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Educating Oncology Nurses with Simulation: A Chemotherapy Spill

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EDUCATING ONCOLOGY NURSES WITH SIMULATION: A CHEMOTHERAPY SPILL

by

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Abstract

The purpose of the QI project was to determine if the use of a simulated chemotherapy spill increased the competencies and confidence of oncology nurses employed on an inpatient chemotherapy unit. An educational QI design was utilized including a confidential voluntary pre and post intervention survey. The simulations were held on a 25 bed oncology unit. Twenty-nine RNs participated. The simulation objective was to locate and follow the current hospital policy, the MSDS for the particular drug and clean up the simulated spill based on the current policy. Twelve simulations were conducted. Only 20.6% of RNs had been previously exposed to a chemotherapy spill. More than half of RNs felt the simulation resembled real life and all felt that the simulation very much or somewhat prepared them to handle a chemotherapy spill. The results of the comparable questions were all statistically significant ($P = <0.001$) and suggest that the simulation did increase the nurses' awareness of and comfort in locating the current hospital policy and MSDS. RN's reported increased knowledge of the contents within a chemotherapy spill kit and an increase in feeling prepared to deal with a spill in the future. An unintentional finding revealed omissions and discrepancies in the current policy. Future research to include larger cohorts in multiple oncology settings is needed to support educating nurses with simulation. Simulation may also be useful in creating, reviewing and revising policies.

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Background/Statement of the Problem

Since the passing of the Affordable Care Act (ACA), an estimated 32 million newly insured patients have put a demand on the need for educated competent nursing personnel. Along with the influx of patients, the ever-changing advances in technology have also increased the need for new and improved educational programs. With nurses being the largest population in healthcare, the Institute of Medicine (IOM) has paired with the Robert Wood Johnson Foundation to examine ways to improve healthcare. A key concept discussed in the IOM's future of nursing report (2011) is, "nurses should achieve higher levels of education and training through an improved education system that promotes seamless academic progression"(pg.S5). The report stresses that the educational competencies need to be improved for both pre and post nursing licensure. Also noted was the lack of correlation between continuing education and competency. The authors suggest a change in educational practices. One suggestion is the inclusion of simulation technology in nursing education programs (IOM, 2011). Most importantly, the education provided to future nurses must be based on providing an education with the tools needed to demonstrate, evaluate and improve standards, quality and safety of patient care (IOM, 2011). Through a review of the literature, it has become evident that Human Patient Simulation (HPS) is being used in more health care curricula and is associated with improvements in patient safety, improved assessment skills and self-awareness. The use of simulation allows nurses to practice in a safe environment where they are allowed to make errors without harming an actual patient and learn from their actions (Jeffries, 2013).

In 2004 the National Institute for Occupational Safety and Health (NIOSH) posted an alert geared toward healthcare workers to increase awareness in preventing occupational exposures to antineoplastic drugs used in the health care settings. The alert emphasized the risks that exposure to hazardous drugs such as chemotherapy may cause

healthcare workers. Effects from exposure can include skin rashes, infertility, miscarriages, birth defects, and even the possibility of developing leukemia or other cancers (Center for Disease Control and Prevention [CDC], 2004).

During the handling and administration of any hazardous drug such as chemotherapy, there is always a potential for an unintentional leak or spill. Chemotherapy spills are rare and nurses are often inexperienced and lack knowledge in the proper technique of containment and disposal of spills. Unfortunately, there is a scarcity of information regarding the procedure in handling spills. The current education in regards to chemotherapy spills for oncology nurses is integrated in the Oncology Nursing Society and Oncology Nursing Certification Corporation (ONS/ONCC) Chemotherapy Biotherapy Certificate Course. The course provides each nurse with 15 continuing education credits and a provider card for the administration of chemotherapy. The course covers an overview of all aspects involved in chemotherapy including the biology, physiology, patient education, administration and side effects of chemotherapy. One chapter is dedicated to the safe handling and disposal of hazardous drugs. Only a few pages are dedicated to chemotherapy spill management. A chemotherapy spill cleanup video is offered as an option and is noted in the margin of the text. At the conclusion of the online course, the nurse may or may not receive a test question in relation to a chemotherapy spill as there are many formulations of the test (Polovich, & LeFebvre, 2014).

Fortunately, chemotherapy spills do not occur very often. Spill kits are placed into the patient's room and never opened which leaves the nurses inexperienced in the handling and use of the contents within the antineoplastic kits. During one of the online Oncology Nursing Society Chemotherapy Biotherapy certificate courses, nurses from around the United States were commenting on the need for further training in the area of chemotherapy spills. Some direct quotes from a few nurses during the interactive portion of the online course include:

> "I love the idea of having a mock "spill drill". It would be a great learning experience for all staff members."
>
> "I agree with the mock spill drills too! I feel like the few times I've been involved with a chemo spill, it's been stressful and frantic, and we're not always sure what to do (depending on the size/type of drug). Doing a drill once a month or every few months would definitely increase everyone's comfort level."
>
> "I agree with the "mock code" idea as well. As part of our yearly Safe Handling of Biohazardous Medication check off, we watch a video, but hands on would be more valuable."

In addition, several nurses on the oncology unit have stated that they have never seen the contents of a spill kit out of its package (Personal Communication, June 2015).

At The Miriam Hospital the protocol for the administration of chemotherapy includes having a spill kit available at the site of administration. Information is provided to guide nurses in the event of a chemotherapy spill in the Miriam Hospital policy NU-53, Antineoplastic Agents (chemotherapy), containment and disposal of spills. The policy is located on the intranet and states, "It is the responsibility of the Registered Nurse (RN's) who administer antineoplastic agents to respond to a cytotoxic spill..." (Lifespan, TMH, 2014, p. 1), (Appendix A). A RN should feel comfortable and confident with this level of responsibility when the need arises to utilize an antineoplastic spill kit.

The purpose of the quality improvement (QI) project was to determine if the use of a simulated chemotherapy spill increased the competencies and confidence of oncology nurses employed on an inpatient chemotherapy unit. The QI project was an educational quality improvement design that included both a pre and post intervention survey to measure the oncology nurses levels of competence and confidence during a chemotherapy spill. The simulation was based on and guided by the current Miriam Hospital Antineoplastic Agents (chemotherapy), containment and disposal of spills policy, revised in May (Lifespan, TMH, 2014).

Literature Review

A review of literature was conducted using OVID Medline (R) and Google Scholar. Key words searched included simulation in healthcare; simulation in healthcare and nursing; simulation in healthcare nursing and education in acute care setting; simulation, oncology, nursing and competencies. The amount of information available in relation to simulation in healthcare revealed over 470,000 articles. The search was narrowed to include only articles that were in English, full text and peer reviewed articles. Articles pertaining to radiation oncology, pediatrics, gynecology or psychology were eliminated. The period searched was mainly narrowed to 2005-2015 except for the information gathered for history purposes, no time restrictions were utilized.

Cancer

According to the Centers for Disease and Control and Prevention (CDC), the leading causes of death in the United States in 2014 included heart disease, cancer, chronic lower respiratory diseases, unintentional accidents followed by strokes (CDC, 2016). Cancer is a large concern for the US citizens as it is the second leading cause of death. In 2015, roughly 1,658,370 new cases of cancer will be diagnosed. This figure does not include cancers that are not reportable to the CDC such as noninvasive, basal or squamous cell skin cancers (American Cancer Society (ACS), 2016). Cancer is defined by the National Cancer Institute as:

> A term for diseases in which abnormal cells divide without control and can invade nearby tissues. Cancer cells can also spread to other parts of the body through the blood and lymph systems. There are several main types of cancer. Carcinoma is a cancer that begins in the skin or in tissues that line or cover internal organs. Sarcoma is a cancer that begins in bone, cartilage, fat, muscle, blood vessels, or other connective or supportive tissue. Leukemia is a cancer that starts in blood-forming tissue, such as the bone marrow, and causes large numbers of abnormal blood cells to be produced and enter the blood. Lymphoma and multiple myeloma

> are cancers that begin in the cells of the immune system. Central nervous system cancers are cancers that begin in the tissues of the brain and spinal cord. Also called malignancy (National Cancer Institute (NCI), 2016, para. 1).

Approximately 14.5 million people in the US were living with a diagnosis of cancer in 2014. The diagnosis effects each person in a different way. Some receive active treatments and others may have finished their treatments and may be living with no further signs of the disease. Approximately 1,620 Americans die each day from a cancer related death. That is the equivalent to 589,370 deaths in 2015 due to cancer (ACS, 2016). Although these figures are high, we have been seeing a downward trend in deaths over the last few years. The Northeast had greater than a twenty percent decrease in the number of deaths from cancer, as compared to the lowest decline seen in the South of approximately fifteen percent. It is estimated that 29,000 people avoided death from cancer in 2011 (Seigel, Miller, & Ahmedin, 2015). The five-year survival rate for all types of cancer was 69 percent between the years of 2005 and 2011, a significant increase from the years 1975 to1977 at which there was only a 49 percent survival rate. The increase in survival can be attributed to earlier diagnosis and advances in treatment modalities (ACS, 2016).

Cancer treatments.

Cancer treatment plans vary greatly from patient to patient and depend on the diagnosis, staging of the cancer, clinician recommendations and patient requests. Treatment options may consist of chemotherapy, biotherapy, surgery, radiation or a combination of the above. Expectations of care will also guide the treatment option decision. Therapy will be decided upon depending if the patient is seeking full cure with complete treatment, palliative care with treatment geared toward symptom relief or comfort care only. (Polovich, Olsen, & LeFebvre, 2014). For the sake of this paper, we will concentrate on chemotherapy and biotherapy as the treatment.

Chemotherapy refers to cytotoxic drugs used to treat tumors. There are multiple formulations of cytotoxic drugs and treatment depends on the type and site of the malignancy. The drugs are administered systemically and attack the body's cells during specific phases of replication. The drugs are not able to discriminate between healthy cells and cancer cells therefore, they tend to cause overall damage and have multiple treatment complications. Newer drugs based on genetic makers have a targeted approach to cell death and decrease the incidence of complications (Polovich et al., 2014).

