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Award Number: W81XWH-10-2-0061

TITLE: Simulation Learning PC Screen-Based vs. High Fidelity

PRINCIPAL INVESTIGATOR: Kristine Qureshi, R.N., DNSC, APHN-BC, CEN
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Fort Detrick, Maryland 21702-5012

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13. SUPPLEMENTARY NOTES					
14. ABSTRACT The purpose of this project is to develop and test a model that can be used to compare different types of simulation learning for military and civilian nursing trauma skills. The model will enable measurement and comparison of changes in knowledge, skills and attitudes of the learner, as well as overall cost effectiveness for each type of simulation (PC screen based vs. high fidelity simulation). The final model will be useful for evaluation of simulation learning for many other military and civilian nursing (and other types of healthcare providers) clinical skills. This is completion of the first year of the project; the first pilot scenario has been developed; now Phase II IRB and CRADA approval must be secured in order to test the initial pilot module and three other subsequent modules on human subjects. There are no research findings to report at this time.					
15. SUBJECT TERMS Simulation Teaching Methods					
16. SECURITY CLASSIFICATION OF:			17. LIMITATION OF ABSTRACT	18. NUMBER OF PAGES	19a. NAME OF RESPONSIBLE PERSON
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INTRODUCTION:

As the number and complexity of disasters increases across the world, increased attention is being paid to disaster and trauma nursing. Since 2001, the US has experienced numerous significant natural, technological and human made disasters. Presently, a large number of military nurses are directly involved in providing care to wounded soldiers on the battlefields of Iraq, Afghanistan, and other areas throughout the world. Core disaster nursing competencies have been identified, but we have yet been able to identify the most efficient and effective methods for competency based disaster nursing education. The purpose of this project is to identify the most efficient and effective method for teaching trauma nursing skills to military and civilian nurses. The project is being conducted at two research sites, namely: the University of Hawaii at Manoa (UHM), and the Tripler Army Medical Center (TAMC). There is a principle investigator (PI) for each site (Dr. Kristine Qureshi –UHM; and COL Hopkins-Chadwick- TAMC). This research effort will develop and pilot test an evaluation model that can be used to compare different learning and cost effectiveness outcomes for PC screen based (PCSB) learning versus high fidelity simulation (HFS) learning for military and civilian trauma nursing skills (i. e., trauma triage, airway management, and complex wound management). The model developed will be useful for future research about the best methods for the use of simulation for clinical skills training military and civilian clinicians.

BODY:

As per the scope of work, the first year of this project focused on hiring personnel, completion of local and second tier IRB and CRADA, material acquisition, simulation equipment training, initiation of collaboration with other military simulation specialists, and development and testing of one pilot module for high fidelity and PC screen based simulation

1. *Hiring personnel:*

- a. Personnel for the project were hired during the first year of the project including: a project manager, information technology support staff member, two graduate students, and an investigator with expertise in the area of health economics.
- b. The project experienced changes in the nursing investigators at TAMC. COL Hopkins-Chadwick was reassigned to San Antonio Texas, but remains on the project as a second PI. At TAMC, MAJ. Leilani Siaki was assigned to serve as a TAMC nursing investigator on the project. During August of 2011, MAJ. Siaki was deployed to Afghanistan, and a new TAMC nursing investigator has been assigned --Dr. Judy Carlson. Since Dr. Carlson is a civilian employee, we expect that she will be able to remain on the project through the end.

2. *Completion of local and second tier IRB and CRADA:*

- a. Immediately upon notice of the award, IRB applications were submitted to both UHM and TAMC. The UHM IRB application was answered within one month and the project was deemed to be exempt. However, we did not receive a response from the TAMC IRB until April, 18, 2011. We were informed that only phase I (which involved no human subjects) was approved, and that once the simulation modules have been developed, these protocols, along with all data collection sheets, evaluation tools and consent forms must be submitted and approved before we can pilot test the pilot module.
- b. A second submission to the TAMC IRB for pilot testing the first module was submitted by MAJ Siaki before she was deployed to Afghanistan. The submission was not approved and we were informed that all modules for the project and accompanying documents must be submitted before IRB and CRADA approval can be provided. To date we have developed a recruitment flyer, data collection sheet, consent form, and simulation model economic data collection tool which will be submitted to the TAMC IRB, with all modules for the project. At this point in time, we expect to complete development of all of the modules (pilot module and three training modules) by the end of February, 2012.

- c. We did not anticipate correctly the amount of time it would take to obtain approvals from: Scientific Review committee, Institutional Review Board and the CRADA. Therefore, we expect that we will need to file for a no cost extension, and extend the project for one more year.

3. *Procurement of simulation equipment and investigator team training*

- a. All simulation equipment (including two SIM MAN 3G mannequins along with trauma modules) was ordered, delivered and installed. Upon installation we found that one mannequin was defective and certain parts (one arm and lungs) were returned and new replacement parts were procured.

All investigators underwent training for use of the simulator (3G Sim Man) training from the vendor (Laerdal), and the project graduate student has gone to additional training to become a super user.

4. *Collaborate with other simulation experts and specialists (military and civilian)*

- a. It was recommended that the research team collaborate with other simulation experts.

Three investigators and one graduate assistant attended the International Medical Simulation Society conference in New Orleans during January, 2011. At this conference they networked and conferred with both military and civilian simulation experts. In addition, two investigators visited US Army Simulation Activities located at Fort Sam Houston, Texas and Camp Bulliss during February, 2011 and conferred with a variety of military simulation experts.

- i. At the IMSS conference the following sessions were attended by at least one of the project personnel: Structured debriefing; Inter-professional simulation and structure workshop, Research consensus summit: State of the science; Sim Wars; How health professionals think: implications for clinical education; Methodology for rapid evaluation of simulation evaluation tools; Update on tools for simulation evaluation; Podium Presentations; Plenary sessions, I, II and III; Foundations of experiential learning: Adult learning theory in simulation; Essentials of simulation based education: An introduction to simulation and basics of debriefing; Game based learning for clinical and patient education; Experiences in healthcare related serious game development; Mastery learning principles and simulation; Simulation roadmap; qualitative vs. Quantitative research in simulation; Simulation enhanced distance learning g: Local training.

- ii. At the visit to Fort Sam Houston, the project team met with Dr. Don Johnson, who is Professor and the Directors of Research, Northeastern University, US Army Graduate Program in Anesthesia Nursing, Fort Sam Houston, Texas. Dr. Johnson has conducted work in the area of simulation research and has authored the following article: Johnson, D., Flagg, A. and Dremsa, TL (2008). Effects of using humans patient simulator vs. a CD-ROM on the management of patients exposed to chemical warfare. Available at:

<http://www.ncbi.nlm.nih.gov/pmc/articles/PMC2779609/>

Both of these endeavors have been useful informing the development of the model.

5. *Development and testing of one pilot module for high fidelity and PC screen based simulation*

- a. The content for the first pilot module has been developed, but we are not able to pilot the material on human subjects until the second IRB review and CRADA requirements are approved. Attached is a copy of the draft for the first pilot module (Attachment C). The first CRADA document, which has been developed and signed by UHM is awaiting signature from TAMC as well as CIRO. An appointment is being scheduled with the IRB officials at TAMC to review the timeline for such. (It should be noted that there have been changes in some of the TAMC IRB personnel, so a personal visit is expected to expedite the process.)

KEY RESEARCH ACCOMPLISHMENTS:**REPORTABLE OUTCOMES**

- Approved Protocol
- Items to be submitted with new Protocol
 - Recruitment flyer
 - Data Collection Sheet
 - Consent Form
 - Simulation model economic data collection tool
- Module Content
 - C-spine Pilot algorithm

This project is not in the phase for discovery of research findings. Outcomes will be reported during year two of the project and reported at the next annual report.

CONCLUSION:

This project has not yet obtained results that can be reported. Results will be summarized during the second year annual report.

REFERENCES:

Not applicable

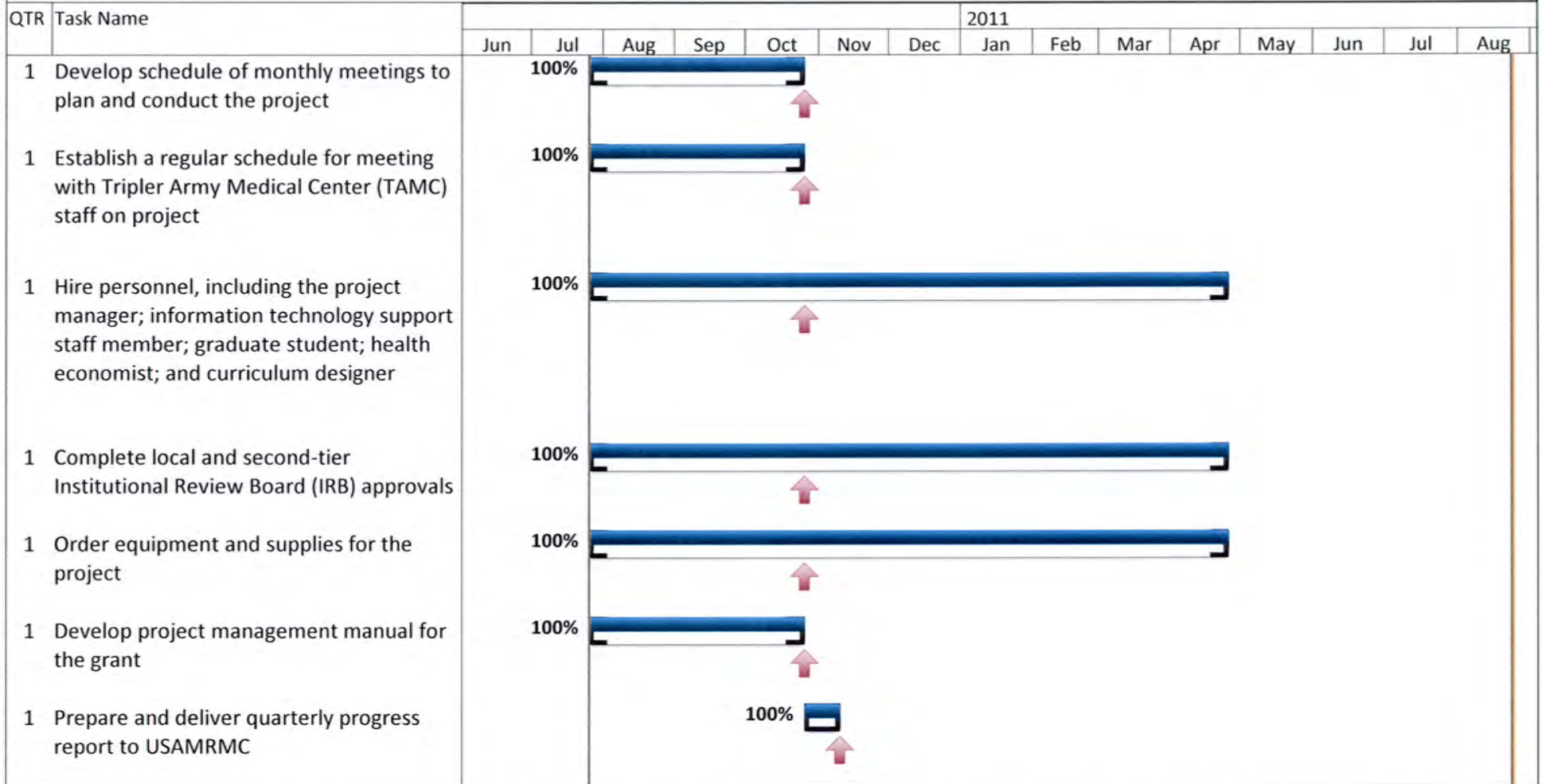
APPENDICES:

- Attachment A: Simulation learning PC screen-based vs. high fidelity – progress chart
- Attachment B: Approved Protocol: Simulation Learning: PC-Screen Based (PCSB) versus High Fidelity Simulation (HFS)
- Attachment C: Recruitment Flyer
- Attachment D: Data Collection Sheet
- Attachment E: Consent Form
- Attachment F: Simulation model economic data collection tool
- Attachment G: C-Spine Pilot algorithm

SUPPORTING DATA: N/A

Project: Simulation Learning PC Screen-Based vs. High Fidelity Project - Progress Chart

