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Chemotherapy and exposure risk for home health nurses

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Chemotherapy and Exposure Risk for Home Health Nurses

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Doctor of Nursing Practice Program

The University of Alabama in Huntsville

College of Nursing

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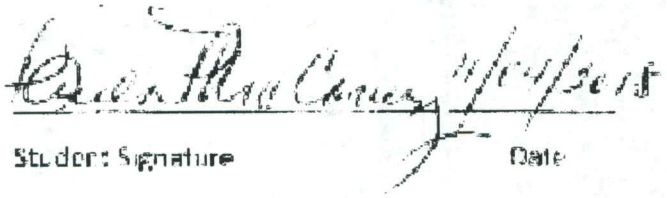

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DNP PROJECT APPROVAL FORM

Submitted by Paula P. McCovery in partial fulfillment of the requirements for the degree of Doctor of Nursing Practice and accepted on behalf of the Faculty of the School of Graduate Studies by the DNP project committee.

We, the undersigned members of the Graduate Faculty of The University of Alabama in Huntsville, certify that we have advised and/or supervised the candidate on the work described in this DNP project. We further certify that we have reviewed the DNP project manuscript and approve it in partial fulfillment of the requirements for the degree of Doctor of Nursing Practice.

Dr Brenda Talley
_____ Committee Chair

(Date) November 5, 2018

_____ DNP Program Coordinator

_____ College of Nursing, Associate Dean for Graduate Studies

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ABSTRACT

The School of Graduate Studies

The University of Alabama in Huntsville

Degree: Doctor of Nursing Practice College: Nursing

Name of Candidate: Paula P McCovery

Title: Chemotherapy Exposure Risk and Home Healthcare Nurses

Abstract

Background: Treatment advances have extended lifespans of many who have cancer, resulting in an increasing demand for home administration of chemotherapy. The home healthcare nurse is in the forefront for the delivery, monitoring, and management of chemotherapy administration in the home. The administration of chemotherapy, oral and intravenously, poses a threat to the well-being of nurses in any setting, but the risk may be increased in the home setting, due to inadequate knowledge and procedural support.

Purpose: The purpose of this project was the develop strategies to enhance the safety of Registered Nurses who administer chemotherapy in the home setting.

Plan: This project has two aspects. The first is a synthesis of the evidence which produced recommendations for policies, processes, and protocols aimed at safe and appropriate chemotherapy administration and handling. The second arose from the evidence and is the basis of an educational curriculum and deliverable program. This was aimed at improving the knowledge of home health nurses who may administer chemotherapy. The educational program was tested/implemented with the agency nurse educators with their feedback considered critical. This began with an assessment of current knowledge via a self-reporting questionnaire, also used as a post implementation evaluation of acquired knowledge.

Outcomes: The pre and post intervention questionnaires was deemed useful in determining information current knowledge and specific intervention related content post intervention.

The educational materials and the recommendations for policy and procedures related to home chemotherapy administration were shared with the agency.

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According to the American Cancer Society, approximately 1.7 million new cancer cases are expected to be diagnosed in 2018 (ACS, 2018). The increase incidence of cancer will result in an increased demand for cancer treatment. Drug treatment for cancer, referred to as chemotherapy, is common in the acute inpatient and outpatient clinic settings but also can be provided in the home by nurses. Nurses are an essential and integral part of the care of cancer patients. Nurses rendering this care must have a specialized knowledge and skill base in the administration and management of chemotherapy, which utilizes drugs effective for the treatment of cancer but that pose a risk for unwarranted or accidental exposure. The administration of chemotherapy, oral and intravenous (IV), places nurses at an increased risk for exposure to hazardous agents regardless of the setting. Home healthcare nurses may be at an increased risk for exposure related to their practice setting. Expert knowledge and clear procedural guidelines can reduce that risk. The focus of this project relates to the potential risks to nurses in the provision of chemotherapy in the home.

Many patients prefer receiving chemotherapy treatments in the home. Home chemotherapy administration places patients in a comfortable and familiar environment. The amount of time needed to travel back and forth from clinics or a hospital setting is diminished. Chemotherapy agents administered in the home also decreases disruption of daily life activities (Crisp et al., 2014). In a qualitative study conducted by Hall and Lloyd (2008), 15 patients with breast cancer were recruited. Ten of the study participants received chemotherapy at home. Participants stated that being at home afforded them an increased level of privacy and comfort. The participants who received chemotherapy in the home found it easier to ask questions, and anxiety levels were lessened (Hall & Lloyd, 2008).

Background and Significance

One very important issue that arises with an increase of home-based chemotherapy administration is the safety of patients, care givers/ family members and the home health nurses. Nurses must be qualified to administer chemotherapy in the home, and in addition, some screening of candidates for home administration should occur. Home administration of chemotherapy is perceived by recipients as supporting extended independence and comfort (Sprandio, 2010). Though the impact on efficiency and finances remain unclear, evidence suggests that home administration of chemotherapy is perceived by the receipt to be conserving of energy and time and increases quality of life (Corbett, et al., 2015).

The agents currently administered in the home environment are via oral, topical, and parenteral routes. Patients currently receive Capecitabine, an oral medication, and Fluorouracil in the home. These are two of many chemotherapy agents. Chemotherapy agents may be initiated as well as discontinued in the home setting by home health care nurses. Patients will require monitoring for adverse effects. Care givers and patients will need education about management of potential adverse effects. The needs of the patient receiving in home chemotherapy are constantly evolving. New medications, Pemetrexed being one example, are currently in evaluation for administration in the home.

While some risk exists for home health nursing visits, these risks are compounded when the visit is for chemotherapy infusion. Dangers such as the presence of pets, the threat of violence, poor environmental conditions, and lack of control of the work space all tend to increase the possibility of adverse events (Markkanen, Galligan, & Quinn, 2017). The knowledge and the skill of the nurse in handling toxic agents is a significant variable in patient

safety (Bhishamjit. et al., 2015) and must be considered as well in the safety of those who manage and administer the agents.

Obtaining maintaining knowledge and skills is an ongoing challenge for nurses. Nurses who practice in the ambulatory care centers and acute care settings are usually certified to administer chemotherapy. Many nurses specialize and\or are certified as oncology nurses by the Oncology Nursing Credentialing Corporation (ONCC), a national credentialing agency. According to Parker, (1992) chemotherapy can be safely administered in the home through preparation and knowledge of administration and symptom management. The nurses practicing in the home health setting may or may not be certified in chemotherapy administration or as oncology nurses. The purpose of this project is to offer both a structural support for care in the form of information supportive of policies and producers and an initial assessment and continuing education approach to increasing knowledge and skills.

It is extremely important for nurses involved with all aspects of chemotherapy administration to be competent in the safe handling of these hazardous drugs. Hazardous drugs, including chemotherapy agents, are drugs that are known to or suspected to cause adverse health effects from exposures in the workplace. That workplace may be an ambulatory care center, an acute care unit, or the homes of patients. Chemotherapy drugs are very beneficial, and essential in the fight against cancer, however, these drugs can be extremely harmful if not handled appropriately.

Certification

The ONCC requires that Registered Nurses (RNs) have one year of experience in the previous 3 years prior to applying for certification with a minimum requirement of 1000 hours of

oncology clinical experience. The hours must have been obtained within 2.5 years of the nurses' application for certification. The RN should have at least 10 continuing hours of education in oncology. A RN meeting these requirements and passing the exam will be certified as an Oncology Certified Nurse and be able to use the initials OCN. (ONCC, 2016).

The requirements for certification as an Advance Oncology Certified Nurse Practitioner involve two different pathways. Each pathway requires a current, unencumbered license as a RN. One pathway requires graduation from a nurse practitioner (NP) program with a focus in oncology. The second pathway requires the completion of a NP program with a focus in family, gerontology, adult or women's health. Completion of 1000 hours of clinical practice as an adult oncology NP should be obtained within or following the graduate program in addition to the completion of 30 hours of oncology continuing education, or one graduate level oncology course (ONCC, 2016).

Continuing Education

Clearly, as new treatments and medications emerge, it is imperative that the knowledge of the RN be continually updated. Attention should be given to require updated and relevant in-service opportunities. Policies and procedures should reflect the most current best practices. Organizations have an obligation to both orient and to provide continuing education to nursing staff to ensure competency and safety. Many states require minimum hours for RN license renewal but do not specify a specific practice area. The specialized education needed by home health nurses providing care in the home for the oncology patient may not have access to the materials required to support their knowledge base.

Literature Review

A review of the literature was performed using the following databases; CINAHL, Google Scholar, and PubMed Central. Keywords for the search of the databases were nurses, exposure, risks, home health, organizations, change, chemotherapy and hazardous drugs. The literature substantiates the risk of exposure for nurses administering chemotherapy. Interestingly, the review revealed that at one-point latex gloves were the only recommended personal protection equipment (PPE) for the administration of chemotherapy in the home; impermeable gowns were not considered necessary equipment (Parker, 1992). More recent evidence has shown this to be grossly inaccurate.

According to Polovich (2011), the initial step that an organization should take in ensuring the safety of healthcare workers is to determine what hazardous drugs are used in the health care environment. The health care environment for home health nurses is the patients' home. Each drug may require unique measures to ensure safety and may not be appropriate to all settings.

Exposure to hazardous drugs can affect the health and well-being of nurses. These adverse health outcomes include several of the same adverse effects experienced by patients undergoing treatment with chemotherapy. These adverse effects include: alopecia, nausea, vomiting, nasal sores, allergic reactions, abdominal pain, skin and eye injury (Polovich & Gieseker, 2011).