Several side effects and complications can arise when systemic chemotherapy is admistered, many can be life-threatening. Myelosuppression, a side effect of chemotherapy, is a limited production of red, white and platelet cells within the bone marrow (NCI, 2016). Myelosurppression is a dose limitiing toxicity and leads to neutrapenia, anemia, thrombocytopenia and pancytopenia (Polovich et al., 2014). Hallek et al.(2008) defines the grading guidelines for cytopenias from grade zero to five. Grades three and four are considered severe to life threatening toxicities. Hemoglobin (Hgb) and platelet (Plt) levels are graded according the the percentage of decrease from a patients' pretreatment level. A grade three toxicity is defined as a 50 to 74 percent reduction in Hgb or Plt level and anything greater than a 75 percent reduction a grade five toxicity (Hellek et al., 2008).

Neutropenia is a low number of circulating neutraphils. An absolute neutraphil count of greater than 500 but less than 1000 microliters (mcl) is severe, a decline to less than 500 mcl is life threatening as the ablity to fight infection is severly diminished.

Other serious infusion related complications may occur such as extravasations. Extravasation is when the cytotoxic drug leaks onto or under the skin. Some extravasation reactions can be as mild as an irritation or a flare reaction causing redness and local uticaria, while if a vessicant is to extravasate it may cause major skin peeling and even necrosis of that limb (Polovich et al.,2014).

Protocols for administration of chemotherapy.

A search of the literature revealed studies in relation to specific treatment protocols related to a specific adverse reaction, such as nausea and vomiting, or treatment protocols for specific cancers. Literature on administration of chemotherapy was found to be in the form of guidelines or position papers. The Infusion Nurse Society (INS) feel that a nurse should recieve specialty training and or be certified in the specialty to be able to administer chemotherapy. The INS recognizes that the administration of antineoplastic agents may acompany complications in which the nurse should be prepared to address. These complications may include myelosuppression, skin or eye irritations, nausea, vomiting, congenital malformations and fetal loss. Knowledge of safe handling and disposal of antineoplastic agents is important for proper administration, patient education and safety (Infusion Nurse Society, 2002). The American Society of Health-System Pharmasists (ASHP) published guidelines on preventing medication errors related to antineplastic agents. The guidelines define a medication error as, " any preventable event that may cause or lead to inapropriate medication use while the medication is in the control of the health care provider, patient or consumer" (ASHP, 2002, p.1648). As a health care provider responisble for the administration of antineoplastic drugs it is imperitive to be competant in drug identification, proper administration, safe handling, disposal of contaminated items, adverse events and potential interations of the

medications. Each facility should have a plan for competency review to assure that skills are retained and practice is updated as technologies change and evidence based practices emerge (ASHP, 2002, INS, 2002, & Polovich et al., 2014).

Simulation

According to the International Association for Clinical Simulation and Learning (INACLS), simulation is defined as, "A pedagogy using one or more typologies to promote improved and/or validate a participants progression from novice to expert" (Ulrich & Mancini, 2014, p. 6). The Merriam-Webster online dictionary defines simulation as "something that is made to look, feel, or behave like something else especially so that it can be studied or used to train people (Merriam-Webster, 2016). Gaba (2004) has defined simulation as "a technique, not a technology, to replace or amplify real experiences with guided experiences, often immersive in nature, that evoke or replicate substantial aspects of the real world in a fully interactive fashion"(Gaba, 2004, p.i2).

History of simulation in nursing.

Nursing has used simulation for well over a hundred years through the use of role-playing and practicing skills on foods such as injecting needles into oranges. The first simulation mannequin, Mrs. Chase, was created in Rhode Island for use at Hartford Hospital in 1911. The mannequin was created to train health care workers on how to dress, turn and transfer a patient (Weir, 2012). Since the creation of Mrs. Chase, technology and medicine have come a long way. Arabella, another mannequin was created in 1914 and allowed nurses to practice administering injections. In the 1940s, the first male mannequin was provided to the army to assist in teaching medical care (Aebersold, 2016). The capabilities of simulation have expanded to include low, medium and high fidelity human patient simulators. The level of fidelity correlates with the level in which the simulation experience conveys a real life situation. For example, a low fidelity situation may consist of a non-responsive full or partial manikin primarily used to

task train a nurse. A medium fidelity simulator provides the nurse with some isolated feedback such as specific heart or lung sounds. A high fidelity simulator provides the nurse with more of a real life like situation that alters as actions are taken. The high fidelity human patient simulator moves and mimics real life events such as, a patient experiencing a seizure or anaphylaxis (Ulrich &Mancini, 2014).

Simulation in nursing education.

In 2009, the National Council of State Boards of Nursing (NCSBN) conducted a pilot study with the purpose of examining the differences in clinical performance, knowledge and levels of confidence between cohorts of students in various learning settings. The study consisted of 58 senior baccalaureate degree nursing students divided into 3 cohorts: 30 hours of simulation without clinical, 30 hours of clinical without simulation and 15 hours of clinical with 15 hours of simulation. Students were randomly assigned and a pre- and posttest design was utilized. The researchers did not find a significant difference in knowledge acquisition, retention or clinical performance between the cohorts, ($p<.000$). The level of confidence in the simulation and the combo cohort was significantly higher on the posttest with mean values of, (0.34 and 0.36) respectively, compared to the clinical group (0.15), ($Ps<0.05$). Some limitations of the study were lack of inter-rater reliability, it was not double blind, students had 270 hours of previous clinical experience and it was limited to 58 students in one institution (Hicks, Coke & Suling, 2009).

Another study, conducted by NCSBN (2014), a large scale, longitudinal, randomized, control study examined whether simulation could replace regular clinical hours in pre-licensure nursing education and the impact the curriculum had on postgraduate practices. The researchers randomly selected nursing programs throughout the United States and divided the programs into three groups, each with an assigned proportion of simulation and clinical hours. The participants were followed for a total of six months post graduation at their place of employment, 666 students completed the

study. The researchers did not find statistically significant differences in clinical competency ($p= 0.688$), comprehensive nursing knowledge assessments ($p= 0.478$), and NCLEX pass rates ($p= 0.737$). Postgraduate employment data displayed no statistical significance in clinical competency or readiness for practice at six weeks ($p=0.706$), three months ($p= 0.511$), or six months ($p= 0.527$). The researchers concluded that both forms of education produce the same outcome (Hayden, Alexander, Kardong-Edgren & Jeffries, 2014). Although it may seem insignificant that both studies did not show large differences, it is important to the future of nursing education. As more nursing students enter into programs, the spaces and clinical experiences are not always readily available and these studies demonstrate that the use of simulation in the clinical education area is just as effective as the clinical experience and can lead to a higher confidence level.

A pretest and posttest study conducted by Alinier, Hunt, Gordon and Harwood (2006) compared the performance, confidence and stress levels of students in an ICU clinical rotation with and without exposure to simulation training. A statistically significant differences in performance between the control or non-simulation group compared experimental or simulation exposed group, ($p<0.001$) with the improvement in the experimental group. There was no significant difference noted in the level of stress ($p=0.562$ or confidence level ($p=0.819$) between the two groups. The researchers also found a correlation between students who were working in the high technical area and did not feel confident reported feeling stressed ($p=0.002$, Chi-Square, $df=2$, $n=99$) (Alinier et al., 2006).

Simulation is utilized in nursing education to improve safety and confidence in the delivery of care. Through the completion of research, more guidelines are becoming published regarding the use of simulation. Goodstone and Goodstone (2013) developed a medication administration safety tool used in simulation. The tool enables for consistent measurement of performance and safety in medication administration by utilizing a checklist of the rights to medication administration. Simulation made it possible to

analyze medication errors, teach nursing students and create evidence-based guidelines to use in real practice. A cross-sectional comparative study analyzed the differences between a traditional learning method (TLM) verses an active learning method (ALM) using high fidelity simulation, standardized patients and audio video playback. 147 senior nursing students participated, 73 in 2010 and 74 in 2013. The ALM group scored significantly higher in five areas; special and general clinical performance, overall competency, critical thinking and human understanding (p=0.001). The ALM group scored higher than the TLM group, but the difference were not significantly significant in professional attitude (p= 0.24), satisfaction on nursing practicum (p= 0.002) and self-confidence (p= 0.22). The data reinforces that active learning facilitates the development of competency (Shin, Sok, Hyun, & Kim, 2015).

Hennenman, Cunningham, Roche, and Curnin (2007) published a simulation that was successful in teaching safe care to senior nursing students using simulation. The senario revolved arround a patient who had been involved in a moter vehicle accident and is complaining of chest pain. The senario changes based on the actions and reponses of the student. The authors share a complete simulation that has been successful in educating senior nursing students and provides a guide to the reanactment and or the design of a different simulation. Student objectives, alternate senarios, the process of debriefing, patient safety and evaluation methods in relation to the simulation are discussed. The authurs may have decribed how to measure outcomes, but no specific data from the use of the senario is provided.

Simulation and nursing competencies.

Kaplan, Connor, Ferranti, Holmes and Spenser (2011) used an emergency preparedness disaster simulation (EPDS) to educate senior undergraduate nursing students. The EPDS took place in the school's simulation lab created into an assisted living facility that was ravaged by a tornado. The simulation utilized patient simulators, task trainers and live actors. The scenario included 30 elderly residents at various levels

of incapacitation and 90 student participants. Eight to ten final semester senior BSN students are assigned roles and divided into two groups, each group runs through the scenario and the entire group attends the debriefing session. The purpose of the simulation was to increase student's knowledge and skills in the nurses' role of triaging disaster response and teamwork. A post simulation survey was administered and responses were positive, showing the simulation was well organized and the participants felt better prepared and more confident in responding to a disaster situation. The mean scores were between 4.40 and 4.65 on a five point Likert scale for all responses except prompt realistic reaction, 4.04. The positive response from the activity led to the incorporation of the simulation into the curriculum (Kaplan et al., 2011).