Date: Thu 8/25/11


Project Task

Finish

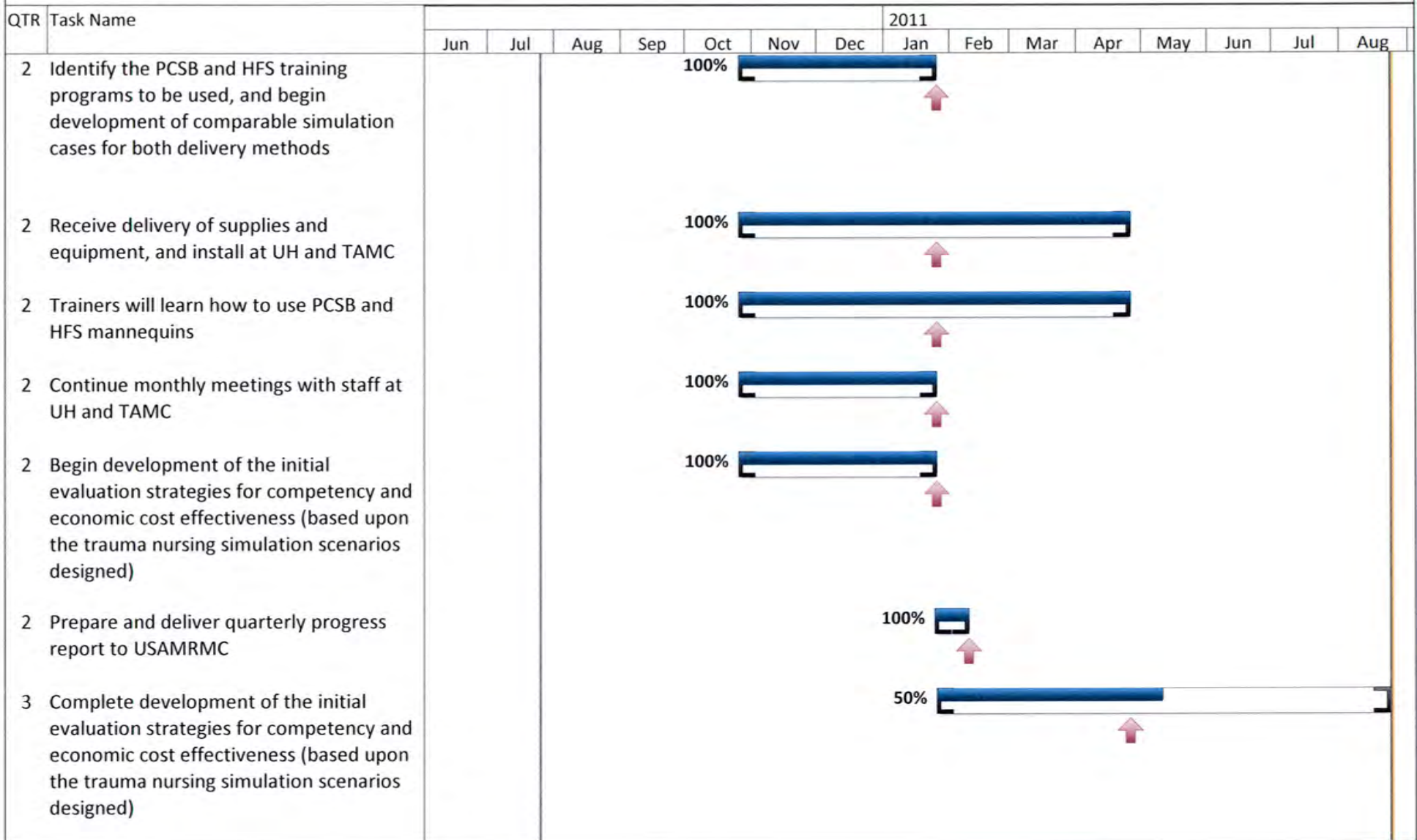
Progress

Start

Deadline

Project: Simulation Learning PC Screen-Based vs. High Fidelity Project - Progress Chart

Date: Thu 8/25/11

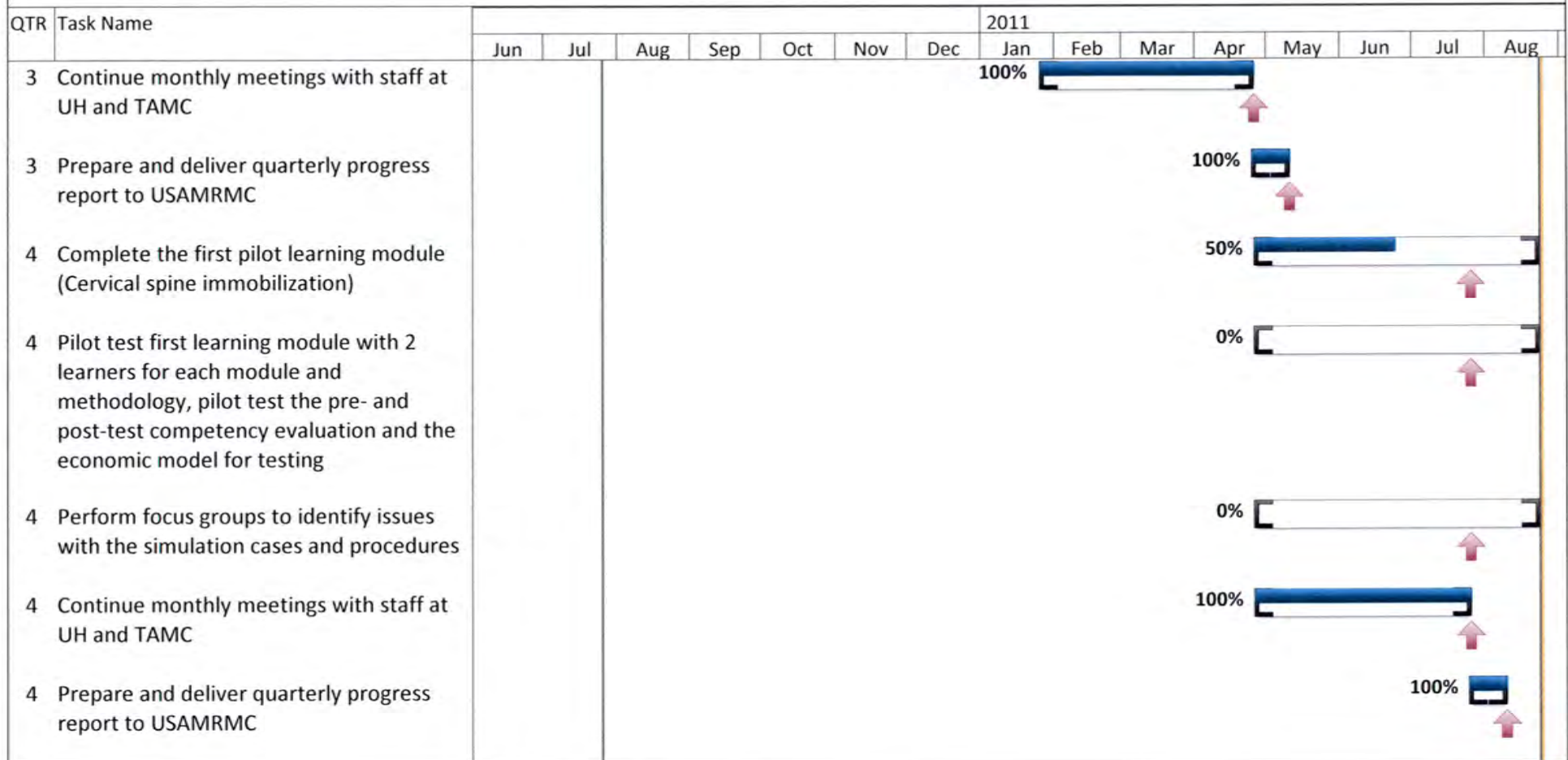


Project Task [] Finish []
 Start [] Deadline []

Progress []

Project: Simulation Learning PC Screen-Based vs. High Fidelity Project - Progress Chart

Date: Thu 8/25/11



Project Task 

Finish 

Progress 

Start 

Deadline 

Attachment B. Approved Protocol - Simulation Learning: PC-Screen Based (PCSB) versus High Fidelity Simulation (HFS)

MCHK-CI

APR 1 8 2011

MEMORANDUM FOR MAJ Leilani A. Siaki, AN, Nursing Research Section,
(ATTN: NRS-NR), Tripler AMC, HI

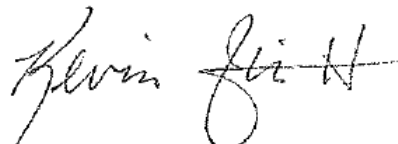
SUBJECT: Approval of Study Initiation

1. Your clinical investigation protocol entitled “**Simulation Learning: PC-Screen Based (PCSB) versus High Fidelity Simulation (HFS)**” was reviewed by the Institutional Review Board (IRB) at Tripler Army Medical Center (TAMC) on 28 February 2011. The protocol for **phase I** was determined to be Research Not Involving Human Subjects. The protocol has been assigned TAMC Protocol No. **25H11**, and is approved for implementation of phase I only.
2. Phase I of the subject protocol only involves technical development of the content of simulation learning modules for each modality of instruction, that is, Research Not Involving Human Subjects.
3. Phases II and III have not yet been reviewed by the IRB. Approval of phases II and III are contingent on the submission and full Board approval of documentation for each of phases II and III, in sequential order. Separate approvals will be issued for each of phases II and III once all outstanding issues are resolved.
4. No further review is required unless modifications are made to the original proposal. This includes, but is not limited to, addition or deletion of investigators and changes in study design. Per TAMC CG Policy Memorandum 20 and the Human Research Protection Program, you are expected to conduct your study in accordance with the standards of good clinical practice and ethical principles.
5. Please note that this is **not** an approval to receive extramural resources (i.e., personnel, drugs, supplies, equipment, money, and gifts from any source outside of TAMC) nor an indication of guaranteed funding from the Department of Clinical Investigation. You must coordinate extramural resource approvals with the Department of Clinical Investigation, Bldg 40, 433-6709. If any extramural resources are received without DA or MEDCOM approval, the individual who receives them may be found in ethics violation and prosecuted for criminal misconduct.
6. All manuscripts, abstracts, or publicly-released information related to research conducted at or sponsored by TAMC must be submitted for approval as stated in TAMC Pamphlet 40-31 **prior** to submission for public release or publication. This includes oral presentations or posters, manuscripts, review articles, abstracts and interviews.

You should retain this letter as part of this protocol's record.

MCHK-CI
SUBJECT: Research Notification

7. If you have any questions regarding this information, please feel free to contact this office at 433-6709.

A handwritten signature in black ink, reading "Kevin Lin-Hurtubise". The signature is written in a cursive, flowing style with a large initial 'K' and 'L'.

KEVIN M. LIN-HURTUBISE, M.D.
Chair, Institutional Review Board

TAMC HUMAN USE PROTOCOL INSTRUCTIONS

APPLICATION FOR CLINICAL INVESTIGATION PROJECT INVOLVING HUMAN
SUBJECTS

SUMMARY PAGE

1. PROTOCOL TITLE: Simulation Learning: PC-Screen Based (PCSB) versus High Fidelity Simulation (HFS).
2. VERSION OF THE PROTOCOL/DATE OF VERSION: Version #1, June 28, 2010.
3. SPONSOR: TATRC project Tripler Army Medical Center & University of Hawaii
4. PRINCIPAL INVESTIGATOR:

Leilani Siaki LTC, AN
Nurse Scientist, Nursing Research Service-Department of Nursing (NRS)
1 Jarrett White Road
Honolulu, HI 96859
808-433-4371
fax: 808-433-2753
CITI Training date: CITI Course Passed on 05/18/2010 (Ref # 2908567)

5. ASSOCIATE INVESTIGATOR(S):

Denise L. Hopkins-Chadwick COL, AN (overall co-PI)
Director of Nursing Science AMEDD Center and School
Fort Sam Houston, TX
614-260-1228
fax: 808-433-2753
CITI Training date: CITI Course Passed on 08/14/09 (Ref # 2829244)

Kristine Qureshi, RN, PhD (overall co-PI)
Nurse Scientist, University School of Hawaii School of Nursing & Dental Hygiene
University Blvd
Honolulu, HI 96859
808-956-2638
fax: 808-433-2753
CITI Training date: CITI Course passed on 06/29/10 (Ref# 4595497)

Dale S. Vincent, MD, MPH
Program Director, Internal Medicine Residency, Tripler Army Medical Center
1 Jarrett White Road
Honolulu, HI 96859
808-433-6063

fax: 808-433-2753

CITI Training date: /CITI Course passed on 10/23/2007 (Ref#1364041)

6. MEDICAL MONITOR (MM): N/A

7. LOCATION OF STUDY: This study has two sites Tripler Army Medical Center, Nursing Research Service and University of Hawaii School of Nursing and Dental Hygiene (UHSONDH).

8. LABORATORIES: N/A

9. TOTAL STUDY DURATION: 3 years

a. Anticipated Start Date: 1 August 2010

b. Anticipated Completion Date: 1 August 2013

10. RECRUITMENT SUMMARY:

a. Number of Subjects and Type of Study Subjects: Normal healthy military Registered Nurses (RNs) (20 military nurses from TAMC and 20 civilians recruited through UHSONDH). Total subjects 44.

b. Anticipated Number of Volunteers to be Enrolled per Month: N/A

c. Anticipated Number of Volunteers to be Enrolled per Year: N/A.

11. REVIEWING IRB(s):

Human Use Committee / Institutional Review Board

ATTN: MCHK-CI

1 Jarrett White Road

Tripler AMC, HI 96859-5000

Phone: 808-433-6709

FAX: 808-433-9246

Committee on Human Studies

1960 East-West Road

Biomedical Building, Room B-104

Honolulu, HI 96822

Phone: 808.956.5007

FAX: 808.956.8683

Email: uhirb@hawaii.edu University of Hawaii

12. SOURCE OF FUNDING:

- a. Funding Source: **Telemedicine and Advanced Technology Research Center (TATRC)**ATTN: MCMR-TT (TATRC)Bldg. 1054 Patchel Street Fort Detrick, Maryland 21702. More specifics can be provided after the final award.
- b. Total Cost of the Project: 799,887
- c. Total Budget for TAMC: no money will come directly to TAMC

13. LITERATURE SEARCH FOR DUPLICATION:

DATABASE	SEARCH NUMBER	DATE SEARCHED	TERMS SEARCHED	NUMBER OF HITS*
Medline (OVID or PubMed) (searched 1986 to present)	2010-590	07/01/2010	Available up on request	PubMed – 0 Related – 13
CINAHL (OVID) (1984 to present)	2010-591	07/01/2010	High fidelity simulation and disasters	1
CAB Abstracts (Dialog #50) (1972 to present)	2010-592	7/2/2010	Available up on request	0
Embase (Dialog #72) (1985 to present)	2010-593	7/2/2010	Available up on request	11
Federal Research in Progress (FEDRIP) (Dialog #266)	2010-594	7/2/2010	Available up on request	0
NIH RePORTER (NIH Research Portfolio Reporting Tool) http://projectreporter.nih.gov/reporter.cfm (current grants)	2010-595	07/01/2010	Simulation training nursing disasters or clinical skills OR “computer programs” nursing training	0
BRD (DoD Biomedical Research Database) (1998-2004) (http://www.dtic.mil/biosys/org/brd)	2010-596	07/01/2010	“computer programs” nursing training	0
DTIC (http://www.dtic.mil) (1965 to present)	2010-597	07/01/2010	high fidelity simulation" nursing training disaster	0
Cochrane Library	2010-598	07/01/2010	Simulation training	0
				* Numbers in this column do not necessarily represent highly relevant studies

- a. Results of Search:

In PubMed only one study focused on nurses and it did not address any of the variables to be considered in this proposed study. The one CINAHL study addressed a disease outbreak only and not other common disaster nursing skills. Of the 11 Embase articles only one addresses nurses and disasters but it was not designed to evaluate the economic impact of the training modalities. Upon review no concurrent research on this topic is published or active. This is not a duplication of any ongoing clinical study.

