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SIMULATION EDUCATION FOR RECERTIFICATION OF VENTILATION ASSOCIATED PROTOCOLS FOR RESPIRATORY THERAPISTS

BY

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Approval of Thesis

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Dedication

I would like to dedicate this thesis to my husband Riley and my parents, Anne and Jim Carling. Without your support this thesis would never have been possible.

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Abstract

High fidelity simulation is an educational tool used in healthcare to mimic experiences encountered in the real clinical environment. It has the potential to enhance teaching and learning across all health disciplines, but it is also a costly educational tool lacking rigourous research to justify and enhance its use. The purpose of this study is to investigate the impact an education session using high fidelity simulation has on Respiratory Therapists' knowledge of mechanical ventilation associated protocols compared to usual methods of recertification. A randomized control trial using pre and post-tests allowed for comparison of scores between the two groups: those that read and reviewed the protocol and education package, and those exposed to simulation education as well as the usual method for recertification. The results are intended to inform educational practices in Respiratory Therapy departments regarding the use of simulation education to recertify Respiratory Therapists in mechanical ventilation associated protocols.

Keywords: Simulation education, high fidelity simulation, Respiratory therapy, Mechanical Ventilation, Recertification

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Chapter One: Introduction

High fidelity simulation (HFS) education is a promising teaching method that requires a large amount of time and financial support to be implemented (Shinnick, Woo, & Evangelista, 2012). As a teaching method in health care disciplines, there is a lack of rigourous quantitative research to support its use, especially on simulation's impact on patient outcomes (Brewer, 2011; Aerobosold & Tschannen, 2013). Quantitative reports of HFS in comparison to other instructional methods frequently contain small sample sizes; fail to report validity of outcome measures, instruction design and multiple process measures for the same skill (Cook et al., 2012). Most reports of the use of high fidelity simulation focus on students, however it is likely that its greatest potential to impact patient care is in its use for continuing education (Gaba, 2004). As new best practices and quality assurance programs are implemented in hospitals, simulation potentially provides the context to improve uptake and adherence amongst front line staff as well as support the avoidance of adverse events (Lucas, 2014). Although the role of simulation in continuing education has great potential, there is a lack of literature describing simulation's use to support professional development in the healthcare field (Lucas, 2014). The role of simulation education in continuing education needs to be further researched however it is a frequently utilized nstructional strategy used to enhance both individual skills and inter-professional collaboration to improve patient safety (Dow, Salas & Mazmanian, 2012). Continuing education and competency maintenance in healthcare professions has become an area of concern as the need to improve patient safety and work in an increasingly complex health care delivery system has become well known (Dow et al., 2012). There is poor

representation regarding the experiences Respiratory Therapists (RTs) have with simulation education in the literature (Matthews & Yachemetz, 2008) and few reports of simulation education's application with mechanical ventilation education. Therefore, this study seeks to quantify the impact simulation education has on knowledge of mechanical ventilation associated protocols among practicing RTs undergoing routine re-certification. The results of the study will be aimed at informing future educational and recertification practices within the RT department.

Research Question

This study aims to quantify the impact a high fidelity simulation (HFS) education session has on knowledge as estimated by post-test scores. The research question is: Are post-test scores on ventilation-associated protocol re-certification exams higher for RTs who are given a HFS education session compared to RTs who do not receive the HFS education session?

Definitions of Terms

RTs are healthcare professionals that assist physicians with diagnosis and treatment of patients with respiratory difficulties. RTs work throughout the Canadian healthcare system in outpatient services such as homecare, pulmonary function labs, and pulmonary rehabilitation centers. Within the hospital setting, RTs practice in Emergency Departments, Intensive Care Units, Neonatal Intensive Care Units, operating rooms and on general wards (College of Respiratory Therapists of Ontario, 2011). Although the specific role of an RT may vary between institutions, their primary roles include: managing and maintaining patent airways, initiating and managing both invasive and non-invasive mechanical ventilation of patients, assisting with

cardiopulmonary resuscitation, administering medications by inhalation and medical gases, and educating patients on management of respiratory diseases (Coxe, 2011).

Mechanical ventilation refers to the use of an artificial airway and a ventilator to artificially move air into and out of patients' lungs to allow for exchange of oxygen and carbon dioxide (Martin, 2013). Two mechanical ventilation associated protocols are referred to in this study. The first is a lung protective ventilation protocol, which limits settings on the ventilator as made by the RT. This is done to protect the patient's lungs from damage that may be caused from mechanical ventilation. The second is the Aerosolized Epoprosterenol protocol, which guides the use of aerosolized epoprosterenol along with mechanical ventilation to improve a patient's oxygenation status. These two protocols are collectively referred to as the mechanical ventilation associated protocols in this study.

To ensure adequate education and competency RTs undergo certification of their skills. Although the College of Respiratory Therapists of Ontario (CRTO) may not require certification of certain skills, the employer may require it (CRTO, 2011). After initial certification these skills are renewed on a routine basis. As RTs deal primarily with the management of mechanically ventilated patients in the Intensive Care Unit, it is required by the Respiratory Department managers that mechanical ventilation associated protocols are recertified by the RTs annually within the health region.

Significance of Study

The results of this study will demonstrate if HFS education sessions result in significantly higher post-test scores indicating enhanced knowledge acquisition of mechanical ventilation protocols for participating RTs. These results will be among the

first to report on the quantifiable impact simulation education has on mechanical ventilation recertification for the RT profession. Furthermore, these results will aim to inform future educational and recertification practices within the RT department.

Chapter Two: Literature Review

Many health professions have begun to use HFS education to respond to changing practice environments. Despite the amount of literature regarding HFS, it is unclear how effective it is, and there is limited empirical evidence to support its use (Cook et al., 2011). This literature review describes the types of simulation, the process involved in HFS education sessions, current applications, as well as the barriers preventing HFS's widespread use. The benefits of HFS education and the specific skills HFS has been shown to have an impact on, will also be reviewed. Next, literature regarding HFS use with RTs, applications of HFS in continuing education and use of HFS for mechanical ventilation education will be highlighted. Last, the conceptual frameworks of learning theories as they relate to HFS education are summarized and gaps in the literature are discussed.

Introduction to Simulation

The term simulation is used to describe the technique of replicating true -life experiences in a controlled environment for healthcare professionals (Gaba, 2004). This technique can encompass varying levels of technology and fidelity. Fidelity refers to the level to which the simulator is perceived by its users to be real (Seropian, Brown, Gavilanes, & Driggers, 2004). Low fidelity simulators do not respond to users or interventions, and are often used for practicing skills; examples include head and neck mannequins for tracheostomy management and endotracheal intubation, and partial or full arms for intravenous insertion (Wilson, Shepard, Kelly, & Pitzner, 2005). Medium fidelity simulators add additional aspects of reality by replicating pulses, heart sounds and/or breath sounds but do not have the added aspects of physiological responses as a

high fidelity simulator would (Seropian et al., 2004). An example of a medium fidelity simulator would be a mannequin head to practice intubations. This mannequin head may not replicate spontaneous breathing or be attached to a monitor to replicate physiological vital signs but it will allow for manual task training and familiarity with anatomical structures of the pharynx. On the other hand, a patient simulator, a full body mannequin that integrates all of these things and responds physiologically to interventions, is considered to be high fidelity (Seropian et al., 2004; Wilson et al., 2005).

Aside from mannequin-like simulators, the simulation experience can also involve role-playing or video analysis to practice and critique patient and coworker interactions. Screen based or virtual reality simulators may also be used to simulate not only the patient but also the clinical environment (Gaba, 2004). Varying types of simulation and levels of fidelity are used to educate healthcare professionals, however the level of simulation used in this study will refer only to full body mannequin high fidelity simulators.

Why Use Simulation?

Simulation allows students to practice skills and be assessed for competency prior to attempting bedside care with a live patient (Moule et al., 2008). During a simulation session students are exposed to a patient scenario in which they will apply medical information, practice procedures or interventions, and assess for the simulator's response to those interventions (Rozansky, 2012). Instructors prepare the simulation scenario to be as realistic as possible, set the expectations and guidelines for the scenario, and determine evaluation criteria to facilitate simulation learning (Brewer,

2011). Endotracheal intubation is an example of a skill that must be mastered by RT students; however ethical issues including using animals or the deceased means that sedated pre-operative patients are frequently used for new clinicians to practice this skill. In the process patients can suffer from complications such as oral trauma and dental damage (Owen & Plummer, 2002). Simulation education provides the opportunity for students to practice a skill like endotracheal intubation, apply theoretical knowledge, and demonstrate their competency without exposing live patients to potential harm (Rozanky, 2012). Literature has also shown that important criteria for simulation sessions includes: the opportunity to provide feedback, repeated practice of skills, practice at a range of varied levels of difficulty, use of a range of learning strategies, and attempt to embody the variation found in true clinical scenarios. Simulation learning also occurs within a controlled environment, allows for curriculum integration and individualized learning, and includes defined and achievable goals (Dowie & Phillips, 2011; Issenberg et al., 2005). The benefit of improved learning opportunities and potentially improved patient safety are strong advantages of simulation education.

Current Use of Simulation

The Association of American Medical Colleges (AAMC) performed a survey of 90 medical schools and 64 teaching hospitals to find out how and where schools use simulation for education and training. The survey found that most used full-scale mannequins along with part or partial task trainers. Additionally, more than half of the medical schools used all types of simulation (AAMC, 2011). In 2005, 17 simulation centers were operational across Canada. In a survey of 14 of these simulation centers, it

was found that 93% used high fidelity, 43% used medium fidelity and 36% used both fidelity level simulators (Byrick, 2005). Participants in simulation sessions included medical students, residents, nurses, emergency medical services personnel, inter-professional transport teams and respiratory therapists (Byrick, 2005). Use of the simulation centers were reported to be primarily for training, education, competency assessments, re-certification of advanced cardiac life support (ACLS) and basic life support (BLS), and equipment testing (Byrick, 2005). The use and application of simulation education in all of its various forms, is widespread and promising.

Simulation is used in healthcare education for applying theoretical knowledge and also for practicing task performance and assessment of competency. As individual knowledge and competency are not enough to ensure patient safety, simulation also allows for the unique opportunity to train teams and enhance interdisciplinary collaboration (Gaba, 2004). Another interesting application of simulation is in disaster response training and identification of rare challenges posed to patient care under unique circumstances such as resuscitation in helicopters or ambulances, and with the use of personal protective equipment in outbreak scenarios. Similarly, new research protocols being used in clinical trials can present patient safety hazards, as staff is new to implementing the protocol (Brindley et al., 2008). In this situation, practicing the research protocol in the simulation environment allows for potentially better adherence to the protocol by staff, which in turn will positively affect research data collection and most importantly potential patient safety. Furthermore, simulation has opportunities for educating and improving rapid response or medical emergency teams (Brindley, et al.,

2008). With all of the promising applications of simulation education there are still barriers to its widespread use.

Barriers to the Use of Simulation

In the AAMC survey (2011), participating facilities reported their annual operating budgets for their simulation programs. Although most of the programs had operating budgets of less than $500, 000, 11% of teaching hospitals and 15% of medical schools surveyed reported expenses in the range of $1, 000, 000 to $2,000,000 (AAMC, 2011). Considering the variability in these annual operating expenses and the initial startup expenses, research justifying the cost and indicating the most effective use of simulation education is clearly important. Aside from cost, there are other barriers to simulation.

Another barrier as perceived by healthcare professionals is a lack of time and opportunity to take part in simulation as well as a loss of income (Savoldelli et al., 2005). These barriers were also reported by Chang, Petros, Hess, Rotondi, & Babineau, (2007) amongst surgical residents. After an initial two hour instruction and orientation to the simulator voluntary use was minimal (Chang et al., 2007). Reasons for minimal use of the simulator included lack of time, access to simulation lab and lack of interest (Chang et al., 2007). As such, 70% of simulator usage was during work hours while only 30% was post call or on days off (Change et al., 2007). The healthcare system does not allow for dedicated time away from patient care for continuous training of health care professionals and the cost to allow for this would be substantial. Effects on patient safety are very difficult to assess, thus making justification of such costs difficult despite the successful use of simulation to improve safety in other industries

such as aviation, nuclear power and the military (Gaba, 2004). The demonstrated impact of HFS on patient safety remains unproven in literature (Gallagher & Tan, 2010).

Performance anxiety was described as a barrier to simulation education amongst anesthesiologists: it appears that an important component of a simulation program is that participants feel safe to learn and make mistakes within this learning environment (Salvoldelli et al., 2005). The benefit of making mistakes without subjecting live patients to the consequences is another student-perceived benefit of simulation (Brewer, 2011). Studies have also identified that simulation facilitators must be confident and adept at simulator use for programs to be successful; however there is a lack of instructor training resources (Brewer, 2011; Dowie & Phillips, 2011; Sportsman, Schumacker & Hamilton, 2011). This lack of qualified and experienced simulation educators has been identified as a barrier to simulation education use in Canada (Byrick, 2005; Leblanc et al., 2011). Despite the noted barriers, benefits of simulation education have also been reported.

Benefits of Simulation

Since the impact of simulation on patient safety can be difficult to determine, researchers have turned to survey based studies in an attempt to assess its effectiveness. Results from a qualitative study of nursing students involved in simulation education found three main themes emerged: 1) an increase in confidence, 2) an increase in learning, and 3) support for simulation education after participating in sessions and testing (Moule et al., 2008). Enhanced confidence was also found in other studies assessing students' responses (Baillie & Curzo, 2009; Brewer et al., 2011). Similar

results were found in a study investigating the impact HFS had on pharmacy resident's knowledge, confidence, and competency in advanced cardiac life support (Eng et al., 2014). Participants rated confidence using a 5-point Likert scale pre and post HFS education sessions (Eng et al., 2014). The median confidence rating amongst participants increased from 3.2 to 4.0 ($p=0.001$) (Eng et al., 2014)

Researchers have attempted to quantify the impact of simulation education through pre and post-testing of knowledge levels and skills performance. In a study of nursing students, pre and post knowledge tests and objective structured clinical examinations (OSCEs) were used to assess improvement in basic life support (BLS) and manual handling (MH) skills (Moule et al., 2008). This study found a mean knowledge score increase in BLS testing of 5.6% ($t=5.6$, $p<0.001$) and MH testing of 4.1% ($t=3.6$, $p<0.01$) (Moule et al., 2008). Eng et al., (2014) had similar results. Median knowledge scores amongst first year pharmacy residents on a 20 questions multiple choice exam in regards to advance cardiac life support increased from 65% to 88% ($p=0.001$) post HFS education (Eng et al., 2014). These results indicate that simulation education can impact knowledge scores with testing yet it is unclear if this improvement in scores results in improved patient outcomes.

