in the first quarter of the project as per our modification plan.

From an administrative perspective, the contracts between ASU and BannerHealth have been signed and the project is well under way. We have established a project administration protocol. Dr. Mark Smith and Dr. Kahol who are the Principle Investigators on the project meet on a weekly basis to discuss project details and administration. The minutes of the meetings are maintained and are available on request. We are currently in the process of applying for TATRC IRB approval. Currently the research being conducted deals with developing the infrastructure for the required interface. From this regard, all the objectives of Quarter 1 have been met.

From a research perspective, we have made several advances and many that go beyond the proposed timeline. The first has been hiring of the required expertise for the project. Three research PhD students have been employed for the project at Arizona State University. The PhD students are from Biomedical Informatics domain. One PhD student has been hired to work on the development of virtual environments while the second PhD was hired to focus on cognitive psychological foundations of team behavior and evaluation framework for the project. A master's student from Computer science was hired to help build the virtual environment through AI driven simulations and an industrial designer and graphics designer was hired to help develop graphical models of the virtual environment. These hires have completed the scientific hires at the ASU side.

From resources perspective, Groupware software, ThinkTank, has been ordered and we have also placed the order for laptops to be employed for the project. We have also purchased the simulators to be employed for the group interaction study.

The project was to complete these administrative goals and hiring goals by the first quarter. However we have moved speedily towards taking some initial steps towards other goals.

In task 2, dedicated to Use Creation, we have now worked with clinical champions in Trauma services at Banner Good Samaritan Medical Center to develop 33 use cases of collaborated decision making in trauma surgery. These cases are available on request, included is a sample as follows:

A 65 year old woman with a history of coronary artery disease, congestive heart failure and chronic cholecystitis presents to the emergency department with sudden onset of severe generalized abdominal pain. She reports no change in her bowel or bladder function and denies fever, chills or nausea. Her vital signs on admission are: T=98.6° F; BP=151/95 mmHg;

HR=125/bpm (irregular); RR=17/min; Pox 98% (room air). She is a frail appearing woman in severe distress, writhing in pain. Her abdomen is soft, minimally distended, with mild tenderness to palpation. Rectal examination reveals heme negative stool. You are covering the emergency department as the surgical consultant.

[1] Give a percentage to each of the following for the most likely diagnosis (total must add up to 100%).

- (A) Bowel obstruction*
- (B) Cholecystitis*
- (C) Mesenteric ischemia*
- (D) Gallstone pancreatitis*
- (E) Myocardial infarction*

While you are speaking with the family, the emergency department physician decides to make the patient NPO, place a nasogastric tube, initiate intensive intravenous fluid replacement and place a Foley catheter. The patient remains hemodynamically stable, but her symptoms persist and her urine output begins to decline.

[2] Give a percentage to each of the following for your preferred course of action (total must add up to 100%).

- (A) Continue intensive medical management in the ICU setting*
- (B) Laparotomy*
- (C) Mesenteric angiography*
- (D) FAST scan*
- (E) CT angiogram*

After obtaining appropriate laboratory tests, you contact your surgical colleague to assume inpatient management. The next day, you find out that the patient was taken to surgery for exploration, and that a superior mesenteric artery bypass graft was performed as part of the procedure.

[3] Give a percentage to each of the following for your reason as to why the bypass was likely performed (total must add up to 100%).

- (A) Patchy pattern of small and large bowel necrosis*
- (B) Dusky bowel seen from the ligament of Treitz to the transverse colon*
- (C) Clot throughout the superior mesenteric vein*
- (D) Infarction of half of the small bowel due to adhesive closed loop obstruction*

A few things to note about these cases are: First, they are designed to have multiple questions associated with the same beginning cases. In each question we propose to ask the group to

make choices collaboratively. We will also in certain iterations ask different subgroups (nurses, residents etc.) to answer questions separately to enable the subgroups to see the answer and understand why they differ. Further, in order to compensate for the complex nature of healthcare decision making and the probabilistic nature of decision making, we ask groups to give a probability of choices and diagnosis rather than simply choosing the most appropriate answer. We also ask users to give us a qualitative description behind their decision making process. Thirty-three such cases have been developed by an initial cohort of experts. We will validate this through an independent bench of clinical experts who will provide answers to the questions and we will develop consensus on the correct answers and format of the question.

