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USP <800> Compliance: A Hazardous Drug Safe Handling PPE Toolkit for Infusion Nurses

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Executive Summary

Problem: Safety concerns have existed for more than 40 years about how hazardous drug (HD) exposure contributes to long- and short-term adverse health outcomes for healthcare workers (HCWs). Careless handling may cause toxic residues to infiltrate hospital environments and patient care areas, and can even be traced to patients' homes. New government regulations will require healthcare organizations to minimize exposure risks to HCWs by fully implementing the U.S. Pharmacopeia (USP) Convention Chapter 800: Hazardous Drugs: Handling in Healthcare Settings (USP, 2016) on December 1, 2019. According to Polovich and Olsen (2017), "The implementation of the USP <800> Standards will represent an important step forward for nurses and other potentially exposed HCWs" (p. 1).

Context: The proposed Doctor of Nursing Practice (DNP) project will implement an HD safe-handling personal protective equipment (PPE) toolkit at an ambulatory cancer infusion center to improve nurses' adherence with the USP <800> Standards and hospital policies addressing PPE use when handling, administering, and disposing of HD.

Proposed Interventions: Interventions for this project will consist of (a) an HD safe-handling PPE toolkit for infusion nurses, (b) a PPE observation tool, (c) an expert panel discussion, (d) a nurses' skills session, (e) safe-handling adherence between observation and self-assessment survey, (f) hazardous drug administration safe handling peer-to-peer checklist, and (g) a performance dashboard to display progress.

Proposed Outcome Measures: Outcome measures include (a) 90% or higher compliance rates with PPE use and (b) sustained adherence to USP <800> Standards and hospital policies for safe HD handling to 100% by February 2020.

Section II: Introduction

Problem Description

Healthcare organizations are preparing for the implementation of the USP Chapter 800: Hazardous Drugs-Handling in Health Care Settings (USP <800>), where regulatory standards will provide enforceable safe-handling protections for all HCWs to minimize HD exposure risks (USP, 2016). As USP <800> changes how HDs are managed, organizational efforts to educate staff and ensure acceptance from HCWs will drive new worker safety protections (Andrews & Dill, 2018). Despite scientific evidence of known exposures and adverse health outcomes related to residue exposure, resistance to the use of PPE or other safe-handling measures during preparation, administration, and waste disposal continue among infusion nurses. Adverse health outcomes may include genetic changes, developing certain cancers, birth defects and fetal abnormalities, organ toxicity, and infertility, among others. According to Hennessy and Dynan (2014), "Resistance is based on the denial of risk, insufficient information, lack of policy enforcement or regulation, or lack of provision of safe-handling devices" (p. 497).

Infusion nurses have not well received policy efforts to change from recommended PPE guidelines for HD administration to mandatory requirements. Studies have shown that nurses' PPE use is inconsistent across the country. The primary focus for implementing this evidence-based practice (EBP) initiative is two-fold: (a) USP <800> requires HCWs to wear proper PPE when handling HDs, and (b) nurses need to consistently adhere to USP <800> standards and organizational policies during patient care. The proposed quality improvement (QI) intervention is of interest to the organizations' "Environment of Care" Workstream Committee whose purpose is to prepare ambulatory health care units for compliance with USP <800> Standards. The outcomes are of interest to the organizations' Cancer Committee because it satisfies the

"Quality Improvements" Standard 4.8 of the Commission on Cancer Program accreditation requirements. Until recently, the organization's efforts have been placed on developing inpatient compliance, with minimal attention paid in ambulatory care settings. To address infusion nurses' reluctance to wearing PPE, the organization must understand how it contributes to this phenomenon, eliminate barriers to allow for best practice, and implement changes to improve safety and compliance.

The setting will be an ambulatory infusion center (AIC). The AIC has 36 infusion treatment chairs available for chemotherapy and non-chemotherapy patients. The study will involve the observation of experienced infusion nurses, defined as having two or more years of experience in chemotherapy administration, to determine the baseline compliance rate of PPE use with HD handling. All nurses are required to possess a chemotherapy and biotherapy certification card that demonstrates sufficient training and competence in the area of HD administration processes and drug knowledge. The first goal is to observe at least 90% of the nurses prepare, administer, and dispose of HDs over a four-week period. Fifteen nurses are eligible to participate in the quality improvement (QI) project. At the organization where the project will be implemented, policies specific to PPE requirements with HD handling are currently under review and revision. However, the Oncology Nursing Society (ONS) states that standard-specific gloves (ASTM D6978), non-permeable gowns, face masks and eye shields (or goggles), and respirator masks be readily available for PPE use at a minimum. The project will follow the ONS guidelines for PPE use with HD handling until policies have been approved for the infusion center.

Available Knowledge

Hazardous drug residues pose a real threat to the health and wellbeing of staff, patients and families, and the environment when left uncontrolled or mismanaged. The National Institute for Occupational Safety and Health (NIOSH, 2016) reported more than eight million HCWs in the United States are potentially exposed to HDs. Furthermore, HCWs with long-term, low-level occupational exposure have shown an increased risk of adverse reproductive outcomes and other unwanted health issues (Connor, Lawson, Polovich, & McDiarmid, 2014; Hon, Teschke, Shen, Demers, & Venners, 2014). McDiarmid and Condon's (2005) research identified a 20% increase in chromosomal abnormalities of HCWs who had a 'moderate' level of hazardous drug handling (>100 handling events of chemotherapy within six weeks). Lack of diligent organization and worker accountabilities, inconsistent oversight, and environmental exposure have caused irreversible harm and death in some cases (Smith, 2010). Toxic residues found on common healthcare surfaces may spread to patient homes, exposing cohabitants, family pets, and the environment (Bohlandt, Sverdel, & Schierl, 2017; Connor, Zock, & Snow, 2016; Yuki, Sekine, Takase, Ishida, & Sessink, 2013).

PICOT Question

Would the development of an HD safe-handling PPE toolkit improve infusion nurses' compliance and adherence with PPE use during HD handling and comply with USP <800> standards and hospital policies for HD safe handling by February 1, 2020?

Literature Review

I conducted a literature review using CINAHL, Cochrane Library, and PubMed databases to locate current information on the health hazards of residue exposure and recent EBP recommendations to improve PPE use in nurses. More than 50 articles from 2005 to 2019 were

located in the database search, with 15 selected for further review. Findings demonstrated a clear and present danger regarding HD exposure and the need to implement mandatory EBP policies for PPE use and environmental oversight. Excluded articles were those that focused on hospital HD administration, routes of administration other than intravenous (IV), anesthesia HDs, and occupations outside the healthcare setting. Keywords for the search included *hazardous drugs, occupational health, protective equipment, safety standards,* and *USP <800>*. Final literature selection criteria were determined after analyzing the strengths, weaknesses, limitations, and quality of evidence using the Johns Hopkins Nursing Evidence-Based Practice Tool (Dearholt & Dang, 2016). There were five Level IA, four Level IIA, and six Level IIIA quality ratings for the selected articles, which represents a quality approach for selecting the evidence for this project. A summary of the evidence is available in an evaluation table (see Appendix B). The articles and research studies identified three themes: (a) HD residues found in patient homes after treatment, (b) organizational responsibilities, and (c) nurses' responsibilities to practice and provide safe care for others, including the environment of care.