Using Simulation for Skill Acquisition

To review literature regarding HFS use for skill acquisition, studies of specific healthcare professionals were reviewed. Evidence regarding specific skills was also reviewed, followed by evidence of the impact of simulation education across a variety of skills and healthcare professions.

Simulation for Medical Resident Skills

Barsuk et al. (2009) attempted to indirectly assess the impact a simulation education program had on patient outcomes by assessing key quality indicators in central venous catheter (CVC) insertions. In the Barsuk et al (2009) observational cohort study included 103 second and third year internal and emergency medicine residents. Twenty-seven of the residents received traditional training without simulation and 76 received simulation training (Barsuk et al., 2009). Pre and post-tests between the two groups were compared along with the perceived confidence and the following quality indicators: 1) the number of needle passes required, 2) arterial puncture, 3) need for CVC adjustment after chest radiograph, 4) successful CVC insertion, and 5) pneumothorax (Barsuk et al., 2009). Simulator trained residents reported statistically significant fewer numbers of needle passes, arterial punctures, CVC adjustments post chest radiograph and higher success rates (Barsuk et al., 2009). There was no difference in self-confidence ratings and these ratings did not correlate to performance on quality indicators (Barsuk et al., 2009). Although this study was a small sample in a single institution and relied on resident's to recall quality indicators, the results indicate that a simulation education program improved performance of CVC insertions (Barsuk et al., 2009).

Wayne et al. (2008) investigated using simulation for another skill performed by medical personnel, the thoracentesis. Thoracentesis is a skill that internal medicine residents have rated even lower confidence in performing than CVC insertions (Wayne et al., 2008). The study investigated the impact a two-hour education session involving a video and practice with a thoracentesis simulator had on competency in performance of thoracentesis (Wayne et al., 2008). Forty third-year internal medicine residents took

part and completed pre and post-tests (Wayne et al., 2008). Pre and post-tests included demonstration of the skill in simulation and assessment using a 25-item checklist along with a multiple choice written examination (Wayne et al., 2008). It was found that the simulation session improved post-test scores by 71% (Wayne et al., 2008). This study did not make use of a control group so comparisons were not made between the simulation education session and other forms of educational interventions; as well, there was no assessment of skill transfer to the actual clinical setting (Wayne et al., 2008).

Aside from CVC insertion and thoracentesis, the use of simulation for mastery of other skills, such as laparoscopic totally extraperitoneal inguinal herniorrhaphy repair and cardiopulmonary bypass simulation have been reported in other studies (Zedenjas et al., 2012; Hicks et al., 2011). However, pre-tests were not administered, and there was no use of a control group or comparison to other education interventions (Zedenjas et al., 2012; Hicks et al., 2011). The literature demonstrates the successful use of simulation for skill acquisition, however it fails to quantify simulation's impact or compare it to other educational interventions.

Simulation with Respiratory Therapists

In the AAMC (2011) survey, 40 to 60% of the participants responded that RTs also took part in their simulation programs. Of the 14 simulation centers surveyed in Canada, 71% reported RTs participating in simulation programs (Byrick, 2005). Despite the involvement of RTs in simulation programs and a long history of simulation in the RT discipline, there is little literature describing or supporting the use of simulation in respiratory therapy (Matthews & Yachemetz, 2008). One study looked at RTs scores on performance of a mini-bronchoalveolar lavage (BAL) (Tuttle et al.,

2007). The RTs were tested prior to any additional education and the mean score was 73 ± 10% and did not correlate to the number of BALs performed prior to testing (Tuttle et al., 2007). After completing web-based education packages, the mean scores increased to 77 ± 11%, but after simulation education, the score increased to 95 ± 5% ($p<0.01$) (Tuttle et al., 2007). To further assess the benefits of the simulation education, 24 of the RTs were randomly asked to re-test 90 days afterwards, and the mean score was 92 ± 8% indicating good retention of knowledge post simulation training (Tuttle et al., 2007). Also worth noting, 76% of the RT's felt simulation was a necessary part of the recertification process (Tuttle et al., 2007). The number of RTs that felt uncomfortable with simulation dropped from 28% to 0% after the training sessions (Tuttle et al., 2007). Although this study was not set up as a randomized control trial and the additive effects of multiple learning strategies are a limitation, it does indicate that simulation training is an effective tool for maintaining competency that should be further investigated (Tuttle, et al., 2007).

Simulation with Medical Emergency Teams

The use of simulation training has been studied with the development of medical emergency teams (MET), also known as rapid response teams. The MET team frequently involves respiratory therapists (RTs). Hence, research on the education of such teams has also involved RTs. A quality improvement study of a MET team by DeVita, et al. (2005) involved physicians, Registered Nurses (RNs), and RTs. The participants were asked to complete simulation scenarios involving the need for rapid emergency response to simulated vital and physiological signs (DeVita et al., 2005). Pre-testing and web based seminars were completed prior to simulation. Participants

did not perform the same role more than once in the scenarios (DeVita et al., 2005). Data was analyzed using Cochran's Q to account for changes in scores across repeated outcomes (DeVita et al., 2005). It was found that simulator survival increased from 0 to 90% across the simulation sessions; this difference was statistically significant with a Cochran's Q of 12.6, p=0.002 (DeVita et al., 2005). A critical task completion rate (TCR), the completion of a task that maintained life in the simulated patient, was also assessed and found to improve from 31% to 89% across the sessions (Devita et al., 2005). Overall, the Devita et al. (2005) study demonstrated that simulation education could improve multi-disciplinary team performance, and simulator outcomes. Further investigation is warranted to determine if the improvements in simulator outcomes are carried over to patients in the clinical setting.

Use of Simulation for Endotracheal Intubation

Endotracheal intubation (ETI) is a skill that requires many hours of practice to establish proficiency. Hall et al. (2004) compared clinical success rates for ETI of paramedic students prepared with traditional training to those prepared with simulation. Both student groups underwent didactic training; the control group then did 15 intubations in the operating room under the guidance of an anesthesiologist while the intervention group did 10 hours of ETI using simulation (Hall et al., 2004). The two cohorts were then formally assessed on 15 intubations in the operating room and data was analyzed for success and complication rates (Hall et al., 2004). Results show that the intervention and control groups' success and complication rates were not significantly different, thus it was concluded that simulation is as effective a method of preparation as the traditional operating room training (Hall et al., 2004). The study did

not standardize the number of attempts or amount of individual time spent practicing ETI in simulation, instead students were considered prepared when deemed to demonstrate the skill competently by an observer (Hall et al., 2004). Weaknesses in this study include the method of instruction by the trainers for both cohorts was not adequately described or standardized, and the method for categorizing intubation difficulty was also not clearly defined (Hall et al., 2004). Bias may have also played a role in the results as the observers evaluating success of intubations and the assisting anesthesiologists were not blinded to which research group students had been assigned to (Hall et al., 2004). Despite the limitations of this study, these results indicate the strong potential for simulation education to be as effective as traditional teaching methods in endotracheal intubation while mitigating potential harm to patients.

Owen and Plummer (2002) developed a structured teaching program to use simulation to prepare students for ETI. Most of the 115 participants were medical students, but paramedic and other healthcare professional students also participated in the structured education sessions (Owen & Plummer, 2002). The session began with students watching a video demonstrating ETI, followed by gaining familiarity with the equipment required (Owen & Plummer, 2002). Students then observed instructors performing ETI before attempting the procedure themselves (Owen & Plummer, 2002). First attempts were completed on low fidelity simulators with immediate feedback from instructors (Owen & Plummer, 2002). Once students adequately performed ETI on low fidelity simulators, common mistakes were reviewed and attempts were made on higher fidelity simulators that could replicate more difficult intubations (Owen & Plummer, 2002). Student feedback was used to determine the optimal length for instruction and

practice time, group size and general perception of the simulation session (Owen & Plummer, 2002). Results indicated that sessions should be no more than 90 minutes long with 12 to 14 attempts at ETI, and groups of two participants at a time was optimal (Owen & Plummer, 2002). Although this study did standardize the method of instruction and optimize group size, it did not formally assess student competency, rather only elicited student feedback, which was all generally positive. Owen and Plummer (2002) established some guidelines for developing an effective structured simulation education session on ETI however did not determine if this translates to clinical skills at the bedside.

A study involving neonatal residents did evaluate the effectiveness a simulation session had on neonatal simulation skills and the translation of those skills to the clinical learning environment. A group of 13 residents who had successfully completed the Neonatal Resuscitation Program within two months underwent a two hour-long neonatal intubation education session lead by two senior Respiratory Therapists (Finan et al., 2012). Prior to the education session, residents were assessed on their ability to intubate a high fidelity neonatal simulator using a global rating scale and a validated checklist. The average score was 65.4 $\pm$ 18% on the check list and 3 $\pm$ 0.7% on the global rating scale (Finan et al., 2012). Following the initial assessment, no more than three residents at a time attended the educational session prior to a clinical rotation through a Neonatal Intensive Care Unit. The education session included didactic learning, demonstration of the skill by the facilitators along with opportunity to repeatedly practice until the participants felt confident in performing the skill. The session also included each resident performing intubation during two scenarios

involving a term infant and a pre-term infant. Following the education session the residents were assessed again using the global rating scale and validated checklist. Average scores improved post educational session on the checklists, 93 + 5% ($p<0.0001$) and the global rating score, 3.92 + 0.4 ($p<0.003$) (Finan et al., 2012). Residents then performed endotracheal intubation within the Neonatal Intensive Care Unit during clinical rotations and were assessed by Respiratory Therapists trained on the use of the checklist. During the validation of the checklist residents from the previous year had been scored using the same checklist but had not received the educational session. This provided a cohort of data to compare that of the residents who had received simulation education. Success rates for the intervention group were 67.5% compared to 63.15% in the cohort group; this difference was not statistically significant ($p=0.06$). The intervention group's mean checklist score was 64.6 + 20% compared to the cohort group's mean checklist score of 82.5 + 15.4% (Finan et al., 2012). The intervention groups check list score was significantly lower than that of the cohort group ($p=0.001$) (Finan et al., 2012). These results indicate that the simulation education session did not translate to clinical performance of that skill. The potential reasons for this given by Finan et al., (2012) include greater anxiety amongst the simulation group, increased difficulty dealing with anatomical anomalies and interferences in real life compared to simulation, use of concurrent feedback during simulation that was not provided during real life attempts. There are also several limitations in the study to consider, baseline demographic data was not collected and although none of the residents had previous neonatal experience data regarding intubation experience in other populations was not collected. The cohort group was

also assess later in their clinical rotation and may have had increased clinical confidence (Finan et al., 2012). This study had a small sample size but does add to the literature in the use of a validated checklist. It is important that future research continue to assess the translation of skills taught using simulation to clinical practice and patient outcomes.

Simulation Across Many Skills

A systematic review of 26 studies investigating the effects high fidelity simulation has on knowledge and skills in nursing and medical education found that there is a benefit of improved knowledge and skills scores on examination with simulation preparation (Yuan et al., 2012). The 26 studies reviewed included nine English, and 17 Chinese, of which 16 were randomized, controlled trials, one was a non-randomized control trial and nine were quasi-experimental studies (Yuan et al., 2012). All studies compared high fidelity simulation using human patient simulators or emergency care simulators to usual teaching practices such as didactic lectures without simulation (Yuan et al., 2012). The particular skills assessed in the studies reviewed varied but tended to focus on emergency management and resuscitation efforts in: 1) advanced cardiac life support (ACLS), 2) advanced trauma life support (ATLS), 3) cardiopulmonary resuscitation (CPR), 4) chest trauma, 5) neonatal resuscitation, and 6) first aid training (Yuan et al., 2012). Despite the shown benefit on knowledge and skills examination scores with simulation, the review of the literature fails to show a clear benefit in using objective structure clinical examinations (OSCEs) (Yuan et al., 2012). It was noted in the studies reviewed, authors often failed to validate checklists or performance assessments, or reach sufficient sample size to have the power to

determine simulation's effect (Yuan et al., 2012). Despite the limitations of these studies, the value of the effect simulation has on participants' knowledge is of interest.

Cook et al. (2011) performed a meta-analysis of 609 studies investigating the impact simulation education had on health care professionals' learning outcomes. The studies included in the analysis involved both new and practicing health care professionals from any discipline including physicians, dentists, nurses, chiropractors, and veterinarians (Cook et al., 2011). Studies were sub-categorized by how learning outcomes were assessed (Cook et al., 2011). Results from studies assessing knowledge gains comparing pre and post-tests were pooled for effect size (Cook et al., 2011). Although the effect sizes from the individual studies varied, the pooled effect size of 1.20 indicates a large gain in knowledge with simulation training (Cook et al., 2011). This inconsistent but pooled effect was also seen in those studies assessing gains in the time to completion of skills, end product quality of skills, efficiency of the process and evaluation of behaviours (Cook et al., 2011). For those studies assessing the effects simulation training had on patient care outcomes, the inconsistency was also high, however pooled effect size was moderate (Cook et al., 2011). Although studies on simulation education have inconsistent results to date, it does appear that there is an effect when these studies are pooled and analyzed across many subject areas and health care professionals. However, respiratory therapists are not well represented in the literature despite a long history of simulation education use for healthcare professionals (Matthews & Yachemetz, 2008).

Simulation and Continuing Education

Although simulation is primarily utilized in educating and assessing competency

of new students preparing for clinical practice, simulation can also be used in continuing education. Simulation to facilitate continuing education is important, as post-graduate continuing education of health care professionals is often infrequent and unstructured (Gaba, 2004). Furthermore, as patient acuity and health care complexity continues to increase, innovative approaches to continuing education will need to be developed (Dow, Salas, & Mazmanian, 2012). By using simulation, skills can be refreshed, and procedures rarely performed can be practiced to maintain one's competency (Gaba, 2004). This method of education may also be used to assess clinical competency and the rate of skills decay (Dow et al., 2012). Simulation may facilitate the integration of continuing education into the health care system rather than leaving the burden of cost and time to the professionals themselves. The use of simulation training for continuing education of experienced healthcare professionals is likely to be the most costly of simulation programs to implement but also most likely to have impact on patient care and safety (Gaba, 2004). Implementation of simulation for continuing education purposes is more likely to result in routine use of simulation education, which in turn will allow for improved support, familiarity and impact of simulation education (Brindley et al., 2008). The role of simulation in developing a culture of continued quality improvement and patient safety is paramount (Brindley et al., 2008).