We have also evaluated the currently available options to host the virtual world (task 3). We evaluated SecondLife®, ActiveWorlds® and Forterra Inc®. From our perspective, we were interested in evaluating the virtual worlds with regards to accessibility, configurability and security. From accessibility, SecondLife® is the most popular system. However it ranks lowly on configurability and security. It is impossible to track interactions using their platform. However ActiveWorlds and Forterra Inc® Olive software have high security, and configurability. There are SDK tools to monitor activities and Olive® comes with significant pre-made scenarios. It is however very expensive (\$30,000 per six months) as compared to ActiveWorlds® which is only \$2,000 per year. From that perspective, we chose ActiveWorlds®. We are currently working on understanding the SDK and developing our capabilities to build the virtual World.

We have also made some progress in choosing the platform for web 2.0 tools. We have chosen MOJO platform for developing open source Wikipedia, blogs and other collaborative tools. We plan to integrate these tools with the ThinkTank software.

We have also made headway in developing evaluation framework for our study. One of our goals is to develop a multilayered strategy for evaluation. We have identified key behavioral variables that we will track during team training in our simulation. These variables were identified by review of important cognitive literature and medical literature on seeing the impact of training and how simulation training can help in improving clinical proficiency.

We are on track with our new modification plan and will achieve our goals as per stated timeline in the modification plan.

Key Research Accomplishments

1. Evaluation of currently available Virtual World Tools
2. Development of collaborative use medical case studies for Trauma Surgery.
3. Commitment from clinical teams to participate in the project and replacing one morning conference for surgical residents with our team training protocol as an educational activity.
4. Development of an evaluation framework for observing effects of simulation training on the floor.

Reportable Outcomes

1. Presentations by Dr. Kanav Kahol on Virtual Social Networks in Biomedical Informatics Colloquium at Arizona State University.
2. A course being designed by Dr. Kanav Kahol on Virtual Social Networks to be taught in Spring 2010 in Arizona State University.
3. A position and design paper on generic evaluation framework has been submitted to Journal of Biomedical Informatics. (It is included as an appendix to this submission) [8].

Conclusions

Although the project began late, we have made progress in achieving our goal of providing persuasive team training technology for clinical teams. The team has been established and we are rapidly procuring the necessary materials for the project. We expect to have IRB approval within the next five months which would enable us to conduct controlled experiments on development of collaborative tools and architecture for this project. The methodology focuses on socially relevant practices. The added layer of computer supported collaborative work will enable addressing not only simplistic training but also the enhanced engagement and collaboration of physicians and medical practitioners in more complex cognitive training.

References

- [1] Q. Ali, Q. Ali, F. Murad, M. Abdullah, and A. Z. A. M. A. Z. Malik, "The Role of Telemedicine for Pre and Post Operative Evaluation of Elective Surgical Patients," presented at e-Health Networking, Application and Services, 2007 9th International Conference on, 2007.
- [2] R. M. Baecker, *Readings in human-computer interaction: toward the year 2000.*: Morgan Kaufmann Publishers., 1995.
- [3] L. A. Campbell and B. H. C. Cheng, "Object-Oriented Modeling and Automated Analysis of a Telemedicine Application," presented at Proceedings of the 10th International Workshop on Software Specification and Design, 2000.
- [4] Y. L. Chan, Y. S. Lim, and D. D. Feng, "Web-based multimedia collaboration system for medical images analysis and diagnosis," presented at Selected papers from the 2002 Pan-Sydney workshop on Visualisation - Volume 22, Sydney, Australia, 2002.
- [5] L. Alem, S. Hansen, and J. Li, "Evaluating clinicians' experience in a telemedicine application: a presence perspective," presented at Proceedings of the 20th conference of the computer-human interaction special interest group (CHISIG) of Australia on Computer-human interaction: design: activities, artefacts and environments, Sydney, Australia, 2006.
- [6] E. Frumento, E. Bianchin, and L. Guerriero, "Echo-cardiography on the Web: design and set-up of a virtual community of experts," presented at Proceedings of the 2003 ACM symposium on Applied computing, Melbourne, Florida, 2003.
- [7] B. Fogg, *Persuasive Technology: Using Computers to Change What We Think and Do (Interactive Technologies)* New York: Morgan Kaufmann, 2002.
- [8] K. Kahol, C. Noe, S. Srivastava, and M. Smith, "Complex Interventions for Complex Systems: How Simulation can Help (submitted)," *Journal of Biomedical Informatics* 2009.

