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Simulation Measurement and Prediction of Poor Central Line Performances

by Graduating Senior Residents in Internal Medicine

A thesis submitted in partial satisfaction

of the requirements for the degree Master of Science

in Clinical Research

by

Sai-Hung Hui

2013

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ABSTRACT OF THE THESIS

Simulation Measurement and Prediction of Poor Central Line Performances by Graduating Senior Residents in Internal Medicine

by

Sai-Hung Hui

Master of Science in Clinical Research University of California, Los Angeles, 2013 Professor Robert M. Elashoff, Chair

Central venous catheter (CVC) placement is one of the most common yet invasive procedures in hospitals associated with significant morbidity, mortality, and financial burden. There is a paucity of literatures about graduating senior resident CVC performance in academic training hospitals. Baseline CVC performances of senior residents were measured, and the risk factors for poor performance were identified on a high fidelity CVC simulator. 28 of total 40 internal medicine senior residents within the last 2 months of residency training from 2010 and 2011 participated. 8 subjects forfeited the procedure before completion. Incorrect anatomical landmark identification and threading the guide-wire with excessive force on the first attempt were the two most predictive risk factors in predicting residents' poor CVC placement. Predictions and quantification of different patient safety outcome variables based on identified risk factors were made possible with various statistical models. The thesis of Sai-Hung Hui is approved.

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2013

To my parents, Tak-Ming and Au-Chu, for their love and sacrifices in making who I am today.

To my wife, Rena, for her endless support and love, in making our family the happiest place on earth.

To my mentor, Professor Jerome Hoffman, for his belief in me and his exemplification of a true academian.

To UCLA MSCR Faculty for their dedication to prepare and teach students for the challenges in future clinical research.

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The baseline central line performance of the senior resident data was presented at 2012 International Meeting for Simulation in Healthcare, San Diego, CA

Abstract: Hui SH, Stein S. Baseline central venous access performances of graduating senior medicine residents. *Simul Healthc.* 2012;6(6):523

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Jeremy Smith, UCLA MS2 has presented the data at 2013 Western Student Medical Research Forum, Carmel, CA.

Chapter 1: Introduction

It is estimated that physicians place more than 5 million central line catheters (CVC) in the United States annually. (1) CVC-related complications are common (Table 1). The complications and their treatments are significant burdens to both patient safety and the healthcare system finances (2-4). In 2002, the Centers for Disease Control (CDC) estimated an annual rate of 250,000 CVC-associated infections in United States with an attributable mortality up to 25 percent. Each infection costs \$56,000 to treat with total costs ranging up to \$2.3 billion (5). This cost, however, does not include other known complications such as thromboembolic events and mechanical injuries (Table 1).

Furthermore, as of 2008, mandated by Section 5001(c) of the Deficit Reduction Act, the CDC and Centers for Medicare and Medicaid Services (CMS) identified CVCrelated complications as hospital-acquired conditions (HAC). Under this act, hospitals will not receive additional payment for treatment of HAC (6). This recent change in federal funding of hospital payments significantly impacts and deepens the financial burden of treating CVC complications. Therefore, studies identifying factors to reduce CVC complications and improving patient safety become prudent as CVC placement is one of the most common yet invasive procedures performed at a hospital.

In most academic hospitals, CVCs are routinely placed by junior residents under direct supervision of senior residents who are in turn supervised by attendings. Because of this traditional training hierarchy, it becomes rather common that senior residents do not place CVCs often in their last year of residency training as most CVCs are done during their junior years. One could therefore easily argue that because placing a CVC is generally accepted as a psychomotor skill that requires repetitive practices, the graduating senior's abilities to perform CVCs by themselves in a safe manner may be questionable. In fact, very limited literature exists in examining the procedural performance of senior residents or faculty. Guzzo *et al* found that the senior mentors of trauma residents performing CVC were significantly less likely to consistently utilize maximum sterile precautions in both emergent and elective situations (7).

It is therefore important and logical to 1) examine whether or not senior residents are capable of placing CVC in a safe manner at baseline, and 2) analyze the predictors of poor performance.

Background on Simulation Training in Medicine:

Not only have simulation modalities become part of training and evaluation standard in different segments of the aviation industry and the military, they are also gaining momentum at a rapid rate in medicine, especially in procedural training (8). Simulation offers specific teaching and a learning environment where physicians can safely explore their mistakes on simulators instead of on a real patient. For a high stake invasive procedure such as CVC placement, the steepest portion of the learning curve and its associated mistake-making can safely happen on a simulator. As a result, the expenses on real patients are minimized, and the close relationship between patient safety and simulation training of physicians becomes more evidently important.

In fact, the traditional teaching philosophy of "See one, Do one, Teach one" is no longer considered appropriate as a result of much-heightened safety concerns by the general public and different medical governing bodies. In the report by the Institute of Medicine, "To Err is Human: Building a Safer Health System," it was strongly advocated that new medical technologies should be accompanied by simulation-based education and certification requirements (12). Currently at graduate and post graduate levels, multiple medicine specialty societies proposed simulation-based courses as a part of the credentialing process (9-11). For example, the American Board of Internal Medicine has recently approved an option of lab-based simulation for Interventional Cardiology to earn Continuing Medical Education credits toward their requirement for Maintenance of Certification. The American Board of Anesthesiology and the American Board of Emergency Medicine have instituted similar requirements for a simulation-based experience for Maintenance of Certification as well (13, 14). In 2011, the Association of American Medical Colleges reported that 95% of medical schools in the United States use simulation modalities into different curricula (29).