Assessment of the impact of simulation on practicing healthcare professionals is less investigated than simulation education used with students or residents. Buckley and Gordon (2011) assessed the impact simulation had on graduate medical-surgical nurses. Participants completed a 14-hour course consisting of pathophysiology, clinical

presentation and management guidelines of deteriorating patients (Buckley & Gordon, 2011). The content covered systematic assessment of the cardiovascular, respiratory and neurological systems (Buckley & Gordon, 2011). Following this didactic course, participants practiced technical skills in two 3-hour workshops (Buckley & Gordon, 2011). Team-building and communication exercises were also a part of training prior to participating in the high fidelity simulation scenarios (Buckley & Gordon, 2011). Three months after the simulation sessions, participants were asked to complete a survey (Buckley & Gordon, 2011). Seventy-six percent of the participants complied: 87% of the participants self-reported that the workshop had improved their ability to deal with emergencies in a systematic way, and 79% of the respondents reported using the skills one to five times in the three months following the session (Buckley & Gordon, 2011). These findings indicate that simulation can be successfully used in combination with didactic learning to enhance post-graduate nurse education and result in more clinically confident nurses (Buckley & Gordon, 2011).

Similarly, Klipfel et al. (2012) found that simulation education can be used in suit to provide continuing education to train teams to adequately deal with emergency situations with a focus on interdisciplinary teamwork and patient safety. In this study the Mayo High Performance Teamwork scale was used to allow participants to rate team functioning prior to and after completion of the in situ simulation emergency scenarios (Klipfel et al., 2012). The study found that Mayo High Performance Teamwork Scale increased by 0.7 or more for questions dealing with verbal communication, situational awareness, and avoidance of errors or clarification (Klipfel et al., 2012). Participants also completed a questionnaire regarding satisfaction with

simulation education (Klipfel et al., 2012). 87% of participants agreed that the experience improved their confidence in emergency situations as well as their ability to effective communicate and provide transfer of accountability (Klipfel et al., 2012). This study supports Buckley and Gordon's (2011) findings that simulation can support improving responses to emergency responses, however adds to evidence by providing experience and impact of in situ simulation rather than dedicated off unit courses. This method of simulation may improve access to simulation education as a means of continuing education.

In 2000, the American Board of Anesthesiology (ABA) changed requirements for anesthesiologists to maintain certification. Anesthesiologists must now complete a four part series of activities over a 10-year period to maintain certification with the fourth activity being a simulation training session. Furthermore, these simulation sessions must meet the ABA standards for high-quality simulation programs. One report describes a simulation program meeting ABA standards and generally had positive feedback from participants (Levine et al., 2012). There was no further assessment of the program to investigate the impact it had on knowledge or patient outcomes (Levine et al., 2012). The need for simulation as a means of continuing education was echoed in a needs assessment involving certified registered nurse anesthetists (CRNAs) (Cannon-Diehl et al., 2012). In this needs assessment, survey results indicated that 91% of CRNAs had experienced high fidelity simulation as a student but only 1% had as part of continuing education (Cannon-Diehl et al., 2012). Fifty-seven percent of respondents did not have access to simulation education at work but 77% were interested in gaining continuing education credits using simulation

(Cannon-Diehl et al., 2012). Results of this needs assessment indicate that there are large knowledge gaps in the appropriate use of simulation for continuing education and inadequate opportunities despite a 77% willingness to participate (Cannon-Diehl et al., 2012).

Simulation and Mechanical Ventilation

Mechanical ventilation is a costly and commonly used resource required by many patients in the intensive care setting (Wax et al., 2006). Mechanical ventilation is an intervention associated with high rates of morbidity and mortality (Goligher, Ferguson, & Kenny, 2012). Yet, new evidence guiding best practices in regards to mechanical ventilation is slow to be adopted and inconsistently applied by clinicians (Wax et al, 2006; Goligher et al., 2012). Furthermore, there is a general lack of knowledge of evidence based practices, disease pathophysiology, technical expertise, adherence to guidelines and recommendations made to patient care regarding mechanical ventilation (Rubenfeld, 2004; Goligher et al., 2012). Some of the barriers identified for adhering to best practice guidelines include a lack of awareness, familiarity to guidelines, disagreements with guidelines, and complacency with established practices (Rubenfeld, 2004). Varying strategies for changing clinician behaviour and overcoming such barriers exist, however specific educational models are the most familiar to healthcare professionals. In particular, educational models based on adult learning theories and involving interactive experiences over lectures are considered to be more efficacious (Rubenfeld, 2004). Large lecture based educational sessions when used alone without commitments to change practice have been shown to result in poor behavioural change of practicing clinicians (Domino, Chopra, Seligman,

Sullivan, & Quirk, 2011). Education interventions for only the physicians is not adequate to change care surrounding mechanical ventilation, as the intensive care setting also involves working closely with ICU nurses and RTs along with other health care professionals (Rubenfeld, 2004).

A study investigating the use of simulation to improve adherence to ventilator-associated protocols, was completed by Jansson et al. (2014). Ventilator associated pneumonia (VAP) is among the most frequently encountered nosocomial infections in critical care units. It is associated with increases in morbidity and mortality as well as costs and Intensive Care Unit patient stays. A reduction in VAP has many benefits for both patients and health care systems (Jansson et al, 2014). VAP prevention bundles have been shown to reduce the incidence of VAP however these bundles work best when implemented all together. As such, compliance with each aspect of the VAP bundle is of utmost importance in order to benefit from this important patient safety initiative (Safer Healthcare Now!, 2012). Jannson et al. (2014) provided simulation education regarding VAP bundle implementation and compared knowledge scores on a validated multiple-choice test to a control group. This study found no statistically significant differences in test scores between the two groups, however did find that there was a statistically significant difference between clinical adherences to VAP bundles. Clinical adherence to the bundle was assessed using a validated VAP bundle observation schedule (Jannson et al., 2014). This study is significant not only in its assessment of the use of simulation education for management of the mechanically ventilated patient and promotion of evidence based patient safety practices, but also in its assessment of simulation's impact to actual clinical performance. The study is

limited however, by its small sample size and the poorly described contribution of the interprofessional team to aspects of the VAP bundle observation schedule.

Literature shows methods of appropriate mechanical ventilation in patient care vary greatly despite research supporting particular practices (Rubenfeld, 2004). Examples include the use of low tidal volumes in patients with ARDS/ALI, and the routine and standardized approach to assessment for readiness to wean along with titration of oxygen and withdrawal of mechanical ventilation (Rubenfeld, 2004). However, RTs and nurses do perceive appropriate mechanical ventilation to be facilitated by use of written protocols along with education based on research and sound rationale behind the protocols (Rubenfeld et al., 2004). As such, the use of simulation education of bedside personnel should be investigated regarding mechanical ventilation to improve this aspect of patient care.

In a study involving nurse practitioner students, participants underwent mechanical ventilation education using an online web-based education package or simulation sessions. The difference between pre and post-test scores was statistically significant in both groups, however post-test scores were not significantly different between the two groups (Corbridge et al., 2010). Despite the lack of improved knowledge in the simulation group over the online web-based education group, students that participated in simulation scored higher satisfaction rates than those in the online session (Corbridge et al, 2010). In another study investigating simulation education's impact on knowledge of mechanical ventilation, 60 first year internal medicine residents were randomly assigned to two groups (Schroedle et al., 2012). The first group received traditional training with no simulation, while the second received both

traditional training and a four-hour long simulation education session two weeks prior to their rotation initiating (Schroedle et al., 2012). During the simulation session, residents were exposed to a rapidly deteriorating patient care scenario requiring intubation, mechanical ventilation and rapid interpretation of lab reports along with administration of pharmaceuticals (Schroedle et al., 2012). Following the scenarios, debriefing sessions were conducted. A 14 -item checklist developed using the Delphi procedure was used to assess resident's bedside skills (Schroedle et al., 2012). Residents who participated in the simulation session received statistically significant higher scores than those who received traditional training only (Schroedle et al., 2012). Despite this difference in scores, there were no differences in reported self-confidence between the two groups (Schroedle, et al., 2012). This study indicates that simulation training in mechanical ventilation can improve bedside performance in nurse practitioners and first year residents.

Knowledge Scores and Assessment Methods

To date, many of the studies examining the impact of simulation on knowledge and clinical performance have used varied methods of assessment. Assessment methods have included knowledge and multiple-choice tests (Corbridge et al., 2010; Moule et al., 2008; Schroedle et al., 2012; Wayne et al., 2008), checklist scores (Finan et al., 2012; Schroedle et al., 2012, Wayne et al., 2008), clinical success rates (Hall et al., 2004, Finan et al., 2012), OSCE scores (Moule et al., 2008), self-reported Likert scales (Eng et al., 2014), self-reported quality indicators (Barsuk et al., 2009), the Mayo High Performance Teamwork scale (Klipfel et al., 2012) and observation schedules (Jannson et al., 2014). This variability in assessment methods and the lack of validated

assessment methods was echoed in a meta-analysis assessing the impact of simulation education on various clinical skills (Yuan et al., 2012). This raises the question of whether the various assessment methods can adequately capture the impact simulation may have on learning.

Although written tests alone may not be adequate to examine clinical and practical skills, there is some indication that knowledge scores are related to performance (Russel, Hoiriis, & Guagliardo, 2012; Hauber, Cormier, & Whyte, 2010). A study by Hauber at al. (2010) investigated the relationship between student nurses' test scores in two courses to their ability to perform within the simulation environment. The students' performance was measured by their ability to adequately maintain the patient's mean arterial blood pressure and oxygen saturation throughout the simulation scenario (Hauber et al., 2010). The measured physiological variable in the study was the mean arterial blood pressure and the oxygen saturation levels. There was a significant and direct correlation between participants' grades in the adult health course and the measured physiological variable (Hauber et al., 2010). However, the relationship between the students' fundamentals course grade and the physiological variable had a significant and indirect correlation. This difference in correlations may reflect the differing foci within the two courses (Hauber et al., 2010). The authors noted that the fundamentals course focused on mastery of psychomotor skills, which requires implicit memory, whereas the adult health course focused on knowledge of facts and their relationships (Hauber et al., 2010). These results indicate that education sessions focusing solely on knowledge and memory have little transference to skill performance

compared to courses that focus on understanding what findings mean and what appropriate actions need to be taken as a result (Hauber et al., 2010).

In contrast, a study investigating the correlation between exam scores in a clinical skills course and OSCE scores among chiropractic students revealed a statistically significant, moderate correlation between the two scores (Russel et al., 2012). Similarly, a study investigating clinical performance as a predictor for successful completion of the National Physical Therapy Examination (NPTE) found a small relationship between the two scores (Luedtke-Hoffman, Dillon, Utsy, & Tomaka, 2012). Clinical instructors assessed clinical performance using a clinical evaluation tool during student's clinical placements (Luedtke-Hoffman et al., 2012). The correlation between the scores on this tool and the NPTE had a small but statistically significant correlation (Luedtke-Hoffman et al., 2012). The variability in results and correlation between knowledge test scores and clinical scores reflect the need to consider assessment methods when interpreting results of studies investigating the impact of simulation education on test scores.

Conceptual Framework

As the technology influencing simulation-learning experiences grows, there is a need to understand the learning theories behind the use of high fidelity simulation in health care education. Without this important theoretical underpinning, simulation education will be taken over by technological fads rather than the learning theory required to ensure appropriate, effective and successful simulation education sessions (Bland & Wood, 2011; Parker & Myrick, 2009). To date, simulation education literature does not adequately discuss learning theories in session design (Kaakinen &

Arwood, 2009; Rourke, Schmidt, Garga, 2010). In a systematic literature review of nursing simulation education, of the 160 articles discussing simulation session design, only 16 referred to using a learning or developmental theory to develop the sessions (Kaakinen & Arwood, 2009). Simulation learning opportunities allow for students to practice psychomotor skills, apply theoretical knowledge as well as explore the social aspects of working within a care team.

Learning Theories

Behavioural learning theory. Behavioural learning theories are rooted in Pavlov and Thorndike's work, which theorized that behaviour, was in response to reward or reinforcements (Bilings & Halstead, 2009). This theory was called the law of effect and later the stimulus-response theory (Billings & Halstead, 2009). This theory is characterized by the feeling that behaviour is learned, and can be manipulated by reward and environment (Billings & Halstead, 2009). Behaviourist learning theory is instructor dominated with highly structured learning activities and students following instructors' directions (Billings & Halstead, 2009). The downfall of this theory is the limited student involvement in the learning process (Billings & Halstead, 2009). Today, traditional behaviourist theories are less prominent in modern education and have given way to new interpretive, learner centered pedagogies (Billings & Halstead, 2009). However, there is the acceptance that this form of learning theory may still have a role to play when it comes to mastery of psychomotor skills and learning in the sciences (Parker & Myrick, 2009). In these circumstances, the limited conscious effort and automatic recall may indeed be very vital, and behaviourist-learning strategies may at times be necessary (Parker & Myrick, 2009). It also appears that the behaviourist's

theory perceives the mind as a memory bank (Parker & Myrick, 2009). Without repetition, this knowledge bank will erode (Parker & Myrick, 2009). This importance of repetition seems to ring true with learners and instructors in terms of psychomotor skills (Parker & Myrick, 2009). The behaviourist learning theory can be used as a guideline for simulation learning where psychomotor skills need to be practiced (Parker & Myrick, 2009).

Psychomotor aspects associated with the simulation session designed for this research project involves the set-up of the Aerosolized Epoprostenol apparatuses and integration into the mechanical ventilation circuit. Behavioural learning theory is taken into account in the design of this simulation session; however, behavioural learning theorists view learners as having sponge-like minds who simply absorb new material from the instructor. This approach to teaching does not work well with the adult learner as adult learners bring their own experience, knowledge and needs to educational sessions and these must be taken into account (Chaves, 2008).

Constructivist theory. Opposed to the sponge-like mind view by the behavioural learning theory, constructivism holds that learning is more of an individual process (Parker & Myrick, 2009). In constructivism, learners interpret new knowledge in their own unique ways and add to or change their existing structures of knowledge in order to create a knowledge base that is satisfactory to them (Parker & Myrick, 2009). Therefore, the role of the instructor changes according to constructivist theory. The instructor is no longer the source of knowledge from which the learner absorbs, but is instead a guide as the learner constructs his or her own meaning of the new knowledge (Chaves, 2008; Parker & Myrick, 2009). The students learn to make their own

connections and methods of problem solving rather than trying to simply adopt another person's way of thinking. Constructivist learning theory coincides well with the exploratory and inquiry based type of learning that can occur in simulation labs. Using this learning theory as a guide, instructors would design poorly structured learning activities forcing students to develop their own hypotheses and resolutions. Following the activity, students could then reflect on the experience to add or change their existing cognitive schema. When using a constructivist approach, the role of the instructor is to develop a problem centered scenario in order to direct students toward a learning objective, provide access to a variety of information resources, and act as a facilitator of the experience. Students then have the responsibility to access the information, think critically about the information and develop a resolution independently (Parker & Myrick, 2009). The constructivist learning theory suits simulation education sessions in which participants must use their knowledge, the health region's protocols and accurately apply them to the scenario.