PROTOCOL

1. **ABSTRACT:** This pilot study will develop an evaluation model that can be used to answer the following question: Is there a difference in competency based learning outcomes and cost effectiveness between learning that is supported by PC-Screen-Based (PCSB) computer simulation vs. use of high fidelity simulation (HFS) mannequins for selected trauma nursing functions? Specifically, the overall goal of this project is to develop an evaluation model that can be used to determine differences in learning outcomes and cost effectiveness between PC-Screen-Based (PCSB) computer simulation and high fidelity simulation (HFS) mannequins not to develop a trauma/disaster skill training course. PCSB curriculum will be purchased for selected trauma nurse functions and the corresponding curriculum will be developed for the High Fidelity Simulator (HFS). Military and civilian nurses will be randomly assigned to one of the two groups (PCSB or HFS), receive about 8 hours of training and be evaluated on psychomotor skills, knowledge, confidence, judgment & problem solving. A cost analysis comparing the two training technologies will also be accomplished.
2. **HYPOTHESIS:**
 - a. HFS supported learning will result in better outcomes than PCSB simulation learning, in terms of knowledge, psychomotor skills, self confidence, judgment, and problem solving.
 - b. HFS supported learning will be less cost effective than PCSB simulation learning.
 - c. The utility of HFS supported learning will increase as the complexity of the disaster nursing functional skills increase.
 - d. The utility of PCSB simulation learning will decrease as the complexity of the disaster nursing functional skills increase.
3. **OBJECTIVES:**
 - a. Technical objective #1. Develop the methodology for comparing the educational and cost effectiveness of the use of HFS (which is expensive) with PCSB simulation (which is low cost) learning methodologies
 1. Develop and pilot test comparable training modules for each trauma nursing function for each simulation methodology. (Note: we will identify an existing simulation training program for the PCSB, and develop corresponding training scenarios that are comparable for the HFS).
 2. Develop and pilot test competency based evaluation tools to measure psycho-motor skills for each of the trauma nursing functions (Note: to be administered pre and post intervention).
 3. Develop and pilot test the indicators to measure the cost effectiveness (economic and societal) of each of the training methodologies.
 - b. Technical objective #2. Pilot test the methodology to establish the degree to which there is a difference in student learning outcomes (for a variety of disaster nursing functions) between the use of HFS supported learning and PCSB simulation learning in terms of:
 1. knowledge (ability to recall specific information);
 2. psychomotor skills (ability to correctly perform the skill, including all essential critical element steps);
 3. self confidence (feeling of ability that one's self can actually perform the task correctly);

4. judgment (ability to make critical decisions and adjustments to the task(s) when confronted with intervening information of data);
5. problem solving (ability to revise ones course of action and steps taken in response to an obstacle or identified barrier to the situation).
- c. Technical objective #3. Establish the degree of cost effectiveness for HFS compared to PCSB simulation learning for a variety of disaster nursing functions (to be stratified and analyzed by degree of complexity and risk). Cost effectiveness will be measured by the following criteria:
 1. Economic costs for: initial purchase and set up of equipment; acquisition / development of training algorithm; ongoing maintenance of equipment; training personnel costs per hour of training with high-fidelity mannequin times the number of hours required for effective training. (Note: exact computation formula to be developed by project economist).
 2. Societal costs: potential cost of injury to the patient (in terms of dollars to provide iatrogenic complications of care, pain, and suffering) if the trauma functional role is not performed correctly (This will be determined by a committee of experts).
4. SIGNIFICANCE: Registered nurses military and civilian respond to and are expected to be ready to respond to disasters. Since training is not without costs, educators, administrators and policy makers need to know what available training to use for what desired skills. Developing a framework that evaluates training modalities while at the same time comparing 2 specific modalities (PCSB vs HFS) for selected nurse disaster skills would be beneficial for decision makers.

5. BACKGROUND:

5.1. INTRODUCTION: **Military and Civilian Nursing Training & Education**

Modern day nursing in Europe and the United States is rooted in military and disaster nursing services. Florence Nightingale is credited with markedly reducing the morbidity and mortality of soldiers during the Crimean War; Clara Barton distributed needed supplies to victims of disasters and battlefield soldiers, and in 1881 she founded the American Red Cross, which laid the groundwork for the development of the US Army Nurse Corps; and during the US Civil War approximately two thousand women volunteered to provide nursing care to wounded soldiers (in both the North and South regions of the country).^{1,2,3} Historically, nurses have served important roles in many wars and conflicts, including: the Spanish American War (1898); World War I (1914-1917), World War II (1941-1945); Korean War (1950-1953); Vietnam War (1964-1975), Desert Shield – Desert Storm (1990-1991), and currently in Afghanistan and Iraq.⁴ Nursing as a profession has continued to evolve since the 19th century, while trauma and disaster nursing has developed into a specialty in both the military and civilian sectors of the profession.⁵ Worldwide, there are now more than 700 serious disasters recorded each year.⁶ The December 2004 tsunami in Aceh Indonesia resulted in more than 130,406 deaths, 36,836 persons missing, and more than 500,000 persons displaced and rendered homeless.⁷ Since 2001, the US has experienced a number of disasters that resulted in significant injury and death among its citizens, e.g., the World Trade Center and Pentagon attacks of

September 11, 2001, the deliberate dissemination of Anthrax during the same year, Hurricanes Katrina and Rita, and numerous significant wild fires, earthquakes and floods. In the U.S., trauma accounts for 4% of deaths, is the leading cause of preventable deaths for persons under the age of 44, and is a leading cause of disability across the age spectrum.⁸ Currently, there are a large number of military nurses directly involved in providing care to wounded Soldiers on the battlefields of Iraq, Afghanistan, and other areas throughout the world. Military nurses are also actively engaged in peace keeping missions, and serve as key members of the healthcare teams that provide care to the nation's veterans, including those who have been wounded.⁹ Military nurses have an expanded mission, namely, to provide support for combat commanders during time of war, conserving the fighting strength during military missions, providing care to victims during humanitarian and peacekeeping missions, and tending to the wounded Soldiers, veterans and military families.¹⁰ With the large number of international conflicts and disasters, trauma nursing has taken on an added importance for both military and civilian nurses. Competency in trauma nursing functions is essential to assure safe and effective care to civilians and Soldiers alike. In the U.S. there are approximately 90,000 civilian emergency nurses, whose job it is to focus on rapid assessment, immediate intervention, and stabilization during the acute phase of illness or injury.⁹ As a result, there are renewed calls for the improvement of disaster and trauma education in schools of nursing, as well as for practicing nurses in both the military and civilian sectors. The American Nurses Association reported at its 2007 Quadrennial Policy Conference on Nursing Care in Life, Death and Disasters that nursing schools should expand the disaster nursing content, and that it should be competency-based to assure the appropriate level of their graduates.¹¹ Some researchers have found that the current disaster nursing education and post graduation training programs are lacking. Williams, Nocera, and Casteel¹² conducted a systematic literature review of the effectiveness of disaster skills training among healthcare workers. They found that there is a severe lack of standardized and objective tools, and a dearth of rigorous research in this same area. Furthermore, they recommend that evidence-based evaluations must be conducted to assure the effectiveness of the performance of healthcare providers during disasters.

Simulation for Teaching Healthcare Worker Disaster Response Skills

Increasing interest surrounds the use of high-fidelity simulation (HFS) to teach psychomotor skills, improve student knowledge and perceptions of self confidence, and increase student satisfaction with learning processes for complex health-related procedures. Many researchers have found the use of simulation for disaster skills training to be effective for emergency care and disaster responders.^{13,14,15} There are broad levels of simulation typology, which range from partial task trainers, PC screen-based simulation (PCSB) learning, standardized patient protocols, to full-scale simulation with the use of high-fidelity mannequins (e.g., Laerdal SimMan®).¹⁶ Several studies have demonstrated that students' knowledge, skills and abilities improve with the use of simulation; however, few researchers have conducted comparisons between different levels of simulation learning. For instance, Subbarao et al.¹⁷ evaluated the utility of using video clinical vignettes along with HFS for civilian-based weapons of mass destruction and acute patient management training.

The authors found that simulation was effective for such training, with post-test scores being statistically significantly higher than pre-test scores; however, there was no comparison with another simulation methodology. Another group of investigators compared the use of simulation-based learning with problem-based learning methodology. They concluded that simulation learning was superior to problem-based learning for acquisition of critical assessment and management skills¹⁸; however, problem-based learning is also labor intensive, costly to conduct, and likely to be more expensive compared to simulation learning. Brannan, White and Bezanson¹⁹ evaluated the difference in cognitive skills and confidence levels with the use of a human simulator and face-to face interactive learning. These investigators found that student ability to answer questions was higher in the human simulator group, but simulation had no effect on confidence levels. Nyssen et al.²⁰ analyzed the training value of PCSB vs. mannequin-based simulation learning for the treatment of anaphylactic shock among anesthesia residents. These researchers found little difference in learning outcomes between the two methods, but concluded that PCSB learning was better for teaching technical skills, while mannequin based learning was more effective for teaching crisis management and decision making. Blum et al.²¹ studied the effectiveness of the use of simulation team training to increase communication and information sharing among anesthesia residents. Surprisingly, in this study the researchers did not find any improvement in the level of information sharing with the use of simulation learning, but concluded that team building to improve information sharing might actually require longer periods of time than was available in the study.

Use of Simulation for Nursing Trauma Skills Training

The discipline of nursing has adopted the use of simulation for general nursing education as well as for trauma nursing skills training. Parker and Myrick²² have reported that while the use of human patient simulators in nursing education has markedly increased, little research has been conducted to support the use of such technology. While some researchers report that the use of simulation mannequins is highly effective in terms of learning outcomes, others have found conflicting results. Kardong-Edgren, Anderson and Michaels²³ compared differences in pre- and post-test scores for nursing students who were taught about congestive heart failure via lecture vs. the use of both low- and high-fidelity simulation mannequins. They found no statistical differences in the scores among the three groups. Bruce, Bridges, and Holcomb²⁴ documented their efforts and end results for improving military nurses' trauma skills through the use of simulation learning. These authors reported significant success for increasing the military nurses' ability to provide trauma care to severely wounded Soldiers. Solnick and Weiss²⁵ conducted a comprehensive review of the literature to examine the use of HFS in nursing education. They identified only one study that had used an experimental design to compare clinical skills among two groups of nursing students who received skills training with use of simulation vs. traditional methods. In this one study, it was found that six months later the simulation training group had better skills compared to the traditional group. In their review, Solnick and Weiss also noted that while there exists a large amount of nursing literature that addresses simulation learning, most of this literature focuses on

the perceived benefits of simulation learning (i.e., confidence levels, usefulness for practice, realism of the experience, etc.) rather than measuring actual competencies. They recommend conduction of rigorous experimental design studies to answer the important questions regarding simulation in nursing education. Weiner²⁶ reports that there is an important need for competency-based curriculum for disaster nursing preparation, but currently available simulation activities are not adequate to fully prepare nurses for complex disaster response. It is clear from the literature that much more needs to be known about simulation and its utility for trauma response education for nurses.

Cost of Simulation Learning for Nursing & Medical Education

To date, research which articulates methods for conducting economic analyses on the use of simulation (regardless of type) has been sparse. Harlow and Sportsman²⁷ conducted an economic analysis of the use of high-fidelity simulators for general nursing skills education by comparing the cost of HFS mannequins to a clinical skills instructor. Cost factors in this study included: annual costs for classroom space; annual clinical laboratory costs; initial and ongoing simulation investments; salaries for simulation and clinical instructors, and expected time horizon for the project. They found a slim margin of difference in favor for use of simulation only when the salary of the clinical instructor was adjusted upward. This study team did not examine learning outcomes or societal costs or benefits (e.g., less procedural error on real persons) for either method. Another group of investigators evaluated the feasibility, self-efficacy and cost of use of HFS for helicopter flight physician training. Qualitative analysis of learning outcomes indicated that use of HFS was useful for teaching the residents about recognizing the challenges encountered during flight transport; however, based on the economic analysis, the authors concluded that the costs of this type of training is high (\$440 US per student per session, and 22 hours of clinical faculty time).²⁸ There are additional factors to consider when calculating cost/benefit ratios for simulation learning. For example, there are opportunity costs in terms of student time, as well as equipment depreciation and maintenance, personnel and space costs for a simulation laboratory, and costs for development of simulation scenarios that must be considered. Several benefits must also be considered. Simulation, when used effectively, (i.e., it maps to the level and degree of learning that needs to occur) has the potential to better prepare providers, so that during times of crisis, some degree of experience for new or rarely used skills can support the practitioner performing the procedure. While this seems intuitive, the evidence to support this has yet to be demonstrated.

The Way Ahead

These results will be used to design a larger study that is adequately powered to evaluate the tools developed in phases I, II, and III. Given the rapidity with which technological applications are being developed, it is important that commanders and CEOs have valid and reliable methods of evaluating training options when allocating resources to insure nurses receive needed initial and continuing education in the most efficient, cost-effective means possible.

Summary

There are many levels and types of simulation that can be used for educating military and civilian nurses for disaster response role functions —ranging from simple PCSB learning to HFS learning. Presently, there is little actual experimental evidence to support use of simulation, or which levels produce better learning outcomes. No studies were found that compared competency-based learning outcomes and cost between the use of PCSB computer simulation and HFS mannequins for trauma nursing functions. Safe, effective trauma nursing care can serve to reduce the morbidity and mortality associated with acute traumatic injuries in the civilian and military sectors.²⁹ Given the finite resources for nursing education and training, it is necessary that the most efficient, cost-effective methods be utilized for such training. This two-year pilot study will develop an evaluation model that can be used to answer the following question: *Is there a difference in competency based learning outcomes and cost effectiveness between learning that is supported by PC screen-based computer simulation vs. use of high fidelity simulation mannequins for selected trauma nursing functions?* Developing a framework for answering this question will serve to shape military and civilian nursing curriculum for disaster skill response training. It will provide a uniform method for comparing learning outcomes and cost effectiveness between different methodologies for instruction, assisting commanders and CEOs in resource allocation, and will have broader applications for many other disaster nursing skills in the military and civilian sectors.