Nurses' exposure to chemotherapy has been linked to premature births, still births, spontaneous abortions, infertility, and irregular menstrual cycles (Eisenberg, 2009). According to Eisenberg (2009), a survey of 3000 oncology nurses revealed that those who administered chemotherapy before and during pregnancy were 2.3 to 5 times as likely to have premature births

or have children with learning disabilities. In a bio-monitoring study conducted by Santovito, Cervella and Delpero (2014) with nurses including 20 nurses handling the substances and matched control subjects, suggested that a continuous long-term exposure to hazardous drugs may result in increased levels of sister chromatid exchanges. Sister chromatids, or chromatids are the identical halves produced during the M phase of cell division. Each chromatid is genetically identical and held together or attached by a centromere (McCance, Huether, Brashers & Rote, 2010). Sister chromatid exchange involves the breakage of both DNA strands and is induced by mutagens that interfere with DNA replication. Mutagens are substances that can alter the genetic makeup of an organism. Chemotherapy agents are considered mutagens. The formation of sister chromatid exchanges has been associated with cellular repair and cytotoxicity. Few laboratories in the United States perform the type of tests that would detect the presence of sister chromatid exchanges therefore making this type of monitoring of exposure impractical (Polovich, 2011).

Exposure to hazardous agents can be related to various points along the pathway of administration. These pathways include delivery of chemotherapy agents to the infusion room to assisting a patient with toileting (Eisenberg, 2009). Nygren and Lundgren (1997) detected platinum in the blood of nurses involved with patient care but not with Cisplatin administration. It was concluded that the exposure occurred during the routine care of patients performed without the use of PPE.

Exposure to hazardous drugs may occur in several ways and includes inhalation via the respiratory system, absorption via skin or mucous membranes, accidental ingestion during administration, and through disposal of equipment or when handling the bodily waste of patients or vomitus (Polovich & Gieseker, 2011). Chemotherapy drug exposure is also facilitated by lack of or inappropriate use of PPE.

Barriers for compliance with safe handling of chemotherapy drugs were also identified in the literature. Eisenberg (2009) acknowledges that while the body of knowledge regarding the short and long-term effects of exposure to anti-neoplastic agents is growing, compliance with recommended safety guidelines among nurses involved with chemotherapy administration is neither widespread nor consistent. Barriers to using PPE identified by Eisenberg (2009) included insufficient supplies, uncomfortable equipment, lack of knowledge, nurses' belief system, and old habits (Eisenberg, 2009).

Gavin et al, (2004) conducted interviews with home healthcare nurses in a study to address their concerns and attitudes regarding chemotherapy administration in the community. The nurses were practicing in communities in England. Nurses verbalized concerns during the interviews regarding education and training. Only after the rates of referrals for home chemotherapy increased were the nurses offered an education and training program (Gavin, How, Condliffe, & Depledge, 2004). Fransman, et al. (2007) conducted a study of 4,393 nurses, both those exposed and unexposed to antineoplastic drugs. The unexposed nurses served as the control group. Exposure to the antineoplastic drugs was estimated using a dermal measurement based on handling tasks. Nurses who were highly exposed, measured as 0.74mcgs per week, experienced a longer time to conceive, had infants with low birth weights and had a higher incidence of preterm labor (Fransman, et al., 2008)

Data from the 2011 National Institute for Occupational Safety were examined to estimate perceived and actual risk of exposure to chemotherapy by health care workers. The sample consisted of 1,800 nurses who in the last week had administered liquid chemotherapy. An astonishing 14% reported an adverse administration event in the last 7 days. Regression modeling revealed that engineering controls and the use of protective equipment are predictive of

lower adverse events. While the use was highly variable, it was clear that the organization's use of a comprehensive safety program including hazard controls and clear communication of safe handling practices significantly decreases the probability of adverse events (DeJoy, Smith, Woldu, Dyal, Steege & Boiano, 2017).

The available literature is highly suggestive of the hazards that practicing nurses may face in the management and administration of chemotherapy agents. Risk can be reduced by organizational support for a culture of safety, by firmly established protocols, by effective communication, and by attention to education.

Theoretical Framework

Promoting Action on Research Implementation in Health Services (PARIHS) was the theoretical framework used for this study. PARIHS was developed by Kitson, et al. (2008) as a method to explain the success or failure of evidence to practice implementation projects. The model has been appraised as useful in guiding the design of implementation interventions (Kitson, et al, 2008). PARIHS allows for the implementation of evidence into practice by utilizing 3 components, evidence, context and facilitation. The successful incorporation of evidence into practice will occur when evidence coordinates with professional beliefs, healthcare conditions are receptive to implementation of interventions, which includes supportive leadership or stakeholders, facility culture, an appropriate evaluation system, and the availability of means to facilitate implementations (Kitson, et al, 2008).

The evidence component of the framework call for evidence that is robust and consisting of different levels. Levels of evidence for the project ranged from low to moderate. According to Kitson, et al. (2008). According to Kitson et al. (2008), evidence includes research evidence,

professional knowledge, clinical experience, patient preferences and experiences. The merging of the evidence into practice involves a team effort. There should be a shared understanding of advantages, disadvantages and risk when comparing old practices to new.

Context for the framework is the setting or environment in which healthcare services are received. It is the setting in which change will occur. The setting for this project consists of the healthcare agency and the patient's home. Contexts that are considered as learning environments are more conducive to change. The culture, which is a part of context, that is characterized by decentralized decision making with an emphasis on the relationship between management and staff are more conducive to facilitating change (Rycroft-Malone, 2004). Leaders are a key factor for the implementation of evidence into practice. Transformational leaders have the ability to change cultures that favor the integration of evidence into practice. Transformational leaders can inspire staff to share the vision which results in clearer roles, effective teamwork and improved organizational structure (Rycroft-Malone, 2004).

The third component of the PARIHS framework is facilitation. Facilitation means to make easier, therefore a facilitator is one who has the appropriate roles, skills and knowledge to assist other practitioners to change or improve their practice by implementing evidence into practice. Facilitators may assume the role helping and supporting practitioners to change attitudes, behaviors and ways of working (Rycroft-Malone, 2004). All three components of the framework are interrelated when introducing, implementing and evaluating the implementation of evidence into practice of the individual and the organization (Rycroft-Malone, 2004).

Each aspect of the model was evidenced by the commitment of the nurse educators at the agency who recognized the need for practice enhancement by reviewing the evidence from the literature. Both the context and facilitation were supported by their leadership.

Project Implementation

This project had a dual approach to minimizing the risk of chemotherapy in the home: (1) the creation of an educational curriculum that would help minimize health risks for both the patients and nurses related to chemotherapy administration and (2) the development of a policy and procedure that would support safe administration and follow up. Policies and procedures would include recommended guidelines for safe handling of hazardous drugs, appropriate education and required skill set. These guidelines, developed from standards and related literature, translated into the determination of the knowledge base required for safe administration. The educational needs were then determined on that basis.

Setting

The project site was a home health care agency engaged in chemotherapy administration in the home located in the Southeastern United States. Specifically, the agency is contracted by area hospitals to disconnected patients at the completion of chemotherapy infusions in the home. The number of patients seen on a weekly basis receiving chemotherapy in the home varies. There may be intervals when there are as few as 25 patients seen within a week. The agency is a Medicare and Medicaid certified provider and part of a private, family owned and operated business. The owner has many agencies throughout the Southeast and employs approximately 600 Registered Nurses (RNs).

Human Subjects Protection

Permission was obtained from the agency to implement the project. Application was made and approved by the Institutional Review Board of the University of Alabama in Huntsville (Appendix A). Written consent was obtained from each of the RNs who participated in the educational aspect of the project (Appendix B). Data obtained related to participants were

maintained in a password protected file and discarded at the end of the project. Participant responses were anonymous.

Participants

Participants were RNs employed at the home health agency. All participants involved were over 21 years of age, able to read and write English, and a voluntary participant. Registered Nurse participants were licensed in their state of practice, and either be engaged, or potentially engaged in the process of the administration of chemotherapy in the home. Each had completed employee orientation and considered by management as competent to administer chemotherapy in the home setting.

Assessment Tools

A self-reporting questionnaire was developed based on recommended guidelines for handling hazardous drugs. The self-reporting tool was used to identify the individual nurse's practice experience regarding the handling of hazardous drugs. The self-reporting questionnaire served to discern their current practices. The guidelines and recommendations the guide for developing the questions were based were guidelines of the American Society of Clinical Oncology (ASCO) and the Oncology Nursing Society (ONS). The guidelines and recommendations include the use of personal protective equipment (PPE), the appropriate handling of chemotherapy spills, disposal of chemotherapy containers and tubing, the disposal of body fluids from patients receiving chemotherapy and much more. (Appendix C).

The questionnaire was adapted from ONS and provided data regarding oncology certification, length of nursing practice and knowledge of safe handing for hazardous drugs.

A pre and post test was developed to test the participants' knowledge base regarding hazardous drugs prior to and after the educational intervention. Policy and procedure recommendations were informed by the data collected from these assessment tools. The same assessment tool was used for the pre and the post test.

The Educational Phase

Using the synthesis of the literature, professional guidelines and standards, and the responsibilities of the RNs as described by the agency, a curriculum was developed as an educational resource for the agency RNs. Due to changes in leadership, the staff nurses were not available for participation, though the RNs who have the responsibility for educating the staff did participate and provided excellent feedback.