Validity and Feasibility on Simulation Research and Training in CVC:

Numerous simulation-based studies regarding CVC placement have repeatedly shown encouraging and promising results in improving patient safety (15-20). Britt *et al* found that central line simulation before an ICU rotation will lead to higher

performance and reduced complication rates compared to control group (15). The simulation group also self-reported a significantly higher level of comfort and ability than the control group. Velmahos *et al* found that the simulation group scored significantly higher in the repeat test, achieved a higher score on the check-list, required fewer attempts to find the vein, and showed a trend toward less time to complete the procedure (16). Wayne *et al* showed that there was a significant reduction of CVC-related blood stream infection rates after CVC simulation training for residents rotating in a medical Intensive Care Unit (ICU) (18, 19). They further reported approximately \$700,000 were saved by the reduced numbers of CVC complications and a significant 7-to-1 return ratio offered by simulation training intervention (20). The feasibility of simulation-based research in CVC placement and its complications have been demonstrated by these studies.

An important concept in simulation-based research in clinical areas is the concept of *skills transfer* or *transfer validity* - how do training and performance on the simulators translate into clinical practice change and outcomes (21)? Several studies have attempted to measure this concept of skills transfer and showed favorable results (22-26). In a randomized trial, trainees who received simulation-based laparoscopic training performed faster and with fewer errors than those who had not had simulation training in performing an actual laparoscopic cholecystectomy (22). Improved airway management skills by simulation training were shown as well (23, 24). In terms of performing pediatric procedural sedation simulation training yielded higher adherence to patient safety guidelines (25). In 2008 Wayne DB *et al* was able to show that

simulation-based education resulted in a significantly higher rate of adherence to American Heart Association's Advanced Cardiac Life Support (ACLS) guidelines and provided better quality of care during actual cardiac arrest event (26). Most recently, Evans *et al* with support of *the* Agency for Healthcare Research and Quality (AHRQ) funding showed that residents trained by simulation were able to have more success in first attempt of cannulation and success rate of CVC placement than those in the control group (17). AHRQ has so far offered over 10 million dollars funding exclusively for simulation-based research in patient safety (45).

Study Objective and Aims

Since the 1999 report by the Institute of Medicine, *"To Err is Human: Building a Safer Health System"*, the general public has grown increasingly concerned with the concept of patient safety. Currently there is a paucity of literature measuring graduating senior resident procedural performance and analyzing the risk factors in predicting poor performance from the patient safety perspective. CVC was chosen as a target procedure due to the fact that it is one of the most common invasive procedures and it carries significant morbidity and mortality (2-5). With the significant financial burden on hospital administration caused by the aforementioned change of federal CDC and CMS funding, it becomes increasingly important to examine ways to improve procedural competence of hospital staff and potentially reduce CVC complications. Therefore, my thesis study focused on two aims: 1) To measure the performance of CVC placement by graduating senior residents on a high fidelity CVC simulator

2) To identify the risk factors of poor CVC performance by graduating senior residents

Table 1: BLOOD STREAM INFECTION AND MECHANICAL COMPLICATIONS RATES DUE TO CENTRAL VENOUS CATHERTERIZATION

| | Internal Jugular | Subclavian Vein | Femoral Vein |
|--|------------------|-----------------|--------------|
| Infection rate (rate per 1000 catheter- days) | 8.6 | 4 | 15.3 |
| Thrombosis rate (rate per 1000 catheter- days) | 1 – 3 | 0-13 | 8-34 |
| Arterial puncture | 3% | 0.5% | 6.25% |
| Pneumothorax | 0.1-0.2% | 1.5-3% | n/a |
| Hemothorax | n/a | 0.4-0.6% | n/a |

Adopted from Graham AS, et al. Central Venous Catheterization, Video in Clinical Medicine series. NEJM 356; 21.

Chapter 2: Manuscript

Introduction:

More than 5 million central line catheters (CVC) are placed in the United States annually (1). As one of the most common yet invasive procedures performed in a hospital setting, it carries significant risks to the patients and financial burden to the society (2-4). In 2002, the Centers for Disease Control (CDC) estimated annual rate of 250,000 CVC-associated infections in United States with an attributable mortality rate of up to 25 percent and a total cost ranging up to \$2.3 billion (5). Numerous mechanical complications also have been reported at alarming high rates (27). Furthermore, recent changes of federal financial reimbursement plans exclude payment to hospitals for treatment of conditions that do not exist pre-admission, i.e. hospital-acquired conditions (HAC). These CVC-related complications are considered HACs and are excluded for hospital reimbursement (6).

In most academic hospitals, CVCs are placed by junior residents under direct supervision of senior residents who are in turn supervised by attending physicians. Because of the tradition of having junior residents routinely place CVC due to the training hierarchy, it becomes rather common that senior residents do not place CVC often during the last year of the residency training. One could therefore easily argue that because placing CVC is generally accepted as a psychomotor skill that requires repetitive practices to maintain a certain level of competence, the senior resident's ability to place CVCs by themselves in a safe manner may be questionable due to the

aforementioned training hierarchy. Very limited literature exists in examining the performance of senior resident or faculty in procedural performances under this premise (7). Therefore this study has two aims: 1) examine whether or not the senior residents are capable of placing CVC in a safe manner at baseline before they graduate, and 2) identify risk factor contributing to the poor performance of CVC placement.