- 5.2. **MILITARY RELEVANCE:** The mission of the U.S. military and the Department of Defense (DoD) healthcare team is to support combatant commanders in peace and war operations by conserving the fighting strength, providing care to victims during humanitarian and peacekeeping missions, and tending to the wounded Soldiers, Retirees, and their Families. In addition, with the advent of increased potential for foreign terrorism on U.S. soil, the military also has an added responsibility with regards to Homeland Defense. Today, the U.S. military healthcare system provides care for more than 9.2 million persons, including those on Active Duty, Retirees, Reservists, and Family Members.³² As of June, 2009 the number of professional nurses employed by the U.S. Military and Department of Veterans Affairs was 95,724. (Personal communication: J. Rychnovsky, PhD, RN, Capt. US Navy Nurse Corps Detailee, Senator D. Inouye, August, 2009). The Nurses that serve in this system span the ranks of active duty, military reserve, and civilian sectors. Currently the U.S. is involved in major military conflicts in Afghanistan and Iraq. As modern war has evolved, firepower has increased but lethality has decreased. Today, only 10% of Soldiers wounded during war die from their injuries.³³ Frequently, military personnel involved in combat operations require emergency care that is serious enough to warrant medical evacuation. As of February, 2009, more than 9,000 U.S. military personnel from Afghanistan, and 45,583 from Iraq have required medical evacuation.³⁴ Many of these service members will require ongoing care long after their tour of duty in the conflict zone has ended. Nursing plays an important role in providing such care to these Warriors during the immediate aftermath as well as long-term. Trauma nursing has evolved as a distinct specialty. Today the scope of trauma nursing includes provision of trauma related care in the pre-hospital, emergency

department, peri-operative, intensive care, surgical wards, rehabilitation, and outpatient arenas.³⁵ In the military sector, the number of both active duty and civilian nurses employed in each of these areas is large. A well prepared military nursing workforce that is competent across critical emergency and disaster nursing functions has the potential to save even more lives, reduce morbidity, and enhance rehabilitation efforts. The US Army Medicine Strategy Map for assuring health of soldiers describes the strategic plan to maximize value in health services, provide global operational forces, team building, balance innovation with standardization, and optimize communication and knowledge management.³⁶ Identification of an effective and efficient model for evaluating military nurse training for acute care and long-term care for war related injuries will contribute to a system which assures that our Soldiers, their Families and our Veterans receive the best care possible, and is in sync with this Strategy Map. It is therefore imperative that we determine whether the use of high fidelity simulation learning is superior in terms of improving competency, for what skills, and at what cost per unit of training? Training for military nursing must be effective in terms of preparing competent practitioners at a reasonable cost. This pilot study will develop a method for evaluating and comparing PCSB learning with HFS mannequin learning for a variety of military trauma nursing functions. The evaluation model that is developed through this project will be useful for examining other training modalities for military and civilian nursing functions in the future.

6. PROTOCOL DESIGN:

- 6.1. OVERVIEW: This proposed two-year quasi-experimental pilot study and feasibility trial aims to develop and test a methodology that compares HFS mannequin vs. PCSB simulation based learning methodologies for disaster and trauma nursing functional skills. The pilot study sample will consist of military and civilian registered nurses (N=40); each of the participants will be randomly assigned to participate in one of two different training methodologies — either HFS mannequin or PCSB simulation learning — for selected trauma nursing functions (i.e., trauma triage, airway management, and complex wound management). Each participant will receive an orientation to use of both PCSB and HFS learning to assure equivalent baseline psychomotor skills for each method of learning. Comparable training lesson plans will be utilized for each treatment arm, and the competency of each trainee will be evaluated pre-and post-training by an evaluator who is blinded with regards to the trainees' prior experience as a professional nurse, as well as the assigned method of training intervention (HFS vs. PCSB learning). Curriculum development will start with a pre-developed simulation-based training program from which a corresponding, comparable, simulation training program will be developed for the comparative method. For each trauma nursing function, two lessons with comparable content will be utilized, one that is HFS-based and the other that is PCSB. Registered nurses in the civilian (n=20) and active military (n=20) sectors will be randomly assigned to one of the training methodologies. Each participant will undergo pre- and post-testing of their competency for the trauma nursing functions under study. The learning and cost-effectiveness outcomes will be measured and compared for each trauma nursing

function by type of intervention, including an examination of any differences between the civilian and military nursing cohorts. Analysis will include control for prior professional experience. A health economist will work with the investigators to develop a model for evaluating the cost effectiveness of each intervention (HFS vs. PCSB simulation learning). Overall competency will be measured in terms of knowledge, psychomotor skills, self confidence, judgment, and problem solving abilities while cost effectiveness will include analysis of the actual costs for the training per student per skill trained for each method.

YR01	Quarter	Essential tasks / activities
Phase I	1	• Develop schedule of monthly meetings to plan and conduct the project • Establish a regular schedule for meeting with Tripler Army Medical Center (TAMC) staff on project • Hire personnel, including the project manager, information technology support staff member; graduate student; health economist; and curriculum designer • Complete local and second-tier Institutional Review Board (IRB) approvals • Order equipment and supplies for the project • Develop project management manual • Prepare and deliver quarterly progress report to USAMRMC
Phase I	2	• Identify the PCSB and HFS training programs to be used, and begin development of comparable simulation cases for both delivery methods • Receive delivery of supplies and equipment, and install at UH and TAMC • Trainers will learn how to use PCSB and HFS mannequins • Continue monthly meetings with staff at UH and TAMC • Begin development of the initial evaluation strategies for competency and economic cost effectiveness (based upon the trauma nursing simulation scenarios designed) • Prepare and deliver quarterly progress report to USAMRMC
Phase I	3	• Complete development of the evaluation strategies for competency and economic cost effectiveness (based upon the trauma nursing simulation scenarios designed) utilizing the subject matter experts • Continue monthly meetings with staff at UH and TAMC • Prepare and deliver quarterly progress report to USAMRMC
Phase II	4	• Pilot test first learning modules with 2 learners for each module and methodology, pilot test the pre- and post-test competency evaluation and the economic model for testing • Continue monthly meetings with staff at UH and TAMC • Prepare and deliver quarterly progress report to USAMRMC

YR02	Quarter	Essential tasks / activities
Phase III	1& 2	• Conduct power analysis • Begin full scale pilot: recruit full complement of participants N=40), conduct pre- and post-training competency evaluation, and apply economic analysis model. • Continue to collect data, begin analysis of data, (qualitative and

		quantitative) - Continue monthly meetings with staff at UH and TAMC - Prepare and deliver quarterly progress report to USAMRMC
Phase IV	3	- Analyze data - Continue monthly meetings with staff at UH and TAMC - Prepare and deliver quarterly progress report to USAMRMC
Phase IV	4	- Disseminate findings: submit publication; present at professional conferences (e.g. Annual Asia Pacific Military Medicine Conference) - Prepare and deliver the final report to USMRMC

6.2. INSTITUTIONS/GROUPS RESPONSIBILITIES: Tripler Army Medical Center is partnered with University of Hawaii School of Nursing and Dental Hygiene. The research team will be led by two over-all collaborating Principal Investigators (PI), namely, Dr. Qureshi from the University of Hawaii at Manoa Department of Nursing (UH), and Col. Hopkins Chadwick, from the AMEDD Center and School, the on-site PI will be MAJ Leilani Siaki, Tripler Army Medical Center (TAMC). They will develop and organize the infrastructure for the study. This will include a research manual that will contain the research protocols for recruitment of participants, obtaining informed consent to participate, development of training and evaluation protocols, collection of data, security of data, meeting and communication procedures and logistics for the study in general. Together both sites will evaluate PCSB curriculum, approve of HSF developed curriculum, decided on evaluative tools, conduct the focus group trial of training and evaluation (2 at UH, 2 at TAMC), make adjustments, recruit trial participants (20 from each site) randomly assign to either PCSB or HFS training then conduct evaluation. The curriculum developer, economist, statistician, and simulation trainer will all be at UH while each site with have a program manager, graduate assistant and information technology assistant. The UH-based simulation trainer will train UH and TAMC staff and trainees. A TAMC investigator will evaluate UH trainees while a UH investigator will evaluate TAMC trainees.

6.3. ENDPOINTS: Please refer to the methods section.

6.4. SAMPLE SIZE: This feasibility pilot study is intended to design and test a model that can be used to evaluate different types of simulation learning in terms of educational and cost effectiveness outcomes. Phases II and III includes the use of four (4) and forty (N=40) subjects respectively; half (n=22) will be civilian and half (n=22) will be military nurses. As this is a feasibility pilot study, no power analysis is required. However a power analysis will be done based on the information from phases I and II prior to conducting the full scale feasibility pilot study in phase III.

Four (n=4) of the subjects (2 civilian and 2 military nurses) will participate in the initial pilot testing of the newly developed tools, instruments and training modules. Based upon the findings from this pilot test, the instruments will be refined for use by the larger group (n=40 - 20 civilian and 20 military nurses). Four subjects for the initial pilot testing of the newly developed tools, instruments and training modules is deemed to be adequate, as in this phase we aim to measure usability of the material.

Forty (40) subjects for the full pilot (20 civilian and 20 military) is an adequate sample size to determine differences in learning outcomes and cost effectiveness based upon an anticipated differences between each of the education methods being tested (PC screen based vs. high fidelity simulation). Sample sizes for feasibility pilot studies such as this have a recommended minimum of 10 to 15 per group³⁷. To account for possible attrition, this study was funded based on an n of 20 in each group.

6.5. STUDY GROUP DESCRIPTIONS AND DETERMINANTS OF STUDY GROUP DESIGN: See 6.4 above.

6.6. POPULATION TO BE STUDIED: Nurses will be recruited from a variety of professional specialties, including emergency department, critical care, medical surgical and community based settings. This will allow us to establish pilot findings for a variety of types of nurses. Nurses from each of these areas will be asked to volunteer to receive the training. Each participant will be randomly assigned to receive training via HFS mannequin vs. PCSB method.

6.7. AGE RANGE: 18-65 years old.

6.8. GENDER: Male and Female

6.9. DESCRIPTION OF TEST ARTICLE OR DEVICES: N/A

6.10. DATA AND SPECIMEN COLLECTION: Please refer to the methods section. It is important to note that in its current form this proposal is an already approved and funded TATRC project it is also a development project meaning the specific curriculum and evaluation measures have not been developed as they are developed addendum/modification requests will be made to the IRB.

6.11. MONITORING: NA

7. METHODOLOGY:

7.1. METHODS: **Phase I:** Phase I activities will include organization of the study project, obtaining local and second tier IRB approvals, ordering supplies and equipment for the project, and working with the curriculum designer to develop the content comparable training modules for each modality of instruction.

a. IRB approval for minimal risk review will be requested from local and second-tier review Boards. It will be the responsibility of the PI's to prepare and submit IRB requests to UH and TAMC. Each PI will facilitate the IRB submission for their respective institution. Once local approvals have been granted the protocol will be submitted to the USAMRMC Human Research Protections Office (HRPO).

b. Development of the training modules for each modality which are comparable:

- i. The over-all co-PI's will be responsible for identifying specific content for the educational modules. Pre-developed simulation training modules will be obtained, and then comparable modules will be developed for the alternate methodology. Both of these investigators have extensive experience in emergency and critical care nursing, including trauma nursing. The project curriculum designer will guide the technical development of the simulation learning modules for the project. Adobe CS4 Design Premium and SitePal software program will be utilized to support the development of the PCSB learning modules.
 - ii. A group of 4-5 subject matter experts (SME) in the selected trauma nursing skills and simulation learning will be convened to articulate the learning module curriculum, and evaluate equivalence of the modules for each modality. The SME's will come from a variety of disciplines, and include those who have at least seven (7) years of trauma expertise and experience in the following domains: direct trauma care, web based trauma curriculum development, mannequin based trauma curriculum development, research/academic expertise. Each SME will be asked to assess the content of each module, and evaluate for validity of the content and also compare for equivalency. Subject matter experts will be selected based upon a consensus of the research team relative to fit with the criteria noted above. Some of the specific details of the project will be need to be articulated as the project unfolds (once curriculum is reviewed and selected an addendum will be submitted to the IRB for approval)
- c. Development of specific measures (once developed an addendum will be submitted to the IRB for approval)
- i. Student demographic information sheet: a standardized participant demographic information sheet will be developed which will collect data regarding, age, gender, ethnicity, specialty in nursing, prior professional experience, self assessed computer literacy skills, prior experience with and attitudes towards simulation learning.
 - ii. Development of the evaluation criteria for the learning outcomes and cost effectiveness Once the learning modules are finalized, pre and post tests will be developed. They will include both qualitative and quantitative evaluation indicators. Cognitive testing will be conducted for each of the evaluation tools, and critical element checklists will be developed (See Table 1). Content of each training module and corresponding pre and post tests will be reviewed for content accuracy and comparability. Content validity and inter rater reliability for each of the evaluation tools will be conducted. The health economist will then review the learning methodologies and expected learning outcomes and develop a model for determining the cost effectiveness of each of the teaching modalities. The investigators will work with the health economist to develop factors related to technical complexity as well as degree of risk and potential consequences for adverse events for each of the trauma nursing functions, so that these qualitative factors can be included in the cost

effectiveness considerations. The model will be validated by a group of trauma nursing experts from TAMC as well as the UH School of Nursing (see Table 2.)