Appendices

Complex Interventions for Complex Systems: How Simulation Can Help

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Abstract

Complex environments such as critical care and hospital systems overall require a comprehensive risk mitigation and error management strategy. However conventional mechanisms of intervention are not adequate for complex environment given the inherently interlinked, dynamic and non-linear nature of such complex environments. These factors make evaluation, prediction and implementation of interventions extremely hard and often intractable. This means there is a need for novel mechanisms and a theoretical framework for designing complex interventions for complex environments. In this paper, we argue that complex interventions for critical care environments can be designed suitably through a multi-layered strategy of design, development and evaluation that centers around using simulation science. We present a framework to (a) design and develop interventions for critical care environments and (b) evaluate the impact of these evaluations on individual skills', team cognition and system performance metrics. We present a case study of a simulation centered intervention based on central venous catheter placement based on this framework and measure its impact in terms of decreased patient complications. Evaluation of the developed and implemented intervention showed reduction of upto 98% in different types of patient complications and further shows that safe interventions can be designed using this framework that translate to better patient care and reduced costs.

1. Introduction

Healthcare systems are complex systems with many interacting agents and dynamic emergent behavior. Healthcare system was not necessarily designed to be complex and its nature has been an evolutionary process. From the initial days of simple doctor-patient relationship, healthcare today has expanded to include a multitude of factors that increase the complexity of the system. This is true at various levels of healthcare wherein multitude of people interact with other people and now a myriad of complex technology. The presence of such dense inter-related network structure of interactions between these entities makes operations in complex networks often intractable. This can be seen in workflow of patients, workflow of activities and workflow of healthcare professionals. From an intervention perspective, healthcare industry poses a special problem. The cost of failure in healthcare is very high and unacceptable even in the smallest of degree. This makes design, implementation and evaluation of any intervention extremely risky and often what may seem to be an unproductive activity. However interventions in complex environment need to be understood at a fundamental level to understand how to successfully implement interventions and ensure that these interventions will improve patient safety.

This paper is an attempt to establish a generic framework for interventions in healthcare environments. The proposed framework deals with design, development and evaluation of interventions and is strongly interconnected with the use of simulation science in complex environment. In past work people have proposed methodologies for development of interventions in complex environments. Many of these methodologies are focused on specific areas but have generic principles that can be extrapolated to other environments. A key factor has been the use of good educational and training strategies for teams and individuals. Using educational modules, it is possible to train professionals on protocols and methodologies that need to be followed for implementation and measurement of interventions. A major issue lies in

the quality of education and type of education. While didactic knowledge is important and necessary, there is also a need for practice based learning for proper implementation.

Another element that has been proposed is the use of situation monitoring tools. Situation monitoring roughly refers to suite of tools and technologies that enable operators in an environment to be aware of the condition of the system. Sophisticated systems for situation monitoring may even include decision support that enables user to take premeditative actions that can alter a situation. Situation monitoring tools are very useful in increasing the ability of users to alter and monitor the situation but may increase cognitive load of the user which may alternatively lead to even a higher chance of errors.

Another important tool that has recently become a popular intervention is the use of structured communication and structured vocabulary in daily operations of the system. An example of this intervention is the SBAR Tool using which subjects need to communicate about any event in a structured manner. The structured protocol includes first describing the Situation (**S**), then giving Background (**B**), followed by discourse on Analysis (**A**) and finally generation of a recommendation (**R**). Using systems such as this, it is possible to eliminate communication errors but implementation of this system in clinical environments is hard. This is further complicated by the need for emergency and critical care wherein it is hard to follow protocols such as this for every interaction.

While all these interventions are well grounded in theoretical work mostly in the aviation domain and can be thought of being important and implementable in the clinical environment, there is a need for an effective implementation methodology. An effective implementation methodology would allow for (a) means to test the implementations (b) support the adoption of the interventions and (c) means to measure the effect of interventions. In order to do so, there is a need to understand the nature of healthcare system and develop a working model of the system.