Schaar, Ostendorf and Kinner (2013) integrated the six key competencies of the quality and safety education for nurses (QSEN) initiative into their simulation curriculum. Four senior level nursing students carried out a simulation on postpartum hemorrhage and 37 remaining students observed using the provided observer record. All participants were debriefed based on six competencies as follows: safety, patient-centered care, teamwork and collaboration, informatics, evidence based practice and quality improvement. The process was repeated for 39 new students enrolled in the second session. The inclusion of QSEN works in several ways. First, the expectations are laid out and the student is taught to include QSEN in everyday thinking. Next, the competencies provided a guide for both the simulation and the debriefing process to touch on each of the six concepts. The development of the observer record was successful and later used in the development of critical care, pediatric and medical-surgical simulations. More research is needed to validate the efficacy of the QSEN simulation observer record (Schaar et al., 2013).

Simulation in acute care.

Simulation has expanded in undergraduate nursing education and is expanding into the acute care setting. Simulation is used to evaluate and improve nurses' skills,

competencies and confidence but is also capable of creating system wide changes. Lassche & Wilson (2016) descibe how the Quality Health Outcome Model (QHOM) is utilized to evaluate the intervention, the client, the system and the outcome. A simulation created for one purpose may reveal human factors or system issues that can be improved. The finding may change as the simulation is repeated on different shifts with diverse staffing patterns. The simulation allows for trial and error with no harm to to patients (Lassche & Wilson, 2016). In 2009 the Joint Commission (JC) began requiring health care agencies to use a systematic, measurable way to evaluate employee competencies. The observation of skills performed during a simulation is an acceptable method of evaluation by the JC (Hallenbeck, 2012).

Poor communication has been identified as one of the leading causes of medical errors. Severson, Maxson, Salentiny Wrobleski, and Dopzois (2014) conducted a descriptive qualitative study to examine videotaped simulation-based team training (SBTT) and debriefing from the nurse and physcian prespectives. Participants consisted of 19 nurses and 9 surgeons who volunteered from an inpatient medical surgical unit at a large academic medical center. The volunteers participated in three high fidelity simulations in a dedicated simulation center. The simulations consisted of an anastomotic leak and sepsis, postoperative respiratory distress, and severe postoperative pain. A debriefing was held after the simulation and video clips from interactions between the nurse and physician were played and discussed. Video transcripts were then broken down, analyzed and grouped into themes. A major theme was the importance of leadership to organize, direct and set expectations. Other themes consisted of closed loop communication, clearly defining roles and developing situational awareness and mutual support (Severson et al., 2014).

Another study by Garside, Rudd, and Price (2012) used a combination of video and HPS for stokes and transient ischemic attack (TIA) assessment training (STAT). The program was geared towards all nurses and junior doctors in an emergency room setting

and yielded 192 participants over a one year period. The program began with an introduction lecture reviewing the identification and immediate care of stroke and TIA patients followed by seven simulations. Participants completed an online multiple choice assessment before and after the program and a voluntary program feedback form. The results showed significant improvements in self-confidence in the clinical assessment of stroke patients ($P < 0.01$) and self-confidence rating for the preparation and administration of stroke ($P < 0.01$). The usefulness of the simulator for the training was rated highly by participants receiving a median score of nine on a ten point scale. The program was such a success it spread though many regions in England (Garside, et al., 2012).

Disher, et al. (2014) conducted a pilot study using a quasi experimental design to determine the effects of nurse's ability to detect and respond to a deteriorating patient on a cardiac stepdown unit. A pre and post intervetion 12 item questionaire and a confidence scale was administered to 23 cardiovascular nurse participants. The intervention was a high-fidelity simulation of a COPD patient in respiratory distress. The 15-20 minute intevention took place on the actual unit the nurses worked on and was followed by a debriefing period. The results showed significantly higher levels in both knowledge ($t(22) = -3.097$, $p < .01$) and confidence ($t(22) = -3.172$, $p < .01$). A great benefit to the study was that it was conducted on the unit in which the nurses worked on making it more realistic and using the space and equipment that is used in everyday practice (Disher, et al., 2014).

Simulation in Oncology

As technology improves, more people are surviving cancer and requiring care and treatments that are more complex. This increase translates into an increased need of competent, knowledgeable, trained professionals to provide quality safe care. The IOM report (1999) brought forth a concern related to ensuring quality of care for cancer patients. According to the IOM, " A high-quality cancer care delivery system should translate evidence into practice, measure quality, and improve the performance of

clinicians" (Ferrell, McCabe & Levit et al., 2013, p. 235). To achieve this goal the clinicians need tools and initiatives to assist them with quickly incorporating new medical knowledge into routine care. The American Society of Clinical Oncology (ASCO) and the Oncology Nursing Society (ONS) came together in 2009 and developed guidelines for the safe ordering, administration, and prepartation of antineoplastic therapy in the outpatient setting. The group updated the standards in 2011 to include the inpatient centeres and again in 2013 to address the oral formulations of antineoplastic therapy (Neuss, et al., 2013). The new guidelines set forth by ASCO and ONS as a result of the IOM's concern over nurses providing safe quality cancer care caused an oncology quality coordinator of a large urban hospital to organize a multidisciplanary inter-facility chemotherapy task force council (CTFC). Vioral and Kennihan (2012) describe the CTFC developed standardized forms based on the ASCO/ONS standards of care and created ten individual educational vignettes. For the course, each participant was invloved in a total of ten simulations that consisted of a vignette, followup, evaluation and proof of completion with 4.5 continuing education hours (Vioral & Kennihan, 2012).

Muehlbauer, Parr, and Perkins (2013) provided a review of simulation and its use in oncology and demonstrated the process in which simulation is used to validate competencies. The oncology nurse's experience in dealing with the aspects of chemotherapy can vary greatly based on the census, staffing, specialties and organizational layout. Nurses involved in the simulation scenario worked on a medical-surgical unit in San Diego. The nurses go for extensive periods of time without administering or caring for a patient receiving chemotherapy. Nurses are required to attend a two-day ONS chemotherapy/biotherapy course followed by a hands on session at the chemotherapy infusion center. Annual competencies are assessed by using the iStan high-fidelity simulator. Not all nurses would pass on the first simulation, as they would have to display expected competencies during the simulation. When chemotherapy spills are addressed, the extent of the simulation is to demonstrate safe handling techniques and

verbalize correct management of a chemotherapy spill. No hands on practicum is provided.

A study by Crannell (2012) included a total of 69 nurses participating in a simulation in groups of two to three. The competency assessment was divided into two parts, a question and answer session in relation to chemotherapy orders and safe handling followed by a case-based simulation. To evaluate each participant, a chemotherapy competency checklist was created for pre-administration, administration and post administration tasks. A pre and post five point Likert scale survey was administered to measure nurses' confidence on chemotherapy verification, transcription, safe handling, administration and spill management. The results were very positive in all areas of confidence eliminating all together never performed and very uncertain. The fact that 99% of nurses in the study felt confident or very confident in relation to chemotherapy spill management after the simulation reinforces the concept that simulation-based learning increases confidence levels of nurses (Crannell, 2012).

Theoretical Framework

Kolb's Experiential Learning Theory (ELT) was chosen to guide the creation of a chemotherapy spill simulation to increase safety, awareness, competence and confidence in oncology nursing practice. Kolb's first use of the ELT was back in 1971. Since then the theory has been expanded on. The theory was greatly used all over the world and addresses learning and educational issues in multidisciplinary areas. ELT has been used in professions such as medicine, nursing, accounting, law and psychology (Kolb, 2014). The ELT was chosen for several reasons. First, a simulation exercise is meant to provide the learner with an opportunity to experience the presented situation in a non-threatening environment. Keeton and Tate (1978) defined experiential learning as "Learning in which the learner is directly in touch with the realities being studied it is in contrast with the learner who only reads about, hears about or writes about these realities but never comes in contact with them in the learning process."(Kolb, pxviii). Second, the naturalistic views of Kolb's theory are also appreciated as they stress that the experiential learning theory was only useful if the scientific world was accompanied by academic knowledge. The naturalistic view is in line with the concept that education, work and personal development are all contributing factors to experiential learning (Kolb, 2014). Finally, according to Kolb (1984) the cycle of learning included certain concepts for learning to occur. The concepts of learning included concrete experience, reflective observations, abstract conceptualizations, active experimentation and functions best in a realistic environment (Ullrich & Mancini, 2014). The proposed simulation of a chemotherapy spill encompasses all of stated concepts. Each nursing participant brings with them their own real-life experiences, concrete experience. The prior experiences may be as simple as completing the reading on a chemotherapy spill in an assigned program to actually being involved in a chemotherapy spill in the past. With their prior knowledge, each person will have individual factors that will guide their choices during the simulation process and reflective observation. During the simulation process, the participants will

contemplate how to complete the scenario successfully. The hospital policy will reveal how to clean the spill. Next, the nurses will perform the actions including opening the computer, locating the policy, and beginning the cleaning process. Finally, the simulation will be located on the unit the nurses work on and will have all the resources and equipment that would be used if an actual chemotherapy spill occurred, allowing participants to function in a realistic environment.

A pre-planned simulation with specific goals and potential errors will be presented and allow for individual thought processes to develop a plan of action. The plan is guided by the concrete experiences of the individuals involved in the simulation. The individuals are potentially forming patterns and looking for significance in the scenario presented. The more realistic the scenario the more chance the individuals will be enabled to bring forth previous knowledge and experience to guide decisions and actions.

The last component of the simulation process is the debriefing. The debriefing is where all participants are given the opportunity to reflect on the process of the simulation and discuss what went right and what could be changed. The debriefing process allows everyone involved to gain insight and learn from the actions taken during the simulation, both positive and negative actions and implications are addressed.