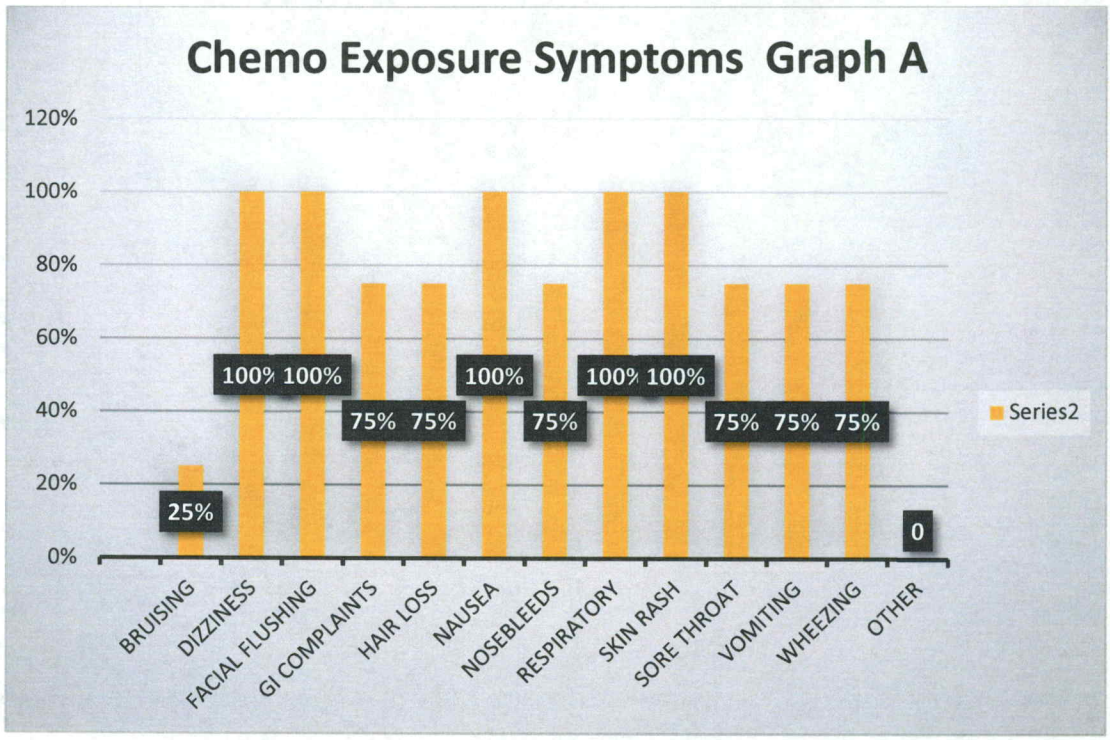
The self□reporting questionnaire (see Appendix E) was administered after signed consent was obtained from participants. The pretest (Appendix G) were completed prior to an educational intervention.

The participants then took part in the educational program (Appendix F). The educational offering included the several types of chemotherapy agents, oral and parenteral, risks and methods of exposure to chemotherapy agents and safe handling recommendation guidelines from the American Society of Clinical Oncology and the Oncology Nurses Society (Appendix C). The educational sessions utilized lecture, prepared handouts (Appendix I) and support from a PowerPoint presentation (Appendix J). At the close of the educational session, participants completed a post educational posttest (Appendix G).

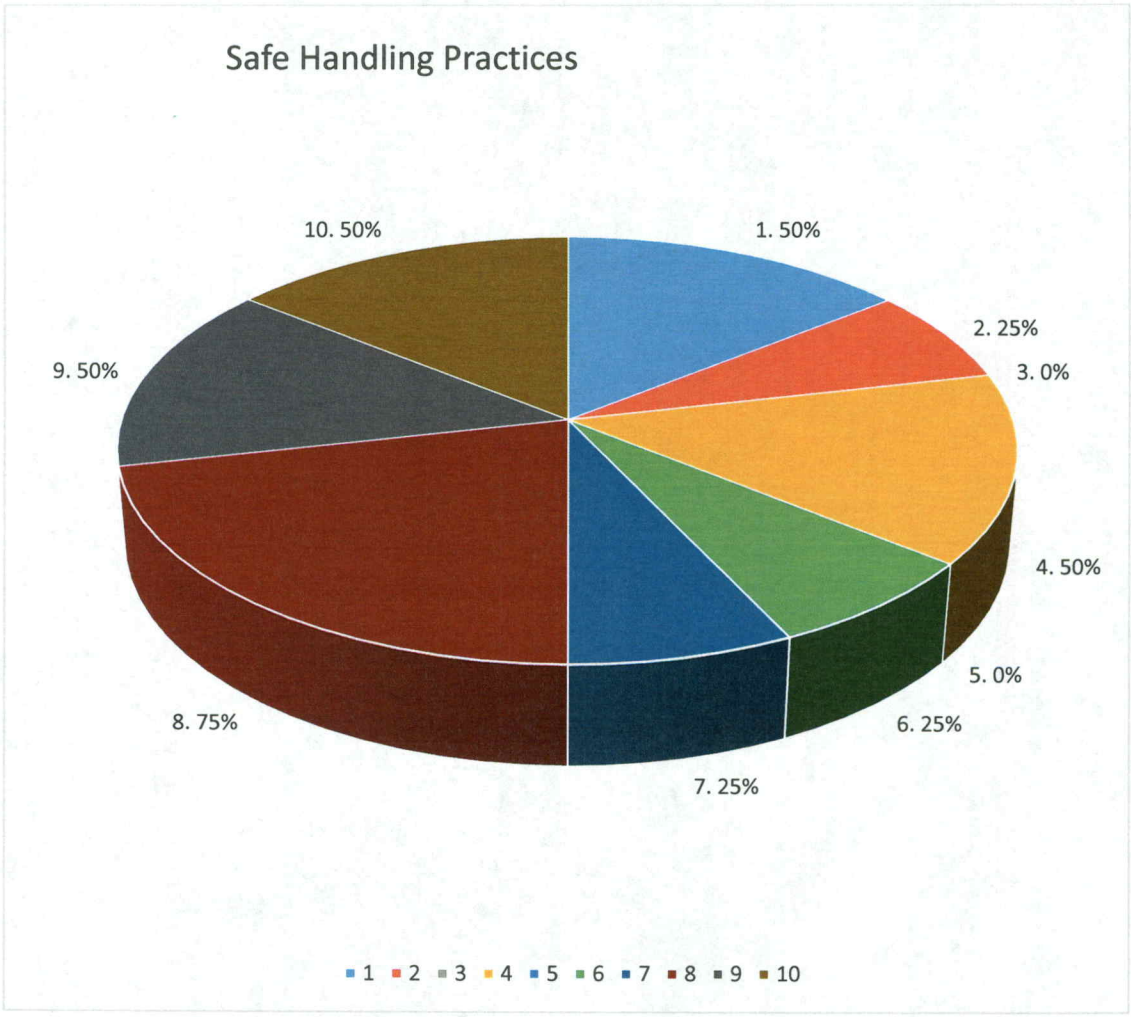
Results

One of the project participants withdrew consent to participate in the project resulting in 4 total participants, 3 clinical educators and a facility administrator. Data was gathered from the Chemotherapy Exposure Risk Questionnaire (Appendix C). Pre and post educational session. data included symptoms of chemotherapy exposure, length of time working with hazardous drug, and most importantly hazardous drug handling practice. Three of the four project participants could identify symptoms of chemotherapy exposure to include dizziness, facial flushing, nosebleeds, GI complaints, hair loss, respiratory symptoms, vomiting, wheezing, and skin rash. The percentage of participants able to identify symptoms of exposure ranged from 75 to 100%. Only one of participants could identify bruising as a symptom of chemotherapy exposure. (see graph A).

Participants in the project identified the length of time handling chemotherapy drugs as 0 to 4 hours per week with no changes in schedules for the past year. No accidental chemotherapy spills were identified. Regarding the length of time participants had administered chemotherapy drugs, responses ranged from "take down only" to 0. The questionnaire also asked participants whether the home health agency offered educational training for chemotherapy administration. All the participants responded "no" for this question. 3 of the 4 participates answered "yes" to the question regarding the presence of a post exposure plan.



The responses for the handling of hazardous drug practices varied. These questions involved wearing personal protection equipment and the availability of a hazardous drug spill kit for home use. Responses ranged from always to never. Responses were dependent upon the individual practices of the nurses in relation to chemotherapy administration and what was considered chemotherapy administration.



1.Chemo certified gloves worn

2.Doubled Chemo gloves

3-Double Latex gloves worn

4. Chemo gowns

5. Eye goggle

6. Disposable booties

7. Disposable hair covering

8. Hazardous waste container

9. Protective devices

10.Hazardous drug spill kit

The presentation outlining the evidence and results of exposure to hazardous drugs did engage the facility administration and clinical educators, resulting in a discussion of policy and procedures of the facility regarding chemotherapy administration.

Development of Policy and Guidelines

The agency leadership graciously shared the framework of their involvement in in-home chemotherapy. While the actual policy and procedures are propriety and cannot be shared in this document, the skills and knowledge required of the RNs for involvement in chemotherapy is outlined.

According to the agency leadership, the company has a protocol for the "take down" of chemotherapy in the home. A take down is the discontinuation of a chemotherapy infusion in the home. Patients may receive a continuous chemotherapy infusion in the home ranging from 48 hours to 21 days via an implanted vascular access device, sometimes referred to as a port. Percutaneous inserted central catheters (PICC) may also be used for continuous chemotherapy infusions. Home health care agencies are contracted to disconnect patients from the infusion lines and flush the central catheter with normal saline followed by a heparin solution.

Home health nurses serve as a liaison between the patient and the hospital or outpatient clinic. Patients may contact home health care nurses directly to troubleshoot infusion pumps, if dislodgement of Huber needles occur or for potential leakage of chemotherapy. It is the position of the Oncology Nursing Society (ONS) that all RNs who administer or care for patients receiving chemotherapy outside of the oncology setting, which includes the home, receive specialized education to include a didactic component and a practicum (Polovich, Olsen, & LeFebvre, 2014).

The nursing knowledge and skills required for these activities were aligned with the guidelines and professional standards (Appendix C), and the synthesis of the relevant literature. (Appendix D).

Evaluation

The evaluation of the project included a post assessment after the educational intervention. The post assessment occurred immediately after the educational intervention and was compared to the pre -education assessment. A discussion with the agency's clinical education staff reviewed the current recommendations and guidelines for safe handling of chemotherapy/ hazardous drugs. The clinical educators, as well as administration, recognized deficiencies in the agency's protocols and policies. The agency was given recommendations to improve protocols, procedures and communication with facilities that contract the nurses for the take down process, or for care of patients who may be receiving oral chemotherapy agents as well to assist in establishing a safe handling protocol for nurses involved with patients receiving chemotherapy in the home (Appendix H)

The protocols or policy and procedures should address the education of nurses and patient caregivers. The patient caregivers also include the home health nursing assistant providing care for patients within the home. The education or training should address safe handling of chemotherapy in the home according to guidelines established by the American Society of Clinical Oncology (ASCO) and the Oncology Nursing Society (ONS) safety standards and should be offered on a continuous basis to include nurses newly hired. Periodic education and training should be offered as changes occur with chemotherapy administration. Nurses should be educated as to the type of chemotherapy drugs which patients may be receiving as components of their cancer treatment for early recognition of possible drug exposure risks. It is important to note that the participants in the educational program are the nurse educators responsible to the on-going in-service education of the staff.