While there are various models of the healthcare systems, at a very simplistic level healthcare system can be understood as a pack of dominoes. Much like dominoes, that stand in assembly and a fall of one domino may make other dominoes fall too, healthcare departments and professionals continuously influence each other and any intervention even in the smallest degree meant only for a single entity will influence the other entities in a system. This *domino effect* can be seen in a variety of situations in the healthcare system but is especially true in interventions. For example a simple change to blood transfusion protocol may completely change the workflow and changes may be felt in several departments. This domino effect in general breeds a conservative approach to any interventions. While it is necessary to be careful with any changes to the system, it limits testing or implementing revolutionary changes. There is hence a need for a novel methodology for implementations. Such a methodology should lay the theoretical foundations for enabling higher quality teaching and education, enable situation monitoring, better communication and situation monitoring. Further the methodology should enable a better testing methodology and a means to measure the impact of the interventions in all the *dominoes* of the healthcare system.

2. Current role of simulation science in intervention management in healthcare

The use of simulation science in complex environments is a well-established research area. At one level, simulation science helps understand complex systems. An Example of such an effort is using mathematical models to predict ant behavior in ant colonies. On the other hand, there is also work on using models of complex systems such as ant colonies or swarms to model everyday events. This work is generally seen in computational neuroscience, neural network and computational intelligence community. Simulation here of course refers to mathematical simulations. Mathematical simulations have been employed in clinical realm for a variety of purposes including measurement of the impact of interventions. While most of this work has been at the level of physiological prediction or epidemiological predictions, there have been

some attempts at using simulation to predict impact of certain types of interventions on workflow and clinical practice. These simulations are based on principles of complexity: they depict dynamic and emergent behavior, simple processes interact to create complex ones and the effects cannot be predicted by simply monitoring one component. The main issue with these simulations especially at the clinical practice and the hospital management level, is that they cannot be verified in a direct manner. Hence many of them remain at a theoretical level with not much practical implications.

Another type of simulation that has made a major impact on the healthcare industry is the virtual reality/physical simulations for medical education. There are several studies that show the validity of simulation as an education tool. Simulation training is emerging not only as an innovative way to teach clinicians, but as a method to also decrease the error rates in surgery and improve patient care and safety through evaluation. The Accreditation Council of Graduate Medical Education (ACGME), which is the governing body of medical curriculum in United States, has provided detailed standards on medical competency. The toolbox for evaluation recommended by ACGME has listed simulation training as the most effective evaluation strategy for medical procedures listed under the patient care competency [3]. In addition simulation was listed as an effective evaluation tool for investigatory and analytic thinking, knowledge and application of basic sciences, patient care management plan development and execution, and ethically sound practice.

Virtual reality/physical simulations have been employed for educating residents and objective measurement of skills. This covers the teaching and education element of the interventions part but not entirely. Simulations are a tool in enabling learning but by themselves cannot completely implement interventions. There is a need to develop comprehensive curriculums that use didactic approaches and practice based learning in order to train clinical professionals.

In most cases, both these branches of simulation science have not been merged into a single comprehensive effort. However being able to develop an intervention management system that uses mathematical simulations to predict how an intervention may change workflow or may influence outcomes and then uses simulation training to reinforce good practices would form a robust and scalable platform for intervention management. It is also important to note that a combination of these methodologies may enable us to develop and evaluate a testing methodology to measure and monitor the impact of interventions on outcomes. This paper proposes a hybrid methodology that combines all these three efforts, (mathematical simulation for theoretical predictions, virtual reality simulations for training and simulation validation) to have an intervention management system.

3. Framework for Intervention Management in Complex Environments

Figure 1, shows the generic intervention management framework.

Figure 1. Intervention Management Framework

A key element in this framework lies in acknowledging the domino effect in complex environments and hence having a multi-tiered strategy. The first lies in design of interventions. Conventionally design of interventions is done through planning and involvement of focus groups and design groups. While this is an important initial step, often development of interventions in silo is not an effective means of achieving high impact. In many industries it is not possible to get formative evaluation data as such testing may lead to avoidable errors. Mathematical simulation can play an important role in bridging the gap between empirical formative validation and design stage. Mathematical simulations can predict the impact of interventions and serve as a means for designers to modify the interventions. Formation of

mathematical models requires data from the hospitals quality departments or other involved department. These databases serve to provide theoretical validation of the intervention and what impact it may have on the complex system. While such system does not necessarily allow for formative evaluation, it does allow for formative design through simulation. It is hence important that the simulation is reasonably accurate. This can be ensured by following the established conventions of mathematical simulations like dividing data into test and train tests, ensuring that data preprocessing is performed and that the simulation shows trends that suggest its validity.