The National League for Nursing / Jeffries Simulation Framework (NLN/JSF) was chosen to be used in conjunction with Kolb's theory in the creation of the QI project. The NLN/JSF was chosen mainly because it was developed by nurses for the purpose of creating a simulation environment that is consistent with the simulation process. The framework provides opportunities for research, growth, education and is based on the experiential learning theory (Jeffries, 2013).

The NLN/JSF is based on five subdivisions that must be present to create a successful simulation. The subdivisions are the facilitator, the participant, educational practices, the simulation design and the outcomes (Jeffries, 2013).

The facilitator is a guide in the simulation process and considered a key component to assuring the process goes as planned. Some duties of the facilitator may consist of providing prompts or proposing questions. The facilitator also holds a key role in the debriefing process at the completion of the scenario. The participant is any group or individual that is partaking in the simulation. There are participants that play a response-based role and ones that play a process-based role. In the process based role the participant is the active learner. In the response-base role the participant is not part of the active learning and may be an observer only (Jeffries, 2013).

The educational practices portion of the framework is instrumental to improving the participant's performance, learning and satisfaction. Areas focused on include active learning, feedback, diverse learning styles, student faculty feedback and high expectations. A simulation design is created using five characteristics: objectives / information, fidelity, problem solving, participant support cues and reflective thinking.

The last subdivision of the framework is the outcomes. Expected outcomes need to be addressed prior to the start of the simulation and evaluated at the end. Some examples of outcomes include skills learned, knowledge and critical thinking gained (Jeffries, 2013).

During the Mock chemotherapy spill, the student researcher is the facilitator that provides information, cues, and identifies expected objectives to be accomplished. In the proposed simulation of a chemotherapy spill, the current hospital policy will be used as a guide for the simulation as well as the objectives. Two to three participants will take part in each scenario, one will be the patients nurse and the others will be active assistants. Each group will be informed of the objectives, given a detailed report of the situation and encouraged to use any resource they would normally use, a computer or other staff members. The simulation design is a low-fidelity simulation of a chemotherapy spill in a patient's room or in the hallway that resembles a real setup of a chemotherapy infusion that has an issue causing a leak. The staff is instructed to follow hospital policy to rectify

the situation. The expected outcomes are consistent with the objective presented in the beginning of the simulation. The facilitator leads the debriefing process providing constructive feedback and active listening. The debriefing is used to discuss and learn from what went well and what could be improved on an individual, group and systems level.

Methodology/ Process for Implementation

Purpose

The purpose of the QIP was to determine if the use of a simulated chemotherapy spill increased the competencies and confidence of oncology nurses employed on an inpatient chemotherapy unit.

Design

A mixed method design was used to evaluate the QIP. A pre and post intervention survey containing questions based on a Likert scale with an option for open ended comments was distributed prior to the simulation of a chemotherapy spill and directly after the completion of the simulation. Both the pre and post surveys were created by the primary researcher to conform to the QIP objectives and purpose. A copy of the pre and post survey is provided in appendix B and C. Reliability and validity testing were done by asking eight individual nurses with different specialties and levels of experience that were not part of the study to review the surveys. The nurses were also asked to report any areas that they had trouble understanding, could not answer or if they had any suggestions for change. All responses were positive and only minor changes were necessary.

Sample

The QIP sample included 30 registered nurses (RN) employed on the inpatient oncology/medical surgical unit. Level of nursing experience ranged from less than one year to over 20 years. The nurses were comprised from various ethnical backgrounds including, Caucasian, African American and Asian. Of the 30 nurses, about 90% hold a baccalaureate degree in nursing (BSN), two a master's degree (MSN) and all others an associate degree in nursing (ASN). The sample was predominantly female with only three males. All RN's worked on the unit in which chemotherapy is administered but the levels of experience vary greatly. The sample consisted of new and experienced RN's with no chemotherapy experience, RN's with new limited experience administering

chemotherapy and RN's with several years of experience in the administration of chemotherapy.

Site

The QIP was conducted at The Miriam Hospital, a 247 bed Magnet facility located in Providence Rhode Island. The hospital's oncology/medical surgical unit consists of 25 beds. The number and type of chemotherapy administration continuously vary based on patient's individual needs and range from zero to ten treatments per week. Chemotherapy regimens vary from a single drug administered over several minutes to a multidrug regimen administered over a two-week duration.

Supplies

All patients receiving chemotherapy have a chemotherapy spill kit, intravenous pump, chemotherapy gloves, gowns, goggles, a sign posted for chemotherapy precautions and a designated yellow bucket for the disposal of chemotherapy waste. The actual hospital supplies were utilized in the QIP to maintain a high level of fidelity. All supplies were obtained from the hospital unit or hospital central supply. Whenever possible expired or unused open supplies were used and reused to reduce waste and cost for the project. See Appendix D for a complete list of supplies. The costs of supplies needed for the simulation exercise were covered by the educational budget of the unit. The survey supplies, informational letter for the study, food coloring and simulation design was provided by the primary researcher.

Procedure

Approval of The Miriam Hospital 4B clinical nurse manager Charlene Ainscough and assistant manager Tara Dobbing was obtained on 6/5/2015 (Appendix E). Approval of Chief Nursing Officer and Vice President of patient care services Maria Ducharme was obtained on 7/16/2015 (Appendix F). The development of tools used in the project including an information email (Appendix G), objectives, informational letter (Appendix H), color coded pre and post surveys (Appendix B and C respectively) were completed

by the student researcher. Simulation scenarios (Appendix I), skills check list based on hospital policy and chemotherapy biotherapy course (Appendix J) were created, validated and approved. Each document was presented to a Rhode Island College (RIC) faculty member (Debra Servello), the nurse manager (Charlene Ainscough) and the nurse educator on the inpatient oncology unit (Julia Twining) for review and received verbal approval.

After all aspects of the project were organized and outlined in detail, a request for institutional review board (IRB) approval was submitted to Lifespan's and RIC's IRB for permission to implement the research study as outlined in the proposal. All requested revisions were addressed, additional documentation and corrections were completed and IRB permission was granted from Lifespan IRB on December 14, 2015 (Appendix K) and Rhode Island College IRB on February 21, 2016 (Appendix L).

An informational email was sent to the nurse manager and forwarded to all registered nurses who work on the oncology unit explaining the simulation process, who would be running the simulations, when the simulations would occur and the option to participate in the study to contribute to evidence based practice. (See appendix G) The email included a detailed description of the simulation, the expected role of individuals and the importance of participation in all aspects including the debriefing process. The letter also explained that although the chemotherapy spill simulation is mandatory, the participation in the pre and post surveys were optional.

The simulation exercise and the QIP was also discussed at monthly staff meetings. The meetings addressed the implementation of a chemotherapy spill simulations that were put into action until each nurse had participated and received credit. All nurses that attended the staff meeting were encouraged to consider participation in the research study by completing an anonymous, voluntary, confidential, short pre and post survey at the time of the simulation.

Selection process.

Participants worked in teams of two to three. A random participant was chosen to be the primary nurse for the simulated patient receiving chemotherapy. The nurse was chosen after all eligible nurses working at the time of the simulation are identified on sheets of 2x2 papers and a name was drawn from a cup. One to three other eligible nurses were chosen to help the primary nurse with the chemotherapy spill. The only exclusion criteria was if the nurse had previously participated in the simulation or she/he is not a regular staff member on the oncology unit. Each nurse was required to participate in the full scenario exercise one time but the pre and post surveys were completely optional. All RNs who participated in the simulation were paid as the simulation occurred during their normal shift time and will be considered a portion of their chemotherapy competency assignments.

Pre-survey.

The participants were asked to participate in the optional survey portion of the project. It was stressed that participation is completely voluntary and that all information collected will be confidential and not linked to any individual. They were asked to use their mother's birthday as an identifier so the pre and post-test could be matched for data comparison. If this information was not known or another method is preferred, then they were advised to use the last four digits of their phone number or the street they live on. The researcher stressed the need to use the same selected information on both surveys as this was the only identifier to compare the pre and post data and was not meant to link an individual to the data. The participants were handed a color coded pretest survey and a copy of the informational letter. The researcher verbally summarized the informational letter as it was being distributed and encouraged discussion of any questions or concerns. The facilitator requested all copies of the survey be placed in the designated sealed box whether they chose to participate or not so that participants and nonparticipants could not

be identified. Time was allotted for reading the informational letter and completion of the survey.

Simulation process.

The overall goal of the simulation was to give the participants the opportunity to experience the scenario in a realistic safe environment with the hope that they will be aware of what to expect and what is expected of them during a similar real-life situation. The simulation was facilitated by a student researcher, who was a co-worker with 18 years of oncology experience and training in the development and execution of a simulation experience.

After the pretest survey was completed, the facilitator provided the participants with an overview of a scenario, described their expected roles and acknowledged that they may utilize any resources that they would normally use such as each other, the phone, a computer or policy manual on the unit. The objectives of the simulation are listed below. The objectives were explained and made available during the simulation for the participants.

Simulation objectives.

1. Staff will demonstrate ability to locate the current hospital policy on chemotherapy spill management.
2. Staff will demonstrate the ability to locate material safety data sheets (MSDS) for appropriate drug and can locate the section on Accidental Release Measures/Spills/Clean up.
3. Staff will demonstrate the steps utilized to clean up a large chemotherapy spill (greater than 5mls) following current hospital policy for spill containment and clean-up of a spill greater than 5ml.
4. Staff will verbalize need to notify clinical manager (nursing supervisor for off shifts) and the Safety Office.
5. Staff will verbalize need to complete an event report (safety net).

The participants were then directed to the chemotherapy spill simulation. Three different scenarios were alternated to allow for different actions and precautions (Appendix I). The facilitator described the situation and allowed the participants to intervene according to hospital policy. The facilitator used a template created from the objectives and TMH policy NU-53 (Appendix A) to check off completed objectives and take notes for areas of reflection for use in the debriefing process (Appendix J). The objectives, the template and debriefing process remained the same during all three scenarios. The time frame to complete the scenario varied from group to group taking from ten to twenty minutes.