Application to Practice

Nurses and other stakeholders should identify and embrace the benefit of the project which is the reduction of hazardous drug exposure for nurses in the home. The reduction of exposure risk would include not only nurses but unlicensed caretaker or nursing assistants and family members as well. The need for appropriate PPE use during chemotherapy administration according to recommended guidelines is an evidence-based policy that would need to be adopted as usual practice under all circumstances, including take down of chemotherapy infusions. A huge barrier that prevented the adoption of PPE as usual practices identified in this home health care agency is lack of education.

Resources needed to facilitate the sustainability of the practice change were also considered. Support for ongoing education of all personnel and of the individuals and families involved should be maintained. A plan for monitoring of compliance is another factor which will contribute to sustainability of the practice change proposed by the project.

The benefit of the project is an improvement in the processes for the safe handling of hazardous drugs for nurses whose practice area is the homes of patients. Nurses who administer or those who are involved with the process of administration of chemotherapy drugs will become more aware of the risks of exposure and more proactive in minimizing personal exposure. Facilities will also recognize their role in ensuring the safety of these nurses while they are caring for patients being treated for cancer in the home.

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Appendix A

THE UNIVERSITY OF
ALABAMA IN HUNTSVILLE

August 23rd 2017

Dr. Brenda Talley

Associate Professor

College of Nursing
University of Alabama in Huntsville

Dear Dr. Sheldon,

The UAH Institutional Review Board of Human Subjects Committee has reviewed your proposal, *Chemotherapy and Exposure Risk of Home Health Care Nurses,* and found it meets the necessary criteria for approval. Your proposal seems to be in compliance with this institutions Federal Wide Assurance (FWA) 00019998 and the DHHS Regulations for the Protection of Human Subjects (45 CFR 46).

Please note that this approval is good for one year from the date on this letter. If data collection continues past this period, you are responsible for processing a renewal application a minimum of 60 days prior to the expiration date.

No changes are to be made to the approved protocol without prior review and approval from the UAH IRB. All changes (e.g. a change in procedure, number of subjects, personnel, study locations, new recruitment materials, study instruments, etc.) must be prospectively reviewed and approved by the IRB before they are implemented. You should report any unanticipated problems involving risks to the participants or others to the IRB Chair.

If you have any questions regarding the IRB's decision, please contact me.

Sincerely,

Bruce Stallsmith

IRB Chair

Professor, Biological Sciences

Appendix B

Chemotherapy and Exposure Risk of Home Health Nurses Project Consent Form

You are being asked to participate in a research project focusing on home health nurses involved with the administration of chemotherapy in the home and the potential risk for exposure to hazardous drugs, specifically chemotherapy. You are being asked to take part in this project because you are a nurse employed with a home health care agency that provides care to oncology patients in the home who may receive chemotherapy drugs as part of their cancer treatment. Please read this form carefully and ask any questions you may have prior to agreeing to take part in the study.

What the study is about: The purpose of this project is to learn about the potential or actual risk of exposure to chemotherapy drugs experienced by home health nurses. What we will ask you to do: If you agree to participate in this project, we will ask you to complete a questionnaire, a pretest and a posttest. The pretest and the questionnaire will be completed prior to an educational session and the posttest will be completed after the educational program. The questionnaires will include questions about whether you have been involved with any chemotherapy drugs in the home, length of nursing career, knowledge regarding personal protection equipment and safe handling of chemotherapy guidelines. The pretest, posttest and questionnaire should take approximately take about 30 minutes to complete. The educational program will last for 45 to 60 minutes.

Risks and benefits:

There are no expected risks associated with your participation. There are no specific benefits to you for participating in the project.

Compensation: There is no compensation offered with this research project.

Your answers will be confidential. The records of this project will be kept private. In any sort of report we make public we will not include any information that will make it possible to identify you. Research records will be kept in a locked file; only the researchers will have access to the records.

Taking part is voluntary: Taking part in this study is completely voluntary. You may skip any questions that you do not want to answer. If you decide to take part, you are free to withdraw at any time.

If you have questions: The researchers performing this project are Paula P. Parker, Dr. Brenda Talley, Dr. Leslie Adams and Dr. Lenora Smith. Please ask any questions you have now. If you have questions later, you may contact Paula P. Parker at pp0017@uah.edu or at 205-586-0567. If you have any questions or concerns regarding your rights as a participant in this project, you may contact Dr. William Wilkerson, IRB Chair at the University of Alabama-Huntsville, at 1-256-824-6100 or at irb@uah.edu

You will be given a copy of this form to keep for your records.

Statement of Consent: I have read the above information and have received answers to any questions I asked. I consent to take part in the study.

Your Signature _____ Date _____

Your Name (printed) _____

Signature of person obtaining consent _____Date _____

Printed name of person obtaining consent _____ Date _____

Appendix C

Self-Reporting Questionnaire

CHEMOTHERAPY EXPOSURE RISK FOR HOME HEALTH NURSES QUESTIONNAIRE

A. Work History

1. How many hours a week do you usually work with hazardous drugs (either handling or in the area where they are being handled)?

_____

2. Has this schedule changed over the past year? _____ YES _____ NO

If yes, how has it changed?

_____

_____

3. In the course of the past year, have you been around an antineoplastic drug spill?

__YES __NO?

If yes, please give approximate date or dates (if this occurred more than once).

If yes, approximately how large was the spill? _____ Less than 5 ml _____ More than 5 ml If yes, did you clean it up? _____ YES _____ NO

If yes, what protective clothing were you wearing when the spill occurred?

_____

4. In the course of the past year, have you accidentally breathed in, or had skin contact with an antineoplastic drug or solution? _____ YES _____ NO

If yes, how often?

5. Please check the most appropriate answer as it applies to your hazardous drug handling practice

1= Always 2 = Often 3 = Sometimes 4 = Rarely 5 = Never

_____I wear chemo certified gloves

_____I double glove with chemo certified gloves

_____I wear latex gloves and double glove

_____I wear gowns certified for chemo use

_____I use protective eye goggles

_____I have used disposable booties

_____I use disposable hair coverings

_____I use a hazardous container for disposable of chemo bags and tubin

_____Chemotherapy infusions have a protective device, i.e. Pha-Seal, attached to tubing

_____I have a hazardous drug spill kit available for in home use

6. Do you have a chemotherapy/ biotherapy certification? Yes_____ No _____

7. How long have you administered drugs which are considered anti-neoplastic or hazardous in your practice? _____

8. Are you an Oncology Certified Nurse? Yes_____ No _____

If yes, for how long_____

9. Does your home health agency offer educational training for chemotherapy administration?

Yes_____ No _____

10. Does your home health care agency have a post exposure plan? Yes _____No _____

11. Are physical assessments performed for those nurses who are involved with hazardous drug/ anti-neoplastic drug administration? Yes_____ No _____

If yes, how often? i.e. every 6 months, yearly _____

12. Does the home health agency provide you with PPE?

Yes _____ No _____

Appendix D

Pre/Post Test

1. In your practice do you care for patients receiving oral or parenteral chemotherapy?

Yes _____ No _____ Don't Know _____

2. Are latex gloves adequate for handling chemotherapy medications?

Yes_____ No_____ Don't Know _____

3. A patient drops his Revlimid on the floor, the nurse picks up several tablets with her hand. What Is this a risk for exposure? Yes _____ No _____

If yes, what type of risk is it? _____

4. A patient on your case load is receiving Nilotinib. The patient has been experiencing a sore throat and difficulty swallowing. During your home visit, the patient asks that you crush the medication for him, so he can swallow it easier. Is this acceptable? Yes ____No _____

5. List 4 routes of exposure to chemotherapy/ hazardous drugs.

1. _____
2. _____
3. _____
4. _____

6. Is it necessary to have a chemotherapy spill kit in the home of patient who receive continuous infusions?

Yes _____ No _____

7. What is the process for your agency for the disposal of chemotherapy and materials contaminated with chemotherapy? (i.e. infusion tubing, syringes)

_____

_____

8. What type of equipment is needed when providing incontinence care for a patient who has received chemotherapy in the past 24 hours? How would you instruct the home health aide?

_____

_____

_____

9. You are disconnecting a patient from a continuous 5FU (Fluorouracil). The tubing is not clamped and approx. 10ml drops on the floor. Is this considered a chemotherapy spill?

Yes _____ No _____

10. Nurses are not required to wear personal protective equipment (PPE) to administer subcutaneous injections of Bortezomib. All that is needed to administer the subcutaneous injection is chemotherapy gloves.

Yes _____ No _____

11. Oral chemotherapy drugs are not classified as hazardous.

True _____ False _____

12. The use of PPE is one of the most effective means to prevent occupational exposure to chemotherapy/ hazardous drugs. List 3 PPE items to be used when handling chemotherapy/ hazardous drugs.

1. _____
2. _____
3. _____

Appendix E

Content Outline of Educational Intervention

A. Types of Chemotherapy Drugs

B. Routes of Administration:

   a. Oral

   b. Parenteral

   c. Subcutaneous

   C. Different Aspects/Component of Chemotherapy Administration

   D. Potentials Routes of Exposure

   a. Inhalation

   b. Dermal

   c. Oral

E. Appropriate Types of PPE

F. Education of Nursing Staff including HHAs

G. Education of Caregivers/Family

Appendix F

Journal Article Handout

Lester, J. (2012). Safe handling and administration considerations of oral anticancer agents in the clinical and home setting. Clinical Journal of Oncology Nursing 16(6), E192-7. doi: 10.1188/12.CJON.E192-E197

Safe Handling and Administration Considerations of Oral Anticancer Agents in the Clinical and Home Setting

Joanne Lester, PhD, CRNP, AOCN®

The use of hormonal, chemotherapeutic, and targeted biologic oral agents has exponentially increased since the early 2000s. Oral therapies have the advantage of persistent exposure of the cytotoxic drug to tumor cells and the tumor environment. The use of oral anticancer agents provides therapeutic drug treatment for patients with cancer in the comfort of their home or alternative settings, such as retirement homes and assisted living or extended-care facilities. Practices to ensure safe storage, handling, administration, and disposal of oral agents are necessary to prevent additional exposure of hazardous substances to the environment, professionals, patients, family members, and caretakers. Providers should consider potential barriers to adherence and compliance and develop strategies to ensure optimal therapeutic benefit prior to initiation of oral agents.