Hazardous drug residues found in patient homes. Yuki et al. (2013) tested the urine of family members of three cancer patients who received at least one of two antineoplastic drugs (cyclophosphamide [CP] and fluorouracil [5-FU]) during the first 48 hours after IV chemotherapy treatment. The objectives were to determine if (a) any detectable levels of HD agents exposed family members, (b) whether environmental contamination occurred inside the home, and (c) how long a drug remained in the patient's urine 48 hours after treatment. Urine samples were collected from patients and patient family members, and swipe tests were obtained from common home surface areas to detect if CP or 5-FU residues were present. Predetermined acceptable drug levels for CP were 0.01 and 5ng/ml urine for 5-FU. Cyclophosphamide was

detected in eight of 12 swipe tests (0.03 – 7.34 ng/cm2) in one of the homes. Swipe tests in homes of treated patients with 5-FU reported drug levels below the predetermined threshold; however, there are currently no defined acceptable levels of HD exposure.

Swipe tests from toilet seats and bathroom sink faucets had the highest level of HD residue (3.02 and 0.57 ng/cm2); floors around toilets and bathroom doorknobs measured 0.03 and 0.09 ng/cm2. Most importantly, patients continued to excrete antineoplastic drugs at low levels over more than four days through urine, feces, and standard breathing patterns. Family members who handle potentially contaminated waste products, such as urine, stool, vomit, or other excreta, should receive specific safe-handling instructions to control the spread of contaminants in the home setting. While most research focused on controlled health environments, it is imperative that patients receiving HDs be better informed and prepared in case of potential exposure situations to families and friends.

Bohlandt et al. (2017) conducted an environmental and biological study inside 13 homes of treated cancer patients to confirm potential HD residues on household surfaces. The researchers wanted to determine whether HD levels were measurable in the cohabitants of treated patients. Thirteen study participants received outpatient IV chemotherapy in an oncology infusion clinic. The researchers obtained 265 samples from home surfaces, including bathroom toilets, floor and sink handles, and kitchen surfaces. Every specimen had substantial levels of HD residues, but cohabitant urine samples did not detect any trace of IV chemotherapy residues.

Crickman and Finnell's (2016) systematic literature review covered 13 years of articles, from 1979 to 2014, to understand the need to implement HD control measures in different settings. Healthcare workers, especially those who are not responsible for medication administration but clean up after a treated patient, are among the highest at-risk population. The

findings are worrisome because families often become primary caregivers after chemotherapy treatment. Recommendations regarding PPE selection and choice, HCW competencies, increased professional oversight, and medical monitoring of high-risk staff will be mandated requirements in the USP <800> regulations. These articles indicated that HCWs must also practice safe handling in controlled settings to minimize personal risk; they must also educate and inform the public.

Organizational responsibilities. Clark, Zickar, and Jex (2014) developed a field study investigating the influence of role definitions on the association between safety climate and employees' organizational citizenship behavior. Providing safe working conditions requires a significant commitment on the part of leadership and stakeholders. Unfortunately, an organizations' obligation to provide safe, patient-centered care often overshadows or conflicts with ensuring that staff also deserves safe working conditions to provide that care. For example, scheduling patients for infusion therapy requires an acuity-based, decision-making process, yet nurses are often scheduled to treat far more patients than is safe with HD administration. Clark et al. stated that nurses who feel appreciated, protected, and respected by their organization are more likely to go above and beyond expectations to provide optimal patient care.

In 2017, He, Mendelsohn-Victor, McCullagh, and Friese completed a cross-sectional, multi-state survey offered to Oncology Nursing Society (ONS) members (N = 654) to examine whether the organization's safety culture correlates to nurses' use of PPE. The study involved nurses working in ambulatory care centers in three states across the United States; 67% of the oncology nurses responded to the survey. One tool used to collect data was the Revised Hazardous Drug Handling Questionnaire (Martin & Larson, 2003; Polovich & Olsen, 2017). The sample mean for the PPE-use score was 2.4 (SD = 1.0) out of a maximum score of 5.0.

Nurses self-reported that 26% were involved in an HD spill, 90% wore only one pair of chemotherapy-approved gloves, and other PPE supplies were infrequent. He et al. (2017) found that if nursing workloads increased by one patient, the odds of an HD spill increased by 3.0% (*OR* = 1.03, 95% CI [1.01 – 1.06], *p* = 0.01). He et al. recommended that nurse managers monitor and adjust patient acuity, ensure that PPE is readily available, and provide ongoing HD training to prevent adverse events. Furthermore, the authors stressed the need for organizations to commit to a culture of safety that may include modifying the nurses' workload and environment, if necessary, to accommodate safe-handling practices and self-protection during the HD-handling process (He et al., 2017).

Nurses' responsibilities to provide safe care. The most recent study by Friese, Yang, Mendelsohn-Victor, and McCullagh (2019) concluded that despite decades of research, PPE use remains suboptimal and that professional organizations, policymakers, clinical experts, and healthcare systems align to guide best practices to ensure public safety. The randomized controlled study, from 2015 to 2017, involved 12 academic healthcare ambulatory oncology centers across the United States and included nurses who handled HDs (*N* = 396). All data were collected from a secure website where participants accessed learning modules and completed questionnaires to self-report PPE use. The intervention did not improve adherence among participants. Therefore, the authors suggested that nurse leaders standardize education and HD policies and procedures and enforce personal accountability regarding safe-handling steps and PPE use (Friese et al., 2019). Under USP <800>, efforts to provide oversight and safe handling across oncology settings will no longer be considered recommendations or guidelines.

DeJoy et al. (2017) examined predictors of PPE use, safe-handling components, and adverse events associated with HD exposure in nurses (*N* = 1,814) and concluded that adherence

to recommendations is inconsistent. Interestingly, PPE use was worse and less predictable among more experienced nurses during chemotherapy administration than among their less experienced colleagues. The study assessed organizational safety climate and nurses' perceived safety climate regarding PPE, engineering controls, and adverse events associated with IV HDs. DeJoy et al. found that nurses' perceptions about exposure risks were low and that they understood organizational policies to merely be guidelines for PPE use. A comprehensive health and safety program emphasizing hazard controls is critical to promote safer behavior among all HCWs.

Summary of the Evidence

The literature review suggests that HD controls are inconsistent and that workplace contamination may lead to HCW and patient exposure to toxic agents. Both international and national research conducted in ambulatory oncology practices support stricter, even mandatory, PPE utilization and endorse environmental and biological monitoring for the detection of harmful residues, similar to radiation exposure monitoring of HCWs (Bohlandt et al., 2017; Boiano, Steege, & Sweeney, 2014). Summaries from the literature review reveal gaps in safety controls. Researchers concluded with recommendations for HD controls that focus on (a) better engineering controls, such as closed-system transfer devices (CSTDs) and biologic safety cabinets; (b) administrative controls, such as updating policies and procedures and improving access to information; (c) work practice controls, such as acuity-based scheduling and reducing workloads and crowded spaces; and (d) ensuring the mandatory use of PPE. Furthermore, nurses are aware of the hazards associated with exposure but continue to exhibit risky behavior.

Rationale/Conceptual Framework

The Orem model of nursing or self-care deficit nursing theory was developed by nursing theorist Dorothea Orem and covers a broad spectrum of general concepts for nursing

consideration and application (Alligood, 2014). The theory is comprised of three related parts: (a) the theory of self-care, (b) the theory of self-care deficit, and (c) the theory of nursing systems. Some of the theory's relativity to this project include: a person's knowledge of potential health problems is needed for promoting self-care behaviors, the prevention of hazards to human life and wellbeing, and responsibility for their care, as well as others who require care (Vincent, Pischke-Winn, Pakieser-Reed, & La Fond, 2016). This model depicts how health professionals have as much of a responsibility to care for themselves as they would care for others (Younas, 2017).