Experiential learning theory. It can be argued that in regards to adult learning, constructivism can be experiential learning (Sutherland, 1997). Simulation education is rooted in experiential learning. Kolb's theory of experiential learning describes the process by which learners add experiences to existing knowledge frameworks (1984). According to Kolb's theory of experiential learning, one learns through experience by performing, known as extension, and from the experience by reflecting, known as intention (Lisko & O'Dell, 2010). At the same time, theoretical knowledge informs practice and practical experience furthers theoretical knowledge. HFS thus fits well with Kolb's theory of experiential learning, with the debriefing portion of simulation

being essential for reflection (Waldner & Olson, 2007). In Kolb's experiential learning theory, there are four steps of learning that occur throughout extension and intension. They are: 1) concrete experience, which is the basis for learning, 2) reflective observation, where making sense of the experience occurs, 3) abstract conceptualization which uses logic and ideas to understand the experience, and 4) active experimentation, where testing of theories and further experiences are had. Although some learners will focus on certain stages more than others, all stages must occur to some degree for learning to take place (Lisko & O'Dell, 2010). Although experiential learning theorists will place more emphasis on the reflective aspects of learning than constructivists, the two theories' guiding principles coincide well. Each views the student's previous knowledge and experience as part of the learning and development of further knowledge (Sutherland, 1997). The theory of experiential learning is best suited to the use of simulation for re-certification of respiratory therapists in ventilation-associated protocols. RTs bring their own previous experiences and knowledge to the simulation session, and through the simulation experiences learn to add, change or enhance existing knowledge of the protocols.

Gaps in the Literature

To date much of the literature regarding the use of simulation education is qualitative and descriptive in nature. Studies are needed that further quantify the impact of high fidelity simulation education (Brewer, 2011). Researchers must move beyond description and begin to assess the justification of HFS, improve the understanding of the most appropriate applications of this approach and address the cost effectiveness of it (LeBlanc et al., 2011). There is a need for improved scientific rigour in high fidelity

simulation research and future studies should aim to include pre-tests, larger sample sizes, and validated tools for assessing both knowledge and performance (Cook et al. 2011). Future studies of adequate scientific design are needed to justify the use of simulation.

Aside from research to justify the use of simulation, research should aim to further inform the design and implementation of simulation education scenarios (Cook et al., 2011). There is a need to assess how to support both students and facilitators to effectively use simulation education (Dowie & Phillips, 2011). The appropriate integration of simulation into curriculums, particularly post-graduate education, is also an area in need of further investigation (LeBlanc et al., 2011).

The profession of respiratory therapy has a long history of simulation use but it has yet to adequately document and contribute to literature regarding high fidelity simulation use in the profession (Matthews & Yachemetz, 2008). RTs have been included in simulation education programs aimed at interdisciplinary teams, such as medical emergency response teams, (DeVita at al., 2005) and to recertify skills to complete Broncho-alveolar lavages in mechanically ventilated patients (Tuttle et al., 2007). Despite RTs primary role of managing and maintaining mechanical ventilation, studies investigating simulation use with mechanical ventilation education programs have involved nurse practitioner students and medical residents (Corbridge et al., 2010; Schroedle et al., 2012), but not RT's. There is a need to improve mechanical ventilation skills and guideline adherence by bedside practitioners; the use of simulation education programs aimed at RTs may serve this purpose (Rubenfeld, 2004; Wax et al., 2006). There is an opportunity for RTs to be at the forefront of further developing simulation

in health care professionals (Rozansky, 2012). The role of simulation in assessment and retention of RTs clinical competency needs to be further researched (Tuttle et al., 2007). RTs also have the opportunity to be involved in research to further understand barriers to implementing evidence based ventilator practices and simulation's role in changing clinician behaviour and its impact on ventilator associated practices (Rubenfeld, 2004; Wax et al, 2006). Further assessment of simulation's impact on not only educational outcomes but also patient outcomes is also warranted (Wax et al., 2006). The proposed research study will help fill existing knowledge gaps by quantifying the impact simulation education has in terms of test scores, when used within the RT profession for recertification of ventilation associated protocols.

Chapter Three: Methodology

Research Design

The quantitative research paradigm is rooted in positivism, which holds that all phenomena can be scientifically investigated using empirical evidence (Sale et al., 2002). This empirical evidence is used to find the one truth that is free from the influence of human perception (Sale et al., 2002). Conversely, the qualitative research paradigm holds that reality and truth are socially constructed and as such there are multiple realities and truths, which can be explored through various methods using small and purposeful samples (Farrelly, 2013). Qualitative methods can be helpful in better understanding the student experience with simulation and can highlight areas in need of improvement for program developers (Lasater, 2007). Although the qualitative data will assess participants' perception of simulation, a quantitative research paradigm was better suited to the research question under investigation in this study. The quantitative research method used in this study aimed to determine if HFS education improved post-test scores assessing knowledge of protocols among RTs. Upon recruitment, it became evident that only a small sample size could be obtained. Under advisement of the research supervisor, qualitative data collection was added to the research study design. The mixed methods design aimed to determine if HFS education improved post-test scores assessing knowledge of protocols among RTs and illicit participant feedback on the advantages and disadvantages of HFS compared to the usual practice of only reading the self-directed learning manuals.

The overall goal of this study was to inform future educational and re-certification practices by quantifying the impact HFS education has on RTs knowledge

regarding ventilation associated protocols. Therefore, a quantitative, pre-post-test randomized control trial was chosen for the research study design. This design was also chosen in response to a call for more rigourous quantitative research in the simulation education literature (Brewer, 2011).

All participants were asked to write a pre-test to estimate baseline knowledge of the protocols under investigation prior to being given any educational materials on the protocols to be reviewed. Half of the participants were randomly assigned to review the educational materials and protocols on their own time prior to writing the post-test. This procedure followed the health region's current practice for recertifying RTs. This group was referred to as the control group. The other half of the participants were assigned to the intervention group and were required to register for a HFS education session of two hours in length. A day was chosen during which participants that were assigned to the simulation group could attend the HFS education session while at work. Two HFS sessions were held with two participants each. A simulation session size of two participants has been shown to have no impact on student's subjective experience or exam performance (Rezmer et al., 2011). After completing the HFS education session, the intervention group participants wrote the same post-test to assess knowledge of the protocols under investigation. All participants were asked to keep questions on the pre and post-tests confidential and not discuss potential answers with one another until completion of the study. This study design allows for comparison of mean pre and post-test knowledge scores within each group and post-test scores between the two groups. Findings will allow for a better understanding of the impact HFS education has on test scores in comparison to the usual method for ventilation associated protocols re-

certification. All participants also completed a demographic survey to allow for a descriptive statistic report of the recruited sample.

Study Variables

Variables in this study were the pre and post-test scores within the two groups: the control group and the HFS group. The dependent variables were the mean pre and post-test scores on the knowledge exam and the independent variable was the educational intervention: the HFS education session or the usual read and review method. Demographic variables may impact the generalizability of study results; therefore, the demographic survey was used to report information about other variables such as participant's age, sex, number of years practicing as a RT, confidence with HFS education sessions and protocols.

Research Question

The research question in this study was "Are post-test scores, when adjusted for pre-test scores, on ventilation-assisted protocol re-certification exams higher for RTs who are given a HFS education session compared to RTs who do not receive the HFS education session?"

Setting

All HFS education sessions and testing took place in the health region's Education and Research Network Center. This is a center dedicated to the education of students, residents and continuing education of staff in the health region. The center contains a library, lecture hall, several smaller workrooms and simulation labs. The study was primarily conducted in the simulation labs. These labs are equipped with a high fidelity simulator and additional equipment such as airway equipment, monitors,

defibrillators, mock medications and instruments to complete assessments and interventions on the mannequin.

Participants and Recruitment

All recruited participants were currently practicing RTs in the health region. To recruit participants, an information letter (Appendix A) was sent to all RTs on staff informing them of the research project and inviting them to participate. The letters were placed in staff mailboxes, and posters describing the study were displayed in the staff room. As well, an electronic copy of the information letter was sent to the RTs through the staff email system. The investigator attended a staff meeting to describe the study, and also provided morning reminders about the study after shift change. The maximum potential sample size was 38 participants, but only eight RTs volunteered for this study.

Sampling

The sample was both a convenience and purposive sample (Trochim & Donnelly, 2008) as the intent of the study was to investigate the use of simulation in the RT profession as a means for re-certification and continuing education. RTs that wished to participate in the study were asked to sign a consent form (Appendix B). The consent form was attached to the study information letter and only those RTs that signed the informed consent form were included in the study. The participants returned signed consent forms to the investigator.

After informed consent was obtained, participants were randomly assigned to the control group or the intervention group by use of GraphPad QuickCalcs (Motulsky, 2013). Random assignment to either group was chosen to attempt to equalize the two groups in terms of any known or unknown confounding variables (Suresh, 2011). If

participants were asked to allocate themselves to the group they wished to participate in, it could be likely that the two groups would differ in a significant way. For example, it is likely that the type of RT that wished to sign up for an extra two hour education session to re-certify would be different from the RT that would prefer to sign up for the usual method of reading through the materials only. The differences that could account for such preferences, comfort and familiarity with simulation or eagerness and involvement in continuing education for example, could likely have an effect on research outcomes. Due to the small sample size available in this research study, it is possible that a simple randomization method may have resulted in unequal group sizes. For this reason, the method of block randomization was chosen to allow for roughly equal group sizes (Suresh, 2011). GraphPad: QuickCalcs software (Motulsky, 2013) was used to randomly select the way each group of participants was assigned to the study groups. This method is known as a two-phase block randomization (Vickers, 2006). GraphPad: QuickCalcs randomly assigned two participants to each of the two study groups, which produced blocks of four. With the resulting blocks of four there were six different ways that four participants could be assigned to the control and intervention group evenly. Even though random assignment of participants to the two groups was followed, due to the small sample size, sufficient scientific rigour in comparing test scores could not be realized.

Instruments

Pre and post-tests. The instrument that was used in this study had not been used previously. This was due in part to the lack of research investigating the use of HFS education with RTs for protocol recertification, but also because the tests had to be

specific to the health region's ventilation protocols. Therefore, the instrument was developed for this study and content validity and clarity was established by using a small expert panel that included the researcher, the health region's senior RT, the RT educator and the RT manager (Trochim, 2006).

Demographic survey and qualitative data. Data regarding participant select characteristics and other variables were collected using a demographic survey (Appendix C). Participants were asked to complete the survey after they completed the post-test. The survey asked for information regarding their age, number of years practicing as an RT, number of hours spent preparing for the post-test, and confidence participating in high fidelity simulation sessions and performing protocols. The survey also had four qualitative questions which asked participants to comment on the perceived advantages and disadvantages of their respective educational intervention and on their learning experience.

Data Collection

To complete the pre-test, all consenting participants arranged a time to individually write the pre-test under supervision of the investigator or a research assistant. At the time of the pre-test, all participants were given a package containing three coded identification stickers to use on the tests and the demographic survey as their personal identifier. Participants were instructed to affix a coded identification label to the pre-test rather than labeling the test with their names. Upon completion of the pre-test, participants in the control group were given the education package and a print out of the ventilation protocols being re-certified. Control group participants were given a deadline of one month for reviewing the educational material and protocols, and

completing the post-test and demographic survey. A time was coordinated with each participant in the control group and the investigator to complete the post-test and demographic survey. This ensured that educational material was not reviewed during the post-test.

A date on which the intervention group participants were scheduled to work on the same day was identified; then these participants were emailed to notify them the HFS session would be held on that date. Participants in the intervention group also arranged a time to individually write the pre-test and receive the same educational package and protocols as the control group. This occurred within three weeks of the scheduled HFS session. The HFS session was held on a Saturday afternoon and a research assistant provided workload coverage for participants to attend the HFS session. Two HFS sessions were held with two participants in each session. Each HFS session followed the outline found in Appendix D. Upon completion of the HFS session, participants completed the post-test and demographic survey while in the simulation lab. The investigator was present to ensure that the post-test was written individually without consulting written education materials. Again, all tests and surveys were labeled with the coded identification number given to the participant. This method protected participant's privacy while allowing the survey, pre and post-tests from each participant to be matched. The investigator, using an answer key, marked the pre and post-tests. All answers were multiple choice or fill in the blank.

Due to the very small sample size involved in this study, open-ended questions were added to the demographic survey to provide qualitative data. These questions asked participants to list the benefits and disadvantages of the educational intervention

to which they were randomly assigned. The survey also asked participants to comment on, if and why, their respective education method improved their perceived level of competence of the two protocols under investigation. Finally, both groups were asked if they had a preference for the HFS sessions or the self-directed learning method. All direct quotations answering the open-ended questions were reviewed and interpreted using thematic analysis. These themes were compared and contrasted between the two groups, control and intervention. This qualitative data adds to the study, as the quantitative data alone in such a small sample size will not be sufficient to allow for scientific rigour in the data analysis.

Ethical Considerations

Although re-certification of the ventilation-associated protocols are required annually by the health region's Respiratory Therapy department, it was important to ensure participants were aware that participation in the study was entirely voluntary and that they could withdraw from the study at any time (Morgan et al., 2006). Choosing not to participate did not affect an RTs standing in the department and they were to simply re-certify in the usual manner and their test scores would not be included in data analysis. Although the charge RT, RT educator and RT manager were supportive of the study and assisted with its implementation, they were not involved in data collection or analysis. Only the investigator, who did not hold a position of authority in the department, was involved in the data collection to ensure the RTs did not feel any power imbalance. Furthermore, to ensure fairness, all participants that were randomly assigned to participate in the control group were offered the same HFS education session as the intervention group upon completion of the study (Canadian Institute of

Health Research, 2010). These ethical considerations ensured that participants did not feel distress, or exclusion, as a result of participating in this study. Ethical approval of the study was received from both the Athabasca University Research Ethics Board and the health region's Research Ethics Board.

All paper versions of tests and surveys were kept in a locked filing cabinet. All electronic versions of data that contain identifying information were stored in a password-protected file on a password-protected computer to ensure participants' privacy (Morgan et al., 2006). The only people that viewed the data are the investigator and her thesis supervisor. The paper files will remain in a locked filing cabinet and the electronic data files will be password protected for five years at which time all paper versions of the data will be shredded and electronic files will be deleted.

Chapter Four: Results

Descriptive Statistics

All data analysis was completed using SPSS version 19. A total of eight RTs participated in the study out of the possible 38. All eight participants completed the study; none were lost in follow up. Of these eight participants, four were randomly assigned to the intervention group and four to the control group. The majority (75%) of participants were female, and half of the participants were in the 20 to 30 year age range, while half also had one to five years of experience working as an RT. Table 1 provides a summary of the sample's demographic data.