Often mathematical simulation will have to account for social factors. As the interacting agents in the real world are humans, simulations need to account for human tendencies, errors and other factors. This is generally achieved by using sociological factors in the simulation and using standard equations for such simulations. For example, there are equations that may define communication dynamics between teams. These equations can be suitably employed to model issues with communications. Another factor that needs to be considered in simulation, is to account for differential task complexity. This can be modeled through known equations but by setting the parameters in a domain specific manner.

Evaluation at this stage of intervention design amounts to theoretical validation of the concept of intervention. In other words, validation at this stage shows (a) if the simulation is sufficient to model the complex environment and (b) if the simulation is sufficient for checking the impact of intervention. From a mathematical simulation perspective, it is important to ensure that the simulation represents real world data which is ensured by validation of the predictions. It is also important to validate the simulation from an interventions perspective. This is done by ensuring that the simulation can impact the expected variables in the simulation and show trends that are expected by the designers.

The second phase of the intervention management plan lies in training using simulation and other methodologies. In this case, simulations refers to virtual reality tools and physical simulators that can aid and abet the training process. Simulations in this case help in practice based learning and further help in training for errors. More often than not simulation based training is only employed for teaching best practices. However research in cognitive psychology has shown that concept learning is enhanced by training for best case, worst case and the prevalent case scenarios. It is hence important to expand the role of simulations to show the different methodologies for implementing an interventions. This can also help in further validation of the mathematical simulation thereby serving two purposes: (1) to increase the robustness of learning of the students and (2) to further validate the mathematical simulations. Simulation based learning is also an efficient way to conduct large scale lab based validations. When dealing with naturalistic environments, it is not possible to control for different types of parameters and variables. While researchers have made significant advances in analysis and data collection in naturalistic environments, complete experimentation in such environment is not possible or at best may take a significant amount of time. Hence simulation and simulation-based training can play a major role in conducting controlled experiments. For example in the clinical realm, it is possible to fix the condition of the virtual patient and test different physicians on that patient. It is also for example possible to present different conditions of patients and test clinicians. Other type of variations such as bad communications, introduction of noise and other environmental factors, lack of situational awareness can be easily simulated and clinicians can be trained on how to handle these events. Another very important role that simulation can play is in adverse event management. Often clinicians encounter adverse events and without proper training, the clinicians cannot deal with the ramifications of the decision making both at an individual level and at a collective level. In aviation, adverse event management is an important part of training for interventions. It is always important for designers to acknowledge that

interventions can lead to undesirable results and there is a need for contingency plan development. Initial simulation training can actually serve as the basis for delineation of environmental conditions that may lead to adverse event and also for testing of a contingency plan. These laboratory validations are necessary for implementation of an effective intervention plan.

In the final stages of the intervention management plan, implementation is executed. Implementations should however be well planned and it is helpful to have an implementation document that is designed based on experiments in mathematical simulations and training simulations. This implementation document can serve as a useful aid for clinicians on the floor and often can be supplemented by handy guides and reminders. In order to evaluate the quality of implementation two methods can be employed. The first method is qualitative in nature that involves, interviews, shadowing and observations. Such type of evaluation can serve to (a) measure behavioral changes due to intervention, (b) measure organizational changes and culture of safety changes, (c) serve as a means of narrowing down potential events that can be tracked to see the positive or negative impact of interventions and (d) allow for qualitative feedback on the interventions. Designing a pre-intervention, post intervention study, can aid in measurement of all these effects. It is also important to note that such observations can indeed help in identifying certain events that could explain the impact of intervention directly on patient safety. For example, observations could reveal if clinicians who are participating in an intervention were able to treat their patients better than clinicians who did not participate in the intervention. In real naturalistic environments, where doctors often work in teams and it is hard to exactly identify the cause of events, with observations it is plausible to find at a gross level events that could be tracked and patient data could be analyzed to find the impact of interventions.