Donabedian's conceptual model, developed in 1966, provides a framework for developing, implementing, and evaluating this intervention (McDonald et al., 2007). Applying the components of the model to this project include the assessment of structures, processes, and outcomes relative to ambulatory oncology infusion centers associated with the management and safe handling of chemotherapeutic agents. According to Donabedian, the physical setting would be determined as the Cancer Center's AIC. The elements would include the mission and values of the organization, leadership skills, staff knowledge levels, adequate staffing and scheduling, suitable workspace, and patient population. Other elements to support a safety culture include having access to HD waste bins, chemotherapy spill kits, and CSTDs.

The process includes interventions that occur within the AIC that contribute to the outcomes of safe drug delivery, such as HD administered by oncology trained nurses. Developing standard work and tip sheets that outline the responsibilities and steps for each stage in the HD-handling process, including any associated interdisciplinary tasks, are aspects of process outcomes. Evidence-based guidelines and regulatory mandates specific to HCWs and patient safety are specified in the USP <800> Standards.

Finally, an outcome is the final product combining both structure and process. A favorable outcome would have a sustainable structure and process that reduces the risk of HD contamination at all stages of handling. Poor outcomes allow for failures, such as inconsistent use of PPE by nurses or other processes contrary to EBP recommendations. Different relevant outcomes include improved patient perception of safety scores from Press Ganey surveys and reduced costs due to employee health matters related to HD exposure. Nurses' attitudes and perceptions about protecting themselves to protect others will align with policies and procedures and other best practice initiatives and comply with the USP <800> Standards.

Specific Aims

The objectives are to develop, implement, and evaluate an HD safe-handling PPE toolkit to learn if infusion nurses' adherence to PPE use will improve to 100% with HD handling and comply with the USP<800> standards and hospital policies for safe handling by February 2020. The specific aims of the project are to determine if (a) based on direct observation, nurses comply with USP <800> requirements and hospital policies for HD handling when administering and disposing of IV chemotherapy (as defined in the PPE toolkit); (b) based on nurse self-assessment, PPE standards and hospital policies for safe handling were followed at least 90% of the time; and (c) any differences are noted in nurses observed and self-assessed adherence to PPE standards and hospital policies for safe handling. If differences are noted, additional peer-to-peer coaching will be considered until 90% compliance has been reached.

Section III: Methods

Context

Personal protective equipment use has been defined in the literature as a critical element required for handling HDs at any step in the process. The administration process for ambulatory infusion nurses to safely administer HDs will require enhanced training on selecting, donning and doffing PPE, and proper disposal of contaminated equipment. According to Friese et al. (2019), "Education and engagement of nursing personnel are not sufficient to improve PPE use. However, systematic approaches may result in improved practice" (p. 255). The proposed intervention will include the development of an HD safe-handling PPE toolkit to guide best practice with antineoplastic drug administration and proper waste disposal methods.

The key stakeholders of the proposed DNP project include staff in the AIC where the project will take place, the Assistant Unit Manager (AUM), the Cancer Center Executive Director, the Director of Cancer Services, the Cancer Committee, and the "Environment of Care" Workstream Committee. Also, the USP <800> Committee will be interested in the outcome of the DNP project because the results may be applicable to other hospital-based AICs within the healthcare system. The Cancer Committee has chosen this project as one of its' Quality Improvement (QI) initiatives for 2020. Each year the Cancer Committee must report QI results directly to the Commission on Cancer (COC) Programs to maintain accreditation. This project meets Program Standard 4.8 (Quality Improvements, see Appendix B). Finally, the USP <800> Standards are not optional, and the Cancer Center must comply with all applicable standards.

Proposed Intervention

The purpose of implementing an HD safe-handling PPE toolkit is intended to gain better PPE adherence from infusion nurses in the AIC and to create an environment where a culture of

safety can exist. The DNP project will be conducted in an AIC adjacent to a large tertiary medical center campus. The AIC consists of the following healthcare personnel: 15 registered nurses, two patient care associates (previously called nurses' aides), one Assistant Unit Manager (AUM), one unit secretary, and five oncology nurse practitioners (NPs). Nurses generally work 10-hour shifts from 8:00 a.m. to 6:30 p.m. The AIC is open seven days per week. The AUM reports directly to the Director of Cancer Services weekly, the Executive Director of Cancer Center monthly, and to the Cancer Committee at least quarterly.

The Cancer Committee provides program oversight and also ensures compliance with all rules and regulations set forth by federal, state, and local authorities. The Committee is also responsible for engaging in QI projects centered on quality patient outcomes and patient safety to meet the COC standards for Cancer Centers (see Appendix B). This committee is aware of QI methodology and familiar with the elements of Donabedian's conceptual framework of structure, process, and outcome. However, the COC has outlined specific steps for project compliance, which includes creating an independent QI committee to oversee all cancer center projects. A description of the COC's project steps is described in a *Basic Steps of Standard Compliance Flow Sheet* (see Appendix C). I will work directly with the QI Committee on this project.

The interventions will be implemented over five months, from September 2019 through February 1, 2020. Once the project is completed, and evidence of improvement in nurse adherence with PPE use and compliance with hospital policies and USP <800> standards are achieved, the plan is to analyze and report the interventions' results to other executive leadership in the health system. To ensure Internal Review Board (IRB) approval is not required for the implementation of the project, I will submit a DNP Statement of Non-Research Determination form to my DNP Committee (see Appendix D), as well as provide a request for review to the

healthcare system's IRB to confirm this is a QI project. The interventions will consist of: (a) the development of an HD safe-handling PPE toolkit, (b) PPE observation tool, (c) observations of chemotherapy safe-handling adherence, (d) expert panel discussion, (e) nursing skills session, (f) safe-handling adherence between observation and self-assessment survey, (g) hazardous drug administration safe handling peer-to-peer checklist, and (h) the use of a performance dashboard. Each of these interventions will be described in detail.

Hazardous drug safe-handling PPE toolkit. The toolkit will contain available evidence as described in the literature, align with the policy manual, and become a practical guide for frontline infusion clinicians. The toolkit will be divided into three sections: Part A (Portfolio of the Evidence), Part B (How to Implement Interventions), and Part C (Resource Tools). Part A will contain current EBP research and methods (evidence table) and hospital and AIC policies for safe HD administration. Part B will include a PowerPoint training module for HD PPE selection. Part C will contain useful tools, such as the confidential Pre-Observation tool, hazardous drug administration safe handling checklist for peer-to-peer feedback, and observations of chemotherapy safe-handling adherence tool. Furthermore, a list of common HDs provided by the ambulatory care pharmacy will be added for reference and include exposure risk levels and specific PPE requirements for potential low-, moderate-, and high-risk situations.

Confidential pre-observation assessment. Confidential observations of staff nurses' handling, administering, and discarding chemotherapy waste will be done by the DNP student, a clinical nurse educator, two oncology registered NPs, and one infusion pharmacist to determine the baseline level of adherence using an established PPE observation tool (Hennessey & Dynan, 2014). I will collect and analyze results to determine the current adherence rate of PPE use

before the intervention based upon recommendations from the Cancer Committee and "Environment of Care" Workstream Committee groups.

Expert panel discussion. An educational session introducing the USP <800> Standards related to PPE use will be provided by a panel of oncology certified nurses, an occupational health nurse, a clinical nurse leader, medical oncologist, and pharmacist to increase awareness of personal risks associated with HD exposure and to address potential and actual barriers that hinder compliance in the current practice environment.

Nurse skills session. The AIC nurses will attend a 2-hour skills session to introduce them to the concepts of the USP <800> Standards within the department. Orem's self-care deficit theory will be used to teach how the theory applies to personal safety and nursing practice. The nurses will also receive feedback on the current state of safe-handling methods in the unit and how the focus of the DNP project includes improving the workplace environment to promote a culture of safety. A PPE demonstration and practice session will be provided, and a peer-to-peer tip sheet and the toolkit will be introduced.