Methods:

Study Cohort:

This was a single center prospective observational cohort study with approval from UCLA-Olive View Institutional Review Board. The cohort consisted of third year residents of UCLA-Olive View Internal Medicine Residency in the year of 2010 and 2011. Inclusion criteria included senior residents in their last 2 months of training before graduation. Exclusion criteria included prior experiences with CVC simulation training. All 40 third year residents in their last 2 months of training before graduation met inclusion criteria and were directed to participate in the study under the direction of their residency training program director and chief residents. 28 residents of the 40 third year residents were recruited consecutively. 12 residents were not able to participate due to scheduling conflict, and no self-censoring by the subjects occurred according to the chief residents who were responsible of scheduling. No resident met exclusion criteria. All subjects were blinded to the purpose and the outcome measures of the study before arriving at the UCLA-Olive View Medicine Intensive

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Care Unit (ICU) where the study took place. All subjects were also instructed to not share any information about the study to other potential subjects.

Study Protocol:

All subjects first underwent a standardized 20-minute orientation to a high-fidelity CVC simulator (Model #BPH-600, Blue Phantom, WA). During the orientation, the subjects were introduced to different unique features of the simulator - simulated red solution representing arterial blood from the simulated carotid artery, simulated blue solution representing venous blood from the simulated internal jugular vein, and how the pulsation of the simulated carotid artery and the compressibility of the simulated internal jugular vein would appear when the ultrasound machine is used. The selfsealing property of the simulated skin prevents subjects from finding needle marks left by the previous subject. Important limitations of the simulator were also demonstrated including the immobility of the simulator neck, the lack of vital signs such as heart rate, oxygen saturation and blood pressure, and the inability of the simulator to converse with the subjects. Of note, instructions on ultrasound machine operation and CVC placement were not given during the orientation prior to the study.

After the orientation, the subjects were specifically instructed to place an internal jugular CVC on the simulator on a patient bed at Olive View-UCLA Medical ICU as if they were in a real patient encounter. The subjects' CVC performances were recorded by a handheld recorder in an anonymous fashion that no personal identifiers would be recorded. Personal identifying belongings like watch, ring, and jewelries

would be covered by full body sterile gown including face mask. Hand movements and maneuvers of CVC equipment and ultrasound machines were also focused by the recording. All subjects agreed to be video-taped for their CVC placement. A faculty outside of UCLA-Olive View Internal Medicine Department scored these anonymous recordings based on the listed outcome measures below.

Outcome Measures:

The primary outcome measured whether the subjects could complete the CVC placement (Forfeit vs Success) on the CVC simulator. "Forfeit" was defined as whenever the subject self-decided to quit performing the procedure after encountering difficulties. The decision to forfeit the procedure was solely made by the subject whenever he or she felt uncomfortable to continue the procedure and felt the need for the assistances from the fellows or the attending physicians. It is important to note that the subjects did not receive any prior instruction on when he or she should forfeit the procedure.

The secondary measurements included standardized measures of CVC procedural competence (28) and certain complications allowed by the simulator capability. Other common CVC complications such as blood stream infection and pneumothorax could not be measured because the simulator does not simulate these complications. The secondary measures are: 1) number of carotid arterial punctures, 2) number of needle stick attempts before successful cannulation, 3) length of time before successful internal jugular vein cannulation in seconds, 4) length of time before subjects asking for additional help and forfeiting the procedure measured in seconds, 5) whether or not the subject thread the guide-wire without excessive force on the first attempt of cannulation, 6) whether or not the subject was able to identify correct anatomical landmarks, 7) whether or not the subject was able to operate ultrasound machine and probe correctly, 8) whether or not sharps were disposed of properly in the disposal bin, 9) whether or not consent form was obtained, 10) whether or not complete sterile techniques including gown wearing and hand washing were implemented, and 11) whether or not the guide-wire was removed.

Of note, carotid artery puncture was identified as simulated red solution flashback in the needle compared to blue solution flash back as venous blood on the CVC simulator. A needle stick attempt is defined by one of two ways: 1) when the needle was completely removed from the skin, or 2) when the large proportion of the needle was retracted and reinserted even though the needle tip still remained inside the simulated skin. The time measurements began when the finder needle first touched the skin before needle insertion. Excessive force used during the guide-wire threading was determined by the presence of the kinks on the guide-wire. For the anatomical landmark identification, subjects were asked to identify the borders of Sedillot's triangle (10) on the simulator after the procedure was completed or forfeited.

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Covariates include the timing of the last CVC the subject supervised and the timing of the last CVC placed by him or herself alone. Each was sub-categorized by 1) within 6 months, and 2) more than 6 months ago.