Table 1

Demographic Characteristics of Study Participants

Characteristic	N	Percentage (%)
Age (Years)		
20 – 30	4	50
31 – 40	2	25
41 – 50	1	12.5
51 and older	1	12.5
Gender		
Female	6	75
Male	2	25
Years as an RT		
1 - 5	4	50
6 - 10	1	12.5
> 10	3	37.5

Table 2 depicts the characteristics of participants between groups. This table aims to compare potential confounding variables. Due to the small sample size, statistical analysis of differences between the characteristics of the two groups was not possible, however from general observation it does appear that randomization provided generally even groups with a few exceptions. There are only slight variations in age

groups, years of professional experience and hours spent preparing for tests. However, there is a major difference between the two groups in terms of gender of the participants. Both male participants were randomized to the intervention group. Another variation is in terms of the number of hours spent preparing for the test compared to their usual way. This question aimed to determine if participants would spend more or less time studying due to the fact that it was a research study. For ethical reasons, scores were not shared with the department's leadership team. The intervention group had two participants who reported to have studied less than usual while the control groups' participants reported that they spent the same or more time than usual preparing. The variations amongst the groups could possibly impact test scores.

Table 2

Comparison of Participant Characteristics Between Groups

Characteristic	Control Group	Intervention Group	N
Age (years)			
20 - 30	2	2	4
31 - 40	1	1	2
41 – 50	0	1	1
51 and older	1	0	1
Gender			
Female	4	2	6
Male	0	2	2
Professional Experience (years)			
1-5	2	2	4
6-10	1	0	1
> 10	1	2	3
Preparation (hours)			
< 1	2	1	3
1-2	1	1	2
2-5	1	2	3
Preparation compared to usual			
Same as usual	3	2	5
Less than usual	0	2	2
More than usual	1	0	1

Test Scores Within the Group

In order to determine if the traditional method of education has an impact on test scores, the mean pre and post-test scores within the control group were to be analyzed using a related t-test. The same analysis was to be completed with the pre and post-test scores of the intervention group to also determine the impact the HFS education sessions had within this group's scores. However, due to the small sample size, the non-parametric Wilcoxon matched pairs test was completed. For the control group, the difference in pre-test and post-test scores did not reach statistical significance ($p=0.066$). Similarly, the difference in pre-test and post-test scores in the simulation group did not reach statistical significance ($p=0.068$). The difference in pre-test and post-test scores within the control group yielded a standardized test statistic of 1.84 and an effect size of 0.920. The difference in pre and post-test scores within the simulation group yielded a standardized test statistic of 1.83 and an effect size of 0.910.

Test Scores Between Groups

Using a Mann-Whitney U test, the distribution of total pre-test scores across both the HFS and control group were not different ($p = 0.200$). Post-test scores were then compared between the two groups to assess for any change in scores using an ANCOVA to enable to account for baseline scores since it is considered a co-variate The level of statistical significance was set at $p<0.05$. The results of the ANCOVA showed that there were no significant differences between the control and intervention group's post-test scores when pre-test scores were accounted for ($p = 0.905$). The 95% confidence interval for post-test scores in the control group was 32.6 to 42.7, and for the HFS group it was 31.3 to 41.4. Table 3 provides a summary of the HFS and control

groups test scores.

Table 3

Comparison of pre and post-test scores between groups

	Pre-test		Post-test	
	Control	HFS	Control	HFS
Mean	26	29.5	37.5	36.5
Median	25	29	38	36
Standard Deviation	5.1	2.6	4.4	1.9
Variance	26	7	19.7	3.7

To determine if there was an association between rating oneself as confident in administering the protocols under review and post-test scores, a Kendall's tau and Spearman Rho correlation were performed. A Kendall's tau b correlation of 0.248 ($p = 0.453$) and Spearman Rho correlation of 0.283 ($p = 0.496$) was not statistically significant. This indicates that there is a weak correlation between confidence rating and post-test scores, and that it was not statistically significant.

Qualitative Data Analysis

Advantages of Self-review

Convenience. When asked to list the advantages of completing the usual education package as a means to refresh knowledge of the protocols under investigation, it was consistently noted that the ability to "do it at your own convenience", "on your own time", and "study when [you] wanted" too was advantageous. The convenience of completing the learning package in accordance with the participants' own wishes and schedule was clearly a perceived advantage. The flexibility for participants to complete the package "as many times as you need to" and "not feel rushed" in order to feel competent with the protocols was also a perceived

benefit. Overall, the flexibility of using the learning package according to one's own preference was the main advantage to this learning method.

Competence. Participants were asked if reading the self-directed learning manual improved their competence in the application of the two protocols. All participants felt that it was beneficial to review the learning package. Participants felt that reading the learning package helped to "refresh my memory", "review material and background of information in the protocols as well as the procedure", "review theory of knowledge and made me more confident in set up and delivery". One reason for the value of this review was given as, "I tend to forget some of the back ground info after doing the protocols every day work." It was noted however that although reading the learning package was "good review" that participants would "have a paper copy" of the protocol in front of them when setting up Aerosolized Epoprostenol. This comment seems to question the need for such learning and review if the participant will not memorize the protocol anyway.

Disadvantages of Self-review

Some disadvantages of completing the self-directed learning module included the focus on theoretical knowledge as depicted by one participant's comment, "only know the theory, don't actually do." Another participants comment, "Usually learn things better when I perform them" depicts the disadvantage reading the self-direct learning module had due to the lack of practical application of the skills. The lack of guidance, support and feedback to assist with questions was also a commonly noted disadvantage from quotes such as, "no immediate feedback" and "no one to ask questions to." This method of learning was also perceived to be less interactive;

therefore learners would lose interest in the material. It is worth noting that the same autonomy and flexibility experienced when reviewing the self-directed learning module was also noted to be a disadvantage, since it required the participant to create time to read the material or take the initiative to study during breaks at work. This theme is adequately captured by one participant's quote, "No one wants to read at home and therefore if busy at work studying is neglected." From the participant's quotes it is evident that the lack of interaction, hands-on learning experience and structured time was a disadvantage to the self-direct learning module.

Advantages of a Simulation Session

Hands-on practice. Participants indicated the advantages of simulation included that the interactive and hands on style of learning resulted in better, more practical learning. Statements such as, "hands on experience a plus", "helps cement things that aren't often used" illustrate this point. Other comments included, *"*Able to ask questions when certain situations arise in simulation*"*, "able to ask questions and receive immediate answers." These quotes illustrate the opportunity HFS allowed participants to learn from each other and the simulation facilitator. One participant noted, "Discussions develop with others that bring other ideas to mind, and it helps to see other people's point of view" while another commented that HFS allowed participants to, "see how others do things and increase learning." The HFS education session also provided an opportunity to see how others completed the tasks and address any bad habits that RTs had developed during their years of practice. This practical hands-on learning also allowed the opportunity to practice trouble-shooting scenarios as one participant stated, "Hands-on with equipment set up is much easier than visualizing

what you need to do. Also, it allows you to make errors, see their outcomes and correct them." This benefit of making errors in a safe environment was also noted by another participant, "able to see what I'm doing right and wrong with protocols with hands on simulation." Other participants added, "Can actually practice with own hands what need to be done", "it allowed us to trouble shoot with [Aerosolized Epoprostenol] circuit set ups, that look straight forward on paper, but required some trouble shooting in real life." The opportunity for practical application of knowledge was deemed to be an advantage of simulation.

Participants were asked if HFS education improved their competence in the application of the two protocols under investigation. One participant felt that since she/he was very familiar and competent with the two protocols, the simulation education was not very useful. However, another participant noted that, "If it was on something that I wasn't very confident with then I believe that it would have helped a lot." Another participant felt that it was more helpful for one protocol over the other: the Aerosolized Epoprostenol protocol was deemed to be a "complicated process so hands on very helpful" while they felt that the self-directed learning packages was "dry reading." However, this same participant did not perceive the session to be as effective for the lung protective ventilation protocol as there are aspects of the protocol they no long feel are clinically appropriate; "do not follow the Fi02/PEEP recommendations."

Disadvantages of a Simulation Session

The same advantages of simulation learning were also listed as disadvantages of this learning method. It was noted that while simulation provided the practical, hands on portion of learning, the theoretical and background information could at times be lost

in the focus on completing the tasks; "some of the background information is lost, focus on task." The simulation session was deemed to be more "more time consuming if need to do recertification on day off" and difficult to arrange than completion of the education package as well. Although, the interaction between participants was noted to increase learning as an advantage of simulation, there were also concerns expressed that, "If done with multiple people may not get full experience." Similarly, this same teamwork may detract from an individual's ability to demonstrate knowledge as "working in pairs may not accurately reflect the knowledge of each party individually." The simulation sessions were not for testing or demonstrating competence but as a learning experience only, however it is clear that this participant was concerned about the opportunity to demonstrate their individual knowledge separate from their team member. The disadvantage of simulation, as perceived by the participants, appears to be the lack of convenience and the worry of obtaining a full experience while competing for simulation time with other participants.

Preference for Simulation or Self –Directed Learning

To learn which method of learning participants preferred after considering the advantages and disadvantages of the respective education interventions, participants were asked which method they would prefer and to explain why. One participant misinterpreted the question and did not directly answer while the remaining seven participants did answer. Four of those seven stated that a combination of simulation and self-directed reading to recertify ventilation protocols was preferred. One participant stated, "Simulation and reading, because you get to review [the] theory on own time, and then someone makes sure you are doing it right, and you are confident

with application." Another participant commented, "Probably both- read a package and then do a simulation. Read, to remind me and doing to reinforce the learning." Similarly, another participant noted that both simulation and reading would be best as, "Need both, but simulation is definitely a benefit especially if [you] haven't had hands on regularly. Good time to identify poor habits developed too, good time to learn from peers." Finally, the last participant in agreement with using both simulation and reading stated; "I like both reading material and hands on experience." In contrast one participant preferred self-directed learning, "because you can set your own schedule and spend as much or as little time as you need." The remaining two participants preferred simulation only. When asked which educational intervention they preferred one participant stated, "Simulation. Personally, I learn better with interactive, hands-on processes." The other participant who also preferred simulation commented, "Simulation, hands on, remember better, can see what I'm doing right or wrong from colleagues and instructor." Overall, the preference for simulation or a combination of self-directed learning and simulation was evident from the participants' comments.

Chapter Five: Discussion

This study aimed to provide quantitative data examining the impact a HFS session would have on test scores regarding two mechanical ventilation protocols, as compared to the usual read and review of the education package approach. Although the findings of the study are limited due to the small sample size, it does provide some initial quantitative data regarding the use of high fidelity simulation in this particular application. The qualitative data also aids in adding information provided by this study.

Although the study results failed to show statistical significance, it is of note that both the HFS and self-directed learning manual education approaches had similar, large effect sizes on post-test scores. From a quantitative aspect, this may indicate that the simulation education was approximately as effective as the standard read and review method of re-certifying in achieving an improvement in test scores. A study with a larger sample size would be required to determine if statistically significant differences are achieved. Hence, repeating the study with a larger population is recommended.

The ability of the study to detect statistically significant differences in test scores may be related to other limitations aside from sample size. One participant raised a perceived disadvantage of HFS as being the loss of focusing on theoretical background as one focuses on tasks and practical application of the protocols while being involved in the hands on session. It is also possible that a written test aimed at assessing participants' knowledge of the protocols failed to assess this aspect of learning. In a study by Jansson et al. (2014) simulation education used to improve nurses' familiarity with ventilator associated pneumonia prevention bundles also failed to show statistically significant increases in knowledge scores in both the simulation and control groups.

However, the study assessed scores not only on a validated multiple-choice questionnaire about ventilator associated prevention bundles, but also on an 86-item ventilator associated prevention bundle observation schedule. The observation schedule is used to ensure consistency in timing along with the aspects of the ventilator associated prevention bundle, which are observed for compliance by researchers. The simulation group did achieve statistically significant improved scores on the observation schedule compared to the control group. This indicates that although simulation did not have a significant impact on knowledge scores, it did on actual clinical skills (Jansson et al., 2014). The results found by Jannson et al. (2014) indicate that knowledge testing may fail to accurately capture improvement in implementing ventilator-associated protocols after simulation education. However a previous study has shown that there are small but statistically significant correlations between knowledge scores and clinical performance (Luedtke-Hoffman et al., 2012) while another demonstrated that any correlation between the two may be related to the focus of course content (Hauber et al., 2010). Further investigation into the variability in results and correlations between knowledge scores and clinical performance along with additional methods of assessment may be required in future studies assessing the impact of simulation education.

Despite similar effect sizes on improvement in post-test scores between the two study groups, the qualitative data suggests participant preference for use of both pre-reading and simulation for recertifying the mechanical ventilation protocols. Overall, when asked which method of education was preferred, of the seven responses, six indicated that combining HFS with some reading preparation was the preferred method

of education for recertifying these protocols. Observations made by the researcher during the HFS education sessions also lend themselves to the merit of HFS education. Observations included participants discussing the protocols under review and critically analyzing their use when participating in the education session. Participants discussed methods of setting appropriate positive end expiratory pressure (PEEP) and noted that updates to the protocol may be needed in the future. Additionally, participants raised some components of the protocols, as not being well followed or ignored in clinical practice and the reasons for such discrepancies between practice and protocol were discussed. The HFS education session appeared to the researcher to have provided a structured time and space for participants to discuss current practice issues and share knowledge about new emerging trends in the care of ventilated patients. It was also apparent from this observation that this teaching method could be useful for introduction of new policies and protocols. Although Brindley et al. (2008) discuss the use of simulation as a manner for introducing research protocols; it could also be useful in pre-screening new clinical protocols to be used in patient care. Simulation sessions could allow for critical reflection and familiarity of new protocols prior to attempting them on real patients, though this benefit would be difficult to capture in quantitative data.

The qualitative data collected in this study also provides insight into perceived advantages and disadvantages for the use of simulation to recertify ventilator-associated protocols. Although the use of simulation in this particular application is not adequately researched, it appears the comments made by participants within this study do coincide with those made by students in other simulation applications. For example, in a study

investigating third year nursing student's perceptions of HFS, a benefit of simulation was putting theoretical knowledge into practical application (Wotton, Davis, Button & Kelton, 2010). This same sentiment was captured within this study with quotes from participants such as, "read to remind me, and doing to reinforce the learning." The results of the two studies do differ however, in that the student nurses found a close relationship between the theoretical background information and the HFS education session (Wotton et al., 2010). In contrast, participants in this study found that a disadvantage of simulation was that the theoretical background could be forgotten as participants focused on the tasks within the simulation study. This is an interesting contrast between the perceptions of students and that of practicing RTs and may represent the differing experiences of the participants in their day-to-day interactions. Namely, students are immersed in theoretical learning's with simulation being the only practical, hands-on application whereas practicing RTs are immersed in the practical aspects of their profession thorough out the day providing patient care. This phenomenon requires further investigation as it may point to different educational needs between students and practicing healthcare providers.