The other method that can be employed is looking at outcomes data such as patient charts, quality improvements, patient satisfaction data and other variables collected from the operations in the complex environment. As mentioned before, by simply analyzing this data, it is hard to establish a level of confidence for the validity of the analysis. However, with the multi-tiered evaluation strategy that is proposed in this paper, can enable a higher confidence analysis system. The mathematical simulations predictions, coupled with laboratory evaluations can provide clues on how the intervention should behave. Further the observations can give a detailed list of events that can be tracked for further analysis. Using these pieces of information, it is possible to do statistical analysis and analyze outcomes data. Care needs to be taken on not overstating the validity of these results but as argued by Penchas et al. it is impossible to predict or measure impacts in complex environments with 100% certainty.

Implementation of a Central Venous Catheter Intervention: A Case Study

In a recent study, it was found that 17% of deaths related to anesthesia complications are related to central venous catheter (CVC) placement error. While there are limited studies that investigate the financial and safety implications of CVC errors, there is agreement that CVC complications are a major burden on the healthcare system. Hove et al. noted that many of the deaths related to CVC placement could have been avoided by education and use of protocols for treatment.

We developed an intervention to address the CVC placement errors. In response to these needs, several commercial simulators for CVC placement have been developed (For example CentraLineMan® from Simulab®). While these simulators are an important aid in medical education, there is a need to define a comprehensive intervention for CVC placement training that systematically includes simulators as well as other educational aids. Another component that needs further elucidation, is the effect of simulation training on patient safety.

There is limited data on simulator's construct validity (Reznek 2002). However the presented data is preliminary and not conclusive in defining the effect of simulation on patient safety.

We aimed to use the above defined methodology to design an intervention for the CVC intervention. The first stage was to develop a mathematical simulation of the various entities involved in CVC. As we were interested in procedural learning and implementation aspects of the CVC, we aimed to model the impact that the lack of knowledge of steps of CVC would have on patient complications or safety. We asked experts to identify the critical steps in CVC line placement and also identify what may happen to a patient if those steps are not properly implemented. These pathways were employed to design an agent based simulation. We employed the NETLOGO software® that models agents and agent based systems to simulate complex behavior. This software has been employed for several purposes including studying team behavior, social phenomena etc. We briefly explain the modeling process and how it was employed to adjust the training curriculum used in the second phase of the study.

We modeled our agent-based systems as follows. Each step of the CVC procedure was modeled as a separate entity with multiple factors that could influence the performance of that step. Each step in the procedure was categorized into being (a) procedural, (b) communication with patient, (c) communication with team, (d) documentation, and (e) clinical knowledge step. A step could belong to multiple classes. This helped us define for each type of category some generic factors that can influence the steps. For example, communication with patients may be effected if the patient is non-cooperative and this would impact all the steps associated with this category.

Factors that influence were identified based on interactions with experts and practitioners on the floor. The agent would give a differential response based on the interaction of these factors. We used dynamical equations to model the behavior of the performer at each level. One of the factors we employed in the simulation was the fatigue level of the operator.

Based on our experiments, we found an exponential relation between possible decision-making errors with the effect of fatigue. We modeled this as a factor in all of the decision-making steps of the simulation. Further it is also known from previous experiments that the effect of fatigue varies with experience. This is seen as a change in parameters of the dynamic equation that defines the impact of fatigue on a given decision making step. This parameter is controlled by the expertise variable in the simulation. The expertise variable also has an impact of what type of steps of the procedure may be wrongly performed due to lack of knowledge or experience. An important variable we included in our simulation was the lack of knowledge of errors and adverse event management skills for the participants.

Similarly other variables were included in the simulation and simulation was performed to track the number of CVC errors that may occur due to different operating conditions. We also classified the type of error into degrees of their effect of patient safety. From the simulations it was revealed that one of the biggest reasons for CVC errors was the lack of knowledge and expertise. In fact expertise and errors showed a correlation of 0.78 which is a high percentage. Secondly the fatigue variable showed a correlation of 0.67 with errors. The simulation also revealed that the lack of error management and adverse event management skills showed a correlation with errors of 0.64. It is important to note that the simulation showed that the lack of knowledge of errors and error management skills often leads to the domino effect in errors and this is consistent with other papers from ethnographic studies that have shown this nature of errors in complex environments. Another interesting unexpected result that was revealed by mathematical simulations was the possibility of residents actually outperforming attending anesthesiologists in CVC insertion. The simulation allows for errors that may creep in because of multiple runs and the simulation showed that with practice, these errors are reduced over time. However as attending currently do not participate in the training, there was a scenario

wherein if the training course showed high retention, then the attendings will be closely matched by residents.