Statistical Analyses:

All statistical analyses were performed using JMP v 10.0 (SAS Institute, Inc). For continuous non-parametric data, the Wilcoxon Mann-Whitney test was used. The Fisher's Exact Test was used for categorical proportion data comparison between forfeited group and successful group. Relative risk was calculated for the correlations between different secondary outcomes and the primary outcome. Backward stepwise selection with minimum Bayesian information criterion was used for multiple logistic and multiple linear regression models in order to identify the predictors (i.e. risk factors) of different outcome variables. Coefficient estimates were converted to odds ratio in the logistic regression model. All analyses utilized p-value <0.05 (two tails) as the statistical significance cut-off. 95% confidence intervals and IQR were reported when appropriate.

Results:

<u>Aim 1 - Measurement of CVC performance by graduating senior residents</u> All subjects reported no previous contact with the CVC simulator and denied any reviewing of CVC placement prior to the study. In Table 1, the primary outcome measured 8 subjects (29%) of a total of 28 subjects forfeited the procedure. They inflicted a total of 15 punctures to the carotid artery and a median of 4.5 needle sticks; they also required a median of 12 minutes and 13 seconds prior to forfeiting the procedure. 63% of the 8 subjects could not identify correct landmarks. 63% demonstrated correct ultrasound machine operation. None were able to thread the guide-wire without excessive force on the first attempt. Only 50% obtained procedural consent while 25% demonstrated proper sharps disposal. Table 2 demonstrates the break down of successful and forfeited subjects in terms of the timing of their last CVC placed and supervised. The relative risk of forfeiting the procedure is 1.25 when the last CVC was placed more than 6 months ago comparing to within 6 months; however, its 95% CI includes 1 which makes the finding statistically insignificant. The findings in Table 2 are further discussed in the limitation section.

For the remaining 20 subjects who finished the procedure (n=20), a median of 1.0 needle stick with a median time to successful cannulation of 255 seconds was demonstrated with only 0.2 arterial punctures. All demonstrated correct ultrasound machine operation. 18 out of the 20 correctly identified anatomical landmarks. However, only 32% of all 28 subjects showed proper sharp disposals and 50% obtained consent. In comparing the CVC performances, numbers of carotid punctures, needle sticks, ability to pass the guide-wire without excessive force on first attempt, and anatomical landmark identification are significantly different between successful and forfeited groups (Table 1). The plots of number of carotid artery punctures and needle sticks in both successful and forfeited groups are demonstrated in Figure 1 and

2 respectively. The rows of each figure are the subject identification number. Each data column represents one subject.

Aim 2 - Identification of risk factors and predication of poor CVC performance Relative risk calculations in Table 3 showed that threading the guide-wire with excessive force on the first attempt and incorrect anatomical landmark carry significantly high risk of forfeiting the procedures. Of note, the relative risk for forfeit due to passing guide-wire with excessive force become infinitely large mathematically because no subject forfeited when they could pass the guide-wire without excessive force. If there were one such subject, the relative risk would become 6.9. Interestingly, the relative risk of incorrect usage ultrasound machine and probe is not significant given that the 95% CI include 1.

Multiple logistic regression in Table 4 demonstrated that each carotid artery puncture and needle stick attempt carry an odds ratio less than 1 when the odds of success is comparing to forfeit. The plausible explanation for these odds ratios is found in the discussion section. Multiple linear regression model in Table 5, 6, and 7 identified incorrect anatomical landmark, passing the guide-wire with excessive force on the first attempt, and incorrect ultrasound usage as significant predictors of the number of carotid artery puncture, needle stick, and the length of time required before successful cannulation. The quantification of the predicted changes in these outcomes was made possible by the coefficient estimates of different predictors in the models. For example, table 5 demonstrates the number of carotid artery punctures can be predicted to decrease according to the negative estimate coefficients of different identified factors - when one is able to thread the guide-wire without excessive force and identify anatomical landmarks correctly. Table 6 demonstrates the length of time before successful cannulation can be predicted to decrease or increase by different time amount based on whether or not the subjects could identify the anatomical landmarks, pass the guide-wire without excessive force and operate the ultrasound machine and its probes correctly.

Discussion:

Morbidity and mortality from CVC placement complications remain high per CDC report with significant financial burden to healthcare system (2-5). This study provided a unique angle to assess the CVC placement performance of graduating senior residents who are responsible for supervising junior residents' CVC placement due to conventional training hierarchy. In academia it is rather common to assume that graduating residents are capable of performing certain required procedures by the time of graduation. However, this study provided contradicting data to this conventional assumption. It identified concerning performances of graduating senior residents in CVC placement, and it further provided prediction and quantification of important patient safety performance outcomes based on different risk factors identified by different statistical modelings.

For the primary outcome measure, out of 28 participating senior Internal Medicine residents for whom CVC placement was a required procedure for graduation, 8 of the

28 residents (29%) could not successfully complete the procedure and decided to forfeit on a high fidelity CVC simulator. This high proportion of the residents being unable to complete the procedure successfully is concerning from the perspective of training because the residents were only 2 months away from residency graduation.

On the other hand, it was equally concerning from the perspective of patient safety that these residents had significant delay of asking for assistances and forfeiting the procedure. They had already spent a median of 12 minutes inflicting a total 15 simulated carotid artery punctures with a median of 4.5 needle stick attempts before announcing forfeiture. As discussed in the methodology section, the decision to forfeit the procedure was solely made by the resident whenever he or she felt uncomfortable to continue the procedure.