Table 1. Learning outcome and measurement methods to be developed for each teaching method

Learning Outcome	PCSB evaluation tools	HFS mannequin evaluation tools
Knowledge (ability to recall specific information)	Written pre- and post-test	Written pre- and post-test
Psychomotor skills (ability to correctly perform the skill, including all essential critical element steps)	- Development of a checklist with critical elements identified for each skill. - Students will be observed while they perform the skill	- Development of a checklist with critical elements identified for each skill - Students will be observed while they perform the skill
Self confidence (feeling of ability that one's self can actually perform the task correctly)	- Development of a written assessment tool - Student interview script - Focus group script	- Development of a written assessment tool - Student interview script - Focus group script
Judgment (ability to make critical decisions and adjustments to the task(s) when confronted with intervening information of data)	- Assessment of student answer on PCSB questions Observation of student during simulation* with use of checklist and evaluator judgment	Observation of students during simulation Standardized checklist and evaluator judgment
Problem solving (ability to revise ones course of action and steps taken in response to an obstacle or identified barrier to the situation)	- Assessment of student answer on PCSB questions Observation of student during simulation* with use of checklist and evaluator judgment	Observation of students during simulation Standardized checklist and evaluator judgment

Note. Reliability will also be assessed between the PCSB online assessment and the observation assessment

Table 2. Examples of trauma nursing functions, potential determination of degree of complexity, and potential level of risk

Trauma nursing function	Degree of	Potential level of risk if not
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	complexity	performed correctly
Trauma triage	moderate	low to moderate (if up-triage is used)
Fluid resuscitation	moderate	high
Airway management (oral airway and head positioning)	low	high
Cervical spine protection,	low	high
Surface trauma	low	moderate
Bleeding control	low	high

E. Phase II: Two (2) registered nurses from each sector (active military and civilian) will undergo usability testing on the two different types of training modules and evaluation tools.

- **Quality control:** the content of each of the training modules will be reviewed for content accuracy and comparability between the two teaching methods, as described in Phase I. Content validity and inter rater reliability for each of the evaluation tools will be conducted. Cognitive testing will be conducted for each survey tool utilized. The PI's will evaluate all aspects of the pilot results and make adjustments to training modules, tools, procedures, and protocols as deemed necessary.

F. Phase III: During this phase we will implement the full training program. Specific methods are as follows:

- *Recruitment of subjects:* 20 active military and 20 civilian registered nurses from a variety of professional backgrounds will be recruited for training. All participation will be voluntary. Recruits will be obtained from TAMC, local hospitals, and other health care agencies.
- *Pre testing:* All subjects will complete a demographic questionnaire, and undergo pre testing to assess the level of knowledge, psychomotor skill, self confidence, judgment, and problem solving for each of the trauma nurse functions. Both written and direct observation will be used for pre-testing measurements. In an effort to control for differences in psychomotor skills for use of a simulator, (and assure an equivalent baseline for use of the learning equipment) each student (PCSB and HFS) will receive the same baseline orientation to PC SB learning and use of the simulator.
- *Intervention – training:* Each participant will be randomly assigned to one of the two learning methodologies (HFS mannequin or PCSB simulation learning). Each participant will complete the series of trauma nurse function training programs. It will take approximately 8 hours to complete the pre-testing and take the training, and 2 hours to complete the post-testing. For the HFS learning method, students will be trained in groups of 6-8 students per session, which is consistent with realistic training session practices, while the PCSB simulation learning students will take the training at their own pace over the course of one week, and will be able to augment their learning with reference books or other

modalities that online students commonly have access to. All training will be delivered by an investigator from the University of Hawaii, namely, Dr. Wong, who will not be involved in the evaluation processes.

- *Intervention – evaluation*: Observational evaluation of all learners will be conducted within one week of the learning, and will be conducted separately (i.e., each student will be evaluated one on one with the evaluator). Written evaluation instruments will be administered, and then an observational evaluation will be conducted, where the student will perform each of the functions and respond to challenge scenarios for each function. In addition, focus groups will be conducted among the students to ascertain their satisfaction with the training program and evaluation methods. The active military nurses will receive their training at TAMC, but will be evaluated by an investigator from the UH, who will be blinded to the experience of the nurse as well as the training method they utilized. Conversely, the civilian nurses will receive their training at UH, but will be evaluated by the investigator from TAMC who will be blinded to the experience of the nurse as well as the training method they were assigned to.
- *Intervention evaluation- economic model*: The economic model that is developed will be applied to determine the actual costs of training (in terms of time required for training, personnel costs, equipment costs, indirect costs for space and utilities, and expected life of the equipment in relation to the numbers of students trained). We will attempt to calculate the actual direct and indirect costs in relation units of training.

YEAR 01				
Phase Quarter	Major Tasks and Sub-tasks	Primary Organization	Product, Event or Milestone	Deliverables
Phase I Q1	Organize the project - Schedule monthly meetings at each site & between sites - Hire support personnel and procure equipment Begin IRB formal approval - Develop and submit IRB approval documents for UH and TAMC	UH & TAMC PI's	- Meeting minutes, with action, date and responsible party lists -Ordered equipment delivered -Hired personnel begin work	Project manual IRB approvals by end of Q2 Quarterly report
Q2	Develop simulation training programs - Identify existing program, develop and pilot test comparison program for alternative simulation method	UH TAMC PI's	One pair of simulation training program for each disaster nursing skill	Three pairs of simulation training programs Quarterly report
Q3	Develop evaluation strategies (use what was learned at SC to shape the training and evaluation materials) Educational effectiveness	UH TAMC PI's	Educational and cost effectiveness evaluation model	Evaluation model to be included in

Simulation Learning: PC-Screen Based (PCSB) versus High Fidelity Simulation (HFS).

Version #1 Date: 7 July 2010

	Cost benefit analysis			Quarterly report
Phase II Q4	Small pilot test learning modules and evaluation & economic model (N=4), & revise as needed	UH TAMC PI's	Revised, final learning modules and evaluation framework	Quarterly report
YEAR 02				
Phase III Q1 & Q2	Conduct full scale pilot: - Conduct power analysis - Recruit participants, (anticipated N=40); conduct pre- and post-training competency evaluation, and apply economic analysis model.	UH TAMC PI's	Research data	Quarterly progress report (Q1 and Q2)
Phase IV Q3	Data analysis: analyze data for educational and cost benefit outcomes;	UH TAMC PI's	Data base and qualitative data	Quarterly progress report
Q4	Disseminate findings: submit publications; present at professional conferences (e.g. Annual Asia Pacific Military Medicine Conference)	UH TAMC PI's	Final report prepared Educational & economic model to compare simulation methods	Final report to USA MRM C

Study limitations: We recognize that there are numerous limitations and potential biases for this pilot study. We will attempt to control for these biases and limitations to the extent possible.

- Content validity and equivalency for each of the trauma learning modules: To assure for validity of the content, as well as equivalency of the curriculum, for each mode of delivery (PCSB vs. HFS), the subject matters experts (SME) for the project will be chosen carefully. The SME's that participate in the study will come from a variety of disciplines, and include those who have at least seven (7) years of trauma expertise and experience in the following domains: direct trauma care, web based trauma curriculum development, mannequin based trauma curriculum development, research/academic expertise. Each SME will be asked to assess the content of each module, and evaluate for validity and compare for equivalency. Subject matter experts will be selected based upon a consensus of the research team relative to fit with the criteria noted above.
- Selection bias: Participants who volunteer to participate may be more enthusiastic with regards to learning and thus the sample may not be representative of the general population of active military and civilian nurses. We will strive to recruit participants from a broad spectrum of nursing specialties, levels of experience and levels of educational preparation to attempt to control for this issue. All participants will be required to have a minimum of a Bachelors degree in nursing, as this is the

minimum level of education for active military nurses, and we aim to achieve groups of comparable educational preparation.

- Validity of self-report bias: during the pre-and post testing phases we will be asking participants to report their experience and attitudes with regards to the different types of learning methods. Responders may not be accurate in their reporting, as they may attempt to provide socially desirable answers. We will stress the confidential nature of the study, and create an atmosphere that is non-threatening and relaxed, to promote accurate self disclosure. Nurses who participate will not be evaluated by a person who serves in any supervisory capacity for that nurse.
 - Confounding factors: There are likely numerous confounding factors that may influence the learning and cost effectiveness outcome findings. We will attempt to identify and control for these factors through the use of a small pilot group to establish the validity and reliability of the evaluation tools and comparability of the training methods with regards to content. In addition, we will randomly assign learners to the training methodology, attempt to assure that the learning environment at UH is comparable to that of TAMC, utilize the same Professor for delivery of the training, and utilize evaluators who are blinded with regards to the background and learning method utilized by each participant.
- 7.2. SOURCE OF RESEARCH MATERIAL: The nurses who will be training either on the PCSB or HFS will be the source of research material.
- 7.3. RECRUITMENT OF STUDY VOLUNTEERS: The TAMC on-site PI and study staff will recruit the TAMC subjects by posting advertisements, advertizing in the TAMC announcements and spreading the word amongst the nursing staff (if flyers are developed they will be submitted to the IRB for approval). The UH PI will recruit civilians from civilian hospitals and the University using a variety of advertizing methods.
- 7.4. INFORMED CONSENT: Once the RN is scheduled to receive training they will be given a consent form (to be developed and submitted to the IRB for approval before consenting subjects). The study will be explained to them when they present for the first training session. For HFS it will be in groups of 6-8 and for PCSB it will be individually. Subjects will have an opportunity to ask questions. The ICD will outline the time investment and specify the test of evaluation that the subject will be expected to perform. The study will be explained by one of the investigators listed on the study. Once written informed consent has been obtained the randomization and training will begin immediately. The subject will be reminded that they may withdraw from the study at any time. An original and a photocopy (or 2 originals if photocopying is not available) of the consent form will be completed and the original kept for the on-site PI's study records and the subject can get a copy. In addition to the subject's signature and date, a place will be reserved for the signature and date of the designated study staff member who administers the consent an investigator listed

- on the study. No study procedures will occur prior to the volunteer giving informed consent.
- 7.5. SCREENING PROCEDURES: N/
- 7.6. DETERMINATION OF ELIGIBILITY:
- 7.6.1. INCLUSION CRITERIA: Nurses will be recruited from a variety of professional specialties, including emergency department, critical care, medical surgical and community based settings. This will allow us to establish pilot findings for a variety of types of nurses. Nurses from each of these areas will be asked to volunteer to receive the training, ages 18-65 both male and female
- 7.6.2. EXCLUSION CRITERIA: Nurses with prior training or experience in the four trauma skills being evaluated will be excluded
- 7.7. RANDOMIZATION AND SUBJECT ASSIGNMENT: For phase I there are only 4 total subjects 2 at each site (TAMC/UH) a coin will be flipped with heads being PCSB and tails being HSF. For phase II the numbers 1-20 will be pulled from a box by the subject. Number 1-10 will be PCSB and 11-20 will be HFS. Each subject in both phases will be assigned a subject identification number which will be used on the evaluation forms. A list linking their name to the subject identification number will be maintained by the project manager at each site. That list will be secured (kept in locked drawer in locked office when not being used
- 7.8. BLINDING: The only blinding will be of the post-training evaluator.
- 7.9. ADMINISTRATION OF THE RESEARCH INTERVENTION(s): Once developed that training is the intervention. Refer to the methods training for specifics.
- 7.10. CONCOMITANT MEDICATION: N/A
- 7.11. SPECIMEN (OR DATA) COLLECTION AND TESTING: see methods.
- 7.12. CLINICAL ASSESSMENTS: N/A not a medical study
- 7.13. DATA MANAGEMENT:
- 7.13.1. OVERVIEW OF CASE REPORT FORMS: No case report forms will be used.
- 7.13.2. SOURCE DOCUMENT: To be developed. Addendums will be submitted and approval obtained before implementation

- 7.13.3. DATA COMPILATION: Spreadsheets will be developed containing only the subject identification number, the linking document will reside with the project manager and be kept under double lock when not in use.
- 7.14. SERIOUS AND UNEXPECTED ADVERSE EVENTS: .
 - 7.14.1. ADVERSE EVENT: N/A not a medical study
 - 7.14.2. SERIOUS ADVERSE EVENT: N/A not a medical study
 - 7.14.3. UNEXPECTED ADVERSE EVENTS: N/A not a medical study
 - 7.14.4. EXPECTED ADVERSE EVENTS: N/A not a medical study
 - 7.14.5. COLLECTING ADVERSE EVENTS: N/A not a medical study
 - 7.14.6. DOCUMENTING ADVERSE EVENTS: N/A not a medical study
 - 7.14.7. FOLLOW-UP OF ADVERSE EVENTS: N/A not a medical study
 - 7.14.8. REPORTING ADVERSE EVENTS: : N/A not a medical study
 - 7.14.9. WITHDRAWAL CRITERIA: Volunteers will be allowed to withdraw from the study at any time without prejudice or loss of benefits to which they are entitled. The TAMC HUC (or the IRB of record) will be notified whenever a subject elects to withdraw from the study in a timely manner.
 - 7.14.10. CRITERIA FOR STUDY TERMINATION: No criteria for study determination, it is based on the willingness of the trainee to continue training and be evaluated.
 - 7.14.11. QUALITY CONTROL AND QUALITY ASSURANCE: This is a TATRC grant and USMRAA will provide oversight and monitoring as well as the TATRC offices.
- 7.15 SPECIAL MEDICAL OR NURSING CARE OR EQUIPMENT: N/A not a medical study.
- 8. DATA ANALYSIS:: Analysis of data and dissemination of findings will conclude this pilot study. Both qualitative and quantitative data analysis will be conducted to evaluate the learning outcomes. Cost effectiveness of each of the learning methods will also be evaluated in collaboration with a health economists. Economic factors will be analyzed quantitatively; Thematic coding will be used with qualitative data.
 - Education outcomes analysis: Using an general linear model (GLM), we will compare the differences in changes from baseline to post training for each of the

participants for the educational outcome variables (knowledge, psychomotor skills, self confidence, judgment, and problem solving abilities) for each of the trauma nursing functions, controlling for factors such years of experience as a nurse. In addition, we will evaluate the qualitative data with regards to students overall satisfaction with the training methodology. Post training program focus groups will be used, field notes will be taken and thematic coding will be performed.