Joanne Lester, PhD, CRNP, AOCN®, is a research scientist in the Department of Nursing Research at Ohio State University Comprehensive Cancer Center–Arthur G. James Cancer Hospital and a clinical assistant professor in the College of Nursing at Ohio State University in Columbus. The author takes full responsibility for the content of the article. The author did not receive honoraria for this work. The content of this article has been reviewed by independent

peer reviewers to ensure that it is balanced, objective, and free from commercial bias. No financial relationships relevant to the content of this article have been disclosed by the author, planners, independent peer reviewers, or editorial staff. Lester can be reached at joanne.lester@osumc.edu, with copy to the editor at CJONEditor@ ons.org (First submission February 2012. Revision submitted March 2012. Accepted for publication March 18, 2012.)

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The continued development of oral anticancer therapies is fueled by ease of administration, absence of hospitalization or clinic visit, acceptable disease outcomes, potential decrease in side-effect profiles, patient satisfaction, less interference in work and social activities, and the paradigm shift that views cancer as a chronic condition (Hohneker, Shah-Mehta, & Brandt, 2011; Moore, 2010). Daily low-dose or episodic scheduling of oral chemotherapeutic agents may reduce the dose-limiting side effects, including marrow toxicities, that are common with bolus IV dosing (Hohneker et al., 2011; Moore, 2010). Oral targeted biologic agents may be prescribed as monotherapies or added to chemotherapeutic regimens, often with few side effects (Weingart et al., 2008). Information about safe handling and disposal should be incorporated into professional, patient, and family education. Standard operating procedures should be in place at every institution to educate patients and family members about safety. Sustaining biohazard safety guidelines and preventing contamination of landfills and water supply is essential (Bartel, 2007). Potential adverse events should be monitored for individual and group effects, with explanation of the adverse-event profile to patients

Literature Review

An electronic literature review was conducted using PubMed, CINAHL®, Web of Knowledge, Access Medicine, Scopus, and Cochrane Library from 1984–2011 with key words such as

chemotherapy, chemotherapeutic agents, oral, antineoplastic, safety, errors, adherence, education, safety standards, and guidelines to identify publications with evidence-based data or guidelines. Fifty articles were retained that described evidence-based aspects of care for the safe administration and handling of anticancer oral agents. Standards of practice or guidelines were identified from the American Society of Health-System Pharmacists (ASHP), American Society of Clinical Oncology (ASCO), British Oncology Pharmacy Association (BOPA), National Comprehensive Cancer Network (NCCN), Occupational Safety and Health Administration (OSHA), Oncology Nursing Society (ONS), and Society of Hospital Pharmacists of Australia (SHPA) (see Figure 1). In addition, an international board of pharmacists reviewed existing policies, publications, and best practices to determine recommendations for safe handling of oral chemotherapeutic agents for manufacturers and distributors, healthcare providers, patients, and caregivers (Goodin et al., 2010)

Safe Handling

In response to concern about the safe handling of antineoplastic drugs, OSHA (1999) defined a hazardous drug as any chemical that may cause a physical or health hazard and provided an extensive list of hazardous antineoplastic IV, injectable, and oral agents, with inclusion of hormonal drugs such as diethylstilbestrol, estrogen products, megestrol, and tamoxifen. OSHA (1999) recommended special handling with concern for acute and chronic workplace exposure. The degree of absorption that takes place at work and the resulting biologic effects are difficult to measure; however, OSHA maintained that those drugs require special handling to minimize short- and long-term effects. Accidental exposure of oral anticancer drugs can occur during transportation, unpacking, storage, handling, administration, and disposal; therefore, guidelines

are necessary for those activities (Birner, Bedell, Avery, & Ernstoff, 2006; Goodin et al., 2011). Figure 2 provides a list of commonly prescribed oral anticancer drugs; however, the list is not inclusive of all therapies or investigational agents (Barton, 2011; OSHA, 1999; Prostate Cancer Research Institute, 2011).

Safe Handling

- Avoid opening capsules and breaking or crushing tablets.
- Transdisciplinary patient education about disease and drug with specialty pharmacist or trained nurse
- Patient education about health-system policies
- Professional training with ongoing competencies for anyone handling drugs and waste products • Cytotoxic labels on all containers or boxes that hold anticancer drugs
- Patient under the care of specialist oncology staff``````
- Safe-handling policies already in place
- Handle oral chemotherapy in same manner as IV chemotherapy; gloves and handwashing at minimum by nurses.
- Proper handling of waste at hom

Administration

- Proper labeling of drugs, including route, dose, and time
- Avoid "use as directed" on prescription.
- Detailed treatment calendar for patient
- Medication reconciliation, including over-the-counter drugs, by provider
- Patient to report medication errors, lapses, and side effects to provider
- Double and triple check for oral agents instituted by nurses and in pharmacy

- Patients to bring in medication bottles to monitor adherence
- Electronic record keeping
- Dose modifications clearly identified, perhaps standardized
- Patient seen by provider before every cycle; frequency of visits outlined
- Verbal and written education for patient, family, and caregiver
- 24-hour telephone access
- Informed consent that serves as contract between patient and provider

FIGURE 1. Commonly Used Guidelines for Safe Handling and Administration of Anticancer Agents Note. Based on information from British Oncology Pharmacy Association, 2004; Goodin et al., 2011; Grampians Integrated Cancer Service, 2008; Jacobson et al., 2009, 2012; Oakley et al., 2010; Weingart et al., 2008, 2011.

Protection of Nurses

Nurses working on general units outside the oncology setting also often are exposed to oral anticancer agents. If continually exposed without proper precautions, those nurses may increase their risks of contact dermatitis, liver damage, spontaneous abortion, or respiratory tissue damage (OSHA, 1999; Wilkes & Barton-Burke, 2011). Skin, eyes, and mucosa are sites of possible irritation from surface- or direct-contact contamination, inhalation, and ingestion. Oral agents should not be crushed, and capsules should not be opened to avoid harm to the person handling the drug. Patients should be reminded not to disturb the drug's integrity and to avoid chewing those agents (SHPA, 2007). If a patient experiences impaired oral intake, the pharmacy should be notified for emulsification of the agent (Lam, 2011; Simmons, 2010; Weingart et al., 2008). The level of protective wear for the administration of oral anticancer agents is relatively unknown; however, people who administer oral agents should wear gloves, avoid direct contact

with the pill or capsule, and wash their hands prior to and after the drug administration (SHPA, 2007). Prior to the administration of liquid medications via oral or enteral tube routes, nurses should put on protective wear, including gown, gloves, and eye protection (ASHP, 2002; Simmons, 2010). Women who are pregnant or trying to conceive should consider transferring to another ward or unit and avoid administering oral agents. Best practice supports the standard measures of gloves, gown, mask, and eyewear for cleanup of significant oral agent spills to avoid direct contact with powder and inhalation dust (SHPA, 2007; Simmons, 2010).

Protection of Patients, Family, and Caregivers

If medications are delivered to the home, courier services should be appropriately licensed to carry hazardous substances. Patients should be advised by their pharmacist or nurse on what action to take if a delivery does not occur, the packaging is damaged, or the drug appears compromised. Tracking and reporting of delivery issues are essential to risk management (Cooper & Depledge, 2004). Patients should be educated about any requirements for storage, such as temperature or light-resistant needs. The patient, family, and caregiver also should be instructed on safe practices with administration of oral chemotherapy, adjustments in dosing, or return of drug to the pharmacy or oncology clinic. Patient education sheets should be available to enhance verbal instructions with reinforcement that oral anticancer agents are toxic substances (Moody & Jackowski, 2010).

Administration of Oral Agents

The prescribing, dispensing, and administering of oral anticancer agents include precautions that can enhance accuracy, adherence issues, and toxicity documentation. Oral anticancer agents represent emerging risk areas and require appropriate professional and lay education about a drug's side-effect profile, role in disease management, proper administration, and adherence to

the planned regimen (Jatoi et al., 2010; Schneider, Hess, & Gosselin, 2011). Evidence-based practices in place for IV anticancer agents should be considered for all oral agents to promote a culture of safety. The avoidance of errors or near misses is imperative; mistakes with any anticancer drug may have deleterious effects, even when only one or two changes occur in a prescribed drug cycle (Jatoi et al., 2010).

Prescribing Precautions

Tools that can provide optimal outcomes when prescribing oral anticancer agents include policies and electronic medical records. Oral agents should be prescribed routinely on chemotherapy order sheets in the same manner as IV chemotherapy, with provision of height, weight, calculated body surface area, age, laboratory values, and clear instructions for the dosage and administration of the drug (Grampians Integrative Cancer Service, 2008). For institutions without electronic medical records, this form may be generated on a unit-based computer program with typed entries to avoid interpretation errors. Medication reconciliation must occur for current medications with documentation of oral anticancer therapy (SHPA, 2007; Weingart et al., 2008). Prescribed information should be verified by two pharmacists prior to dispensing and two nurses prior to administrating. Some institutions have implemented a triple-check system, including three pharmacists and three RNs, prior to the administration of any antineoplastic agent (Jatoi et al., 2010). Most oral anticancer agents can be filled at any pharmacy; however, standard chemotherapy order forms do not typically exist in the retail setting (Weingart et al., 2008). All pertinent information should be relayed in a readable format; provider abbreviations may hinder an understanding of instructions. Local pharmacists may not be as familiar with oral agents and, therefore, may not provide accurate detailed instructions for the patient. Mail-order pharmacies may provide a three-month supply of a drug or automatic refills with no safeguards in place if

oral therapy is recalculated, stopped, or changed (Weingart et al., 2008). Those potential scenarios reinforce the importance of detailed education by the oncology team, including simplistic calendars and detailed written instructions for disposal of hazardous medication. When possible, prescriptions should be filled at specialty pharmacies that are equipped with pharmacists trained in oncology procedures and drugs (Jatoi et al., 2010); however, collaboration with the referring oncology team may enhance local pharmacy use.