Multiple studies of CVC simulation training leading to improved patient outcome have been published. These studies demonstrated that the results of simulation training may have transferred to clinical bedside (15-19, 22-26). Therefore, the resident performances on the high fidelity CVC simulator could reasonably be argued to serve as a surrogate marker of performance on real patients. The high proportion of residents failed to complete the procedure successfully with significant delay of forfeiture may call for residency program directors re-examining the CVC placement performances of senior residents prior to graduation. The patient safety committee of the hospital may also examine the need of establishing CVC forfeiture criteria based on the numbers of needle stick attempt and carotid artery puncture inflicted during the procedure.

The second aim of the study was to identify risk factors for poor CVC placement performance. Incorrect anatomical landmark identification and threading the guide-wire with excessive force on the first attempt were the two most predictive factors. Those residents who could not identify anatomical landmarks for CVC placements are 5 times more likely than those who could to forfeit the procedure. The relative risk for forfeiting the procedure due to threading the guide-wire with excessive force becomes infinitely large mathematically because no resident forfeited when they could pass the guide-wire without excessive force. If there were one such resident, the relative risk would become 6.9.

Incorrect usage of ultrasound machine did not meet statistical significance in increasing the risk of forfeiture whereas numerous studies have previously reported that using ultrasound alone has better success rates of CVC placement than by using anatomical landmarks alone (34-39). This finding may seem counterintuitive. Our study showed that the 90% of successful residents could identify correct anatomical landmarks whereas only 37.5% of residents in the forfeited group could. Both groups had similar rates of correct ultrasound machine operation (Table 1). This finding implies that although ultrasound technology has become standard as a tool to assist CVC placement (40), correct landmark identification continues to remain a fundamental component for the successful CVC placement with the aid of ultrasound.

One needs to know where to put the ultrasound probe correctly on the patient neck for proper needle placement. On the other hand, those who could operate ultrasound correctly is predicted to have decreased number of needle stick attempts and shorter time before successful cannulation based on its coefficients in the regression models. These findings from the regression model are consistent with those aforementioned ultrasound literatures.

For the covariates of when the last CVC was supervised and placed by the residents (Table 2), these covariates as independent variables were dropped from all regression models except the model in Table 5. This illustrates the high probability of recall inaccuracy or bias as these data were provided by the residents themselves. This issue is further discussed in the limitation section.

Subsequent interviews with the residents who chose to forfeit the procedure revealed two common observations are speculated to explain the reasons why the resident chose to continue the procedure despite encountering significant difficulties such as carotid artery punctures and numerous needle sticks without success. "Gambler Fallacy" is a well recognized cognitive error, as described by Presson and Benassi (30, 33). An individual with "Gambler Fallacy" has a tendency to believe that a certain event is less likely to occur because it already has happened many times before, or vice versa, a certain event is likely to happen because an opposite event has already happened numerous times before. Another theme was also observed during the postmeasurement interviews as well, "Sunk Cost Fallacy", which implies that an

individual will be much less likely to withdraw investment from an obvious negative endeavor after having invested significant amount of effort, time and ego. (31, 32)

In our CVC example, the residents appeared to have a misconception or fallacy that because he or she had already missed the internal jugular vein many times, it would be more likely they would locate it next time. Both of these self-perpetuating thoughts, "Gambler Fallacy" and "Sunk Cost Fallacy" may provide a plausible explanation of certain behaviors of those residents who finally forfeited the CVC placement after encountering numerous difficulties and delayed seeking for assistances. Statistically speaking, these two fallacies may explain the odds ratio for carotid artery puncture and needle stick as predictors for forfeiture as 0.03 and 0.5 respectively (Table 4). With the calculated odds ratio of less than 1, it means that the more needle sticks and carotid artery punctures the residents inflicted, the lesser the odds of the resident being successful was. Due to the self-perpetuating nature of these two cognitive errors, the resident would subsequently inflict more damage to the simulator in our study, or potentially to the real patients in real life.

Limitations:

Several limitations exist in this study. A potential confounding variable is that the residents might act differently when dealing with the simulator. In other words, the residents may or may not have chosen to forfeit the procedure later because they were placing the CVC on the simulator instead of a real human being. A few particular efforts were undertaken to minimize this potential issue. They include adding the

standardized orientation before the scenario to familiarize the residents with the simulator, running the simulated scenario at the real ICU environment at where all residents have previously worked, and emphasizing the requirement of residents placing the CVC as if it were a real patient encounter. These steps were necessary to suspend the residents' disbelief in a simulated encounter and re-create a believable and familiar environment for the residents to place a CVC on the simulator the way they would on a real human being.

Moreover, in order to mitigate this effect and eliminate any resident's advantage over others by prior simulator exposure, an exclusion criterion was made to exclude any resident with any prior experiences in working with CVC simulator. No residents in this study met the exclusion criteria. Also, all residents underwent 20-minutes standardized orientation to get familiar with the unique characteristics of the CVC simulator.