Safe-handling adherence between observation and self-assessment. A Qualtrics survey will be sent via email to infusion nurses to obtain self-assessments of adherence to PPE and compliance with organizational policies. Results will be compared to actual observations in the AIC by trained staff.

Hazardous Drug Administration Safe Handling Checklist (Peer-to-Peer Tool). The organization has obtained permission from the authors to utilize this tool created by two nurse researchers, Martha Polovich and Mikaela Olsen. The tool will be useful in providing instructions and feedback on several different HD administration techniques such as IV

infusions, IV push medications, intramuscular and subcutaneous injections, and oral drugs, including liquid preparations (Polovich & Olsen, 2017, p.96-97).

Performance dashboard. A visual display to create transparency and ownership will be posted on the huddle board identifying critical elements of the intervention phases. Metrics will be discussed in daily huddles to encourage participation, brief staff on the current status of the project, and to develop the concept of an environmental safety culture (OSC).

Gap analysis. Better education is needed to ensure that employers and HCWs are fully aware of the risks and potential adverse health consequences of exposure to these toxic drugs (Boiano et al., 2014). For example, nurses who work in high exposure environments understand the inherent risks, yet compliance may be ignored, as evidenced by the lack of PPE use. Additional gaps specific to the AIC include scheduling demands and workload pressures placed on pharmacists and nurses. Research shows that the average patients per day significantly influence total HD precautions. It is safe to say that HD precautions occur with fewer patients per nurse, yet patient acuity levels may change dramatically throughout the day, jeopardizing real-time safety. The gap analysis outlines common issues concerning PPE use and the organizations' conflicting agenda (see Appendix E).

Infusion managers may benefit from a unit-specific acuity scheduling template and a toolkit outlining the risk levels of exposure to staff, including facilitating clinician input on the decision to lower workloads and eliminate structural barriers to safe handling (Mendelsohn-Victor, McCullagh, & Friese, 2017). Hospital, pharmacy, and unit-specific interventions could contribute to a more reliable work environment balance. Safe-handling practices, such as PPE worn by nurses, reduce exposure risks, and the likelihood of adverse health effects from antineoplastic drug residues (NIOSH, 2016). However, not all exposure risks involve nursing

practice, as each step in the handling process, should be managed appropriately. Evidence-based practice, policies and procedures, engineering controls, unit-based workplace designs, and the HCWs commitment to improving safety must guide processes and outcomes (Callahan et al., 2016).

Gantt chart. The project will be divided into four implementation phases, as outlined in the Gantt chart (see Appendix F). The first phase will commence in September 2019. Confidential observations of the AIC infusion nurses' handling, administering, and discarding chemotherapy will be completed by the DNP student, a clinical nurse educator, two oncology NPs, and one infusion pharmacist to determine the baseline level of adherence with safe handling using the established PPE observation tool by Hennessey and Dynan (2014). The second phase will take place in October 2019, where an expert panel discussion will be held for all staff in the AIC. The panel will consist of oncology certified nurses, one occupational health nurse, a clinical nurse leader, infusion pharmacist, and medical oncologist. Nurses will also be provided access to an online survey to perform a self-assessment of safe-handling adherence. Beginning phase three in November 2019, individual nurse audits will be performed to assess compliance with PPE use, and immediate peer-to-peer feedback will be provided to encourage best practice. Phase four will commence on December 1, 2019. Nurses' adherence will be expected to comply with the USP <800> regulations and current hospital policies and procedures for PPE use with all HD handling.

Work breakdown structure. The purpose of the work breakdown structure (WBS) is to have a plan and infrastructure, supporting documentation and metrics tools, comprehensive education strategies, and a monitoring plan to maintain fiscal responsibility and increase chances of sustainability (see Appendices G, H, and I). Since the hospital has been proactively preparing

for hospital and pharmacy compliance, this project will serve as an adjunct to other administration processes requiring PPE use and ensure that the cancer center is provided with the resources necessary for USP <800> readiness.

There are five phases of development in the WBS: (1) initiation, (2) planning, (3) execution, (4) control, and (5) closeout. During the initiation phase, the project manager will attend the organization's USP <800> committee meeting to share information about the proposed project plan and gather recommendations from the group. The USP <800> environment of care committee will sign and approve a charter. The PPE workgroup will develop a preliminary scope statement and solidify team member participation during the planning phase. The DNP student will develop the final project plan, with the cancer committee accepting for final approval.

The execution phase includes a kickoff meeting, verifying and validating the USP <800> PPE requirements, introducing the toolkit, deciding on the quantity of PPE per unit, testing in the AIC, and completing the PPE toolkit. Staff training and Go Live date will be determined. The control phase of the WBS includes project management, project status meetings, risk management, and updating the project management plan. Finally, the closeout phase is one of the essential aspects of the project. An audit procurement and lessons learned session is instrumental because all of the completed steps will be analyzed and reported to various committees involved. All files and records will be collected and archived. Formal acceptance of the toolkit as an important resource for AIC nurses will be realized.

Responsibility/Communication plan. The proposed QI intervention is part of an organizational work stream committee that exists to address the environment of care readiness plan related to USP <800>. The initiative is also of interest to the cancer committee because it

satisfies a mandatory requirement issued by the COC practice (see Appendix J). The cancer committee will make an overall recommendation to the work stream committee to develop, implement, and report on the USP <800> Standards for the entire cancer center. However, a smaller workgroup committee will focus on the AIC project where HCW exposure risks are the highest. Project charter team members will meet weekly to discuss the next steps and progress toward agreed upon goals.

A separate PPE workgroup will oversee the selection of protective equipment and measures while assessing the financial impact on the AIC and organization. Many healthcare personnel will assist with gathering content to be used in the toolkit. Training and monitoring of nurses will be a combined effort by the AUM, clinical nurse educator, and others. The DNP student will work cohesively with each of the groups throughout the process to ensure timely coordination and communication, thereby providing efficient use of available resources and time.

SWOT analysis of the current state. The SWOT analysis (strengths, weaknesses, opportunities, and threats) is a useful tool for identifying many factors that may impact the success of the project (see Appendix K). The following summary of the findings is discussed below.

Strengths. A system-wide approach in how the organization will address the new standards is now in process. Executive leadership and frontline managers are working to identify gaps with HD handling that include transporting, receiving, storing, preparing, administering, and disposing of HD waste. Supplies necessary for safe handling are under review. Standards of practice are being aligned across the healthcare system to improve communication and understanding among physicians, pharmacists, nurses, and many others involved in these critical steps.

Weaknesses. The most significant flaw is the nurses' resistance to wearing PPE with HD administration in the AIC. Even after focused training sessions and reminders in the past, nurses remain complacent (Friese et al., 2019). Without addressing negative attitudes and beliefs toward PPE use, improving personal safety will remain unsustainable. Nurses must understand that personal safety will be jeopardized, and diligent PPE adherence will prevent potential short- and long-term adverse health effects. Policies and procedures for HD handling are contradictory in some settings and merely indicate PPE use as a guideline. However, a renewed focus on USP <800> creates the urgency to reevaluate processes and include the mandatory requirements based on exposure risk factors. Also, increased costs associated with purchasing PPE, waste management, and decontamination wipes are unpredictable.

***Opportunities*.** Opportunities to comply with USP <800> specific to PPE use are making national news and bringing awareness to the public about the risks of HD residue exposure in their communities. Local leaders and waste management services are reviewing external pressure from communities to control environmental HD waste. Increasing demand for patient education provides opportunities for nurses to engage the public on safe-handling awareness, not only in controlled healthcare settings but also inside their own homes.