Another similarity between this study's qualitative data results and that of Moule et al. (2008) is the opportunity simulation allows for collaboration. Participating RTs noted the value of working with their peers to discuss information and practices, see how others perform skills and learn from the facilitator as an advantage to simulation. Nursing students who attended five simulation session noted that there was an added benefit to their learning by collaborating with students from other programs during the sessions (Moule et al., 2008). Additionally, the nursing students were

supportive of simulation's use in education (Moule et al., 2008). The majority of the RTs in this study also supported the use of simulation by stating a preference for a combination of self-direct learning and simulation or simulation only as a means to recertify ventilator associated protocols.

The study found that there was a weak correlation between post-test scores and self-rated confidence in implementing the mechanical ventilation associated protocols. This study did not compare self-rated confidence scores pre and post educational interventions and therefore cannot comment on the impact the respective educational interventions had on perceived confidence ratings. However, perceived confidence has previously been shown not to correlate to quality indicators (Barsuk et al., 2009). As such the weak correlation to post-test scores may be non-significant and trivial in nature.

Limitations

A limitation in this study is the threat to its validity due to social interaction. Participants may have discussed test questions with one another before all participants had completed both tests. This is a potential source of contamination that could result in higher pre-test and post-test scores or post-test scores only. This may result in an exaggerated impact of respective educational interventions. It is also possible that the control group learned about the HFS education session from participants assigned to that group. This could have resulted in compensatory rivalry, where participants in the control group attempted to compete with the intervention group by discussing the tests. Conversely, participants may have ended up with resentful demoralization in which case significantly less effort would be put into the tests than would be if the study were

not taking place (Trochim & Donnelly, 2008). In an attempt to limit these threats to validity, participants were asked to keep test questions and interventions confidential until completion of the study. All participants randomized to the control group were also offered the opportunity to take part in the simulation education session if desired, upon completion of the study in an attempt to prevent compensatory rivalry or resentful demoralization. Despite these attempts to maintain internal validity of the study, the threat of social interaction limits the interpretation of the study results.

Another limitation of the study is in regards to the pre and post-test design. The pre-test is essential for comparing baseline knowledge of the two groups however the pre-test itself may have resulted in learning and/or motivated participants to self-learn areas of the protocols they were less familiar with. This may result in the pre-test being the main intervention rather than the HFS education session, however the use of an ANCOVA in statistical analysis will account for this. Furthermore, an event or natural maturation that occurs between writing the pre and post-test may have resulted in higher scores on the post-test rather than the intervention (Trochim & Donnelly, 2008). Examples include taking more time to review protocols and information, or a clinical opportunity presents to implement the protocol between writing the pre and post-test. In order to estimate these threats to the validity of the study, the survey portion included questions asking participants to compare the amount of time spent preparing for the post-test in this study to the usual amount of time they normally spent on other re-certification tests. Only one participant reported spending more time than usual preparing for tests in this study whereas all other participants reported spending the same or less amount of time than usual. These survey results indicate that this threat to

validity may be limited in this study. The time between the first pre-test writing to last post-test writing was also limited to three weeks in order to reduce the number of events and the amount of natural maturation that could occur within the study timeline. Finally, the pre and post-test design may limit the interpretation of the study results. In order to limit this instrumentation threat, a small panel of experts was used to assess the tests' content and clarity. This test validation process is important for maintaining the integrity of the pre post-test design and reducing this aspect of the study's limitation.

The generalizability of the study results is also a limitation of this study. Due to the size of the health region's RT department and the number of recruited participants, the small sample size limits the power this study has to reject the null hypothesis (Trochim, 2006). Furthermore, this specific, purposive sample limits the generalizability of these results to other health care professions and RT departments with different resources and protocols (Ferguson, 2004). However, this study will serve as a starting point for further research on the specific use of HFS education for recertification of ventilation protocols in the RT profession.

Significance Statement

The results of this research study provide initial data on the use of HFS for continuing education and re-certification of mechanical ventilation protocols in RTs. The quantitative research design was deliberately chosen as a means to provide a recommendation regarding future practices (Farrelly, 2013). Although the results of this study failed to reach statistical significance, the large effect sizes indicate that simulation is comparably effective to the usual read and review methods to recertify. The qualitative results of this study help better understand the barriers, benefits and

potential impact high fidelity simulation education has on continuing education and re-certification processes. Managers and educators can carefully use the results to decide if the high fidelity simulation education sessions are of sufficient benefit to justify the time, effort and resource use within their department. Furthermore, this study serves as a starting point for future studies regarding high fidelity simulation education as a method of continuing education and re-certification in the RT profession as literature in this field is currently lacking.

Future Research Studies

It is clear that the literature on HFS education is a field that is growing; there is an interest in future research to better understand the impact and potential this learning method has. From inter-professional education initiatives and quality improvement, HFS is an educational tool that has much potential (Klipfel et al., 2014). However, there remains a need to understand the transfer of skills gained in HFS education sessions to clinical practice and its impact on patient care (Blum et al., 2010). This study further highlights this need. Studies that assess high fidelity simulation education's impact on not only test scores, but skill assessments and clinical performance with larger sample sizes are needed to quantify the efficacy of HFS. The need for such studies as they relate to ventilation and care of the ventilated patient continues. However, studies at present tend to focus on physicians and nurses training for such skills rather than RTs (Corbridge et al., 2010; Jansson et al., 2014; Schroedle et al., 2012). The lack of quantitative data assessing HFS's impact on clinical practice, coupled with a paucity of RT representation and ventilation skills in simulation research

points to the need for further studies in this field (Blum et al., 2010; Matthews & Yachemetz, 2008).

Conclusion

This study provides some initial data on the use of HFS education for recertification of ventilation-associated protocols in RTs. Although the qualitative data obtained in this study is supportive of simulation's use for this purpose, the small sample size failed to allow for sufficient scientific rigour to provide the quantitative data as intended. Further studies with larger sample sizes are needed in order to provide the quantitative scientific rigour required to better understand the impact HFS has on continuing education in mechanical ventilation amongst RTs.

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Appendix A: Information Letter

Information Letter

Title of Study: Simulation Education for Recertification of Mechanical Ventilation Associated Protocols in Respiratory Therapists

Researcher: Bronwen Carling Masters of Health Studies Centre for Nursing and Health Studies Athabasca University Phone: 289-688-6063 Email: bcarling@lakeridgehealth.on.ca	**Supervisor:** Mariann Rich Assistant Professor Centre for Nursing and Health Studies Athabasca University Phone: 1-866-751-4231 Email: mrich@athabascau.ca
Site Principle Investigator: Jane Heath Registered Respiratory Therapy Educator Lakeridge Health Phone: 905-576-8711 ext 2525 Email: jheath@lakeridgehealth.on.ca	**Research Assistant:** Miranda Oppers Senior Respiratory Therapist Lakeridge Health Phone: 905-576-8711 ext. 4317 Email: moppers@lakeridgehealth.on.ca

I am a graduate student in the Master of Health Studies program at Athabasca University. I am inviting you to participate in a research study, which is part of my master's program. You do not need to decide to participate today and you may discuss your participation in the research project with anyone you feel comfortable with. Lakeridge Health has given me approval for this study to be conducted.

Purpose of Research

High fidelity simulation education is a new, exciting and costly form of education. It has been studied in students from many healthcare professions however information is lacking regarding its use as a continuing education method with Respiratory Therapists, and in particular with the skills surrounding mechanical ventilation. The reason for this research is to provide some quantifiable evidence regarding the use of high fidelity simulation education as part of the re-certification and competency maintenance of respiratory therapy skills surrounding mechanical ventilation.

Type of Research Intervention

Respiratory therapists that agree to participate in this research will be randomly assigned to one of two different groups. Both groups will complete a pre-test regarding their knowledge of a respiratory therapy policy regarding a ventilation protocol and adjunct skill. Both groups will also be asked to complete a survey regarding their demographics such as age group, and years spent practicing as a Respiratory Therapist. The first group will then follow the usual practice of reading the education package and

protocol before completing the post-test. The second group will complete a high fidelity simulation education session of no more than two hours in length regarding the protocol and skill before completing the post-test.

Participant Selection

All Lakeridge Health Respiratory Therapists are invited to take part in this research project. This includes RTs who work fulltime, part time or casual.

Voluntary Participation

Participation in this study is entirely voluntary. Not participating in this research project means that you will be asked to follow the usual re-certification process as set out by the Lakeridge Health Respiratory Therapy department and there will be no repercussions for choosing not to participate. You are free to withdraw from the research study at any time without penalty of any kind.

Duration

For those participants randomly assigned to the first group, it is expected that the pre-test will take approximately 30 minutes, the reading package and protocol can be done independently but is expected to take up to 2 hours, and finally the post-test will take approximately 30 minutes. Completion of the demographic survey is expected to take approximately 5 minutes.
For those participants randomly assigned to the second group, it is expected that the pre-test will also take approximately 30 minutes, the simulation education session will take a maximum of 4 hours, and the post-test will again take approximately 30 minutes. Finally, completion of the demographics survey is expected to take approximately 5 minutes.
The total time required to participate in the study will be approximately three to five hours depending on what group you are assigned to.

Risks

There are no foreseen risks associated with participation in this study. If you do not receive a passing grade on the post-test for this research project you will simply be asked to complete the usual test for Lakeridge Health's routine re-certification process which is required for those not participating in this study.

Benefits

All participants will have the benefit of accessing high fidelity simulation education sessions on the investigated ventilation protocols. Those participants assigned to the first group which does not participate in any high fidelity simulation education session during the research study, will be offered access to the same high fidelity simulation education session upon completion of the study should they wish to take part.

Re-imbursement

Participation in this study is voluntary and no compensation for your time or costs to participate in the study will be provided.

Confidentiality

Participation in this research study is confidential. Only those people that you wish to inform of your participation, or participate in simulation sessions along side you and the researchers will be aware of your participation. All test scores will be labeled using a coded identification number. Paper versions of the test will be kept in a locked filing cabinet and electronic versions of test scores will be kept in a password-protected file. A separate password protected electronic file will contain your name and coded identification number. Only myself as the researcher, and my supervisor from Athabasca University will have access to the data.

Results

Results of this study will be reported in aggregate numbers and no identifiable information on specific participants will be shared.

Right to Refuse or Withdraw

You do not have to participate in this research project and refusal to participate will not affect your standing in the Lakeridge Health Respiratory Therapy Department in anyway. You may also choose to stop participation in the study at any time and your choice to do so will be respected.

Who to Contact

You may ask any questions now, later or at any time during the research project. Should you have any further questions please contact any of the following: Bronwen Carling, phone # 289-688-6063, or email at bcarling@lakeridgehealth.on.ca; OR Mariann Rich, phone # 1-866-751-2431 or email at mrich@athabascau.ca.

The Athabasca University Research Ethics Board has reviewed this study. If you have any questions concerning your rights as a possible participant in this research, please contact Athabasca University Research Ethics Board at (780)-675-6718 or rebsec@athabascau.ca
Should you have any questions or concerns regarding your rights as a participant in this research study, or if you wish to speak with someone who is not related to the study, you may contact the Chair of the Research Ethics Board of Lakeridge Health at (905) 576-8711.

Thank you for your time and consideration,

Bronwen Carling
Graduate Student, Centre for Nursing and Health Studies
Athabasca University
Phone: 289-688-6063
Email: bcarling.lakeridgehealth.on.ca

Appendix B: Consent Form

Title of study: Simulation Education for Recertification of Mechanical Ventilation Associated Protocols in Respiratory Therapists

Researcher:
Bronwen Carling, RRT, HBSc.
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Jane Heath, RRT
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To be completed by the study participant:

	Yes	No
Do you understand that you have been asked to be in a research study?	☐	☐
Have you read and received a copy of the attached Information Sheet?	☐	☐
Do you understand the benefits and risks involved in taking part in this research study?	☐	☐
Have you had an opportunity to ask questions and discuss this study?	☐	☐
Do you understand that you are free to withdraw from the study at any time, without having to give a reason and without affecting your future in the department?	☐	☐
Has the issue of confidentiality been explained to you?	☐	☐
If YES, provide a phone number and/or email to be reached at: Phone #:_____ Email: _____		
Have you been informed that only the investigators will have access to the data?	☐	☐

I agree to take part in this study: YES ☐ NO ☐

_____	_____	_____
Print Participant's Name	Signature of Participant	Date

I believe that the person signing this form understands what is involved in the study and voluntarily agrees to participate.

_____	_____	_____
Print Researcher's Name	Signature of Researcher	Date

THE INFORMATION SHEET MUST BE ATTACHED TO THIS CONSENT FORM AND A COPY GIVEN TO THE PARTICIPANT

Appendix C: Demographic Survey

1. How many years have you been a practicing RT?
   a) Less than five years
   b) Five to 15 years years
   c) Greater than 15 years

2. What is your age range?
   a) 20-30years old
   b) 31-40 years old
   c) 41-50 years old
   d) 51 years or older

3. What is your gender?
   a) Male
   b) Female

4. How long have you worked as a Respiratory Therapist?
   a) Less than one year
   b) One to five years
   c) Five to ten years
   d) Greater than ten years

5. How would you rank your confidence performing the Aerosolized Epoprosterenol protocol?
   a) Very confident
   b) Somewhat confident
   c) Minimally confident
   d) Not at all confident

6. How would you rank your confidence using the Lung Protective Ventilation Protocol?
   a) Very confident
   b) Somewhat confident
   c) Minimally confident
   d) Not at all confident

7. How would you rank your comfort with high fidelity simulation education activities?
   a) Very comfortable
   b) Somewhat comfortable

c) Minimally comfortable
d) Not at all comfortable

8. When was the last time you initiated Aerosolized Epoprosterenol on a patient?
   a) I have never initiated Epoprosterenol on a patient
   b) Greater than a year ago
   c) Greater than 6 months ago
   d) Within the last 6 months

9. When was the last time you initiated the Lung Protective Ventilation Protocol on a patient?
   a) I have never initiated the lung protective ventilation protocol on a patient
   b) Greater than a year ago
   c) Within the last 6 months
   d) Within the last month

10. How satisfied were you with the education you received regarding these two protocols?
   a) Very Satisfied
   b) Somewhat satisfied
   c) Minimally satisfied
   d) Not at all satisfied

11. How many hours did you spend preparing for the post-test?
   a) Less than one hour
   b) 1-2 hours
   c) 2-5 hours
   d) More than 5 hours

12. How does the number of hours you spent preparing for the post-test compare to your usual preparation for recertification tests?
   a) I spent the same amount of time preparing as I usually would.
   b) I spent more time preparing than I usually would
   c) I spent less time preparing than I usually would

13. How confident are you in your ability to implement these protocols in a safe and efficient manner clinically?
   a) Very confident
   b) Somewhat confident
   c) Not very confident

d) Not at all confident

If you participated in the simulation session please skip to question #17. If you did not participate in the simulation session please complete questions #14 to 16.