Another potential confounding variable is the presence of the Hawthorne effect when the participants may act differently knowing that he or she is being assessed or being video-taped in our study. This effect could be minimized if the video camera were hidden at the wall of the intensive care unit. However, hidden remote video camera would be difficult to capture delicate hand movements such as needle insertion and fluid color flashback which would indicate venous or arterial puncture. Therefore, a decision was made to accept the compromise for capturing all possible outcome measures using the hand held camera. Recall bias of the timing of last CVC placed and supervised by the residents appears to exist. In table 2, the relative risk of forfeiting the procedure is higher when the last CVC was supervised and placed within 6 months comparing to more than 6 months ago. These relative risk results were indeed counterintuitive and appears to be reversed - the relative risk of forfeiting the procedure should be higher when the last CVC supervised or placed was more than 6 months ago. Moreover, the timing of CVC supervision and placement were filtered out by the backward selection process in all regression models except one in Table 5. Therefore, it is believed that there may be significant recall bias when the subjects provided information on the timing of the last CVC placement and supervision. One potential solution is to obtain the records of the last CVC placement from the residency office, but the timing of the last CVC supervision were not recorded.

Lastly, although this was a single center study with a relatively small cohort sample size of 28, it actually represented 70% of all senior residents in the last 2 months of residency training from two consecutive years. Fortunately numerous statistical measures reached significance with important risk factor identified that also carries clinical significance and meaning. However, larger sample size from a multi-center center study in the future would be important to conduct.

Conclusion:

This study demonstrated that 29% of graduating senior internal medicine residents could not complete the CVC placement on a high fidelity simulator in their last 2

months of residency training. Incorrect anatomical landmark identification and threading guide-wire with excessive force on the first attempt were the two most important risk factors in predicting poor resident's performance. Predictions and quantification of different patient safety outcome variables based on identified risk factors were made possible with different statistical modelings.

Chapter 2 Tables:

| | Forfeited Group (n=8) | Successful Group (n=20) | <u>p-value</u> |
|---|--------------------------|----------------------------|----------------|
| Carotid puncture* | 1.0 (1-2) | 0 (0-0) | 0.001 |
| Needle sticks* | 4.50 (3.25-7.25) | 1.0 (1-2) | 0.004 |
| Time (seconds) before successful cannulation | n/a | 255 (202.5-527.5) | n/a |
| Time (seconds) before forfeiture | 733 (582-926) | n/a | n/a |
| Able to pass guide- wire without excessive force on first attempt [†] | 0% | 65% | 0.003 |
| Able to operate ultrasound machine [†] | 62.5% | 85% | 0.311 |
| Correct anatomical landmark identification [†] | 37.5% | 90% | 0.001 |
| Correct sharp disposal [†] | 25% | 35% | 1.000 |
| Consent form ^{\dagger} | 50% | 50% | 1.000 |
| Complete sterile techniques [†] | 100% | 85% | 0.536 |
| Successful guide- wire removal [†] | 100% | 100% | 1.000 |

Table 1: SENIOR RESIDENTS BASELINE CVC PERFORMANCES

*The Wilcoxon Mann-Whitney used. [†]The Fisher Exact Test used. Significance cut off is p<0.05. Results are reported as median and IQR

| | Forfeited Group (n=8) | Successful Group (n=20) |
|----------------------------------|--------------------------|----------------------------|
| Last CVC supervised [†] | | |
| More than 6 months ago | 4 | 17 |
| Within 6 months | 4 | 3 |
| Last CVC placed* | | |
| More than 6 months | 3 | 9 |
| Within 6 months ago | 5 | 11 |

Table 2: SENIOR RESIDENTS BASELINE DEMOGRAPHICS REGARDINGLAST CVC SUPERVISED AND PLACED

[†] The relative risk of forfeiting the procedure is 3 when the last CVC was supervised within 6 months comparing to more than 6 months ago. In other words, the relative risk of forfeiting the procedure is 0.33 when the last CVC was placed more than 6 months ago comparing to within 6 months. 95% CI of both relative risks includes 1 (not shown).

* The relative risk of forfeiting the procedure is 1.25 when the last CVC was placed within 6 months comparing to more than 6 months ago. In other words, the relative risk of forfeiting the procedure is 0.8 when the last CVC was placed more than 6 months ago comparing to within 6 months. 95% CI of both relative risks includes 1 (not shown).

Table 3: RELATIVE RISKS OF FORFEIT BY THE PRESENCES OF IDENTIFIED RISK FACTORS

| | Relative Risk | 95% CI |
|---|---------------|-------------|
| Passing the guide-wire with excessive force on first attempt | n/a* | n/a |
| Incorrect Anatomical Identification | 5 | 1.59 - 15.7 |
| Incorrect Ultrasound usage | 2.2 | 0.72 - 6.68 |

* The relative risk for forfeiture due to passing the guide-wire with excessive force reaches infinitely large mathematically. This is because no subject forfeited when they could pass the guide-wire without excessive force in the 2x2 contingency table. If there were one such subject, the relative risk would become 6.9.