The debriefing.

When the simulation was completed the participants were led directly into the debriefing process. The debriefing was begun by the facilitator clarifying inconsistencies within the hospital policy, directing the RNs on what improvements needed to be made, such as what to do with the remaining chemotherapy, what information to collect and report and to whom. All participants were included in the debriefing process to promote learning from the reflection of actions. The facilitator used notes taken during the simulation to help facilitate individual reflections of areas that were addressed well and to clarify areas that appeared difficult. Each simulation discussed five key questions.

1. What do you feel went well during the simulation?
2. What would you do differently if this situation was to occur again?
3. What did you gain from this simulation to use in the future practice?
4. Do you have any questions about the simulation or the current hospital policies?
5. Do you feel you have met the learning objectives with this simulation?

The learning objectives were displayed during the simulation and the debriefing. The debriefing process lasted between five and ten minutes.

Post survey.

Immediately following the simulation and debriefing all participants were asked to fill out the optional post simulation survey using the same identifier as they did for the pre simulation survey and to place it into the sealed box whether or not they chose to participate. All participants were reminded that responses are confidential and no one person will be identified.

Anticipated Time Line

The proposal was submitted to Lifespan IRB mid-October for review. The researcher made adjustments as recommended by the IRB and resubmitted as needed for approval. After final approval from Lifespan IRB, the proposal was submitted to RIC's IRB. The researcher received final approval from IRBs on December 15, 2015 and February 21, 2016.

With IRB approvals the start of the project began in March 2016 and continued until early April 2016. The entire simulation process was repeated on multiple shifts over a four-week period until all oncology nurses had the opportunity to complete the simulation process and, if desired, participate in the research. An opportunity to participate in the pre-survey was given during the introduction to the simulation exercise and at the end of the debriefing period for the post survey. The simulation was repeated twelve times in total. Each simulation lasted for approximately ten to twenty minutes with the debriefing lasting an additional five to ten minutes.

After the final simulation was completed the researcher unsealed the box containing the pre and post surveys. The surveys were separated and sorted for data analysis. Data analysis and interpretation took approximately one week. Findings were recorded and analyzed. The study findings were presented to the staff and management on the oncology unit where the study took place in April 2016 and to Rhode Island College master students and faculty members in May of 2016.

Data Analysis

The sealed box containing the surveys was opened after all surveys were collected. Contents of the box were divided into three categories pre-survey, post survey and incomplete surveys. The pre and post surveys were then paired according to the identifier used. The data was added to an excel spreadsheet and analyzed using statistical measures. Data obtained from pre and post survey's related to years of oncology nursing, past experience with chemotherapy spills, confidence in the simulation exercise and encouraged teamwork were analyzed by looking at the mean and range scores of the data. The remainder of questions were analyzed using a paired t-test method. The paired t-test method displays differences in nurses' comfort in locating policies, MSDS for the specific drug involved in the chemotherapy spill, familiarity with chemotherapy spill kit and nurse's confidence in responding to a spill. Qualitative date was grouped together by categories and used to assist in recommendations for future studies. The surveys are kept in a filing cabinet located at the primary researchers' home office for a period of six months to one year.

Organizational and system factors

Enabling factors that contributed to the process running smoothly included a very supportive management team and a hospital administration that was encouraging and supportive of developing and functioning on evidence based practice. Another key contributing factor in the study was the simulation process was meant to provide each oncology staff nurse with the needed yearly competency for safe hazardous drug handling and chemotherapy spill management. The QIP was planned to take place during the yearly evaluation period that included chemotherapy testing.

There were many areas that presented both actual and potential barriers in the implementation of the QIP. One potential barrier was the willingness of participation of the nurses. In an attempt to lessen the barrier of participation, the researcher stressed on multiple occasions the confidential nature of the data and the purpose of the study.

A second barrier included the level of staffing on the unit and the acuity of the patients at the time of planned simulation. For example, one RN began the simulation process completing the pre-survey, she was interrupted multiple times by a hospice nurse, a doctor and case manager who all required her attention and prevented her participation in the simulation. The researcher attempted to postpone the simulation for several minutes but the RN had too many issues occurring at the same time so the simulation was carried out with the other two chosen RNs. The nurse who was overly busy was selected to participate on a different day. Another potential identified barrier was staff out on vacation or sick leave. It was decided that any staff out on leave will participate in a mock spill but will be excluded from participating in the study, as they were not available in the period of data collection.

Other barriers included time taken away from patient assignments and lack of an updated or actual hospital policy. The current hospital policy gives direction to clean a spill occurring on the floor but it does not give step by step instructions on what to do if the spill occurs on a patient in bed. The policy also does not address protective equipment for the person assisting in clean up, what to do with the remaining chemotherapy, how to document, who to notify of the spill and what information to report. The researcher discussed the policy omissions and the correct actions with the nurse manager and nurse educator and it was decided to provide direction for additions to the policy with the staff during the completion of the simulation and at the start of the debriefing process. As the participants completed the final steps in the policy and verbalized whom they would contact, the researcher clarified areas that lacked direction in the policy. Staff were directed to write down the milliliters (ml) of chemotherapy remaining in the infusion pump, the estimated quantity of the spill and to include this information when reporting to the oncology doctor, in a chemotherapy spill event note and incident report. How to dispose of the remaining chemotherapy was also clarified.

Ethical Concerns

Ethical concerns that were considered included providing one group within a facility with a simulated training and not another and that staff members may feel obligated to participate merely because the student researcher is a fellow employee. Since all oncology nurses were invited to participate equally, there was no discrimination in gender or ethnicity.

Results

The results presented are based on the 29 RN's employed on an inpatient oncology unit at The Miriam Hospital in Providence, RI. Each RN participated in a chemotherapy spill simulation and voluntarily completed a pre and post survey. Oncology experience varied greatly, the largest group (48.3%) had less than two years of experience and the second largest group (24.1%) reported greater than eleven years of experience. Only 20.6% of participants had been previously exposed to an actual chemotherapy spill, leaving 79.3% with no chemotherapy spill exposure experience.

All 29 participants completed both the pre and post simulation surveys, 2 RN's were not available for the simulations and will complete the simulation at a later date as part of their competency training, but were not included in the study. All data was analyzed using IBM SPSS statistics software version 24, for paired t- tests and frequency analysis (IBM Watson Analytics, 2016). Table 1 presents a comparison of pre and post survey results for questions two through seven, which yielded statistically significant improvements ($p < .001$,CI 95%) in six out of six areas.

Table 1.

Comparison of Pre-Survey Questions to Post Simulation Survey Questions

Question (pre/post)	Mean	SD	t	df	P
2. How Familiar are you with the current policy?	-1.793	1.207	-8.003	28	<.001
3. How comfortable are you locating the policy for a Chemotherapy spill?	-1.483	1.353	-5.903	28	<.001
4. How comfortable are you locating MSDS for the specific drug that has spilled?	-1.931	1.252	-8.309	28	<.001
5. How familiar are you with the contents located in a chemotherapy spill kit?	-2.207	1.236	-9.617	28	<.001
6. How confident do you feel that you could respond to a chemotherapy spill and function according to hospital policy?	-2.034	1.149	-9.535	28	<.001
7. Do you feel that the training you have received has prepared you to handle a chemotherapy spill?	-2.448	1.183	-11.147	28	<.001

SD=standard deviation, df= degree of freedom

Figure 1 displays the pre and post-simulation survey responses for comparative questions two through seven. Note that in the post survey results the responses of not at all, not really and undecided are virtually eliminated, leaving only somewhat and very much as the chosen options.

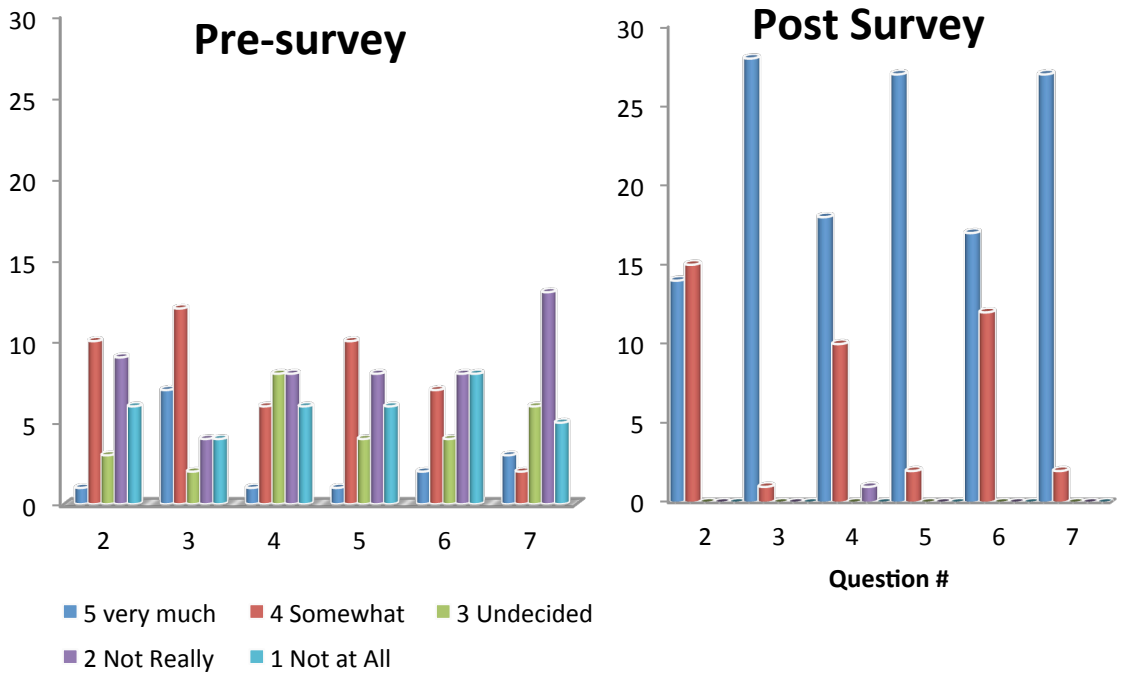

Figure 1. Survey Responses to Questions 2-8.