Chemotherapy

Busulfan, capecitabine, chlorambucil, cyclophosphamide, etoposide, hexamethylmelamine, lomustine, melphalan, methotrexate, procarbazine, and temozolomide.

Targeted Agents

Dasatinib, erlotinib, everolimus, gefitinib, imatinib, lenalidomide, nilotinib, pazopanib, sorafenib, sunitinib, and thalidomide

Hormonal Agents

Abarelix, aminoglutethimide, anastrozole, bicalutamide, cyproterone, diethylstilbestrol, dutasteride, exemestane, estramustine, finasteride, goserelin, leuprolide, letrozole, megestrol, nilutamide, and tamoxifen.

Accuracy

IV chemotherapy medication errors have significantly decreased because of built-in checks and balances from pharmacy to the bedside (Weingart et al., 2008). Such rigid checks typically are not in place for oral chemotherapy orders, even in hospital pharmacies. In a study of medication errors in adult and pediatric populations by Walsh et al. (2008), the most common errors in drug administration were noted in the adult clinic and the pediatric home setting. A study by Weingart et al. (2007) of 42 comprehensive cancer centers in the United States revealed that few routine

safeguards are in place for oral chemotherapy orders. Common indices such as body surface area were not included on 66% of oral chemotherapy orders, and only 25% included the patient's diagnosis or protocol information (Weingart et al., 2007). Few institutions (20%) required a double check by a second clinician, and only 10% required inclusion of the treatment cycle. Serious adverse drug events with oral chemotherapy voluntarily were reported at 25% of the institutions; 33% reported serious near-miss errors (Weingart et al., 2007). Few institutions reported safety precautions to monitor and manage risks associated with oral chemotherapies (Weingart et al., 2007). A proactive risk-assessment study of oral chemotherapeutic drugs by Wiengart et al. (2007) was performed at a comprehensive cancer center in the pediatric and adult clinics. Failure mode and effects analyses were performed for five oral chemotherapy agents used by ambulatory patients, including capecitabine, imatinib, temozolomide, 6-mercaptopurine, and an investigational agent (Weingart et al., 2011). For each drug, major steps were examined with a focus on the prescribing, dispensing, administering, and monitoring stages of medication use (Weingart et al., 2011). Four high-risk failure modes were identified for all five drugs: prescription writing errors, wrong medication or amount dispensed at pharmacy, suboptimal adherence by the patient, or failure of the patient to report adverse effects (Weingart et al., 2011).

Adherence

Noncompliance and lack of adherence may negatively affect the ability of a prescribed regimen to control or eradicate a cancer (Patton, 2008). Adherence to anticancer agents has become problematic because of the increased amount of agents and duration of use, the advent of oral biologic and targeted agents, increased combinations of oral therapy with varying patterns of administration, poly-pharmacy, and the older baseline age of patients with cancer (Maloney &

Kagan, 2011; Moore, 2010). Other barriers related to adherence include poor communication, use of retail pharmacies, economic and reimbursement issues, motivation, and disease or treatment complexity (Hohneker et al., 2011; Simchowitz et al., 2010). Documentation of adherence remains an issue because no method is fail-proof or completely accurate. Suboptimal adherence to a regimen may lead to ineffective outcomes of treatment, drug resistance, and altered response to therapy with resulting disease progression (Moore, 2010). In some instances, poor adherence can be associated significantly with increased risk of death (Thompson, Dewar, Fahey, & McCowan, 2007). Persistence, adherence to duration of therapy, and compliance to the prescribed regimen may be challenging but are central to optimal outcomes (Hohneker et al., 2011). Clinical trials of patients with multiple chronic disease states have recorded adherence issues with oral therapies, including management for HIV, diabetes, cancer, and heart failure (Mattson & Friedman, 1984; Moore, 2010). Adherence issues are common with complicated regimens and patients with significant socioeconomic issues (Moore, 2010; Patton, 2008). Although some patients may welcome the autonomy and sense of empowerment with oral treatment, other patients may struggle with the added responsibilities. Oral treatment may not be ideal for patients who are very ill, have complicated dosing regimens, or live alone with minimal assistance. Patients with cancer have documented adherence as low as 20% in some cases (Partridge, Avorn, Wang, & Winer, 2002). Adherence rates can sequentially decrease over time, resulting in decreased persistence and total amount of drug used (Partridge, Wang, Winer, & Avorn, 2003). Overadherence also can occur in patients with cancer who intake more medication than is prescribed or continue a medication without interruption, which may occur when patients are fearful of disease progression and death or are intentionally unaware about dosing or toxicity profiles. Debilitating side effects sometimes are endured silently when patients maintain therapy

that has been otherwise discontinued or interrupted (Palmieri & Barton, 2007). The advantages and disadvantages of oral therapy must be negotiated among the provider, patient, family, and caregiver to ensure optimal adherence with regard to personal circumstances (Weingart et al., 2008).

Toxicity Documentation

The side-effect profile offers important data to the clinician as well as the researcher. Appropriate and accurate data collection must occur to evaluate the effect of treatment, toxicity profiles, drug safety and tolerability, dose-response relationships, pharmacokinetic parameters, and optimal dose intervals and frequencies (Warren et al., 2011). Limitations in adherence reporting, self-management of drugs, abandonment of treatment, and loss to follow-up may reduce the efficacy of intervention (Faiman, 2011; Streeter, Schwartberg, Husain, & Johnsrud, 2011) and confound therapeutic or clinical trial results. Patients may minimize experienced symptoms over a two- to three-week period; if the clinic visit interval is greater than three weeks, patients may possibly forget symptoms. A mechanism of side-effect reporting is essential to capture patient-reported outcome data and may include a simple diary. Several studies have been conducted on reporting and documenting mechanisms, including the use of electronic methods for data capture and communication, from personal digital assistant devices to computerized logs and automated telephoning (Matthew et al., 2007; National Cancer Institute, 2011). Education must be provided to the patient, family, and caregiver with clear definitions of anticipated side effects and parameters for when to contact the provider's office. The oncology nursing staff may consider an ongoing review of patients receiving oral chemotherapy with episodic phone calls. A 24-hour access phone number, including weekend hours, is essential for a practice that uses oral agents.

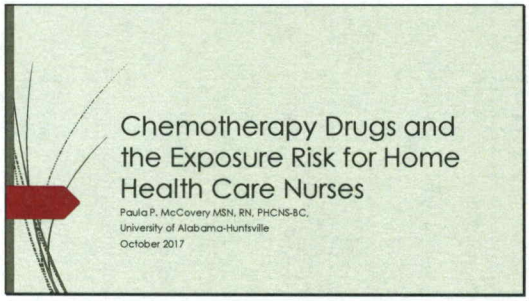
Conclusion

This comprehensive review of published evidence provides data to support safe-handling and administration procedures for oral agents. Strategies to improve accuracy, adherence, and toxicity documentation must be developed and tested, particularly in clinical trial settings when outcomes predicate the future care of patients. Registered and advanced practice nurses are integral to improving the safe handling and administration of oral anticancer agents and should ensure standard operating procedures.

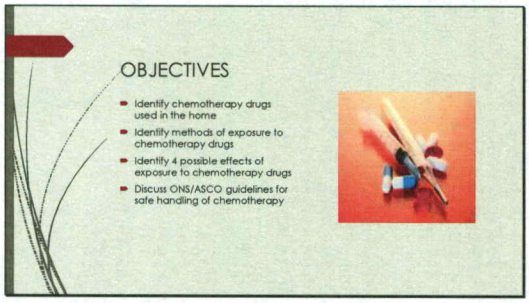
Appendix G

PowerPoint handouts

Slide 1

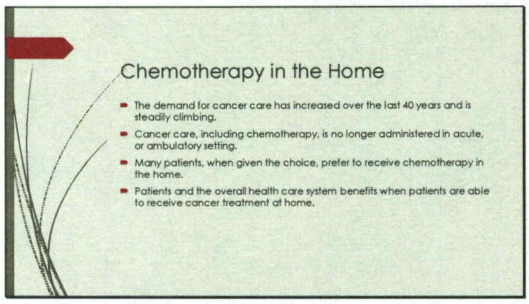


Slide 2

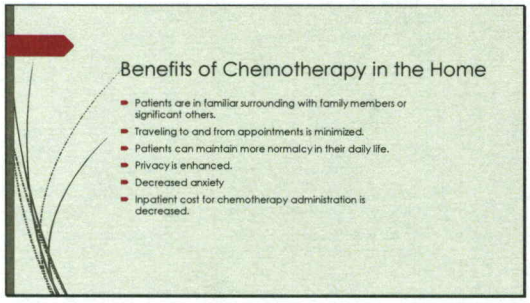


EXPOSURE RISK FOR HOME HEALTH NURSES

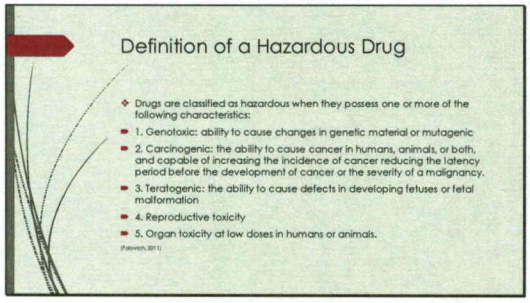
Slide 3



Slide 4



Slide 5



EXPOSURE RISK FOR HOME HEALTH NURSES

Slide 6

Hazardous Drugs

- Drugs that meet the criteria for being hazardous include the following classifications:
- Antineoplastic
- Cytotoxic
- Biologic
- Antiviral
- Immunosuppressive
- Others, such as thalidomide, and conjugated estrogens.
- New drugs are being developed continuously for the fight against cancer and may also meet the above criteria (Polovich, 2011)