With this knowledge, we designed the second stage of the intervention which comprises of simulation driven course. In response to the needs of CVC error reduction, several commercial simulators for CVC placement have been developed (For example CentraLineMan® from Simulab®). While these simulators are an important aid in medical education, there is a need to define a curriculum for CVC placement training that systematically includes simulators as well as other educational aids. Another component that needs further elucidation, is the effect of simulation training on patient safety. There is limited data on simulator's construct validity (Reznek 2002). However the presented data is preliminary and not conclusive in defining the effect of simulation on patient safety.

A curriculum was defined for CVC placement training. The curriculum includes simulation training, other educational aids, performance metrics and evaluation mechanisms. The Banner Simulation System Central Venous Catheter course is a hands-on skills training course which utilizes adult learning principles to maximize time and effectiveness of training this critical procedure.

The course consists of a computer based didactic training includes the following components which are required to be completed with a certain level of competency before being accepted to undergo the hands-on training. The didactic components are an introduction to the course, course objectives, an article that discusses prevention of errors and complications and highlights best evidence based practices, CDC guidelines for maximum sterile barriers, a video component, our internal policy documentation, a checklist of expected and necessary steps to ensure maximum patient safety and a multiple choice test. Once the participant has successfully reviewed the materials as demonstrated by the completion of the test they are granted access into the hands-on training.

The skills based training is completed in the Banner Simulation System and Banner Good Samaritan Medical Center. The participants arrive and view a demonstration of the procedure. Full maximum sterile technique is demonstrated with a simulator and the errors and prevention of the errors are discussed as well as discussion regarding the dos and don'ts of the procedure itself. Ultrasound guidance is demonstrated as well.

The participants then are allowed an opportunity to practice internal jugular and subclavian central line placement. They also have an opportunity to practice with the ultrasound equipment and some pod-cast didactic instruction regarding vascular access. Each participant performs the subclavian procedure using maximum sterile barriers with a physician instructor present. That instructor follows the adult experiential learning model of trial and error while using the checklist to indicate what the participant did or did not do. When the participant feels comfortable they are recorded performing the procedure independently with all the necessary equipment. They are instructed as to any limitations of the simulator and are told to talk through the portions that they are unable to perform due to lack of assistance or limitations.

The information recorded is then reviewed by a physician and compared against the checklist. Key items are weighted on the checklist and failure to perform certain steps results in a failure. The analysis showed high performance of residents and all had achieved 100% on the checklists for various types of simulations and adverse event management by the end of two trials.

In order to measure the effect of the curriculum on patient safety CVC placements during the period when no training was offered (2006) was compared to CVC placements after the training was offered (2007, 2008) through retrospective patient chart analysis. Seven common CVC related complications were identified and isolated for the comparison. The effect of other variables and confounding factors was accounted for in the final analysis. As we had implemented the intervention in a hospital completely in order to compare it, we chose a sister

hospital facility which had trained anesthesiologists placing central venous catheters. We once again compared the 2006, 2007 and 2008 CVC related complications to measure the impact. Figure 2 shows the graphs for common CVC errors for the two groups.