Participants felt the simulation held a moderate to high level of fidelity as displayed in Table 2. Sixty-nine percent felt the simulation would prepare them to handle a chemotherapy spill, 17.2% reported it would somewhat prepare them and 13.8% were undecided. No RN felt the simulation would not prepare them.

Table 2.

Question #1, Post Survey:
Do you feel the simulation resembled a real life situation?

	Frequency	Percent
Not Really	1	3.4
Somewhat	12	41.4
Very Much	16	55.2
Total	29	100.0

Paired correlation analysis of pre and post survey questions, two through seven revealed a statistically significant correlation of response to question six r(29) = .517, P = .004 (table 3).

Table 3

Paired Pre and Post Survey Correlations

		N	r	Sig.
Pair 1	Pre-question 2 & post-question 2	29	.299	.115
Pair 2	Pre-question 3 & post-question 3	29	.207	.282
Pair 3	Pre-question 4 & post-question 4	29	.145	.454
Pair 4	Pre-question 5 & post-question 5	29	.160	.406
Pair 5	Pre-question 6 & post-question 6	29	.517	.004
Pair 6	Pre-question 7 & post-question 7	29	.113	.560

Comments posted on surveys and verbalized during the debriefing process were all positive and related to the learning method and level of satisfaction with the process (Table 4). Numerous RN's stated they felt learning through simulation was more helpful than taking tests or completing computer modules. Several individuals also stated they will feel much more confident if they are faced with a chemotherapy spill now that they have gone through the process step by step and know what to expect.

Table 4

Survey Comments:

Written comments on surveys and during the debriefing process
"It would be helpful, as newly chemo cert RN, to have spill policy as part of training. It's hard to take the minimal info from the ONS class and apply to real life scenario."
"Awesome!!!"
"Appreciated hands-on learning, I feel prepared to handle spill. Much more helpful than simply reading policy."
"Great learning experience"
"I really loved this. I feel more comfortable now!"
"Excellent very informative!"
Verbal Comments During the Debriefing Process
"Wow, there was so much I had no idea about!"
" This sure beats sitting at the computer or taking the tests"
"I do not even give chemotherapy yet and feel comfortable dealing with the spill if it happens."
"This is a cool way to learn."
"So much better than I thought it was going to be, I really liked this."
"I prefer to learn this way, it makes it real, I will remember this if it happens in the future."
"No one paid attention to the patient other than shutting the chemotherapy off."

The Final question on the survey inquired about teamwork. Approximately 90% of respondents felt the simulation very much encouraged teamwork and 10% felt the simulation somewhat encouraged teamwork making it statistically significant at .05 level, $t(33.30) = 4.55, p < .001, df = 28, 95\%$ CI [4.27, 4.83].

Summary and Conclusion

The purpose of the quality improvement (QI) project was to determine if the use of a simulated chemotherapy spill increased the competencies and confidence of oncology nurses employed on an inpatient chemotherapy unit. The QI project was an educational quality improvement design that included a pre and post intervention survey to measure the oncology nurses levels of competence and confidence during a chemotherapy spill. The creation of the simulation was guided by Kolb's ELT, NLN Jeffries simulation framework and the current Miriam Hospital Antineoplastic Agents (chemotherapy), containment and disposal of spills policy (Lifespan, TMH, 2014). IRB approval from both RIC and TMH was obtained.

A total of 29 RNs participated in a mock chemotherapy spill in randomly chosen groups of two or three. A total of twelve simulations were conducted. The participation of all 29 RNs completing the voluntary pre and post surveys made the final data analysis stronger and more reliable.

Results were analyzed with paired t -tests, frequency and correlation statistics. Pre and post survey questions one and eight were non-comparative questions that revealed only 20.6% of RNs had been previously exposed to a chemotherapy spill. More than half of RNs felt the simulation resembled real life and all felt that the simulation very much or somewhat prepared them to handle a chemotherapy spill.

Questions two through seven were comparable questions and all displayed a statistically significant improvement. Three areas which showed the greatest degree of change were, feeling properly trained and prepared to handle a chemotherapy spill t(-11.147,$p<.001$), familiarity of the contents within a chemotherapy spill kit (t(-9.617, $p<.001$) and increased self confidence in responding to a chemotherapy spill according to the hospital policy (t(-9.535, $p<.001$). Results strongly support the use of simulation to increase nurse's knowledge and confidence in relation to attending to a chemotherapy spill. The same six questions were analyzed for correlations between pre and post

responses, all displayed a positive correlation but not at the level considered statistically significant with the exception of question five. Question five asked about the knowledge of the contents within the chemotherapy spill kit and was found to be statistically significant, further supporting the use of simulation to increases the nurses' knowledge. Larger studies are required to break down and compare data in relation to years of oncology experience, and the development of knowledge and confidence. The results suggest that simulation has increased the nurses' awareness of and comfort in locating the current hospital policy and MSDS for a specific drug as well as an increase of knowledge in relation to what is inside the chemotherapy kit and feeling properly trained to deal with the spill according to hospital policy.

One factor that may have influenced the experience was the neutral to positive attitudes of the belief that the simulation would prepare them to handle a chemotherapy spill. All responses were either "undecided" to "very much" that the simulation would better prepare them to handle a chemotherapy spill. Another area of exploration could pertain to nurses' attitudes about the simulation experience and differences in improvements of knowledge and confidence. Throughout the simulation process, it was necessary to reach out for assistance from other members of the team whether it was to ask what was next on the policy directions or to have someone hold a bag. Remarkably, all participants felt that the simulation at least somewhat encouraged teamwork.

The QIP revealed that through the use of simulation a closer observation of the policies and practices may reveal system issues to be addressed in relation to updating the current policy to match the needs of current practices.

Unanticipated findings

The use of simulation may have increased the nurses' knowledge and confidence but it also revealed areas that needed to be improved upon on at the systems level. The simulation of a chemotherapy spill was played out step by step according to the current hospital policy in a controlled, supervised, non-threatening environment. The process

allowed for a clear visualization of all steps included in the policy, emphasizing steps that should be added, removed or readjusted. One small discrepancy, the color and amount of labels in the chemotherapy spill kit did not match what was documented on the policy. The labels are used to seal the designated bags that contain the materials used to clean the chemotherapy spill. The discrepancy could be due to a change in manufacture. The color of the labels did not correlate with the policy. The RN was hunting for a yellow sticker and only orange stickers in two different sizes were available. The policy needs to be updated to read "place a sticker labeled CHEMO" to avoid confusion. Often policies tend to be task oriented, fail to look at the overall process, and can exclude important information and or directions that may be important to multiple disciplines. The policy did not address what to do with the remaining chemotherapy that is hanging on the IV pole after the chemotherapy spill was cleaned. The remaining infusion does not go into the designated bags in the spill kit or the yellow chemotherapy disposal bucket located in the patient's room. The remaining chemotherapy needs to be disposed of in a special black hazardous waste container located in the soiled utility room. Another deficit is that the policy does not state what should be documented. RN's were guided to document the remaining volume of chemotherapy remaining in the bag and an estimated amount of the spill in the event note and to report the information to the covering oncology doctor and the pharmacy. The oncologist needs to be aware of the amount of chemotherapy a patient has received. If the bag was almost full at the time of the spill, the oncologist may want to retreat the patient at a lower dose whereas if the spill occurred close to the end of the infusion, the decision may be to do nothing. In emergency situations or when staff are new to an event, omitted steps in a protocol, such as the ones listed above, can alter the process and lead to safety errors. The use of simulation led the researcher to recognize errors and omitted steps in the current policy. Using the information gathered provides an opportunity to improve the process and possibly prevent future safety errors.

Limitations

The results of the QIP demonstrate how the use of simulation could have a positive impact on the knowledge and confidence of nurses during a chemotherapy spill. Although the results were promising, many limitations were discovered during the planning and implementation phases of the QIP. First, the size of the study was limited to only the nurse's employed on the inpatient oncology unit in one hospital setting. Many variables would have existed if results from other facilities were combined, as training and policy's are not universal and could have altered the simulation process. Also limiting the study to one specific facility limits the generalizability of the results to other facilities. A larger study, including multiple settings, would further validate the results.

A second limitation was the hospital policy. The policy did not include many steps needed to respond to a chemotherapy spill. For example, a scenario involving the spill of chemotherapy on the patient and the bed linen could not be utilized as the current policy did not include the proper procedures handle the situation. A chemotherapy spill on the floor with no patient contact was utilized and adjustments were made to include the missing steps for proper procedures, documentation and reporting. The missing steps in the procedure did not affect the flow of the simulation. As a result of the discrepancies found in the hospital policy, steps have begun to revise current policies to match the actions needed.

A potential limitation was the ability and willingness of staff participation. Fortunately, all nurses that participated in the simulation filled out both the pre and post voluntary surveys. Only two RN's employed on the unit were not included in the study results due to unit acuity and vacations, making it a 93.5% participation rate. Some RNs who were randomly chosen to participate had to be deferred to a later date due to patient acuity and nurse availability. These two RNs were able to participate fully at a later time.

Other limitations included a lack of emphasis regarding the patient interaction and education during a chemotherapy spill. The focus of the simulation was the spill and not the patient. It may be helpful to include a nurse acting as the patient in the simulation and

objectives that address patient safety and communication. A final limitation was slow and non-working computers. The researcher maintained a hard copy of the policies in anticipation of computer glitches. Staff verbalized the frustration of programs not loading and the slow rate at which they functioned.