***Threats*.** Threats to meet upcoming USP <800> Standards for PPE use may be associated with the high cost of equipment, regular and random monitoring of the HCW and AIC environment, inability to maintain and recruit qualified nurses experienced with HD practices, and a lack of focus on ambulatory care practices during program development. Also, there may be a loss of funding in the coming years for healthcare programs that strive to meet the demands of the 21st Century Cures Act. This legislation will increase Medicare infusion access to eligible patients and impose significant financial disincentives to pharmacy services. It is vital that PPE

and waste management strategies remain part of this new legislation to prevent the dumping of chemical waste into communities and to ensure accessibility to appropriate PPE.

Proposed Budget

The AIC is the highest user of PPE in the patient care setting within the organization for HD handling. With 2,800 patient visits projected per month in 2020, the costs of providing PPE to HCWs is daunting. The annual cost alone accounts for an increase in the budget of over 20% in 2020. Purchasing departments generally choose contracted vendors to get better pricing; however, various committees are reviewing several other non-contracted vendors to improve pricing options. Nursing is evaluating different PPE products for comfort and ease of use with hopes to improve adherence and compliance.

Nonmonetary benefits include ethical, moral, and harm reduction efforts to protect staff and patients that cannot be quantified into a dollar amount. Interestingly, efforts are underway to create a national registry where health care workers can report HD exposures that include chemotherapy and report adverse side effects experienced such as headache, dizziness, nausea, hair loss, miscarriage, and fertility problems (Friese, et al., 2019). A toolkit will become a quick and useful staff resource to guide best practice. The budget estimates document (see Appendix L) is a rough draft depicting financial considerations for implementing the project. Future dissemination of the toolkit is excluded. Projections include staff education, a learning module, expert panel discussion, pre- and post-observations of PPE use, and peer-to-peer feedback tip sheet tool.

Proposed Outcome Measures

The PPE observation tool will be used to collect pre-intervention data to evaluate the current state of adherence to PPE use with HD administration. To assess observations of

handling, administering, and disposing of chemotherapy, a 15-item yes or no nurse skill checklist will be used. To retrieve self-assessments of nurses' adherence to PPE use and to follow organizational HD policies, a 9-item questionnaire using a 5-point Likert scale response set, ranging from 0 (never) to 4 (always) plus a not applicable option, will be given. The content for this tool is derived from NIOSH, ONS guidelines, USP <800> Standards, and the healthcare organization's updated policies for HD safe handling. Also collected and analyzed will be nurse demographics and professional characteristics through self-assessment survey questions using checkbox and fill-in-the-blank responses.

Proposed Analysis

Data analysis will involve describing the nurse skills checklist frequencies and self-assessment of RN characteristics using medians and quartiles of counts and percentages for all categorical variables. Mean scores for the 9-item self-assessment questionnaire on PPE recommendations will be calculated by averaging responses across administration, disconnection, and disposal of chemotherapy. After matching factors for the nurse skill checklist and self-assessment questionnaire, data will be compared to learn if differences exist in adherence to PPE recommendations and hospital policies for safe chemotherapy handling. All analyses will be two-tailed and will be analyzed at a significance level of 0.05, SAS Version 24.

Ethical Considerations

One of the core Jesuit values is *forming and educating agents of change,* which means teaching behaviors that reflect critical thought and responsible action on moral and ethical issues. Infusion nurses must change attitudes and behaviors on using PPE because of the high-risk nature of harm due to HD contamination. It is morally and ethically irresponsible to subject patients and families to harmful HD residues because of personal convictions. The American

Nurses Association (ANA, 2015) ethical standard that relates to this evidence-based project is Provision 3, “The nurse promotes, advocates for, and protects the rights, health, and safety of the patient” (p. 9).

Provision 3.4 states that nurses have a professional responsibility to promote a culture of safety. This provision extends beyond reporting events and errors that occur to patients and includes “adherence to policies that promote patient health and safety” (ANA, 2015, p. 12). This QI project hopes to empower nurses to behave more responsibly to protect patients from HD exposure while in their care. Also, nurses will educate other staff and the public by role-modeling proper PPE use with HD handling. Efforts will be made to minimize the psychological stress patients, and caregivers may feel while observing the PPE intervention by informing them of the new regulations to improve patient and nurse safety with HD administration. Nurses are encouraged to incorporate HD education into their teaching plan via verbal and written communication methods and emphasize how to prevent home environmental contamination.

Since the focus of this project was on QI, it does not require an IRB approval for implementation, per the University of San Francisco’s IRB. The project was evaluated and approved as a QI project through the University of San Francisco School of Nursing and Health Professionals. However, the healthcare organization requires IRB evaluation, so the DNP project will be referred to the committee for comments and approval.

Section IV: Discussion

Limitations

The hospital has organized multiple interdisciplinary teams to develop a comprehensive program to comply with the USP <800> Standards, yet infusion nurses in the cancer center have not been involved and are unfamiliar with the new mandatory safe-handling requirements. A representative from the Cancer Center will be included in future discussions and planning phases. Personal protective equipment and supplies, such as gloves, gowns, facemasks, eye protection, and respiratory devices, should be tested by nurses for comfort and ease of use. Comfort, choice, and ease of use may be secondary to organizations who must control expenses. Current budgets for the Cancer Center and AIC are under review, and additional funds will be requested to ensure sufficient PPE is allotted to the AIC.

Another limitation is that the DNP project will be conducted in a single center, and even though response rates for the self-assessment survey include the total AIC nursing population, the overall sample size may be too small compared to larger AICs. A multi-center approach would increase the value of the findings related to PPE adherence in AICs. In addition, it is possible the nurses could be evaluated multiple times on different days by different observers. The registered nurses who complete the self-assessments may be different from the ones who are being observed each day.

Furthermore, environmental wipe sampling and staff health monitoring will be costly, yet vitally important for all working in high exposure risk areas. The organization is self-insured for workers compensation and has increased efforts to proactively address additional costs due to employee adverse health events following exposure incidents through staff medical monitoring, HD education and training. Funding for the project should be added to the 2020 budget beginning in July 2019 to make additional preparations for USP <800> compliance by December

1, 2019. However, budget considerations in the Spring of 2019 require an additional 20% increase to cover expenses for PPE, waste disposal bins, sharps disposal devices, increased waste disposal services, and HD environmental monitoring supplies until the new budget has been approved.

Conclusions

Maintaining supportive best practices with HD administration and PPE provides a message of commitment to staff and the public that safety concerns are paramount. Similar to interventions for handwashing to prevent contamination, patients should be encouraged to speak up when they view a situation where PPE should be utilized. Critical components of sustained success are staff education and ownership of the required changes relevant to PPE use, peer-performance monitoring, leadership support, prioritization of workload, and continuous monitoring and feedback regarding performance. The fact that all involved in patient care have a responsibility to maintain the standard is well-established and accepted. Current data are limited on the long-term effects of HD exposure; yet, the literature concludes that there is no well-defined safe level of exposure. Control systems, similar to individual staff radiation exposure tags that monitor monthly levels in the field of radiology, are currently unavailable. Enforceable regulations to protect workers must be monitored by state, federal, and accreditation organizations to increase compliance and to sustain pressure on healthcare providers to consistently provide HD protections.