Table 4: MULTIPLE LOGISTIC REGRESSION MODEL FOR FORFIET ORSUCCESS BASED ON CAROTID ARTERY PUNCTURES AND NEEDLESTICKS WITHOUT STEPWISE SELECTION

| Variable | <u>Odds</u> Ratio | Coefficient Estimate | Coefficient 95% CI | Prob>Chi- square |
|--------------------------------------|----------------------|-------------------------|-----------------------|---------------------|
| Intercept | | 5.24 | | 0.028 |
| Number of Carotid Artery Puncture | 0.03 | -3.46 | -8.28 - -0.88 | 0.045 |
| Number of Needle Sticks | 0.5 | -0.68 | -1.79 - -0.04 | 0.10 |

The Odds Ratio is for Success to Forfeit. Chi-square values were omitted. Pseudo R square value which in JMP reported as R^2 (U) is 0.55

Table 5: MULTIPLE LINEAR REGRESSION MODEL FOR CAROTID ARTERY PUNCTURES BASED ON SECONDARY OUTCOME MEASURES AFTER STEPWISE SELECTION

| <u>Variable</u> | Coefficient Estimate | Coefficient 95% CI | <u>Prob>t</u> |
|--|-------------------------|-----------------------|------------------|
| Intercept | 0.90 | 0.36 - 1.44 | 0.0021 |
| Able to pass guide-wire without excessive force on first attempt | -0.60 | -1.130.06 | 0.031 |
| Correct anatomical landmark identification | -0.61 | -1.170.05 | 0.035 |
| Last CVC placed within 6 months | 0.52 | 0.027 - 1.03 | 0.04 |

T-test scores were omitted

Table 6: MULTIPLE LINEAR REGRESSION MODEL FOR NEEDLE STICKS ATTEMPTS IN THE SUCCESS GROUP BASED ON SECONDARY OUTCOME MEASURES AFTER STEPWISE SELECTION

| <u>Variable</u> | Coefficient Estimate | Coefficient 95% CI | <u>Prob>t</u> |
|--|-------------------------|-----------------------|------------------|
| Intercept | 3.47 | 2.81 -4.13 | <0.0001 |
| Able to pass guide-wire without excessive force on first attempt | -0.79 | -1.270.31 | 0.003 |
| Correct anatomical landmark identification | -0.52 | -1.18 - 0.13 | 0.1126 |
| Correct Ultrasound usage | -0.29 | -0.62 - 0.02 | 0.065 |

T-test scores were omitted

Table 7: MULTIPLE LINEAR REGRESSION MODEL FOR LENGTH OF TIME BEFORE SUCCESSFUL CANNULATION BASED ON SECONDARY OUTCOME MEASURES AFTER STEPWISE SELECTION*

| Variable | Estimate Coefficient | <u>95% CI</u> | <u>Prob>t</u> |
|--|-------------------------|---------------|------------------|
| Intercept | 651.1 | 554.2-748.1 | < 0.0001 |
| Able to pass guide-wire without excessive force on first attempt | -98.9 | -169.228.6 | 0.009 |
| Correct Anatomical Identification | -148.8 | -245.851.9 | 0.005 |
| Correct Ultrasound usage | -186.2 | -285.0287.40 | 0.001 |

*Note: Forfeited group data (n=8) not counted and t-test scores were omitted

FIGURE 1: TOTAL NUMBER OF CAROTID ARTERY PUNCTURE BY EACH SUBJECT IN BOTH SUCCESS AND FORFEITED GROUP



FIGURE 2: TOTAL NUMBER OF NEEDLE STICK ATTEMPTS BY EACH SUBJECT IN BOTH SUCCESS AND FORFEITED GROUP



Chapter 3: Statistical Appendix

Study Methodological Design:

Due to the traditional medical training hierarchy as described in Chapter 1, the goal of the study was to measure CVC placement performance of senior residents. Different methodological designs were considered. Retrospective design was deemed unsuitable because senior residents, particularly the one within 2 months of graduation, performed a very small portion of CVC placement in the hospital setting. They often rotated and worked at different outpatient clinics in which central line placement is not part of daily practice. For those residents who worked on inpatient rotations, the electronic patient data collection of the hospital has gone through drastically different systems in the past few years. The data specifically collected for CVC placement were not standardized and would create many missing data for this study purpose. Cohort sample size would be very small and unstable using retrospective design for this particular population of graduating senior residents. Therefore, prospective observation design using simulation as a research tool was determined.

Because the clinical schedules of residents were predetermined a year ago, it became logistically impossible to reassign residents within 2 months of graduation to inpatient ward rotation where they would have a chance to place CVC. Moreover, the current medical training hierarchy limited the ability to collect data on those CVC placed by

the senior residents alone. As a result, sample size would also be expectedly very small if data was prospectively collected from real patient encounters.

Using simulation as a research tool however would circumvent these logistic difficulties. First, the logistic challenge of scheduling resident on inpatient ward rotations would be avoided as all the available residents would be scheduled into a 2 hour block of simulation assessment session. Secondly, all the graduating residents' data could be collected in a standardized method *in lieu of* different pre-existing data system for the real patient data in the hospital. Third, the simulated environment under which the residents place CVC would be standardized and controlled whereas in real patient encounters different body habitus of the patient would serve as confounding variable that would be very difficult to control. Lastly and more importantly, simulation study design would eliminate the potential ethical concerns - when the graduating senior resident's ability to place a CVC by him or herself on a real patient may be of question under the aforementioned reasoning in the Introduction Chapter. It may be unethical to examine their abilities to place a CVC on a real patient.