Recommendations and Implications for Advanced Nursing Practice

The positive feedback and impressive results from the QIP support the use of simulation to improve nurses' confidence and competence. The researcher encourages APRN's to utilize the data presented to expand the QIP into a larger study encompassing inpatient and outpatient oncology units within several institutions. A larger cohort in a variety of oncology environments will challenge or confirm the findings, leading facilities and educators toward an effective method of educating oncology nurses to confidently and competently attend to a chemotherapy spill. The use of simulation has shown to be a good teaching tool for the nurse and the educator, as all involved develop new knowledge and experiences as the simulation is unfolded. The researcher recommends a new study using a simulation process to develop new policies and to review existing ones in comparison to the traditional read and review process. Many policies are not analyzed or adjusted until a safety issue has been identified, it would be impressive to see a study supporting the use of simulation review and the level of potentially prevented safety errors. Other areas of exploration could pertain to nurses' attitudes about the simulation experience and differences in improvements of knowledge and confidence.

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Appendix A

The Miriam Hospital Chemotherapy Spill Policy

The Miriam Hospital Policy and Procedure	**Subject: Antineoplastic Agents (Chemotherapy), Containment and Disposal of Spills**	**File Under: NU-53**
Issuing TMH Department: Nursing	**Page 1 of 2**	**Latest Review Dates:**
		Latest Revision Dates: 5/14
Original Date: March 2011	**Approval By:**	

Michelle Carpentier

Michelle Carpentier, MSN, RN, OCN
Director of Cancer Services, The Miriam Hospital

Maria Ducharme

Maria Ducharme, MSN, RN, NEA-BC
Senior Vice President, Patient Care Services and Chief Nursing Officer

I. PURPOSE

To promote optimal protection for patients and hospital personnel from accidental spills of antineoplastic (chemotherapeutic/cytotoxic) agents

II. POLICY

It is the responsibility of Registered Nurses (RNs) who administer antineoplastic agents to respond to a cytotoxic spill using the procedure below.

III. PROCEDURE

Equipment

For Small Spills (<5 ml)

1. Personal Protective Equipment (PPE)
2. Nitrile-XTRA powder-free gloves (2 pairs recommended)
3. Non-permeable, long sleeved, cuffed chemotherapy gown
4. Protective eyewear (face shield or goggles)
5. Respirator mask (NIOSH approved) for either powder or liquid spills where airborne powder or aerosol is or has been generated

For Large Spills (≥5 ml-1000 ml): One Chemotherapy Spill Kit per up to 1000 ml spill
Kit should include:

1. Maximum protection gown
2. 3 absorbent towels
3. Two pairs of Nitrile gloves (1 medium pair to wear under the gown cuff and a larger outer pair to wear over the gown cuff)
   Note: If you need sizes different from the ones supplied in kit, double glove with two appropriate sizes of Nitrile gloves available on the unit.
4. 1 respirator mask (NIOSH approved)
5. 1 pair of safety goggles
6. 1 "Chemo Spill" caution sign
7. 1 scoop & brush (to collect glass fragments)
8. 2 *spill control pillows*
9. 2 chemotherapy waste disposable bags (2-gallon and 15-gallon)
10. 6 hazard labels
11. Surface Safe wipes (obtain from medication room)

Techniques

ACTION
1. Evaluate quantity of drug spill. a. If spill <5 ml, proceed to Step #2. b. If spill ≥5 ml, obtain appropriate number of spill kits.
2. Review MSDS for the appropriate drug. Refer to the section on Accidental Release Measures/Spills/Clean up.
3. **Small spills**: Don all PPE. a. Absorb spills with gauze. b. Clean surface with germicidal wipes. c. Discard gloves and all materials in yellow chemotherapy waste container.
4. **Large spills**: Don **all** PPE supplied in kit. a. Block access to spill area, open spill kit and mark with warning sign contained in the spill kit. b. Use spill pillows in the "V" position on the outer perimeter to contain the spill. c. Place absorbent towel(s) over the spill & discard in disposal bag. (If possible, obtain assistance from another person who can hold the disposal bag.) d. Sweep any glass fragments into scoop with brush and place in a puncture-proof container. e. Following the instructions on the package, use Surface Safe wipes to clean the spill area, beginning with the least contaminated area and finishing with the most contaminated area. f. Rinse the area with plain water. g. Place all contaminated materials, pads, towels, padding, and outer gloves in the first waste disposal bag. h. Seal the bag and place it in the second waste disposal bag. i. Place PPE in the second disposal bag, and seal it securely. j. Place yellow sticker on bag and put bag in dirty utility room. k. Wash hands again. l. Notify ESD for required final rinse and cleaning and for bag pick-up.
5. Notify the Clinical Manager (Nursing Supervisor for off-shifts) and Safety Office.
6. Complete an event report.

Appendix B

Pre Chemotherapy Spill Simulation Confidential Survey

Mother's birthday_____

Directions: Please provide your mother's birthday at the top of this survey to enable the researcher to match pre and post survey results while keeping the survey confidential.

Circle **one** answer for each question below.

Years of oncology nursing experience

0-2 3-5 6-8 9-11 11 or more

1. Have you ever been involved in a chemotherapy spill?

never once twice three times more than three times

2. How familiar are you with the current policy for a chemotherapy spill?

Very Much	Somewhat	Undecided	Not Really	Not at All
5	4	3	2	1

3. How comfortable are you locating the policy for a chemotherapy spill?

Very Much	Somewhat	Undecided	Not Really	Not at All
5	4	3	2	1

4. How comfortable are you locating MSDS for the specific drug that has spilled?

Very Much	Somewhat	Undecided	Not Really	Not at All
5	4	3	2	1

5. How familiar are you with the contents located in a chemotherapy spill kit?

Very Much	Somewhat	Undecided	Not Really	Not at All
5	4	3	2	1

6. How confident do you feel that you could respond to a chemotherapy spill and function according to current hospital policy?

Very Much	Somewhat	Undecided	Not Really	Not at All
5	4	3	2	1

7. Do you feel that the training you have received has adequately prepared you to handle a chemotherapy spill?

Very Much	Somewhat	Undecided	Not Really	Not at All
5	4	3	2	1

8. Do you feel this simulation exercise will better prepare you to handle a chemotherapy spill?

Very Much	Somewhat	Undecided	Not Really	Not at All
5	4	3	2	1

Comments:

_____`

Appendix C

Post Chemotherapy Spill Simulation Confidential Survey

Mother's birthday_____

Directions: Please provide your mother's birthday at the top of this survey to enable the researcher to match pre and post survey results.
Circle **one** answer for each question below and provide feedback in space provided. .

1. Do you feel the simulation exercise resembled a real life situation?

Very Much	Somewhat	Undecided	Not Really	Not at All
5	4	3	2	1

2. How familiar are you with the current policy for a chemotherapy spill?

Very Much	Somewhat	Undecided	Not Really	Not at All
5	4	3	2	1

3. How comfortable are you locating the policy for a chemotherapy spill?

Very Much	Somewhat	Undecided	Not Really	Not at All
5	4	3	2	1

4. How comfortable are you locating MSDS for the specific drug that has spilled?

Very Much	Somewhat	Undecided	Not Really	Not at All
5	4	3	2	1

5. How familiar are you with the contents located in a chemotherapy spill kit?

Very Much	Somewhat	Undecided	Not Really	Not at All
5	4	3	2	1

6. How confident do you feel that you could respond to a chemotherapy spill and function according to current hospital policy?

Very Much	Somewhat	Undecided	Not Really	Not at All
5	4	3	2	1

7. Do you feel this simulation exercise has better prepared you to handle a chemotherapy spill?

Very Much	Somewhat	Undecided	Not Really	Not at All
5	4	3	2	1

8. Do you feel the spill simulation encouraged teamwork?

Very Much	Somewhat	Undecided	Not Really	Not at All
5	4	3	2	1

Coments:_____
_____
_

Appendix D

Supply List

Supplies:

Sealed BOX with a slit to hold surveys

Informational letter, provided with pre survey

Pre survey (blue) / Post survey (yellow)

Computer to look up current policy (located in each patients room on this unit)

Yellow chemotherapy precaution sign (reuse)

Yellow chemotherapy disposal bucket (reuse)

Black hazardous disposal bucket (reuse)

Goggles, (reuse)

Purell (in rooms / hallway)

Sink with soap available

Sanitizing wipes (supplied in each room on wall)

Chemotherapy spill kit (reuse entire kit)

IV bag with pharmacy label resembling a chemo infusion. Clearly marked NOT real chemotherapy.

Orange food coloring to add to bag to make more realistic. (Reuse)

IV Tubing (reuse)

IV pump

Bag of chucks to replace wipes in kit between simulations

Box of chemotherapy gloves

All standard personal protective equipment (PPE) including: Yellow precaution gowns, masks and standard gloves.

The competency checklist for cleaning a chemotherapy spill

Appendix E

Approval Letter from Nurse Manager

The Miriam Hospital
A Lifespan Partner

164 Summit Avenue
Providence, RI 02906

July 23, 2015

To Whom It May Concern:

Sherry DeMacedo will be conducting a research study at The Miriam Hospital on "Educating Oncology Nurses with Simulation: A Mock Chemotherapy Spill." Sherry has made me aware of the study including targeted population.

I support this study wholeheartedly. Please contact me with any questions (401) 793-3331.

Sincerely,

Charlene Ainscough

Charlene Ainscough, RN, BSN, OCN

Clinical Manager 4B Oncology/Hematology Unit

Appendix F

Approval Letter from Senior Vice President and Chief Nursing Officer

The Miriam Hospital
A Lifespan Partner

July 20, 2015

To Whom It May Concern:

I have knowledge that Sherry DeMacedo will be conducting a research study at The Miriam Hospital on "Educating Oncology Nurses with Simulation: A Mock Chemotherapy Spill". Sherry has informed me of the design of the study as well as the targeted population.

I support this effort and will provide any assistance necessary for the successful implementation of the study. If you have any questions, please do not hesitate to contact me at (401) 793-2002.