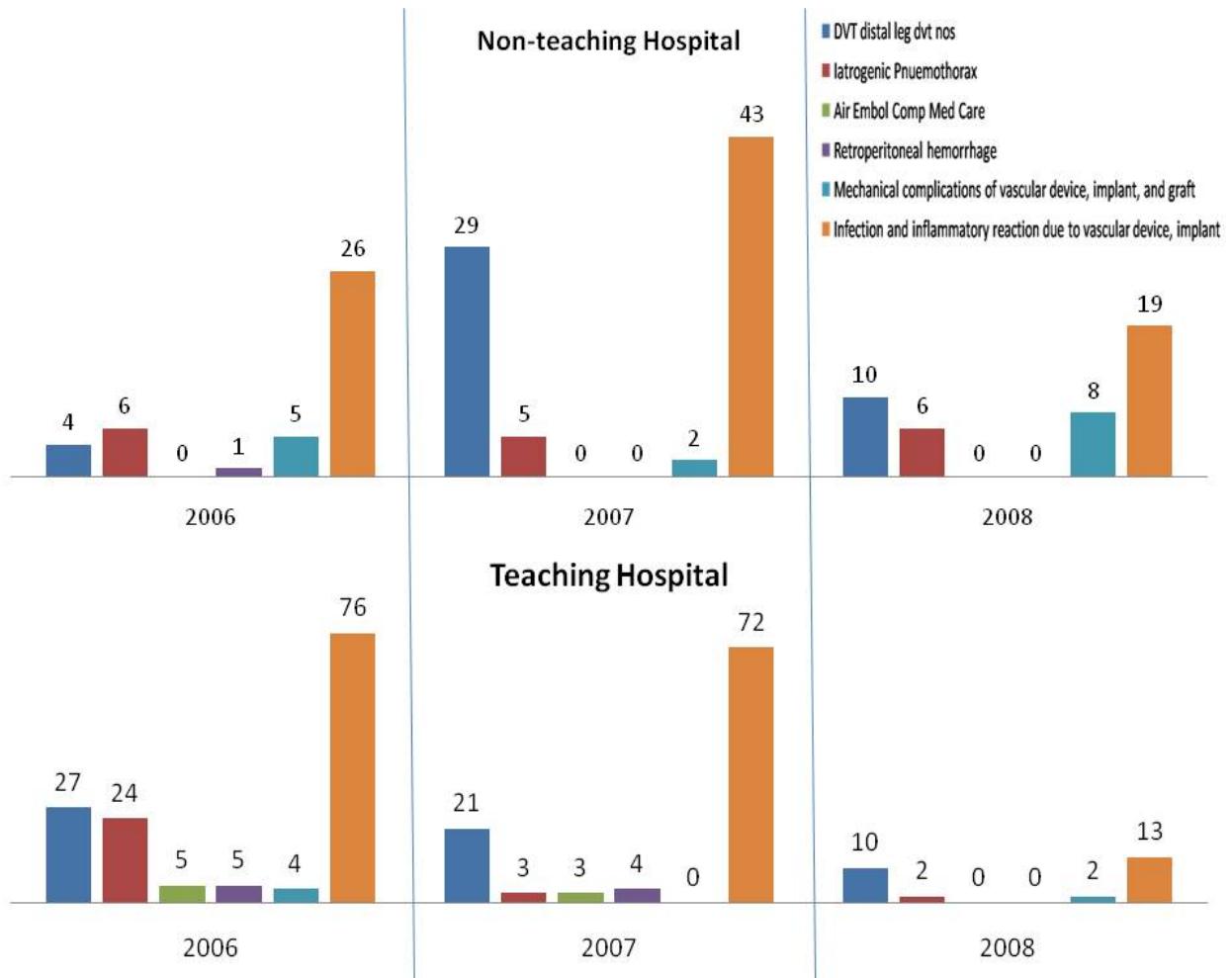


Figure 2. Results of CVC complication pre and post interventions in teaching hospital with training and non-teaching hospital without training.

The results clearly a chronological correlation between the initiation of CVC placement simulation training for residents and a reduction in CVC related clinical complications, and suggests that simulation training of residents can result in lower adverse clinical outcomes from CVC placement. While it is not possible to state with full confidence that only the intervention caused such reduction in errors, our mathematical simulation results and our laboratory

validations suggested that such outcome changes are feasible. Further it is also important to note that as predicted by our simulation, our residents actually outperformed the trained anesthesiologists.

3. CONCLUSIONS

Intervention management in complex environment is a challenging task. However with combination of mathematical simulations and simulation based training, it is possible to design, develop and evaluate effective interventions. In fact it is critical that in complex environments wherein errors are unacceptable, simulation plays a role not only in training but also designing interventions and evaluating the impact of interventions. In several industries it is customary to include simulation as a means of ensuring smooth integration of the interventions into day to day activities. In clinical realm, simulation is often only employed for training phases of interventions. However this research shows the advantages of using simulation science in a more global sense. Our experiments show how such a global perspective can benefit intervention management. CVC errors cost the US Economy several billion dollars per years and the patient complications can often be fatal. Using the global perspective and using simulation science as the basis of the intervention, we were able to record large reduction in CVC related complications and even show that with well designed training and evaluations, novices can conduct procedures equally as well if not better than senior attendings.