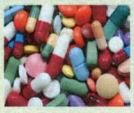
Slide 7

Slide 8

Types of Chemotherapy Administered in the Home

- **Oral Chemotherapy**:

Abiraterone (Zytiga)- Prostate cancer
Capecitabine (Xeloda)-Breast and Colorectal
Dasitinib (Sprycel)-Leukemia
Erlotinib (Tarceva)-Lung
Everolimus (Afinitor)- Breast, Pancreatic, Renal Cell
Letrozole (Femara)- Breast
Imatinib (Gleevac)- Leukemia, Dermatofibrosarcoma



EXPOSURE RISK FOR HOME HEALTH NURSES

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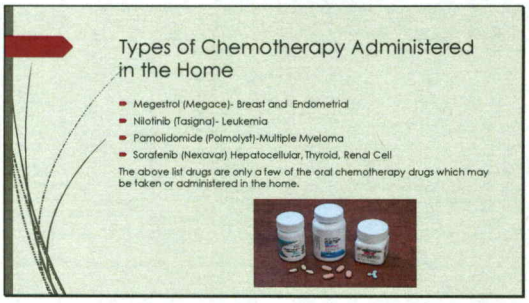

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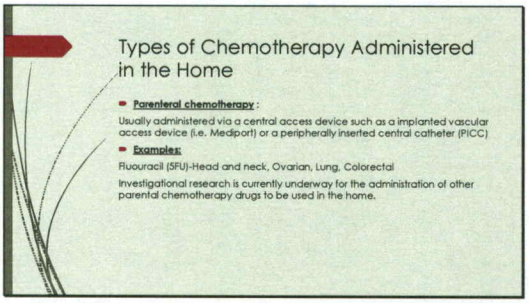

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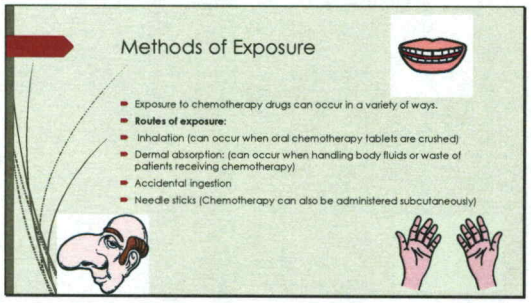

EXPOSURE RISK FOR HOME HEALTH NURSES

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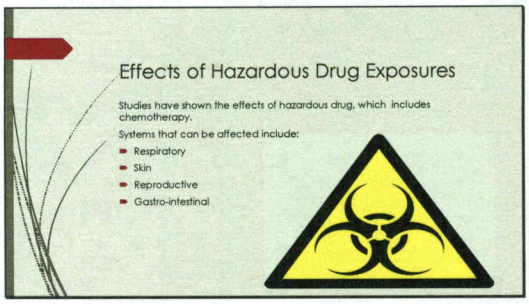

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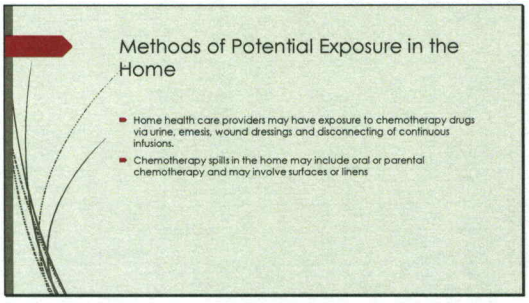

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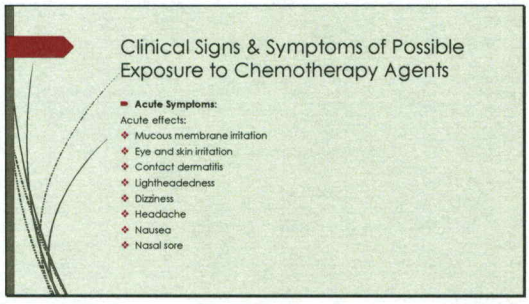


EXPOSURE RISK FOR HOME HEALTH NURSES

Slide 15

Clinical Signs & Symptoms of Possible Exposure to Chemotherapy Agents

- **Latent Effects:**
  - Cancer development
  - Possible fetal loss and birth defects
  - Organ damage

Slide 16

Recommended Guidelines

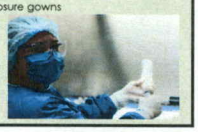
- Guidelines for the safe handling and administration of chemotherapy agents have been developed by the American Society of Clinical Oncology in collaboration with the Oncology Nursing Society.
- Updated to include Standards for Pediatric Oncology in 2016
- Guidelines were first published in 2009 with updates in 2011, 2013 and 2016.
- http://ascopubs.org/doi/pdf/10.1200/JOP.2013.000874

Slide 17

PPE: What, When and Where

WHAT:

- PPE: personal protective equipment
- Consists of the following items :
  - a. chemo safe powder free gloves
  - B. lint-free, low permeability, back closure gowns
  - c. NIOSH approved respirators
  - d. face and eye protection



EXPOSURE RISK FOR HOME HEALTH NURSES

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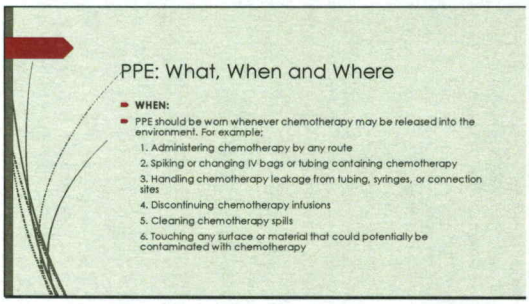

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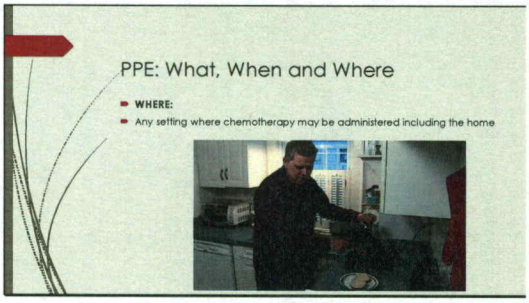

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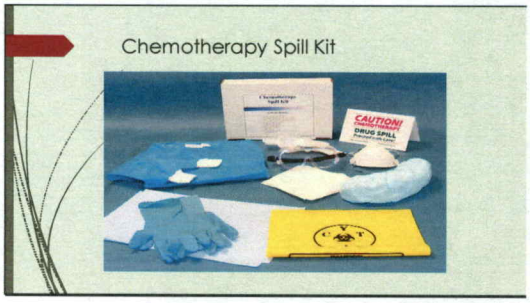

EXPOSURE RISK FOR HOME HEALTH NURSES

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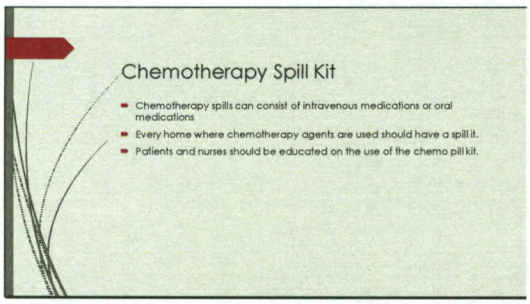

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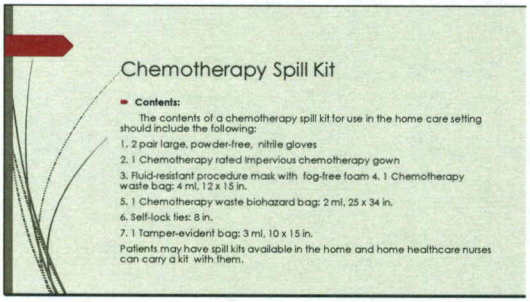

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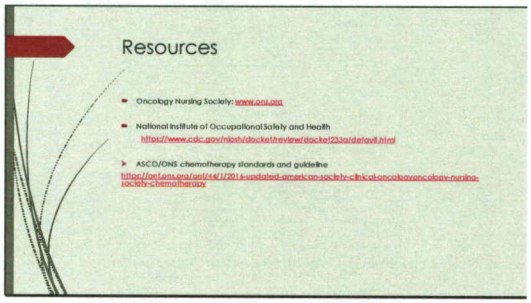

EXPOSURE RISK FOR HOME HEALTH NURSES

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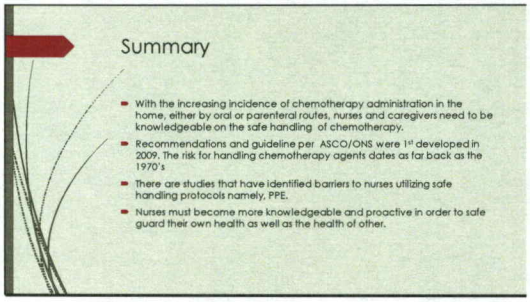

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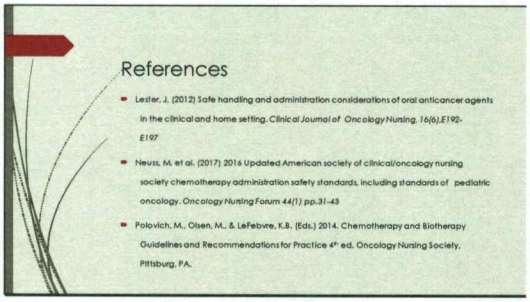