Observational vs Quasi-experimental Design:

The classical features of an observational cohort study design require that the subjects be observed in their natural environment and no intervention be done by the investigators. Our study design on the other hand subjected the participants into a non-natural environment in which their behaviors, i.e. CVC placement, were measured in a simulated environment. One could therefore reasonably argue that the study design was more in line with a quasi-experimental design in which the simulated environment was considered as an intervention itself and all subjects underwent this intervention. Although the author is sensitive to this argument, the author concluded that the current study was more of an observational cohort design because the simulated environment should not be considered as an intervention per se.

Importance of Exclusion Criteria:

An exclusion criterion was created to exclude any resident with prior experiences with CVC simulator training in order to avoid potential bias and maintain every subject at the same baseline level of familiarity with the CVC simulator. No subject was excluded from the study.

Sample Size:

Sample size of 28 would be considered small by conventional standards; however, as the study was observational in nature and the purpose of this study was to describe the baseline performances of graduating senior residents in their last two months of training, the feasibility of recruiting more subjects was inherently limited by the required timing of recruitment which could be only once a year. A multi-center study or multi-residency involvement would be an option with reasonable resources. Fortunately, multiple important measurements of performances reached statistical significances which helped answer the questions posted by this study. Moreover, interpretation of some results shed lights in elucidating the reasoning for certain behavioral pattern or aforementioned cognitive barriers of the subjects' CVC placements such as "Gambler Fallacy" and "Sunk Cost Fallacy".

Reasoning of Primary Outcome Measure:

The primary outcome suitably measured whether or not the resident could place a CVC by categorizing the outcome as "Forfeit" vs "Success". Realistically speaking, placing a CVC itself can be considered a function of multiple smaller tasks that must be performed correctly in specific sequences. In the literatures there are different check list scoring systems in which each steps were classified as major or minor and assigned a numerical score (28). However, the author felt that these kind of scoring systems have inadvertently missed one of the most important outcome measures in a real clinical setting.

One can argue that if the resident forfeits a CVC placement after spending enough time inflicting unintentional injuries to the patient, however many major and minor steps have been correctly performed prior to the forfeiture would not even matter. Therefore, the primary outcome measure of this study was different from those check list scoring systems; it was set to examine whether or not the resident would forfeit the procedure. The secondary outcomes were set to measure different important outcomes related to CVC placement such as number of needle sticks before successful cannulation, number of carotid artery punctures, and others as listed in Chapter 2 outcome measure section.

Outlier Data Handling:

There are data that appeared as outlier data by direct visualization of scatter-plot of independent variables data, particularly from the group of residents who could not complete the CVC placement and chose to forfeit the procedure. Although statistically these data appeared as outlier, clinically they were as important and relevant as they were the study primary outcome measure for statistical calculation purpose. Therefore, the "outliers" of the forfeited group were not handled differently from the rest of the data.

Effect Coding Transformation in JMP statistical software:

In lieu of conventional dummy coding, JMP uses "Effect Coding" by default which codes the categorical variables with values "-1", "0" and "1". "-1" is assigned to the last variable based on ASCII collating sequence. It means "numbers come before the space, the space comes before the upper case letters, and upper case comes before the lower case (41)." Different statistical software has different dummy variable assignments for the reference point. Most programs commonly use 0 for forfeit and 1 for success as the dummy variable assignment. However, the situation with JMP in coding is exactly opposite. Because JMP sees forfeit before success, it will assign success -1 and failure as 1 which is completely opposite to those programs using conventional dummy variable coding. Therefore, in this study, the coding had to be transformed into "Hit" for success and "Miss" for forfeit because "Hit" comes before "Miss" which will then be coded as "-1" (42). Correct coding of the variable is of particular importance when creating logistic regression modeling with JMP because

logistic regression assumes that P(y=1) is the probability of event occurring, i.e. success, so the dependent variable should have the same coding of the desired outcome as 1. As a result of correct coding transformation, the interpretation of coefficient was made relatively easy by multiplying either +1 for success/hit or -1 for failing/miss with the β coefficients of categorical variables.

Regression Model Testing:

Assumptions were tested for all regression models. For homoscedasticity, visual inspection of residual plot against the predicted value was used. The plot unfortunately does not appear completely randomly scattered around the residual line of zero which suggests minimal degree of heteroscedasticity. For example, in the model of Table 7, a better residual plot vs predicted was observed for a better homoscedasticity visualized (Figure 1). The normality was demonstrated by the straight line in the Q-Q plot of the residuals. In other models, different degrees of heteroscedasticity were observed (Figure 2).

Variances Accounting and Fitness of Model Testing:

The Lack of Fit testing values in general for each model are also sufficiently large which means that adding more independent variables into the model would not necessarily account for more variances. Moreover, the Whole Model Test for the entire model results was also significant meaning the model overall is a good fit for the data. The Likelihood Ratio Testing results for the independent variables of logistic regression modeling are statistically significant when the p-values listed in the table are listed significant.

Figure 1: THE PLOT OF RESIDUAL VALUES AGAINST PREDICTED VALUES FROM THE LENGTH OF TIME REGRESSION MODEL OF DEMONSTRATING DEGREE OF HETEROSECDASTICITY



Figure 2: THE HISTOGTRAM AND Q-Q PLOT OF RESIDUAL VALUES DEMONSTRATING NORMALITY FROM THE LENGTH OF TIME REGRESSION MODEL



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