- *Economic analysis:* We will compare the differences in costs (economic and societal) for training between each of the two learning methodologies (e.g. time required for training, personnel costs, equipment costs, indirect costs for space and utilities, expected life of the equipment to calculate cost per unit of instruction, monetary and human costs for medical errors related to each of the trauma skills). *Note: the specific economic factors will be determined in consultation with the health economist, Dr. Juarez. Based on consultation with Dr. Juarez, cost-effectiveness of training with regards to retention of skills over time and timing of refresher courses may also be included.*

9. ETHICAL CONSIDERATIONS:

- 9.1. INFORMED CONSENT: No additional information.
- 9.2. VOLUNTEER IDENTIFICATION AND CONFIDENTIALITY: Volunteers will be assigned a volunteer identification number upon enrollment. This number will be used on their evaluation forms. The linking document will reside with the project manager at each site and be kept in a locked drawer and locked office when not in use. Electronic data transmitted will be password protected but not necessarily encrypted since both institutions do not have the same capability that would not be feasible but the linking document will not be sent electronically but be hand carried if necessary. Volunteers will not be identified in any presentation of the results.
- 9.3. RISK TO VOLUNTEERS AND PRECAUTIONS TO MINIMIZE RISK: A potential risk might arise from stress related to being observed while performing a trauma nursing skill. The benefits of this project are expected to outweigh the risks.
- 9.4. ALTERNATIVES TO TEST ARTICLE, RESEARCH TREATMENT OR RESEARCH INTERVENTION: Not to participate in the study.
- 9.5. BENEFITS TO VOLUNTEERS: A benefit will be that the volunteer trainees will receive additional disaster skill training.
- 9.6. RISKS TO STUDY PERSONNEL AND PRECAUTIONS TO MINIMIZE RISK: None
- 9.7. RISKS TO THE ENVIRONMENT: None
- 9.8. FINANCIAL INCENTIVES TO VOLUNTEERS: None

9.9. MEDICAL CARE FOR INJURY OR ILLNESS: N/A

10. ADMINISTRATIVE PROCEDURES:

10.1. TEST ARTICLE ACCOUNTABILITY: N/A

10.2. DISPOSITION OF DATA: The linking document will be kept in a locked drawer or cabinet in a locked office by the project manager at each site until the end of the project manager's time. Once the study is over the linking document will be kept in the Nursing Research Service Office at TAMC and the Nursing office at UH along with all data collection sheets generated for 3 years.

10.3. ACCESS TO SOURCE DATA/DOCUMENTS: All listed investigators in addition to the curriculum developer, project manager, graduate assistant, information technology assistant, and health economists will have access to the de-identified data (data collection sheets with subject ID number only). Only the project manager from each site will have the linking document until the study is over then the research office will maintain all documents.

10.4. CERTIFICATION OF TRANSLATION: N/A

10.5. PROTOCOL AMENDMENTS: Once the curriculum is decided, developed for the HSF, and the evaluation tools are created amendments will be submitted to the TAMC IRB for approval. Also any recruitment flyers or advertisements will be submitted and the ICD for the phase I pilot test (4 subjects, 2 at each site) and the phase II test (40 subjects 20 at each site) will be submitted for approval before subject enrollment.

10.6. PROTOCOL DEVIATIONS: The HUC will be notified of any deviations.

10.7. PUBLICATION POLICY: Results of this study will be presented in scientific forums orally and in written publications in scientific journals. No identifying information for any of the volunteers in the study will be included in any presentation of data or photographs. Publications will be submitted as per Command review policy.

10.8. RESPONSIBILITIES OF LISTED STUDY PERSONNEL: see Appendix # 2

10.9. RESPONSIBILITIES OF THE MEDICAL MONITOR: N/A

10.10. COMPLIANCE WITH LAWS AND REGULATIONS: The undersigned Principal and Associated Investigators have reviewed this protocol and will conduct the study in full compliance with current Good Clinical Practice Guidelines, HHS regulations, FDA regulations, and Army regulations

10.11. TOP RESPONSIBILITIES OF THE PRINCIPAL INVESTIGATOR:

1. Design and implement ethical research consistent with three ethical principles delineated in the Belmont report.
2. Comply with all applicable Federal regulations impacting the protection of human subjects.
3. Ensure that all research involving human subjects is submitted to and approved by the appropriate Institutional Review Board (IRB).
4. Comply with all applicable IRB policies, procedures, decisions, conditions, and requirements.
5. To promptly report changes or unanticipated problems in a research activity. Normally, changes may not be initiated without HUC approval, except where necessary to eliminate apparent immediate hazards to the human subject or others.
6. Obtain and document informed consent and assent in accord with Federal Regulations and as approved by the IRB.
7. To immediately report by telephone any serious or unexpected adverse experiences which occur to the human subject or others to the Protocol Section Office, DCI (808) 433-7177.
8. To promptly report any change of investigators
9. To prepare continuing review reports at intervals designated by the HUC (or IRB of record) and a final report in accordance with Title 21, Code of Federal Regulations, Part 312.33.
10. To retain in a secure place all IRB research records, signed consent documents, and source documents for at least three years past completion of the research activity.
11. To immediately report to the HUC knowledge of a pending audit by any agency or compliance inspection by the HHS or Food and Drug Administration (FDA) or other outside governmental agency concerning clinical investigation or research."

I have read the foregoing protocol and agree to conduct the study as outlined herein.

11. SIGNATURES: Signatures indicate review, concurrence, sponsorship responsibilities and ability to support protocol. *(This category and the signatures that follow should start on a separate page. This page can then be attached to the final protocol if minor revisions are required by the review committees.)*

(Principal investigator, associate investigators, all investigators' section & department chiefs, and any other department chiefs whose departments are impacted by the study must sign.)

(Leilani Siaki, MAJ, AN Department of Nursing)
On-Site Principal Investigator

Date

(Denise L. Hopkins-Chadwick COL, AN Department of
Nursing)
Associate Investigator

Date

(Kristine Qureshi, RN, PhD University of Hawaii
Associate Investigator

Date

(Dale S. Vincent, MD, MPH)
Associate Investigator

Date

(Lori Trego, LTC, AN DON)
Chief, Dept of Nursing Research Service

Date

12. ATTACHMENTS (as a minimum):

Appendix 1 – References

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Appendix 2 – Investigator Responsibilities

Overview/ background of each overall co-PI: This project will be conducted through the leadership of two Co-Principal Investigators. We have chosen to use this approach because Dr. Qureshi and Dr. Hopkins-Chadwick each bring a special, but different type of expertise to the project. Additionally, this project is a collaborative endeavor between the military and civilian sectors of nursing. It is important for the project that there is a PI from each sector as this will assure that the insights and perspectives of each sector will contribute to the project. We expect that this will serve to add to the utility and applicability of the model that is developed.

Dr. Qureshi is an expert in the fields of emergency nursing, graduate nursing education, and workforce development. She is an associate professor in the School of Nursing at the University of Hawaii at Manoa, and has ready access to the academic and research resources of the UH environment. Dr. will work closely with Dr. Hopkins-Chadwick to direct and manage the project. Dr. Qureshi will serve as the primary Co-PI and will also focus her efforts on assuring that the activities of the project are well integrated across both sites; and direct the day to day activities of the UH site. From her office, the logistical efforts of the project (e.g. scheduling of team meetings, execution of purchase orders and contracts, etc.) etc. will be organized.

Dr. Hopkins-Chadwick has extensive experience in the area of simulation learning methods for trauma education. She is based at TAMC, and will work closely with Dr. Qureshi to assure that the work to be done at the TAMC worksite is completed in an appropriate manner. She will provide the leadership for utilization of the PC screen based learning and high fidelity simulation mannequins, as well as selection of baseline training material from which the corresponding training programs will be developed.

In the event that COL Hopkins-Chadwick is deployed during this project, the following will occur: to the extent possible, she will remain on the project and communicate with Dr. Qureshi via distance, and another PhD prepared nurse researcher from TAMC will join the research team and provide the onsite project management.

Processes for making project decisions: All issues that arise or decisions that need to be made will be thoroughly discussed by the project partners. In the event consensus cannot be reached, final decisions relative to administrative direction will be made by Dr. Qureshi. Dr. Qureshi will be ultimately responsible to assure that management of this project is achieved.

Procedures for resolving conflicts: On this project, consensus will always sought. However, in the event of a conflict, Dr. Qureshi and Dr. Hopkins-Chadwick will confer, and together arrive at a final decision. In the unlikely event of a conflict between Drs. Qureshi and Hopkins-Chadwick, the final decision will rest with Dr. Hopkins-Chadwick.

On-site PI: MAJ Leilani Siaki will be the onsite PI. She will be responsible for directing the work of the study staff. Consenting TAMC participants. Primary POC for the HUC, submitting addendums as they are developed.

Dale S. Vincent, MD, MPH: AI: Dr. Vincent will serve as a content and process expert for the development of the training modules for each of the learning methods.

Health economists: Deborah Tiara-Juarez, ScD, Dr. Tiara-Juarez will serve as the health economist on the project, and be responsible for working with the other investigators to develop the model which will be used to measure the cost effectiveness of the different types of simulation technology for each of the trauma nursing skills in the project. Dr. Juarez is well suited for this project. She received her doctorate from the Harvard School of Public Health, with a major in health economics. She has been an investigator on a variety of research projects that aimed to measure the cost effectiveness of medical procedures.

Clinical Educator Lorrie Wong, RN PhD, Co-Investigator: Dr. Wong is a Clinical Instructor and Director of Simulation at the University of Hawaii School of Nursing. She has 25+ years of experience in the areas of trauma critical care and simulation. In 2005, Dr. Wong was the prime curricula developer of web-based training modules in bioterrorism and disaster preparedness for nursing students which was funded by the State of Hawaii Department of Health. Currently Dr. Wong works with faculty at the School of Nursing to develop, evaluate and adapt simulation scenarios for each of the core clinical courses in the undergraduate program. She has extensive practical experience working with simulation for the training of nurses. She has won numerous awards for teaching and educational service and co-authored several articles related to simulation learning. She will serve as a collaborator in the development of the simulation modules and conduct the high fidelity simulation training sessions. Dr. Wong will serve as a simulation protocol process expert, and will administer the training programs to the participants in the project.

(TBN) Curriculum Designer 1 curriculum designer will be hired for the project. This individual will convert the trauma nurse training modules to the required format (e.g. from PCSB simulation format to HFS mannequin format, or visa versa. S/he will work closely with the PI's as they develop the content for each of the training modules. The curriculum designer will also offer suggestions and consultation with regards to potential methods for presentation of the material. The curriculum designer will also provide input into methods for use of the high fidelity simulation mannequins to achieve learning effectiveness as well as comparability between the two learning methods.

(TBN) Project Managers: Two (2) project managers will be hired for the project, and one will be assigned to support each site (UH and TAMC). Each project manager will be responsible for all operational logistics, scheduling of meetings, maintenance of correspondence and records, coordination of schedules, ordering and tracking of supplies and equipment and other duties as assigned at their assigned site.

Graduate Assistant (TBN): Two (2) graduate assistants (GA) will be hired for the project, and one will be assigned to support each site (UH and TAMC). The GA's will provide assistance with training, evaluation, data entry, data analysis and other duties as assigned at each site that they are assigned to.

Information Technology Assistant (TBN): Two (2) Information Technology Assistants (ITA) will be hired for the project, and one will be assigned to support each site (UH and TAMC). The ITA will provide technical support for the operation of the high fidelity simulation mannequins as well as the PC screen based simulation learning. S/he will maintain the simulation equipment, install software, troubleshoot hardware and software problems, maintain a log of utilization of all of the program simulation equipment, and perform other ITA duties as is required.

Statistician (TBN): One (1) statistician will provide statistical consultation for analysis of the quantitative data. Statistical methods will be suggested, statistical data will be generated.

Simulation learning: PC-Based Screen Based versus High Fidelity Simulation



Screen Based Training

VS



High-Fidelity Simulators

- Participants will be randomly assigned to one of two types of learning (PC screen based or high fidelity simulation) for three trauma nursing skills.
- Each learning session will take approximately one to two hours for each skill.
- Pre and post training evaluation of knowledge, skills, and attitudes will be done.
- Participants will not be paid, but will be provided with a trauma nursing skill reference textbook to use during the training, which will be theirs to keep after the study.

[illegible]

Participant Number _____

Simulation Learning: PC-Screen Based (PCSB) versus High Fidelity Simulation (HFS)**Data Collection Sheet**

Thank you for agreeing to participate in this study looking at PC-Screen Based (PCSB) versus High Fidelity Simulation (HFS). Please complete the following background information.

Gender Male Female

Your year of birth

Ethnicity White/Caucasian
Black/African-American
Hispanic
Pacific Islander / Native Hawaiian
Asian

Number of years of nursing experience as an RN:

Type of unit/clinic you work in:

Are you a Military or Civilian nurse? Military Civilian

What is your highest nursing degree? BS MS other

Rate your level of expertise with PC-screen based learning Novice Advanced Beginner
Competent Proficient Expert

Rate your level of experience with high fidelity simulation learning Novice Advanced Beginner
Competent Proficient Expert

Rate you level of experience with trauma nursing Novice Advanced Beginner
Competent Proficient Expert

***** IRB Members Please note: Once the actual model is developed the following information will be available to attach to this collection sheet:**

- Pre-test questions
- Training syllabus
- Post-test questions

VOLUNTEER AGREEMENT AFFIDAVIT

For use of this form, see AR 70-25 or AR 40-38, the proponent agency is OTSG

PRIVACY ACT OF 1974

Authority: 10 USC 3013, 44 USC 3101, and 10 USC 1071-1087.

Principle Purpose: To document voluntary participation in the Clinical Investigation and Research Program. Home address will be used for identification and locating purposes.

Routine Uses: The home address will be used for identification and locating purposes. Information derived from the study will be used to document the study; implementation of medical programs; adjudication of claims; and for the mandatory reporting of medical conditions as required by law. Information may be furnished to Federal, State and local agencies.

Disclosure: The furnishing of your home address is mandatory and necessary to provide identification and to contact you if future information indicates that your health may be adversely affected. Failure to provide the information may preclude your voluntary participation in this investigational study.