Appendix H

Evidence Matrix

Full Citation	Purpose, Theory, Hypotheses	Design, Sample, Methods, Instruments	Major Findings	Implication for PICOT Question	Quality and Level of Evidence.
Ashley, L., Dexter, R., Marshall, F., McKenzie, B., Ryan, M., Armitage, G. (2011). Improving the safety of chemotherapy administration: An oncology nurse-led failure mode and effects analysis. *Oncology Nursing Forum*, 38(6) E436-444 Doi: 10.1188/11.ONF.E436-E444	Purpose of the study was to assess and improve the administration of hospital-based chemotherapy	Prospective systems focused. Sample consisted of 8-person multidisciplinary team which utilized biweekly team meetings to map the chemotherapy administration process a	Identified 30 failure modes &/or potential errors in the process of chemotherapy administration in a large teaching hospital.	Identified processes in the administration of chemotherapy and the FMEA can be applied to nurses administering chemotherapy agents in the home	Level: III GRADE: Moderate
Easty, A.C., Coakley, N., Cheng, R., Cividino, M., Savage, P., Tozer, R., & White, R.E. (2015). Safe handling of cytotoxic: Guideline recommendations. *Current Oncology*,22: e27-37 doi: https://dx.doi.org/10.3747/co.21.2151	Update and address new issues in the handling of cytotoxic developed since the release of previous guidelines	Developed from 3 systematic reviews using peer and external review.	Outlines procedures for handling of hazardous drugs including preparation, delivery and administration	Direct relationship to exposure risk for nurses	AGREE: 75 GRADE: Moderate
Eisenberg, S (2009) Safe handling and administration of antineoplastic chemotherapy. *Journal of Infusion Nursing* 32(1) 23-32	Outlines and describes the dangers of	Review of the literature	Risks and methods of exposure, barriers of exposure,	Directly relates to the safety of home health nurses when	

DOI:10.1097/NAN.0b013e31819246e0	exposures, how exposures may occur and methods to ensure nurse safety when hazardous antineoplastic agents.		signs and symptoms attributed to acute exposure to hazardous drugs	giving hazardous drugs in the home	
Fransman, W., Peelen, S., Hilhorst, S., Roeleveld, N., Heederik, D., & Kromhout, H. (2007). A pooled analysis to study trends in exposure to antineoplastic drugs among nurses. *The Annals of Occupational Hygiene,* 51(3);231-239 doi:10.1093/annhyg/mel081	This study focused on trends in exposure to antineoplastic drugs since the introduction of	3 cross sectional exposure surveys between 1997 and 2000	Identified the gains in compliance with developed guidelines from 1997 to 2000, however, nurses continue to experience accidental exposure	Relates to PICOT question	Level: III Grade: Moderate
Gavin, N., How, C., Condliffe, B., Depledge, J. (2004). Cytotoxic chemotherapy in the home: a study of community nurses' attitudes and concerns. *British Journal of Community Nursing* 9(1): 18-24	The study purpose was to investigate the policy and practice development regarding community nurses and chemotherapy administration.	Design includes the interview of key informants and review of literature	Identified lack of education of community nurses regarding safe handling of hazardous drugs. Also identified needs for improved policy the part of healthcare agencies.	Directly relates to the PICO question about nurse exposure to hazardous drugs.	Level: VI GRADE: Low

Jacobson, J.O., Polovich, M., Gilmore, T.R., Schulmeister, L., Esper, P., Lefebvre, K.B., Neuss, M.N. (2012). Revisions to the 2009 American Society of Clinical Oncology/Oncology Nursing Society Chemotherapy Administration Safety Standards: Expanding the Scope to Include Inpatient Settings. *Oncology Nursing Forum*, 39(1): 31-38	In January 2011, a workgroup consisting of ASCO and ONS members was convened to review feedback received since publication of the standards, to address interim changes in practice, and to modify the standards as needed.	Forty stakeholders, including medical oncologists, oncology nurses, oncology pharmacists, social workers, practice administrators, and patient advocates, as well as representatives from American Cancer Society, Association of Community Cancer Centers, National Quality Forum, National Coalition for Cancer Survivorship, The Joint Commission, and Institute for Safe Medication Practices met and	Clinical guidelines for chemotherapy administration which can be used over all treatment settings.	Direct relationship to PICO question	Agree grade :85 Level: 1

		using a structured drafted 64 chemotherapy administration safety standards.			
Lester, J. (2012). Safe handling and administration considerations of oral anticancer agents in the clinical and home setting. *Clinical Journal of Oncology Nursing*,16(6):E192-197 DOI: 10.1188/12.CJON.E192-E197	Purpose /goal of the study included a comprehensive review of published evidence for safe-handling and administration procedures for oral chemo-therapy agents	Electronic literature review and review of established guidelines by ONS/ASCO, NCCN, BOPA OSHA	Review of recommendations or major organizations involved in the safe handling of hazardous oral agents	Direct relationship to nurse safety and possible exposure to hazardous agents	Level:1 GRADE: Moderate
Mader, R. M., Kokalj, A., Kratochvil, E. Pilger, A., Rüdiger, H. W. (2009) Longitudinal bio-monitoring of nurses handling antineoplastic drugs. *Journal of Clinical Nursing*, 18(2): 263-269	Purpose/goal of the study is to assess a possible trend in the geno-toxic risk of oncologic nurses during the working year, he studies	Longitudinal bio-monitoring study conducted on 15 nursing staff members on an oncology unit over nine months. Instruments used in the study	PPE was correctly used on this nursing unit, however, geno-toxic changes in nursing although reversible and small were noted.	This study has a direct bearing on risk exposure for ambulatory and home healthcare nurses.	Level: IV GRADE: Moderate

		included the comet assay and sister chromatid exchange test			
Polovich, M., Martin, S. (2011). Nurses' use of hazardous drug-handling precautions and awareness of national safety guideline. *Oncology Nursing Forum*,38(6): 718-726	Purpose of the study is to determine patterns of personal protective equipment (PPE) by oncology nurses during the handling of hazardous drugs (HDs) and to determine their knowledge of the 2004 National Institute for Occupational Safety and Health (NIOSH) Alert and its effect on precaution use.	Descriptive correlational study design. Sample included 330 nurses' wo prepared 7/or administered chemotherapy. Data was collected using a self-report survey, Hazardous Drug Handling Questionnaire	Nurses are educated and aware of safety guidelines, however, they have adopted a gloves only approach for PPE when handling hazardous drugs. Also, all employers do not provide PPE for safe handling.	Responds to the exposure risk for ambulatory care setting as well as home health.	Level: VI GRADE: Moderate
Polovich, M., Gieseker, K.E. (2011). Occupational hazardous drug exposure among non-oncology nurses. *MEDSURG Nursing*, 20(2):79-97	Review of areas of possible exposure to hazardous drugs	Expert opinion	Nurses are at risk of exposure to hazardous chemotherapy drugs in multiple	Related to the exposure of nurses in the home healthcare and ambulatory	Level: VII GRADE: Low

			areas or settings other than the oncology setting	care setting other than oncology.	
Polovich, M., Clark, P.C. (2012). Factors influencing oncology nurses' use of hazardous drug safe-handling precautions. *Oncology Nursing Forum*, 39(3): 299-309.	Purpose and goal of the study is to examine the relationships among factors affecting nurses' use of hazardous drug (HD) safe- handling precautions, identify factors that promote or interfere with HD precaution use, and determine the managers' perspectives on the use of HD safe-handling precautions.	Design is cross sectional, mixed methods. Sample included 165 oncology nurses and 20 managers. Instruments used in the study included Revised Hazardous Drug Handling Questionnaire, Chemotherapy Exposure Knowledge Scale, Barriers to Using PPE scale, Self-Efficacy scale and Perceived Risk scale.	The workplace environment and the number of patients treated in an outpatient setting contributed the consistent use of PPE by the nurses administering chemo	Direct application to the PICO question	Level: VI GRADE: Moderate

Appendix I

Recommendations for Chemotherapy Policy and Procedure for Home Health Agency

The Oncology Nursing Society issued a joint position stamen in collaboration with the American Society of Clinical Oncology and the Hematology Oncology Pharmacy Association regarding the safety of health care workers when handling hazardous drugs. (ONS, 2016). According to the position statement, healthcare workers, which includes nurses and nursing assistants, healthcare workers are potentially exposed to hazardous drugs during drug preparation, administration, disposal and when handling patients waste after treatment with hazardous drugs to include chemotherapy agents. The potential for exposure is increased when hazardous drugs are handled without appropriate precautions.

It is the recommendation of the position statement that exposure risk can be minimized by a comprehensive hazardous drug safe handling program. While a home health care agency involved with chemotherapy administration may not require engineering controls, such as biological safety cabinets and compounding hoods, the components of administrative controls are very necessary for the safety of the healthcare work.

Administrative controls consist of safe handling policy and procedures, hazard communication, and education of staff. The use of PPE is also a significant component in reduction of exposure risk. All nurses who are involved with any aspect of chemotherapy administration should be educated regarding the risk of exposure and practices which are influential in reducing those risk. Not only should nurses be educated, but other health care workers and family members caring for the patients receiving chemotherapy should also receive training and education.

Initial Training:

Nurses involved with the take down process of chemotherapy infusions for home health agencies should receive education and training prior to participating in any aspect of chemotherapy administration including take downs, or the discontinuation of completed chemotherapy infusions in the home. Beyond nurses, nursing assistants should be educated on the use of personal protective equipment when caring for patients in the home who are undergoing chemotherapy treatment. The use of a home chemotherapy spill kit should also be reviewed with the appropriate feedback for competency.

Depending upon the role of the health care worker, initial training should reflect the agency's policy and procedure and include the following:

- Potential health effects of hazardous drug exposure

  Genotoxicity

  Reproductive toxicity

  Carcinogenicity

- Routes of exposure

Skin

Ingestion

Inhalation

Accidental injection

- Personal Protective Equipment

  Gloves (Chemo approved)

  Gown

Respiratory protection

Face and eye protection

Equipment needed for spills

- Work Practice

Use of PPE, donning and removal

Gloves, when and how to change

Handwashing

Appropriate disposal of chemotherapy equipment

- Drug administration practices to limit exposure

Use of interlocking connections

Checking for and use of CSTDs

Avoiding the unspiking of completed infusion bags

How to manage skin, mucus membranes or eye contamination

Home Spill kit and how to use

Spill containment and management

- Patient Care

Appropriate PPE

Handwashing

Handling of contaminated body waste

Handling linens

Skin protection for incontinent patients

The training or knowledge should be evaluated with a post test. Competencies for certain aspects of the training should include feedback demonstrations, such as the use of a spill kit or donning and doffing of PPE.

Training should be repeated on a semiannual or annual basis and upon hire. There should also be a communication between contracting hospitals and home healthcare agencies regarding type of medications, flow rates, and time infusions should end, and type of access device in use for verification of orders.