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Section VI: Appendices

Appendix A: Evidence Table

Citation	Statistical Tools	Data Collected	Quality of Evidence	Highlights from Article
Bohlandt et al. (2017)	Wipe samples/surface monitoring, urine collection, questionnaire on household. Analyses carried out under strict internal and external quality assurances; SPSS Version 21; Spearman rank correlation test/Mann-Whitney-U test for independent variables.	Setting: Patient homes s/p chemo admin Sample: 1) 265 wipe samples/13 homes at two times after chemo from common household surfaces. 2) 62 urine samples from patients and family members on three days. 3) Drugs analyzed: cyclophosphamide (CP), 5-fluorouracil (5-FU), and platinum (PT). Time Frame: Up to 4 days Results: Substantial contamination on every surface type (PT: 0.02-42.5 pg/cm2; 5-FU: ND 98.3pg/cm2; CP: ND-283.3 pg/cm2)	Level: I Quality: A Limitations: Spot samples, both wipe and urine samples, only reflect the current situation and that probably different results may have been found when performing continuous urine collection.	Aim: To evaluate the surface contamination and the potential uptake of antineoplastic drug residues by family members at home of chemotherapy patients. Exposure was evident in patient homes on various surfaces. Adequate hygienic and protective measures are necessary to minimize the exposure risk for cohabitants. Elevated levels in patient's urine more than 48 hours, no drug residues in family members' urine.
Boiano et al. (2014)	NIOSH Survey of Healthcare Workers (an anonymous, multi-module, web-based survey), SAS 9.3 to analyze data.	Setting: NIOSH web-based survey Sample: 98% of 2,069 respondents were nurses Time Frame: Jan 28 to Mar 29, 2011 Results: The survey results show deficiencies related to the lack/infrequency of training, awareness of	Level: I Quality: A Limitations: Survey was targeted to members of professional practice organizations and are not generalizable to all healthcare workers or to all members of each of the	Authoritative guidelines are not being universally followed. Activities that increased exposure risk per respondents, included: failure to wear nonabsorbent gown with closed front and tight cuffs (42%), IV tubing

		employer procedures, and awareness of national safe-handling guidelines. Multiple breaches in safe work practices (CSTDs, luer-lick fittings, needleless system).	participating professional organizations. The survey was only available to members with email addresses and internet access.	primed with antineoplastic drug (6%) or by pharmacy (12%), potentially contaminated clothing taken home (12%), gloves (12%), lack of hazard awareness training (4%). Most common reason for not wearing gloves or gowns was "skin exposure was minimal," but respondents reported skin contact during handling and administration.
Callahan et al. (2016)	Descriptive, cross-sectional correlational design study. Survey Hazardous Drug Handling Questionnaire. Data were analyzed using descriptive statistics and multiple regression analysis. (main research variables: exposure knowledge, self-efficacy, perceived risk, interpersonal influences, and workplace safety climate). Survey Monkey software database, SPSS V21.0, Spearman's correlation coefficients, Wilcoxon rank sum tests.	Setting: The National Institutes of Health Clinical Center in Bethesda, Maryland Sample: 196 eligible/115 RNs working on high-volume HD administration units. Time Frame: Results: Total mean HD precaution use proved highest during HD administration and lowest for handling excreta at 48 hours. Average patients per day significantly influenced total HD precaution: more precaution use with fewer patients assigned.	Level: II Quality: A Limitations: Self-report survey conducted in one specialized research hospital and cannot be generalized without replication to other settings. Nurses were required to attend formal training to administer chemo and biotherapy and gain oncology nursing certification	Purpose: To identify factors associated with oncology nurses' use of HD safe-handling precautions in inpatient clinical research units. Data were analyzed using descriptive statistics and multiple regression analysis. (main research variables: exposure knowledge, self-efficacy, perceived risk, interpersonal influences, and workplace safety climate). Conclusions: Despite high exposure knowledge, barriers to PPE use and conflict of interest may contribute to reduced adoption of personal protective practices among oncology nurses.

				Hospitals and unit-specific factors captured by the predictor variables could contribute to institutional HD policy.
Colvin et al. (2016).	Prospective, mixed-methods study to compare objective and subjective nurse behavior, micro-ethnography and questionnaires.	Setting: Cleveland Clinic Sample: 22 cases of chemo handling observed, 12 of 33 nurses completed questionnaires. Time Frame: Jan 2012 to Mar 2013 Results: Data analysis involved describing the nurse skill checklist frequencies and self-assessment of RN characteristics using medians and quartiles of counts and percentages for all categorical variables.	Level: III Quality: A Limitations: Study conducted in a single center, and the sample size was small. Sample size for nurse observations was small. Lack of uniformity in assessment item working could have led to differences in reported frequencies in adherence to PPE recommendations. One nurse may have been observed more than once on different days. Nurses observed had two or more years nursing experience in oncology nursing and may not have been well matched in the group comparisons. Analyses were based on group findings; no correlations were noted between observed behaviors and self-assessment by individual nurses.	The aims of the pilot study were to examine actual and subjective ambulatory oncology nurse adherence to chemotherapy safe-handling with NIOSH PPE and hospital policy exposure controls. Consistent adherence to practice expectations may require more than an annual competency assessment. Chemotherapy exposure is a team concern in that one healthcare clinician can follow all policies, yet still be exposed to chemo if others fail to do so.
Connor et al. (2014)	Literature search using the following databases:	Setting: Literature review	Level: III Quality: A	Antineoplastic drugs are highly toxic in patients

	• Canadian • CINAHL • CISILO • DTIC, Embase • Healthy and safety abstracts • HSELine • NIOSHTIC-2 • OSHLine • PubMed, Risk abstracts • Toxicology Abstracts • Toxline, Web of Science • WorldCat	Sample: 18 peer-reviewed, English language publications of occupational exposure and reproductive outcomes studies. Time Frame: Literature review completed 1980 to February 2014 Results: While effect sizes varied with study size and population, occupational exposure to antineoplastic drugs appear to raise the risk of both congenital malformations and miscarriage. Studies of infertility and time-to-pregnancy also suggested risk for sub-fertility. Measurement of surface contamination is the best indicator of the level of environmental contamination in areas where Ads are prepared, administered to patients, or otherwise handled (such as receiving areas, transit routes throughout the facility, and waste storage areas). The odds ratio of adjusted models ranged from 1.36 (95% CI, 0.59-3.14) to 5.1 (95% CI, 1.1 -23.6)	Limitations: Small sample sizes 5/8 studies had 10 or fewer exposed cases. All studies had fewer than 20 exposed cases. Limited ability to adjust for confounding; the need to group anomalies that had different etiologies and wide confidence intervals, which reflect poor statistical power.	receiving treatment and adverse reproductive effects have been well documented in these patients. HCW with chronic, low-level occupational exposure to these drugs also appear to have an increased risk of adverse reproductive outcomes. Additional precautions to prevent exposure should be considered (NIOSH). Some studies have shown an association between surface contamination and worker exposure. For pregnant women, the *window of risk* begins one month before conception and lasts through pregnancy (most vulnerable in first trimester). Breast milk is affected by HD exposure. A man's sperm is vulnerable to HDs from as early as 2 months before conception.
Connor et al. (2016)	Not stated	Setting: Article review by experts at NIOSH	Level: III Quality: A	The purpose of the article was to review published studies of

		Sample: not stated Time Frame: not stated Results: A comprehensive safe-handling program for ADs may utilize wipe sampling as a screening tool to evaluate the environmental contamination and strive to reduce contamination levels, as much as possible, using the industrial hygiene hierarchy of controls.	Wipe sample area recommendations: Nurses' station storage area for IV bags Countertops Furniture in patient rooms Infusion pump Door handles, door knobs, other high-touch areas Computer keyboard/mouse Floor in patient room Floor in restroom	wipe sampling for antineoplastic and other HDs, to summarize the methods in use by various organizations and researchers, and to provide some basic guidance for conducting surface wipe sampling for these drugs in healthcare settings.
Crickman & Finnell (2016)	Databases searched: • PubMed • CINAHL • Cochrane Library • EMBASE English language	Setting: Systematic literature review Sample: 29 publications met final review criteria Time Frame: 1979 to 2014 Results: 5 major strategies identified (engineering controls, PPE, medical and environmental monitoring, hazard identification, need for comprehensive HD control program that includes education and training for HCWs). Transparency in every step in the chain of custody is needed. Clear signs or labels, including electronic identifiers, and clear instructions that prompt what to do next are needed.	Level: III Quality: A	The systematic review was conducted to identify evidence-based strategies for protecting all HCWs, from those involved in handling packaged HDs to those who dispose of body fluids of individuals taking these medications. One problem with wipe testing is that there is no minimum acceptable exposure level for chemotherapy or other HDs. Testing workers' urine/blood samples may be difficult to operationalize across large healthcare systems. Financial and ethical implications must be considered, specifically with how to counsel staff members with positive results of urine or blood samples.