PART A(1) - VOLUNTEER AFFIDAVIT**Volunteer Subjects in Approved Department of the Army Research Studies**

Volunteers under the provisions of AR 40-38 and AR 70-25 are authorized all necessary medical care for injury or disease which is the proximate result of their participation in such studies.

I, _____,

having full capacity to consent and having attained my 18th birthday, do hereby volunteer to participate in an investigational study entitled

Simulation Learning: PC-Screen Based (PCSB) versus High Fidelity Simulation

(Research Study)

under the direction of Judy Carlson, EdD, FNP-BC, Kristine Qureshi, RN, CEN, DNSc, and Denise Hopkins-Chadwick, PhD, RN

conducted at Tripler Army Medical Center

(Name of Institution)

The implications of my voluntary participation/consent as legal representative; duration and purpose of the research study; the methods and means by which it is to be conducted; and the inconveniences and hazards that may reasonably be expected have been explained to me by

I have been given an opportunity to ask questions concerning this investigational study. Any such questions were answered to my full and complete satisfaction. Should any further questions arise concerning my rights/the rights of the person I represent on study-related injury, I may contact

the Center Judge Advocate

at Tripler Army Medical Center, Tripler AMC, HI 96859-5000 (808) 433-5311

(Name, Address and Phone Number of Hospital (Include Area Code))

I understand that I may at any time during the course of this study revoke my consent and withdraw/have the person I represent withdrawn from the study without further penalty or loss of benefits; however, I/the person I represent may be required (military volunteer) or requested (civilian volunteer) to undergo certain examinations if, in the opinion of the attending physician, such examinations are necessary for my/the person I represent's health and well-being. My/the person I represent's refusal to participate will involve no penalty or loss of benefits to which I am/the person I represent is otherwise entitled.

PART B - TO BE COMPLETED BY INVESTIGATOR

INSTRUCTIONS FOR ELEMENTS OF INFORMED CONSENT: (Provide a detailed explanation in accordance with Appendix C, AR 40-38 or AR 70-25.)

PARTICIPATION INFORMATION: You have been invited to participate in a clinical research study conducted at Tripler Army Medical Center (TAMC). It is very important that you read and understand the following general principles that apply to all participants in our studies: (a) your participation is entirely voluntary; (b) you may withdraw from participation in this study or any part of the study at any time; refusal to participate will involve no penalty or loss of benefits to which you are otherwise entitled; (c) after you read the explanation, please feel free to ask any questions that will allow you to clearly understand the nature of the study.

Volunteer Agreement Affidavit

NATURE OF STUDY: The goal of this project is to develop a model that can be used to evaluate the effectiveness of different types of simulation training in terms of both a competency-based skill set and cost effectiveness for trauma/disaster nursing skills training. For this study, we are comparing learning via use of screen-based computer simulation (PCSB) versus high fidelity simulation (HFS) mannequins. To our knowledge, no previous studies similar to this have been done for trauma nursing skills.

EXPECTED DURATION OF SUBJECT'S PARTICIPATION: The time required to complete this study will vary. The study will take place over several weeks and requires both pre-testing and post-testing. If you are in the PCSB simulation group, you will take the training at your own pace over the course of one week. If you are in the HFS mannequin group, training will take about three hours. Regardless of which method you complete your training in, you will be asked to return for a post-test and focus group discussion one week after the training. The focus group will gather your opinions about the experience, and your satisfaction with the process. This post-testing should take 1-2 hours.

WHAT WILL BE DONE:

If you agree to be part of this study, you will be asked to complete a brief questionnaire regarding items such as your educational background, number of years as a nurse, your age, and your experience if any, with trauma. You will also be evaluated regarding your level of knowledge, skill, self-confidence, judgment, and problem solving for each of the three trauma nurse functions using a pen and paper test and by observation.

You will then be randomly assigned to either the HFS mannequin or PCSB simulation learning group. You will be asked to complete the series of trauma nurse function training programs. It will take about 1.5 hour of training for each skill including pre-testing. It will also take 1-2 hours for follow-up post-testing and the focus group. The PCSB group will take the training at their own pace over the course of one week, and will have access to other modalities that online students commonly have access to including a trauma nursing reference book. For the HFS participants, training will be conducted with groups of 2 - 8 students per session. All training will be delivered by an investigator from the University of Hawaii, namely, Dr. Lori Wong, who will not be involved in the evaluation processes.

Your competency for performing three trauma nursing skills will be evaluated within one week after completing the training. You will be evaluated one on one with an evaluator. This will include a test, focus group, and direct observation performing each of the three trauma nursing functions. The evaluator will not know which training session you participated in.

INCLUSION AND EXCLUSION CRITERIA: A total of 44 nurses, 22 civilian and 22 active duty military nurses with a minimum of a bachelor's degree will be asked to participate. Nurses from all professional specialties are eligible to participate.

REASONABLY FORESEEABLE RISKS OR DISCOMFORTS: Although we will try to minimize risks, some people may experience psychological stress during any type of testing (e.g.

Volunteer Agreement Affidavit

written exam, observation). However, we think the likelihood of extreme stress in this project is very low. Every effort will be made by the evaluators to put participants at ease however if you experience any psychological stress, please inform the evaluator and the testing will be stopped at your request.

COMPENSATION FOR INJURY: Should you be injured as a direct result of participating in this research project, you will be provided medical care at TAMC, at no cost to you, for that injury. You will not receive any injury compensation, only medical care. This is not a waiver or release of your legal rights. You should discuss this issue thoroughly with the principal investigators: Judy Carlson, Kristine Qureshi, Leilani A. Siaki, and/or Denise Hopkins-Chadwick before you enroll in this study.

BENEFIT(S) TO THE SUBJECT OR TO OTHERS: You will not be paid to participate in this study. However, you will receive training that would potentially benefit your professional practice both now and in the future. Specifically, both your skill with technological learning methods, PCSB or HFS and your competency with these three trauma nursing skills are expected to be enhanced. You will also be able to keep all reference materials used during training.

Nurses in the future may benefit from this study in that researchers, educators, and managers will be able to provide needed training in the most efficient, cost-effective manner that will actually enhance the skill levels of nurses in order to effectively manage the care of their patients.

ALTERNATIVE PROCEDURES OR COURSES OF TREATMENT: This study is entirely voluntary. If you decide not to participate, your job will not be affected.

CONFIDENTIALITY: Information gained because of your participation in this study may be publicized in the medical literature, discussed as an educational model, and used generally in the furtherance of nursing and medical science. Information from this study may be used as part of a scientific publication in medical or professional journals, but you will in no way be personally identified. We will make every effort to maintain the confidentiality of your participation in this study.

Your information relating to this study may be reviewed by the Institutional Review Board (IRB) at TAMC, Clinical Investigation Regulatory Office at Fort Detrick, Maryland, University of Hawaii, and other government agencies as part of their normal duties in protecting human research subjects, and results of the study will be reported to them. The recipients will treat this information confidentially. In the event of publication regarding this study, your identity will not be disclosed.

PRECAUTIONS TO BE OBSERVED BY SUBJECT BEFORE AND FOLLOWING THE STUDY: N/A

CIRCUMSTANCES UNDER WHICH YOUR PARTICIPATION MAY BE TERMINATED WITHOUT YOUR CONSENT: (a) Health conditions or other conditions that might occur which may be dangerous or detrimental to you or your health; (b) if military

Volunteer Agreement Affidavit

contingency requires it; (c) if you become ineligible for military care as authorized by Army regulation.

COSTS TO SUBJECT THAT MAY RESULT FROM PARTICIPATION IN STUDY:

Other than your time, you should incur no costs associated with your participation in this study.

SIGNIFICANT NEW FINDINGS: The results of the research will be made available to you if you so desire. We will provide you with a written summary of the findings.

APPROXIMATE NUMBER OF SUBJECTS INVOLVED IN THE STUDY: Forty-four (44) nurses will participate in this study.

DOMICILIARY CARE STATEMENT: The extent of medical care provided, should it become necessary, is limited and will be within the scope authorized for Department of Defense (DOD) health care beneficiaries. Necessary medical care does not include domiciliary (home or nursing home) care.

FOR FURTHER INFORMATION: For questions about the study, contact the principal investigator:

Dr. Judy Carlson, EdD, FNP-BC
Nursing Research,
Pacific Regional Medical Command
(808) 433-1469
judy.carlson1@us.army.mil

Dr. Kristine Qureshi, RN, CEN, DNSc
Assistant Professor, School of Nursing and Dental
Hygiene
(808) 956-3628

For questions about your rights as a research participant, contact the TAMC Institutional Review Board (a group of people who review the research to protect your rights) at (808) 433-6709.

For questions about research related injury, contact the Center Judge Advocate at TAMC at (808) 433-5311.

Volunteer Agreement Affidavit

IF THERE IS ANY PORTION OF THIS EXPLANATION THAT YOU DO NOT UNDERSTAND, ASK THE INVESTIGATOR BEFORE SIGNING. A COPY OF THE VOLUNTEER AGREEMENT AFFIDAVIT WILL BE PROVIDED TO YOU.

I have read the above explanation and agree to participate in the investigational study described.

I do ☐ do not ☐ (check one & initial) consent to the inclusion of this form in my outpatient medical treatment record

SIGNATURE OF VOLUNTEER	DATE	SIGNATURE OF LEGAL GUARDIAN (if volunteer is a minor)
PERMANENT ADDRESS OF VOLUNTEER	TYPED NAME OF WITNESS	
	SIGNATURE OF WITNESS	DATE

(Date)

(Printed Name of Individual Obtaining Consent)

(Signature of Individual Obtaining Consent)

Simulation Learning PC Screen – Based vs. High Fidelity
University of Hawaii at Manoa

Costs of developing evaluation strategy

Reporting Period: 2011 - 20

Cost Category

Jan '11

Feb '11

Mar '11

Personnel				
Project Team	Name / Notes	Hours	Hours	Hours
Co-PI	Kristine Quereshi			
Co-PI	COL Denise Hopkins Chadwick			
Co-PI	MAJ Leilani Siaki			
Co-I	Judith Carlson			
Co-I	Lorrie Wong			
Co-I	Deborah Juarez			
Co-I	Dale Vincent			
Graduate assistant	Jonathan Kevan			
Graduate assistant	Suresh Kamang			
Program manager	Tracie Bregman			
Consultants				
Consultant	<name>			
Consultant	<name>			
Consultant	<name>			
Consultant	<name>			
Consultant	<name>			
Consultant	<name>			
Contracted services		COST	COST	COST
Training and education				
Other contracted services				
Office operations				
Printing				
Office supplies/postage				
Books/periodicals				
Travel/conferencing				
Training				
Telephone				
Other office operations				
Equipment				
Computer hardware				
Software				
Other equipment				
Other initial costs				

Simulation Learning PC Screen – Based vs. High Fidelity
University of Hawaii at Manoa

Costs of developing PC intervention

Reporting Period: 2011 - 20

Cost Category

Jan '11

Feb '11

Mar '11

Personnel				
Project Team	Name / Notes	Hours	Hours	Hours
Co-PI	Kristine Quereshi			
Co-PI	COL Denise Hopkins Chadwick			
Co-PI	MAJ Leilani Siaki			
Co-I	Judith Carlson			
Co-I	Lorrie Wong			
Co-I	Deborah Juarez			
Co-I	Dale Vincent			
Graduate assistant	Jonathan Kevan			
Graduate assistant	Suresh Kamang			
Program manager	Tracie Bregman			
Clinical consultants				
Consultant	<name>			
Consultant	<name>			
Consultant	<name>			
Consultant	<name>			
Consultant	<name>			
Consultant	<name>			
Contracted services		COST	COST	COST
Training and education				
Other contracted services				
Office operations				
Printing				
Office supplies/postage				
Books/periodicals				
Travel/conferencing				
Training				
Telephone				
Other office operations				
Equipment				
Computer hardware				
Software				
Other equipment				
Other initial costs				

Simulation Learning PC Screen – Based vs. High Fidelity
University of Hawaii at Manoa

Costs of developing high fidelity simulation

Reporting Period: 2011 - 20

Cost Category

Jan '11

Feb '11

Mar '11

Personnel				
Project Team	Name / Notes	Hours	Hours	Hours
Co-PI	Kristine Quereshi			
Co-PI	COL Denise Hopkins Chadwick			
Co-PI	MAJ Leilani Siaki			
Co-I	Judith Carlson			
Co-I	Lorrie Wong			
Co-I	Deborah Juarez			
Co-I	Dale Vincent			
Graduate assistant	Jonathan Kevan			
Graduate assistant	Suresh Kamang			
Program manager	Tracie Bregman			
Clinical consultants				
Consultant	<name>			
Consultant	<name>			
Consultant	<name>			
Consultant	<name>			
Consultant	<name>			
Consultant	<name>			
Contracted services		COST	COST	COST
Training and education				
Other contracted services				
Office operations				
Printing				
Office supplies/postage				
Books/periodicals				
Travel/conferencing				
Training				
Telephone				
Other office operations				
Equipment				
Computer hardware				
Software				
Other equipment				
Other initial costs				

**Simulation Learning PC Screen – Based vs. High Fidelity
University of Hawaii at Manoa**

Costs of pilot testing PC intervention (include set up and clean up time as well as student time)

Cost Category		Sep '11	Oct '11	Nov '11
Personnel				
Project Team	Name / Notes	Hours	Hours	Hours
Co-PI	Kristine Quereshi			
Co-PI	COL Denise Hopkins Chadwick			
Co-PI	MAJ Leilani Siaki			
Co-I	Judith Carlson			
Co-I	Lorrie Wong			
Co-I	Deborah Juarez			
Co-I	Dale Vincent			
Graduate assistant	Jonathan Kevan			
Graduate assistant	Suresh Kamang			
Program manager	Tracie Bregman			
Student (time in training)				
Student	Student 1			
Student	Student 2			
Student	Student 3			
Student	Student 4			
Equipment		COST	COST	COST
Computer hardware				
Software				
Other equipment				
Room usage				
Other costs				