Sincerely,

Maria P. Ducharme, DNP, RN, NEA-BC
Senior Vice President, Patient Care Services and
Chief Nursing Officer

Appendix G

Informational Email

To All 4B Nurses,

Hello. My name is Sherry DeMacedo and I am currently enrolled in the Nursing Masters program at Rhode Island College. I am in the process of completing my masters project and could use your assistance. I have developed a simulation exercise involving a chemotherapy spill. The purpose of the research project is to determine if the use of a simulated chemotherapy spill increases the competencies and confidence of oncology nurses employed on an inpatient chemotherapy unit. This year in addition to the written oncology competencies your nurse manager has agreed to include a chemotherapy spill simulation.

What to expect

Over the next few months two to three staff members at a time will be called to respond to a simulated chemotherapy spill. You will be expected to treat this as an actual event. You may use all resources you would currently use and follow the hospital policy regarding the clean up of a chemotherapy spill. This exercise will be considered as a portion of your oncology yearly competencies.

I would be very grateful for your participation in completing an optional confidential short pre and post survey at the time of the simulation exercise for my research project.

Thank you,

Sherry DeMacedo RN-BC, OCN

Appendix H

Quality Improvement Project informational Letter

I would like to ask you to take part in a Quality improvement (QI) project called Educating Oncology Nurses with Simulation: A Chemotherapy Spill. The QI project is to determine if the use of a simulated chemotherapy spill increases the competencies and confidence of oncology nurses employed on an inpatient chemotherapy unit. This year your nurse manager has included a mock chemotherapy spill exercise for you to participate in as part of your yearly mandatory chemotherapy competency training. The QI project consists of the voluntary completion of a questionnaire/survey before and after participating in the mandatory simulated chemotherapy spill. This information will provide valuable evidence based data to assist in determining if the chemotherapy simulation has an effect on nurses' competencies and or confidence.

Your voluntary completion of the questionnaires will probably take 10-15 minutes of your time. There are two questionnaires, one before the simulation exercise and one after. Each questionnaire has eight questions for you to circle the answer that pertains to you and an area for comments. There are no questions that should cause you any discomfort. Your taking part in this QI questionnaire is completely voluntary. If you do not want to complete the questionnaires, you are free to choose not to fill it out. The completion of the questionnaires may not benefit you personally. I am hoping these completed questionnaires will provide an evidence base to guide our competency training for oncology nurses. The questions from this QI project will be kept confidential. None of the information you provide will have your name or identify you personally. I only ask for your mother's date of birth to match the pre and post questionnaire results together. You may use any number I just request that it be used on both questionnaires.

If you have any questions about these questionnaires or the QI project itself, please feel free to ask or notify the student investigator Sherry DeMacedo by phone 401-497-3781, email sdemacedo_7734@email.ric.edu, Debra Servello the primary investigator at dservello@ric.edu or Cynthia Padula Rhode Island College IRB chair at cpadula@ric.edu.

Thank you very much for your time!

Sherry DeMacedo RN-BC, OCN
Adult/ Geriatric Acute Care Nurse Practitioner Student
Rhode Island College

Appendix I

Chemotherapy Spill Scenario #1

Setting of scenario - A simulated patient receiving 5-fluorouracil via a right chest wall power port has called to the nursing station to report that he became caught on his

chemotherapy line, it became dislodged from the bag, and chemotherapy is now leaking onto the floor. Upon entering the room, you note that the patient has not had any contact with the chemotherapy and there is about 250 ml of chemotherapy spilled onto the floor.

Chemotherapy Spill Scenario #2

A simulated patient calls the nurse stating there is a puddle on the floor and it looks like it is coming from the chemotherapy infusion. This patient has a left arm two lumen power PICC and is receiving a doxorubicin infusion. Upon entering the room, you note the chemotherapy bag is dripping and there are small puddles on the floor. The patient has not had any skin contact with the leaking medication. The chemotherapy bag is partially full and you note about 50 ml have spilled onto the floor.

Chemotherapy Spill Scenario #3

A simulated patient is in the hallway and the wheel of his IV pump has caused a leak of his infusing chemotherapy. The patient is receiving day two of his cyclophosphamide infusion over two hours. The 500 ml infusion was started fifteen minutes ago and there is about 100 ml on the floor in the hallway. The patient has a right chest wall power port and access is intact.

Appendix J

Template

During the simulation the facilitator will check off as objectives are completed and note area to discuss in debriefing

completed	Participants interventions	Facilitators' notations
		Provide report of scenario setting
	Assure patient is safe and remove from danger. Disconnect patient from infusion and observe for any signs of exposure.	
	Locate the current hospital policy on chemotherapy spill management.	
	Locate MSDS for appropriate drug and can locate the section on Accidental Release Measures/Spills/Clean up.	
	Staff will demonstrate the steps utilized to clean up a large chemotherapy spill (> 5mls) following current hospital policy for spill containment and clean up of a spill >5ml listed below.	Monitor and guide for completion of steps in policy. (note specific areas to discuss in debriefing)
	Don all PPE supplied in spill kit properly.	
	Block access to spill area, open spill kit and mark with warning sign contained in spill kit.	
	Use spill pillows in a "V" position on the outer perimeter to contain the spill.	
	Place absorbent towel(s) over the spill & discard in disposable bag. (If possible obtain assistance from another person who can hold the bag.)	
	Sweep any glass fragments into scoop with brush and place in puncture proof container.	
	Following the instructions on the package, use Surface Safe wipes to clean the spill area, beginning with the least contaminated area and finishing with the most contaminated area.	
	Rinse the area with plain water.	
	Place all contaminated materials, pads towels, padding and outer gloves in the first waste disposal bag.	
	Seal the bag and place it into the second waste disposal bag.	
	Place PPE in second disposal bag and seal it securely.	
	Place yellow sticker on bag and put bag in dirty utility room.	
	Wash hands again.	

	Notify ESD for required final rinse and cleaning	
	Verbalize need to notify clinical manager (nursing supervisor for off shifts) and the Safety Office.	
	Verbalize need to complete an event report (safety net).	
	Verbalize need to notify MD and Pharmacy.	
	Verbalize need to document in patients chart including any skin / eye exposure or other injury.	

Appendix K

Lifespan IRB Approval Letter

Lifespan

Delivering health with care.

Research Protection Office
Office of Research Administration
CORO West, Suite 1.300
One Hoppin Street
Providence, RI 02903
Tel 401 444-6246, Fax 401 444-7960

E. P. Bradley Hospital
Rhode Island Hospital
The Miriam Hospital
Newport Hospital
Gateway Healthcare

DATE:	December 15, 2015
TO:	Cynthia Padula, PHD, RN
FROM:	Janice Muratori, MSN, FNP-BC Director, Research Protection Office
SUBJECT:	**DETERMINATION OF NOT HUMAN SUBJECT RESEARCH** FWA-Rhode Island Hospital (RIH) 00001230, The Miriam Hospital (TMH) 00003538 IRB Registration #s: RIH IRB 1 - 00000396, RIH IRB 2 - 00004624, TMH IRB - 00000482
CMTT/PROJ:	216215
TITLE:	[803319-1] Educating Oncology Nurses with Simulation: A Chemotherapy Spill
SUBMISSION TYPE:	New Project
DECISION DATE:	December 14, 2015

Thank you for your submission for this research project. The information you provided indicates the data being used does not include identifiable information. As described, while your study does meet the definition of research, it does not meet the definition of human subject research. The Office for Human Research Protection defines human subject research subject to regulation as:

Human subject means a living individual about whom an investigator (whether professional or student) conducting research obtains:

1. Data through intervention or interaction with the individual, or
2. Identifiable private information.

As your proposal involves obtaining totally de-identified data and you will not obtain the link to the identifiers for these data the Lifespan - The Miriam Hospital IRB has determined you would not be engaged in human subject research as defined by OHRP. Thank you for submitting this information to the IRB for review and determination.

Please feel free to call or email should you have any questions. Please inform the IRB should your role or this study change since some changes may result in a change in IRB determination. Thank you.

Appendix L

Rhode Island College IRB Approval Letter

IRB: #1516-1298 (Servello, Debra) exempt

NoReplyRIC_Elements@topazti.net

Sun 2/21/2016 8:46 AM

To:irb@ric.edu <irb@ric.edu>; Servello, Debra L. <dservello@ric.edu>; DeMacedo, Sherry A. <sdemacedo_7734@email.ric.edu>;

Greetings,

The proposal for the project referenced below has been determined to be exempt by the Institutional Review Board (IRB).

Project title: Educating Oncology Nurse with Simulation: A Chemotherapy Spill

#: 1516-1298
Type of review: Exempt
Proposal type: Original
Principle Investigator: Servello, Debra
Fees received: 1. No fees -- RIC supervised or sponsored
Funding status:

Date: 2/21/2016
Expiration date: 2/21/2021

Click here to access the protocol: https://ric.topazti.net/RIC/Default.aspx?linkParms=NPqkQNfZcnWCXsjumMLPig%3d%3d

You do not need to submit any renewals for this project.

An exemption is not the same as approval. This protocol has been reviewed by the IRB to ensure that it meets the criteria for an exemption. Investigators are encouraged to adhere to the same ethical standards of research as non-exempt research.

You may implement only those materials and methods approved by the IRB. Changes to the protocol topic or methods, including the elimination of previously-approved methods, require prior approval.

If you are using signed consent materials, a PDF of the form(s) with the approval stamp will be uploaded to your protocol. You must use this copy with participants.

Unanticipated problems or adverse events must be reported within three (3) days of your knowledge of the event.

You must keep all research data and consent documents within your possession in a secured location for at least three (3) years after the completion of the study, including publications or presentations of any reports.

Do not reply to this "RIC_Elements" email address because it will not be received by the IRB. Send all correspondence to IRB@ric.edu.

Best Regards,

Cindy Padula, Ph.D.
Professor
Chair, IRB
Rhode Island College
IRB@ric.edu