				Barriers such as understaffing, the physical layout of a unit, and time constraints can negatively impact adherence.
DeJoy et al. (2017)	Data came from the 2011 NIOSH Health and Safety Practices Survey of Healthcare Workers, an anonymous, multi-module, web-based survey. Statistical analyses were performed using SAS 9.4 software in three stages: (1) descriptive analyses, (2) factor analysis of safety perception, and (3) psychometric analyses.	Setting: Online survey Sample: Nurses (*N*=1,814) who had administered IV HDs in the 7 calendar days prior to the survey and whose employer was either a hospital or ambulatory healthcare center. Time frame: Survey was available for 8 weeks. Results: The study showed lower likelihoods of exposure when staffing and resources were adequate and when orders and doses were consistently verified by two nurses.	Level: III Quality: A Limitations: • Cross-sectional study limits the ability to make causal interpretations. • Survey respondents were solicited from membership rolls of professional organizations and may not represent all nurses who administer HDs. • The sample was limited to nurses working in the U.S. • Data collected were analyzed at the individual level. • The collected data were self-reported/could not eliminate bias.	Purpose/Objectives: To examine predictors of the use of PPE and engineering controls and adverse events involving IV HDs in a relatively large and diverse sample of nurses. The study examined the effects of pertinent organization safety practices and perceived safety climate on the use of PPE, engineering controls, and adverse events (spill/leak or skin contact) involving liquid antineoplastic drugs. 14% of nurses reported an adverse event. Results point to the value of implementing a comprehensive health and safety program that uses available hazard controls and effectively communicates and demonstrates the importance of safe-handling practices. Such actions also contribute to creating a positive safety climate.

				Having an adequate knowledge of risks does not automatically produce commensurate precautionary action. PPE use was lower among nurses working in ambulatory infusion centers and be caused by less formalized safety programs and perhaps less direct supervision of those administering HDs. Both of these factors could lead to diminished adherence.
Friese et al. (2019)	Methods & variables: 1. Revised Drug Handling Questionnaire (Martin & Larson, 2003; Polovich & Clark, 2012) 2. Practice Environment Scale (Friese, 2012). 3. Safety Organizing Scale (Vogus & Sutcliffe, 2006) 4. The authors measured knowledge of HD handling using a team-generated, pilot-tested, 10-item questionnaire. 5. Occupational Dermal Survey to measure perceived risk (Geer, Curbow, Anna, Lees, & Buckley, 2006). In a cluster randomized controlled trial, 136 nurses in	Setting: 12 ambulatory oncology settings in the United States. 15 sites were eligible, but 3 declined participating in study 12 sites were randomized 6 sites control arm 6 sites allocated to intervention. Sample: 396 nurses, 257 of who completed baseline and primary endpoint surveys. Time frame: March 2015 to March 2017 Results: Control and intervention sites had suboptimal PPE use before and after the intervention. No	Level: I Quality: A Limitations: First, the study took place in a convenience sample of academic health centers with high-volume cancer programs. (Results may not generalize to smaller or community-based oncology settings). Second, the calculated reliability of the outcome measure in the current sample was relatively low (0.46 for the 3-item measure and 0.5 for the 5-item measure considered in the sensitivity analysis).	Purpose/Objectives: To evaluate whether a web-based intervention improved PPE use among oncology nurses who handle hazardous drugs. Findings: It is clear that education and engagement of nursing personnel is not sufficient to improve PPE use – systematic approaches may result in improved practice. Conclusion: Despite four decades of research, current use of PPE remains suboptimal in ambulatory oncology settings. A theory-informed, web-based educational intervention to

	control settings received a one-hour educational module on PPE use with quarterly reminders, and 121 nurses in treatment settings received the control intervention plus tailored messages to address perceived barriers and quarterly data gathered in HD spills across all study settings. The primary outcome was nurse-reported PPE use. The primary outcome was PPE use, as measured by the previously published Revised Drug Handling Questionnaire (Martin & Larson, 2003; Polovich & Clark, 2012).	significant differences were observed in PPE-use knowledge or perceived barriers. Participants reported high satisfaction with the study experience.		RNs failed to improve PPE use in the ambulatory oncology setting. A multi-faceted strategy (equipment changes, standardized policies, educational efforts, and leadership support) across multiple levels (units, hospitals, and health systems, and professional organizations) may be required to improve adherence to HD-handling guidance. Implications for Nursing: HD exposure confers notable health risks to healthcare workers. To improve HD handling, occupational healthcare workers, health systems, and professional organizations should consider coordinated efforts to implement policy and practice changes. Other Data of Interest: Future research efforts would benefit from development and testing of novel measures of PPE use and evaluation of optimal measurement times after delivering educational

				interventions and delivering study reminders.
He et al. (2017)	1.Cross-sectional, multi-state mailed survey to ONS members (*N*=654) Tool: Revised Hazardous Drug Handling Questionnaire (Martin & Larson, 2003; Polovich & Clark, 2012) 2. Bivariate and multivariable regression analyses 3. Covariates: nursing workloads, nurses' practice environments, and barriers to PPE use 4. Dillman's total design method to maximize response rates (personalized cover letters, $40 cash incentives, three monthly reminders to non-responders) 5. Safety Organizing Scale to measure collective behaviors performed by employees in high-reliability organizations	Setting: Ambulatory oncology practices in CA, GA, and MI Sample: 252 ONS members who administer hazardous drugs Time frame: February to September 2014 Results: 437 nurses completed surveys (67% response). Final analytical sample (*n*=252), 97% women, 79% 43 years or older, 75% with at least 6 years of nursing experience, and 96% worked in outpatient oncology settings. The sample mean for the PPE-use score was 2.4 (*SD*=1) out of a maximum possible score of 5.	Level: II Quality: A Limitations: The internal reliability of the dependent variable – the PPE-use scale – was lower in the current sample (0.61) than previously reported (Geer et al., 2006). The distribution of various PPE (included on the PPE-use scale) had a bimodal pattern; many respondents reported either using PPE very frequently or never. Other limitations included a varying number of respondents per practice (1-12 nurses) and missing data. Roughly a third of practices had only one nurse informant. These limitations are somewhat offset by the large sample size, high response, rate, and geographic diversity.	Purpose/Objectives: To examine patterns and organizational correlates of PPE use and hazardous drug spills. Findings: 26% reported recent drug spill, 90% wore only 1 pair of chemotherapy-tested gloves. PPE use was associated with increased nurse participation in practice affairs, non-private ownership, increased nursing workloads, and fewer barriers to PPE use. Spills were associated with significantly less favorable manager leadership and support and higher workloads. Conclusion: Drug spills occur in ambulatory settings. PPE use remains low, and barriers to PPE use persist. Higher workloads are associated with more drug spills. As nursing workloads increased by one patient, the odds of HD spills increased by 3% (*OR*=1.03, 95% CI [1.01-1.06], *p*=0.01).