**Simulation Learning PC Screen – Based vs. High Fidelity
University of Hawaii at Manoa**

Costs of pilot testing high fidelity simulation (include set up and clean up time as well as student time)

Cost Category		Sep '11	Oct '11	Nov '11
Personnel				
Project Team	Name / Notes	Hours	Hours	Hours
Co-PI	Kristine Quereshi			
Co-PI	COL Denise Hopkins Chadwick			
Co-PI	MAJ Leilani Siaki			
Co-I	Judith Carlson			
Co-I	Lorrie Wong			
Co-I	Deborah Juarez			
Co-I	Dale Vincent			
Graduate assistant	Jonathan Kevan			
Graduate assistant	Suresh Kamang			
Program manager	Tracie Bregman			
Student (time in training)				
Student	Student 1			
Student	Student 2			
Student	Student 3			
Student	Student 4			
Equipment		COST	COST	COST
Computer hardware				
Software				
Other equipment				
Room usage				
Other costs				

**Simulation Learning PC Screen – Based vs. High Fidelity
University of Hawaii at Manoa**

Costs of PC intervention (include set up and clean up time as well as student time)

Cost Category

Sep '11

Oct '11

Nov '11

Personnel				
Project Team	Name / Notes	Hours	Hours	Hours
Co-PI	Kristine Quereshi			
Co-PI	COL Denise Hopkins Chadwick			
Co-PI	MAJ Leilani Siaki			
Co-I	Judith Carlson			
Co-I	Lorrie Wong			
Co-I	Deborah Juarez			
Co-I	Dale Vincent			
Graduate assistant	Jonathan Kevan			
Graduate assistant	Suresh Kamang			
Program manager	Tracie Bregman			
Student (time in training)				
Student	Student 1			
Student	Student 2			
Student	Student 3			
Student	Student 4			
Student	Student 5			
Student	Student 6			
Student	Student 7			
Student	Student 8			
Student	Student 9			
Student	Student 10			
Student	Student 11			
Student	Student 12			
Student	Student 13			
Student	Student 14			
Student	Student 15			
Student	Student 16			
Student	Student 17			
Student	Student 18			
Student	Student 19			
Student	Student 20			
Student	Student 21			
Student	Student 22			
Student	Student 23			
Student	Student 24			
Equipment		COST	COST	COST
Computer hardware				
Software				
Other equipment				
Room usage				
Other costs				

**Simulation Learning PC Screen – Based vs. High Fidelity
University of Hawaii at Manoa**

Costs of high fidelity simulation (include set up and clean up time as well as student time)

Cost Category

Sep '11

Oct '11

Nov '11

Personnel				
Project Team	Name / Notes	Hours	Hours	Hours
Co-PI	Kristine Quereshi			
Co-PI	COL Denise Hopkins Chadwick			
Co-PI	MAJ Leilani Siaki			
Co-I	Judith Carlson			
Co-I	Lorrie Wong			
Co-I	Deborah Juarez			
Co-I	Dale Vincent			
Graduate assistant	Jonathan Kevan			
Graduate assistant	Suresh Kamang			
Program manager	Tracie Bregman			
Student (time in training)				
Student	Student 1			
Student	Student 2			
Student	Student 3			
Student	Student 4			
Student	Student 5			
Student	Student 6			
Student	Student 7			
Student	Student 8			
Student	Student 9			
Student	Student 10			
Student	Student 11			
Student	Student 12			
Student	Student 13			
Student	Student 14			
Student	Student 15			
Student	Student 16			
Student	Student 17			
Student	Student 18			
Student	Student 19			
Student	Student 20			
Student	Student 21			
Student	Student 22			
Student	Student 23			
Student	Student 24			
Equipment		COST	COST	COST
Computer hardware				
Software				
Other equipment				
Room usage				
Other costs				

Simulation Learning PC Screen – Based vs. High Fidelity
University of Hawaii at Manoa

Initial fixed costs
PC INTERVENTION

Reporting Period: 2011 - 2012

2011

2012

Contracted services	Description	COST	COST
Training and education			
Other contracted services			
Equipment			
Computer hardware			
Software			
Other equipment			
Other initial fixed costs			

High fidelity simulation

2011

2012

Contracted services		COST	COST
Training and education			
Other contracted services			
Equipment			
Mannequins			
Software			
Other equipment			
Other initial fixed costs			

DRAFT

University of Hawaii Nursing Consortium Simulation Template

Scenario Title: Cervical Collar and Neck Stabilization Scenario

Created and validated by (Names and date): May 13, 2011

Created by:	Validated by:	Yearly Reviewed by:

Powerpoint lecture and demonstration will take place in the SIMCENTER prior to simulation testing)

Simulation Objectives:

On completion of the simulation exercise the learner will be able to:

1. Assess patients at risk for spinal cord trauma.
2. Correctly select and apply a C-Collar
3. Recognize indicators to cease C-Collar application on patient

Critical Elements:

Learning will:

1. Note that a fall from 20 ft. is a risk factor for spinal cord injury.
2. Reduce patient movement before initiating risk assessment.
3. Select appropriate C-Collar for patient
4. Apply C-Collar with cushioned portion touching patients skin
5. Reassess sensation and movement after C-Collar application

Pathways:

A: High Risk - Requires C-Collar Application

B: High Risk - Neurological deficit present | No C-Collar Application

C: Low Risk - No C-Collar Application

Equipment needed/ setup/props:

Setting: ER

Simulator: Simman 3G, Control PC, Monitor PC

Props: Gloves, gurney, patient wearing BDUs, four different cervical collars (long, regular, short, no neck), litter, dog tags

Personnel: 1 assistant, 1 Sim Tech, 1 student, 1 instructor

Participant Roles:

Learner is an RN who has been called to help out in the ED because the department staff is busy with a multiple motor vehicle crash.

BACKGROUND/DESCRIPTION of SCENARIO (FOR FACULTY KNOWLEDGE)

Sgt is a 24 yo Samoan male who fell 20ft from an obstacle course climbing tower during training this morning. He landed on the grass surface below.. He was alert and oriented at the scene, and did not lose consciousness. His training buddies put him in the back of a pick-up truck and drove him to the ED. Immediate triage VS done by the intake medic are 132/82, HR 94, RR 28, O2 Sat 94% on room air. Intake medic put him on a gurney because he was complaining of being light-headed from not eating breakfast.

Background: Marine SGT assigned to Marine Corps Base Kaneohe.
He is married and has 1 son (4yo).

PMH: healthy male, history of fracture right humerus playing rugby in high-school.
No known allergies.

Last medical clinic VS: 120/78, HR 64, RR 18, T 98, O2 Sat 95%

Medications: no prescription medications and no history of recreational drug or alcohol use.

Brief narrative report from the regular ED staff handing over this patient because of the MASCAL due to the multiple MVC:

READ to Learner:

I have to go quickly, they are coming in. I don't know much about this guy; his buddies just brought him in; he is a 28 year old Marine SGT. Apparently he fell 20 feet off a training tower this morning. He was alert and oriented at the scene. VS in the triage area were: 132/82, HR 94, RR 28, O2 Sat 94% on Room air. He is still alert and oriented; lying on a gurney over there because the intake medic said he was dizzy. You better look at him first. Oh, I hear them now....got to go, good luck.

Manikin Set-up/ Scenario Software

Original setup : 140/82, HR 94, RR 28, O2 Sat 94% on room air. Breath sounds clear in all 4 fields but	Desired Student Responses: Pathway A
--	---

shallow HR regular and normal sinus rhythm. Participant Responses: 1. Alert and oriented 2. Able to move all 4 extremities 3. Complains of lack of sensation in his lower extremities.. 4. No signs of neurogenic shock or spinal shock.	1. Assess situation and the patient for spinal trauma 2. Select size and prepare C-Collar application 3. Perform in-line spinal stabilization 4. Apply C-Collar 5. Instruct patient to remain still pending transport or treatment Pathway B 1. Assess situation and the patient for spinal trauma 2. Select size and prepare C-Collar application 3. Perform in-line spinal stabilization 4. Cease C-Collar application. Maintain present position Pathway C 1. Assess situation and the patient for spinal trauma 2. No neck stabilization required
---	---

Debriefing Issues - List points every instructor should present for discussion:

1. How did you feel about your performance in the simulation session?
2. What do you think was happening to your patient?
 - a. what did you notice (cues) that led you to that decision?
 - b. what were your assessment findings?
 - c. would you have liked to do any additional assessments of tests?
 - d. what interventions did you perform?
3. If you had the chance to do the scenario again, what would you do differently next time?

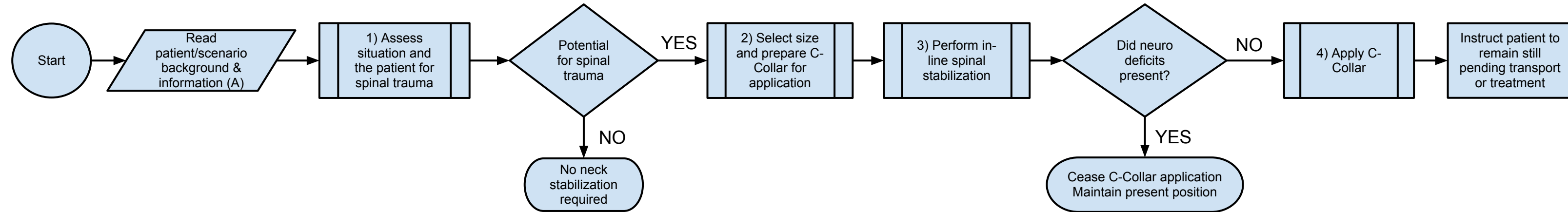
Evidence to support the scenario:

TNCC, New York State Department of Health EMT Basic and AEMT suspected spinal injury protocol, articles???

RevUHMCCW0810

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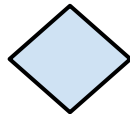
Two Person C-Collar simulation algorithm Pathway A



Legend: Pathway Points



Complex task to be performed by learner



Decision point. Typically true/false type questions



Information given to learner (written, oral, visual)



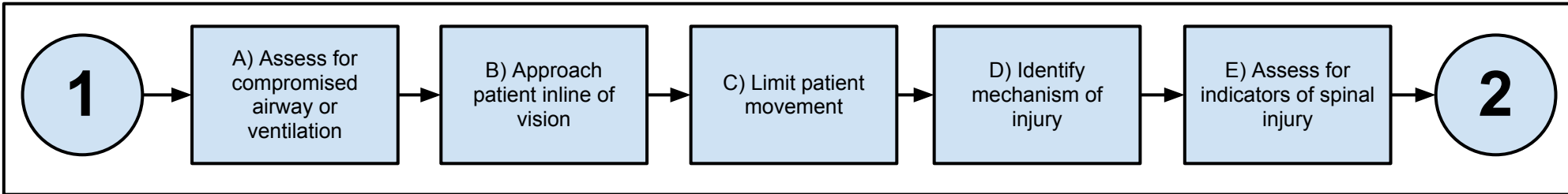
Simple or sub-task to be performed by learner



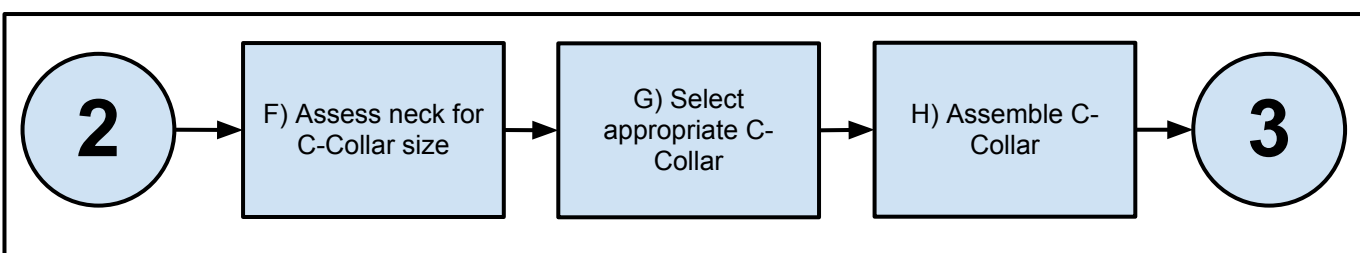
Terminator, end of algorithm.

DRAFT

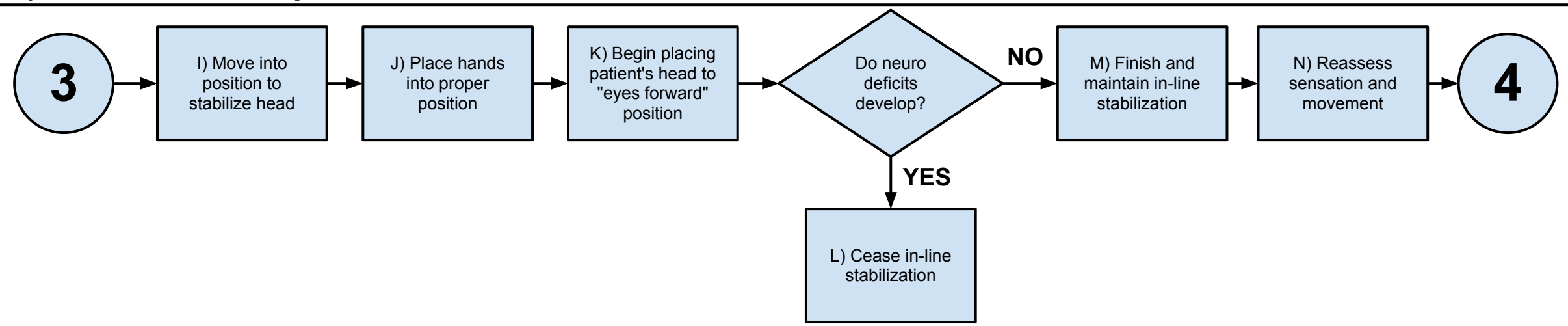
1) Assess situation and the patient for spinal trauma



2) Select size and prepare C-Collar for application



3) Perform in-line spinal stabilization



4) Apply C-Collar