14. What were the advantages of using the self directed learning manual for the recertification process?

15. What were the disadvantages of using the self directed learning manual for the recertification process?

16. Do you feel reviewing the self directed learning manual improved your competence in the application of these two protocols? Why or why not?

17. What were the advantages to participating in a simulation session for the recertification process?

18. What were the disadvantages to participating in a simulation session for the recertification process?

19. Do you feel the simulation sessions improved your competence in the application of these two protocols? Why or why not?

20. Which method of education, simulation or self directed learning manual, do you think you would prefer for preparation of recertification of ventilation associated protocols.

Appendix D: Simulation Session Plan

First scenario: Objective is to use Lung Protective Ventilation protocol, practice setting up Aerosolized Epoprosterenol and Manual Resuscitator set up, practice weaning Epoprosterenol according to protocol and discontinuing protocol.

1) A 5'10" male patient is currently intubated and ventilated with the following settings:

- PCV 20/10 RR 24 It 0.9 Fi02 90%
- Resulting Parameters are: Vt 600 ccs, MV 14.4 lpm Pp 30 cmH20
- ABGs on these settings are: pH 7.30/55/50/0.86/20
- The physician asks you to ensure the patient is ventilated according to the lung protective ventilation protocol and initiate the patient on a trial of Aerosolized Epoprosterenol

Expected changes:

PCV to achieve appropriate Vt range: 292 cc-584ccs, may increase RR, PEEP 14-18 cmH20
OR change to APRV

Aerosolized epoprosterenol set up: Dose (Pt's IBW is 73 Kg, round up to 80Kg therefore initial dose of 8.0 ml, no saline)

New ABGS:

7.32/48/79/0.92/21

Expected changes:

- Pa02 has increased by greater than 20% therefore considered a positive response
- Reduce dose to 40/ng/kg (6.4 ml Epoprosterenol and 1.6 ml saline)

You leave and come back the next day to find the patient on 10 ng/kg with the following ventilator settings:

PCV 20/8 RR 20 It 1.0 Fi02 40%
ABGs: pH 7.35/45/90/0.95/22

You are asked to wean the patient off of the Epoprosterenol

Expected reaction: Increase Fi02 to 50% for 20 minutes prior to D/C Epoprosterenol. After discontinuing Epoprosterenol assess ABGs.

ABGs: pH 7.35/45/50/0.86/22

Expected reaction: restart Epoprosterenol at 10 ng/kg

End of Scenario

Scenario 2- Objective: Recognize missing filter on expiratory limb, manually ventilate patient with epoprosterenol nebulizer in line. Assist with turning patient.

You receive report on a patient that has been set up on Flolan. The patient's ideal body weight has been calculated to be 70 Kg and the minimum effective dose has already been established at 30 ng/kg for this patient and the previous RT has begun to wean the Ventilator settings. Ventilator settings are:

PCV 16/10 It 1.0 RR 20 Fi02 75%

Most recent ABGs on these settings with Flolan at 30 ng/kg are:
pH 7.32/50/82/0.94/24

Shortly after giving report you are called stat to see the patient as the ventilator is alarming and the patient's blood pressure is beginning to drop.

HR 60 bpm, BP 70/40 Sp02 92%

Expected reaction: recognize high PEEP/occlusion alarm and that there is no additional double-walled filter prior to expiratory filter in line. Take patient off ventilator and manually ventilate with nebulizer in line while double walled filter is added and new expiratory filter is placed in line. Place patient back on ventilator.

New vital signs: HR 80 bpm, BP 110/70 Sp02 95%

RN tells you that the patient has gone all day without being turned. Now that the patient is more stable she needs to turn the patient to perform some nursing care.

Expected Reaction: recognize need to assist with turns and does so to ensure that Epoprosterenol is not spilled from nebulizer.

End of Scenario

Scenario 3- Objective: Practice using lung protective ventilation protocol, initiating Epoprosterenol, recognizing a non-response patient and discontinuing therapy according to protocol.

A 24 year old 5'6" woman is intubated and ventilated as follows:

PCV 22/8 It 1.0 RR 14 Fi02 100%

Vt 500 MV 7 lpm Pp 30

ABGS: 7.20/65/45/0.84/22

You are asked to ensure the patient is on the lung protective ventilation protocol.

Expected changes: Decrease PCV to achieve Vt in range of 240-480ccs, Increase PEEP and RR

ABGs: pH 7.30/55/68/0.91/22
HR 150 BP 75/46 Sp02 88%
Pt is being given Levo and boluses

Asked to trial Epoprosterenol

Expected reaction: Set up Epoprosterenol and initiate dose at 50 ng/Kg

Next ABG: pH 7.30/55/65/0.90/22

Expected change: Titrate to 30 ng/kg (3.6 ml Epoprosterenol, 4.4 saline) then off.

End of Scenario

Appendix E: Aerosolized Epoprosterenol Self Directed Learning Module

Human existence is dependent upon oxygen. It is the most essential substance required by the body and plays a critical role in the production of cellular energy. Through the cooperative effort of the cardiovascular and respiratory system, oxygen transport and delivery is possible so that sufficient sources are available to meet cellular oxygen demand. Failure of sufficient oxygen delivery to the cells will result in an inadequate production of cellular energy with death likely ensuing within minutes.

Basics of Oxygenation

The physiologic process of cellular oxygenation is a 3 stage process.

The first stage, external respiration, is itself a 3 stage process that initiates and enables process of oxygen delivery. The first stage, adequacy of ventilation is the gross movement of air into and out of the lungs. The second stage determines the quantity of oxygen exposed to capillary blood. (ventilation-perfusion (V/Q) match) and the third and final stage is the interface of V/Q whereby a sufficient allowance of time must exist so that a complete diffusion and equilibration of oxygen (O2 loading) into the blood supply within the lungs can occur.

The second stage of oxygenation, oxygen transport, is the movement of oxygen to its cellular destination and is dependent upon an appropriate amount of haemoglobin to carry oxygen and a capable cardiac output to deliver it to the cells.

Internal respiration is the final stage whereby oxygen is diffused from the capillaries into the cell (O2 unloading) in response to cellular metabolic needs in exchange for CO2.

Unfortunately in many disease states of the lung, the ability to facilitate internal or external respiration is often compromised by ventilation and/or perfusion inefficiencies.

Distribution of Ventilation

Characteristics of the pulmonary system cause gravity to have a significant effect on the distribution of ventilation and perfusion. As a result, dependent regions of the normal lung (the base when upright or dorsal when supine) will receive a greater portion of each.

Further, the distribution of ventilation throughout the normal lung is not uniform. Regional differences exist as a result of alveolar compliance and airway resistance. As a result, air flow follows the path of least resistance allowing preferential ventilation to occur in those areas where resistance is least and compliance is high. This is most evident when air is added to the normal lung during spontaneous tidal ventilation wherein the gravity-dependent basilar lobes receive the majority of gas while flow linearly decreases to the top of the lung. As a result, in the nongravity-dependent regions of the lung, airflow will exceed blood flow,

Disturbances of Ventilation

Any pulmonary disorder that leads to a change in compliance or resistance will concurrently offer a change in the distribution of ventilation. Increases in airway resistance may result from increased pulmonary secretions, bronchospasm, mucosal edema, tumours and artificial airways.

An abnormal functional Residual Capacity (FRC) also leads to redistribution of ventilation regardless if it is increased or decreased. Both of these situations will lead to

alterations in alveolar compliance throughout the lung as well as concurrent alterations to the distribution of inspired gases.

The application of positive pressure also disturbs the normal distribution of gases by increasing ventilation to the upper, anterior zones while simultaneously decreasing the perfusion to those areas.

Airway closure is a less recognized disturbance where positive intrapleural forces (as occur during a forced expiration) decrease the transpulmonary pressure (the difference between alveolar and pleural pressure) that then result in a compressive force being applied to the airways. When this occurs, airways that are not structurally supported collapse. These airways may include those that lack cartilage and those that are diseased. Because the dependent regions of the lung are prone to the lowest transpulmonary pressure, collapse will affect those regions first.

In healthy individuals, airway closure does not occur until expiration nears the residual volume (RV), if it occurs at all. However, in other cases (e.g., smokers, the obese, children and the elderly), particularly those with other underlying or predisposing factors (small airway disease, poor bronchial muscle tone, pulmonary edema, decreased elastic recoil and during forced expiration), airway closure may occur at higher lung volumes above FRC. This is often seen in individuals with severe emphysema. This early airway closure may also occur in susceptible individuals during tidal ventilation when FRC may be reduced as seen in those who are smokers, supine, under anaesthesia, obese, in pain or bedridden.

Compensatory mechanisms by the body may attempt to match ventilation to perfusion in some given lung segments mediated by localized increases in airway resistance in

response to a reduction or absence of perfusion. This response will decrease ventilation to the region. The resultant decrease in alveolar PCO2 appears to be the chemical mechanism that may enable muscle constriction of the airways that causes the increase in airway resistance. A decrease in surfactant production resulting from a lack of perfusion may also be responsible for this regional decrease in ventilation.

Distribution of Perfusion

Similar to ventilation, perfusion is also gravity dependent and as a result is not uniform through the lung and will vary with body position. Pertaining to perfusion, the lung has been described as a 3-zone model where the regulation and characteristics of perfusion varies in each zone.

Zone 1 is the upper-most area where perfusion is non-existent because alveolar pressure is greater than pulmonary artery pressure causing collapse of the capillary vessels. However, in humans a small amount of perfusion does exist but several factors can occur (a decrease in blood volume, cardiac output or right-sided heart function) that could lead to Zone 1 phenomenon.

Zone 2 provides a moderate level of perfusion where pulmonary artery pressure is greater than alveolar pressure.

Since the pulmonary circulation is a low-pressure system, blood flow increases linearly from the apices to the bases (Zone 3) where, due to greater hydrostatic pressures, perfusion may be 20 times greater.

A number of factors can alter this normal pattern. These include primary disturbances (pathologic changes in pulmonary perfusion) and compensatory disturbances (changes

in response to ventilation changes) where attempts to improve or to restore V/Q matching occur.

Disturbances of Perfusion

Primary disturbances are recognized as localized (pulmonary emboli, vascular tumours or drug induced) outcomes that alter the pattern of perfusion. These are more commonly recognized to result from generalized increases or decreases in pulmonary perfusion. Increases in pulmonary perfusion may be a consequence of an increase in cardiac output from the right side of the heart that causes a greater presence of blood within the lung or an outcome of poor left heart function (mitral stenosis; left-sided heart failure) and the pooling of blood in the lungs.

Conversely, a generalized decrease in pulmonary perfusion may be a product of inadequate blood volume or heart (pump) failure that cause a reduction in cardiac output. This decrease results in less perfusion to the upper lung zones which then contribute to the development of ventilation-perfusion inequality. Likewise, increases in pulmonary vascular resistance (PVR) as a result of pulmonary vasoconstriction may also decrease pulmonary perfusion. Normally, this can be compensated by an increased right-ventricular force but a weakened heart may not be able to pump blood through the constricted pulmonary vessels. As well, PVR may increase due to conditions that promote or cause hypoxemia or acidemia. These may include chronic conditions such as pulmonary fibrosis and pulmonary hypertension or acute illnesses such as Acute Lung Injuries (ALI) or Acute Respiratory Distress Syndrome (ARDS).

To a certain extent, compensatory mechanisms attempt to distribute blood flow to areas of the lung with maximal ventilation. Conversely, as lung volume decreases, more

perfusion is likely distributed to nondependent lung regions in an attempt to maximize the ventilation-perfusion interface.

Hypoxemia

The primary crisis of concern for any significant ventilation-perfusion inequality is the development of hypoxemia. Hypoxemia is defined as an abnormal deficiency of oxygen in arterial blood. Almost all events that cause hypoxemia (excluding changes in cardiac output) are a result of one or more of the following mechanisms.

1. Hypoventilation – ventilation that is less than metabolic need
2. Absolute shunting – blood shunts right to left with no alveolar oxygen exposure
3. Relative shunting – perfusion in excess of ventilation (V/Q mismatch)
4. Diffusion defects – a structural impedance to oxygen transfer in the lungs

When the lung becomes severely diseased and oxygenation becomes increasingly difficult, patients will increase their work of breathing to compensate. Oxygen is provided to lessen the work to breathe but as the patient begins to fatigue (CO2 retention develops) measures must be taken to alleviate distress and potential cardio-respiratory collapse. Despite increases in oxygen therapy, non-invasive or invasive ventilatory support is generally offered to avoid the toxic effects instituted by high oxygen-concentration delivery. Difficulties arise when hypoxemia remains refractory despite ventilatory assistance. It is then necessary to seek alternative therapies to resolve refractory hypoxemia. Advanced ventilatory modes (Airway Pressure release Ventilation or High Frequency Oscillation) may enhance lung recruitment to increase lung surface area to improve ventilation-perfusion inequalities. However, there are cases where ventilation becomes maximized and a means to improve the capabilities of

perfusion is necessary to increase oxygenation. Extra-Corporeal Membrane Oxygenation (ECMO) is one such means but it is not a readily available means of therapy, Therefore, the therapeutic use of prostacyclin, a selective pulmonary vasodilator (SPV) may offer some advantages to improve those ventilation-perfusion inequalities.

Prostacyclins

Prostacyclins (Prostaglandin I_2 [PGI_2] and Prostaglandin E_1 [PE_1]) are naturally occurring prostanoids that are metabolites of arachidonic acid found in the vascular endothelium. Within vascular smooth-muscle cells, prostacyclins bind to cell surface prostaglandin receptors and promote the activation of soluble adenylate cyclase which converts adenosine triphosphate (cATP) to cyclic adenosine monophosphate (cAMP). In turn, protein kinases (enzymes that affect ATP) mediate a cAMP-induced decrease in intracellular calcium and produce relaxation and vasodilation.

As a result, Prostaglandin I_2 and Prostaglandin E_1 are both potent pulmonary vasodilators and inhibitors of platelet aggregation. These properties strongly suggest a role in preventing clot formation in uninjured vessels and producing vasodilation in low resistance vascular beds such as the pulmonary circulation. PGI_2 has also been shown to stimulate endothelial release of Nitric Oxide (NO), another naturally occurring vasodilator found within the body. Intravenous use of prostacyclins has resulted in some benefit to patients suffering from primary pulmonary hypertension.

The use of inhaled prostacyclins was explored several years before the identification of nitric oxide as an endothelium-derived relaxing factor. However, during the 1990s there was extensive research on inhaled nitric oxide (iNO) as a vasodilator, in both animals

and humans. iNO significantly reduces the need for extracorporeal membrane oxygenation among near-term neonates who require mechanical ventilation. Due to this, iNO was approved by Health Canada and the Food and Drug Administration (FDA) in the United States for treatment of hypoxemia associated with persistent pulmonary hypertension of the newborn (PPHN). Unfortunately, its use in states of acute lung injury in the adult population has not been recognized by Health Canada or the FDA. Consequently, when used in the adult population, iNO is used off-label.

Aerosolized Epoprostenol

Epoprostenol Sodium (eg. Flolan ®) is a PGI_2 that acts as a potent inhaled vasodilator when aerosolized although when used as an aerosolized drug, it is also considered off-label. Despite this, several facilities have used inhaled PGI_2 in place of iNO and have noted equal success in case reports and observational studies. Of note, Inhaled PGI_2 is not significantly metabolized within the lung, and arterial concentrations of its inactive metabolite (6-keto-PGF1α) during therapy via inhalation are undetectable, suggesting that there is little absorption into the systemic circulation. In vivo, the half-life of Epoprostenol is 3 to 5 minutes.

This is unlike iNO. Inhaled Nitric Oxide does produce toxic metabolites that must be closely monitored. Further, iNO does have some technical complexities as well as capital equipment and administration costs to provide its therapy whereas Aerosolized Epoprostenol requires only minimal consumable equipment and is a fraction of the cost of iNO. As well, it possesses no known adverse reactions with other drugs.

As previously stated, hypoxemia causes vasoconstriction of the pulmonary vasculature by an important autoregulatory reflex known as hypoxic pulmonary vasoconstriction.

Hypoxic pulmonary vasoconstriction is intrinsic to the lung and is modulated by the endothelial and smooth-muscle cells, but the exact mechanism of this effect is unknown. The regulation of pulmonary blood flow by hypoxic pulmonary vasoconstriction contributes to both the efficiency of gas exchange and pulmonary hemodynamics.

Inhaled vasodilators, like Epoprostenol, offer several clinical benefits to acutely ill patients often found within the critical care unit. Through preferential distribution of PGI_2 to well ventilated areas of the lung, a selective pulmonary vasodilation can occur which allows a reduction in pulmonary artery pressure. The resultant redistribution of pulmonary blood flow to these ventilated lung regions occur with little or no systemic hemodynamic effects. The potential benefits of such targeted pulmonary vasodilation include reduced pulmonary vascular resistance (PVR), reduced right ventricular afterload, improved right heart function, better ventilation/perfusion (V/Q) matching, and improved arterial oxygenation.

As a result, the indications for use of aerosolized Epoprostenol parallel those stated above. These are:

1. Oxygenation Failure - Adult Respiratory Distress Syndrome (ARDS) or acute Lung Injury (ALI) with Refractory Hypoxemia (FiO_2 greater than 0.60 with SpO_2 less than or equal to 93%)
2. Acute, Reversible Pulmonary Hypertension (mean PAP greater than 25 mmHg at rest)
3. Right Ventricular (RV) Failure

While inhaled Epoprostenol has not been conclusively proven to improve outcome in any of the areas listed, it does possess strong physiologic properties and has shown clinical benefit. Therefore, a trial of this therapy may be warranted in the clinical situations described above.

The safe delivery to the patient is done under a protocol method in which dosing is coordinated by patient response to therapy. The provision and management of Aerosolized Epoprostenol is described in the Lakeridge Health Aerosolized Epoprostenol Management policy and is summarized within the Appendix 4 algorithm included in the management policy.

Benefits in Acute Lung Injury and Acute Respiratory Distress Syndrome

Acute Lung Injury (ALI) is a condition in which the normal barriers to fluid within the lung are disabled resulting in an accumulation of fluid within the lung parenchyma and alveoli. This is a result of widespread microvascular injury throughout the lungs causing increased permeability and fluid filtration so that protein-rich fluid enters into the pulmonary interstitium. The acute hypoxemic respiratory failure that arises is a result of a non-hydrostatic pulmonary edema that subsequently develops.

Adult Respiratory Distress Syndrome (ARDS) occurs as a consequence of a variety of critical illnesses with diverse causes and is characterized by a greater level of hypoxemic severity than ALI. This is a consequence of intrapulmonary shunting, areas of low $\dot{V}/\dot{Q}$ and pulmonary hypertension resulting from elevated pulmonary vascular resistance. Patients with ARDS also tend to have coexisting failure of other systemic organs that may congruently lead to a multi-organ dysfunction syndrome (MODS).

The use of selective pulmonary vasodilators like aerosolized Epoprostenol may offer some therapeutic advantages to improve ventilation-perfusion matching. Epoprostenol has been found to produce a selective pulmonary vasodilation largely identical to that produced by INO. As well, both agents have produced comparable increases in the PaO2 whereas inhaled PGI_2 has produced a greater reduction in PVR. Neither agent decreased systemic arterial pressure.

Theoretically, this benefit occurs because a selective pulmonary vasodilator (SPV) will only be delivered via the inspiratory gas to areas of lung that are open and ventilated. Upon delivery, the SPV's short duration of action exerts its vasodilator effect on pulmonary vessels within the ventilated lung unit. This, in turn, improves blood flow to the ventilated regions, which is a heterogeneous/regional process in ARDS, and offers improvement to the $\dot{V}/\dot{Q}$ mismatch that exists. The selectivity demonstrated by these agents is twofold. The first is with respect to the effect only on the pulmonary and not the systemic circulation. The second is due to the effect only on vessels within ventilated lung units. Currently, there is sufficient evidence to support the role of aerosolized prostacyclins as a SPV for hypoxemia due to ARDS, in addition to its use in the treatment of pulmonary hypertension.

Benefits in Acute Reversible Pulmonary Hypertension

Intravenous prostacyclin therapy offers a known benefit to patients with pulmonary hypertension but acute pulmonary hypertension also develops early in ARDS. Pulmonary hypertension and the consequential right-ventricle dysfunction often seen in ARDS patients may correlate with the severity of lung injury as well as be a predictor of a higher subsequent mortality. The primary causes of this pulmonary hypertension are

mechanical obstruction of the pulmonary microcirculation by microthromboemboli (composed of platelets and leukocytes) and hypoxic pulmonary vasoconstriction from alveolar and interstitial edema triggered by inflammatory mediators. To the patient's benefit, Epoprostenol's antithrombotic and platelet-disaggregation effects may help prevent the obstruction of pulmonary microcirculation (endarteritis obliterans, inflammation, and fibrous tissue formation of the arterial inner wall) that is commonly seen post-mortem in ARDS patients.

Benefits in Right Ventricular Failure

The pulmonary circulation is normally a low-pressure, low-resistance circuit that is highly distensible with recruitable vessels that can accommodate large increases in cardiac output. Acutely or chronically elevated pulmonary artery pressure increases PVR and right-ventricle afterload (the resistance the right ventricle pumps against) and results in a progressive inability of the right ventricle to sustain its flow output (decreased right ventricular stroke volume and right-ventricular ejection fraction). This eventually leads to elevated right-ventricle end-diastolic volume, right-ventricle hypertrophy, and right-ventricle failure and in extreme cases can lead to left-ventricular pump failure in critically ill patients and higher mortality. The use of aerosolized prostacyclins may reduce right-ventricle afterload by decreasing PVR and pulmonary artery pressure which is an important goal in the management of acute right-heart failure.

Further, inhaled prostacyclins cause minimal systemic vasodilation, are anti-inflammatory, and inhibit platelet aggregation. As a result, they may be effective against the severe refractory hypoxemia and pulmonary hypertension-induced right-

ventricle dysfunction witnessed in severe ARDS without causing any systemic compromise.

Conclusion

Inhaled prostacyclins have been well documented to fulfill the role as efficacious selective pulmonary vasodilators. Delivery is done under a restrictive dose capacity protocol described in the Aerosolized Epoprostenol Management Policy. The required protocol, equipment and special considerations for its use and the adverse effects that may result are also found within this document.

Resources

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Appendix F: Lung Protective Ventilation Self Directed Learning Module

Introduction

Mechanical ventilation, although necessary to save lives of patients with respiratory failure, can itself be detrimental to the patient. Mechanical ventilation is known to cause both macroscopic and microscopic injury to patients' lungs and is called ventilator induced lung injury. The term macroscopic ventilator induced injury includes barotrauma with the development of pneumothoraces or subcutaneous emphysema. These complications are associated with high tidal volumes, plateau pressure and minute volume requirements. These risk factors are exacerbated when the patient has ARDS or a history of lung conditions such chronic obstructive pulmonary disease. Microscopic lung injury involves damage to the endothelial and epithelial lung cells. Injury of this type results in damage to the alveolar-capillary membrane and release of inflammatory mediators that can further perpetuate not only lung injury but systemic effects as well (Lipes & Lellouce, 2011).

Pathophysiology of Ventilator Induced Lung Injury

Volutrauma

As stress and strain on the alveolar endothelium and epithelium cause damage resulting in leaking of fluid and proteins into the alveoli, pulmonary edema and areas of high surface tension develop. This does not result from high airway pressures in particular but rather lung volumes and end-inspiratory stretch (Siegel & Hyzy, 2013).

Atelectrauma

This refers to the injury caused to the lungs when areas of alveoli go from being collapsed to re-expanded (Siegel & Hyzy, 2013).

Biotrauma

Over distension and cyclical recruitment/de-recruitment of lungs (Volutrauma and atelectrauma) may result in an increase in lung cytokines and other inflammatory mediators. The inflammatory mediators may worsen lung injury but also produce systemic effects, as the lung capillaries are simultaneously more permeable due to injury. (Lipes & Lellouce, 2011).

The role of Ventilation Settings

With the potential injury to patient's from mechanical ventilation it is important that Respiratory Therapists follow best evidence to mitigate further injury from mechanical ventilation. This is possible by following guidelines for ventilation setting for lung protection.

Pressures and Volumes

To limit injury to the patient due to barotrauma, plateau pressure should be maintained at less than 30 cmH20 and to limit volutrauma from alveolar over distension tidal volumes in the range of 4ml/kg to 8 ml/kg should be used. It is also important to ensure that a patient's ideal body weight rather than actual body weight is used to determine tidal volume ranges as actual body weight may result in the overestimation of appropriate tidal volumes (Lipes & Lellouce, 2011). Several studies have shown that limiting tidal volume reduces mortality (Siegel & Hyzy, 2013).

Permissive Hypercapnia

As lower tidal volumes are used, respiratory rates will need to increase to maintain minute ventilation however respiratory rates will be limited by the development of auto peep. As such, it may be necessary to tolerate higher carbon dioxide levels in order to limit alveolar over-distension. To reduce dead space ventilation, consider removing flex tubing and switching to a heated humidifier rather than an HME (Siegel & Hyzy, 2013).

Open Lung Ventilation

To limit injury caused by atelectrauma higher PEEP can be used to maintain recruitment of alveoli. Furthermore, as Fi02 greater than 60% is associated with atelectasis due to denitrogenation of alveoli, reducing Fi02 to values less than 60% and accepting Sp02 ranges of 88-92% is important in lung protective ventilation (Lipes and Lellouce, 2011). In patient's requiring Fi02>60% consider using recruitment maneuvers and/or APRV.

References:

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Appendix G: Lakeridge Health Ethics Approval

RESEARCH REVIEW RATING FORM

The Research Department and REB are to use this form to inform the PI of the status of the study.

Principal Investigator: Jane Heath; Student: Bronwen Carling

Study Title: Simulation Education for Recertification of Mechanical Ventilation Associated Protocols in Respiratory Therapists

Date of Rating:	Status Update for:
	Approval to Commence Study
	Administrative Review
December 2, 2013	REB Review

Approval to Commence Study

☐ REB Approval Not Required. Study is approved to commence.

☐ Final Approval. Both administrative and REB approvals received. Study is approved to commence. Attached is the *Notification of Research Study to Commence* (cc identified programs).

Administrative Review Rating

☐ "Administrative Approval": impact assessment and contract are approved. However, study cannot commence pending REB Approval.

☐ "Administrative Denial": administrative approval not granted because:
[ ] Impact Assessment is not approved
[ ] Contract is not approved

REB Review Rating

☒ "Full Approval – No Revisions Required": scientific and ethical review are approved; however, study cannot commence pending Administrative Approval.

☐ "Approval Pending – Minor Revisions". See recommendations below. Submit revisions to REB as soon as possible.

☐ "Not Approved – Major Revisions Required". See recommendations below. The study must be re-submitted for consideration at subsequent REB meetings.

☐ Clarification Requested.

Recommendations / Additional Comments:

Nicole Stevens December 3, 2013
Research Liaison Date

Note: the study status - by its RID# - will be updated on the LH Intranet Wave as:

- "Active" with expiry date, or
- "Closed" with closure date.

*** NB: Under absolutely no circumstances can a research study commence at LH without the *Notification of Research Study to Commence.***

Appendix H: Athabasca University Ethics Approval

MEMORANDUM

DATE: February 7, 2014

TO: Bronwen Carling

COPY: Marianne Rich (Supervisor)
Dr. Vive Kumar (REB Chair)
Alice Tieulié, Acting REB Secretary

FROM: Dr. Sherri Melrose, Chair, Centre for Nursing & Health Studies Research Ethics Review Committee

SUBJECT: **Revised Ethics Proposal CNHS 13-06:** "*Simulation Education for Recertification of Mechanical Ventilation Associated Protocols in Respiratory Therapists*"

The Centre for Nursing & Health Studies (CNHS) Research Ethics Review Committee, acting under authority of the Athabasca University Research Ethics Board to provide an expedited process of review for minimal risk student researcher projects, has reviewed the above-noted proposal and supporting documentation

I am pleased to advise that the above noted project has now been awarded **APPROVAL TO PROCEED.**

You may begin your research immediately.

This approval of your application will be reported to the Athabasca University Research Ethics Board (AU REB) at their next monthly meeting. The AU REB retains the right to request further information, or to revoke the approval, at any time.

The approval for the study "as presented" is valid for a period of one year from the date of this memo. If required, an extension must be sought in writing prior to the expiry of the existing approval. **A Final Report is to be submitted when the research project is completed.** The reporting form is available online at: http://www.athabascau.ca/research/ethics/ .

As implementation of the proposal progresses, if you need to make any significant changes or modifications, please forward this information immediately to the Centre for Nursing & Health Studies Research Ethics Review Committee Chair via sherrim@athabascau.ca for further review.

If you have any questions, please contact the Centre for Nursing & Health Studies Research Ethics Review Committee Chair (above) or the Research Ethics Board office at rebsec@athabascau.ca

I wish you all the best with your research.