				Implications for Nursing: Managers should monitor and correct aberrant workloads and ensure that PPE is available and that staff are trained. Other Data of Interest: The study findings underscore the need to improve individual adherence through modifiable administrative controls (e.g., commitments to safety culture, improved nurse practice environments, thoughtful attention to nurse workloads, deployment of engineering controls).
Hennessy & Dynan (2014)	Framework for the Model for Improvement (Langley, Moen, Nolan, Norman, & Provost, 1996), a continuous process of tests of change, performance measurement, and feedback was put into place to improve performance. Monthly audits with PPE Observation Tool created by Dana Farber educators.	Setting: Dana Farber Cancer Institute Sample: Infusion nurses in ambulatory care Time Frame: 2009-2014 Results: Previous compliance rates 30%-40% Key components of the sustained success of this initiative are staff education and ownership of the required changes, peer-performance monitoring, leadership support and prioritization of the work, staff involvement in product review and selection	Level: III Quality: A	A program was developed that incorporated not only monitoring and reporting compliance of the use of PPE, but also engaged the staff in audit and reporting activities. Compliance rates improved dramatically over time and have remained at high levels. The goal was to improve compliance with established standards and hospital policy regarding PPE use by nurses administering chemo in the outpatient setting.

		of the PPE, and continuous monitoring and feedback regarding performance.		
Hon et al. (2014)	Wipe samples analyzed for cyclophosphamide (CP). High-performance liquid chromatography-tandem mass spectrometry. Active recruitment of participants via letter of invitation or telephone by members of research team. On-site surveys and self-administration questionnaire.	Setting: 5 hospitals and 1 cancer treatment facility Sample: 115 participants/110 supplied duplicate hand wipe sampling. Staff working in the process of flow of drug within a facility from initial delivery to waste disposal (8 groups of workers identified). Time Frame: not stated Results: 225 wipe samples/20% (*n*=44) were above the limit of detection (LOD) of 0.36ng per wipe. Average concentration per wipe 22.8ng per wipe. (*SD* 1.98).	Level: I Quality: A Limitations: Unable to recruit housekeepers into study because the contract company that employs housekeepers declined to participate. The findings are only representative of the point in time when samples were collected. Samples were based on convenience sampling, which allowed assessment of exposure throughout the day, but does not allow comparison to task-based exposure levels.	The purpose of the study was to determine the dermal contamination levels of healthcare employees working throughout the hospital and to identify factors that may influence dermal contamination. All worker categories had some level of dermal exposure. Highest level of dermal exposure was in administration units who were not responsible for drug administration (volunteers, oncologist, aide, dietician). Regardless of whether or not a worker received safe drug handling training, the proportion of samples above LOD was the same.
Kang et al. (2017)	Observational, descriptive study in 4 parts: a simulation observation, a survey (for both clinical and sim participants), and a follow-up evaluation simulation.	Setting: University of Pittsburgh Sample: 82 HCP, 65 HCP (72.93%; including 3 HCP who participated in the clinical observation). 97% had at least 1 instance of contamination during the PPE doffing process in 2 sim sessions with a simple set and a full-body set. For 130	Level: Quality: Limitations: High likelihood of Hawthorne effect. Because convenience sample of study participants and PPE items from one health care system were adopted, these findings may	Very little is known about how healthcare personnel actually use PPE. Evidence shows that traditional learning methods (e.g., watching educational videos, learning PPE guidelines) are inferior to immersive learning methods, including active learner involvement using

		simulations, the contamination rate was 79% (*n*=103) Time Frame: August 31-September, 2015 Results:	not be generalizable to other clinical settings. Camera lens and lighting may not have captured all contamination.	simulations that include feedback on performance. Contamination breaches appear to be associated with poor HCP PPE techniques, knowledge deficits, and behavior flaws. The study emphasized the need for refining PPE protocols based on further scientific evidence, reinforcing PPE training using innovative methods, improving and standardizing PPE equipment for targeting HCP optimal use.
Lawson et al. (2019)	Self-report questionnaire for pregnant nurses (within first 20 weeks) and non-pregnant nurses (within the last month). Baseline NHS3 questionnaire.	Setting: Online study Sample: 40,000 nurses participating in the Nurses' Health Study born on or after January. 1, 1965 Time Frame: Started in 2010 and is ongoing Results: 12% of non-pregnant nurses/9% pregnant nurses indicated they never wore gloves with HD admin, 42%/38% never used a gown, 32% who crushed HD pills did not wear gloves. Mean age/non-pregnant = 37 years (*SD* 7.26) Mean age/pregnant = 29.5 years (*SD* 4.05).	Level: II Quality: A Limitations: Did not collect info on the use of double versus single gloves, engineering controls, training of safe-handling practices, and reasons or barriers for not following safe-handling recommendations. No information on nurse specialties of respondents. No info on facility type or size, which might affect training personnel.	The purpose of the study assessed glove and gown use by female pregnant and non-pregnant nurses who administer antineoplastic drugs in the U.S. and Canada. Findings underscore the need for further training and education to ensure that both employers and nurses understand the risks involved and know which precautions will minimize such exposures. Adequate time must be allowed for worker to handle these drugs safely.

Yuki et al. (2013)	Urine and wipe samples from patient and family members inside homes. Gas chromatography in tandem with mass spectroscopy-mass spectroscopy or by high-performance liquid chromatography with ultraviolet-light detection.	Setting: 3 patient homes Sample: Time Frame: Results: 35 and 16 urine samples were collected from the three patients and their family members. Drugs were detected in all samples. Cyclophosphamide (CP) in 8 of 12 samples 5-FU exposure below the limit of detection.	Level: I Quality: A Limitations: Sample size small	Purpose: To measure the urinary excretion of Ads of three patients during 48 h after the admin of cyclophosphamide (2 patients) and 5-FU (2 patients) Home exposure was demonstrated. Findings indicate the importance of strict precautions by the members of treated cancer patients, as well as healthcare workers, to reduce exposure to Ads.

Appendix B: Commission on Cancer Program Standard 4.8

STANDARD 4.8
Quality Improvements

Each calendar year, the cancer committee, under the guidance of the Quality Improvement Coordinator, implements two cancer care improvements. One improvement is based on the results of a quality study completed by the cancer program that measures the quality of cancer care and outcomes. One improvement can be based on a completed study from another source. Quality improvements are documented in the cancer committee minutes and shared with medical staff and administration.

DEFINITION AND REQUIREMENTS

Quality or performance improvements are the actions taken, processes implemented, or services created to improve cancer care. Implementation of improvements demonstrates a program's continuous commitment to providing high-quality patient care. The results of a cancer-related quality study provide a baseline to measure and improve quality.

Each calendar year, at least two quality improvements affecting cancer patient care are implemented centrally, departmentally, through disease site teams, or through other program-appropriate methods as directed by the cancer committee. One quality improvement is implemented as a result of data collected from a quality study conducted by the cancer committee. The second improvement can be based on any study or relevant data source.

Sources for quality improvements may include:

- Actions based on analysis and findings of a quality study under Standard 4.7
- Actions to address substandard patient care or process performance
- Changes to improve upon acceptable patient care or process performance

The Quality Improvement Coordinator monitors, reports, and recommends activity related to the quality improvement program; reports regularly to the cancer committee; and recommends corrective action if any area falls below acceptable norms or when undesirable performance is identified. The recommendations and improvements are reported to the cancer committee. The reports are documented in the minutes and shared with the medical staff and administration.

SPECIFICATIONS BY CATEGORY

All programs fulfill the standard as written.

DOCUMENTATION

The program completes all required standard fields in the SAR.

Each calendar year, the program uploads:

- Completed documentation for the implementation of the quality improvements
- Cancer committee minutes in which the results of the improvements were reported

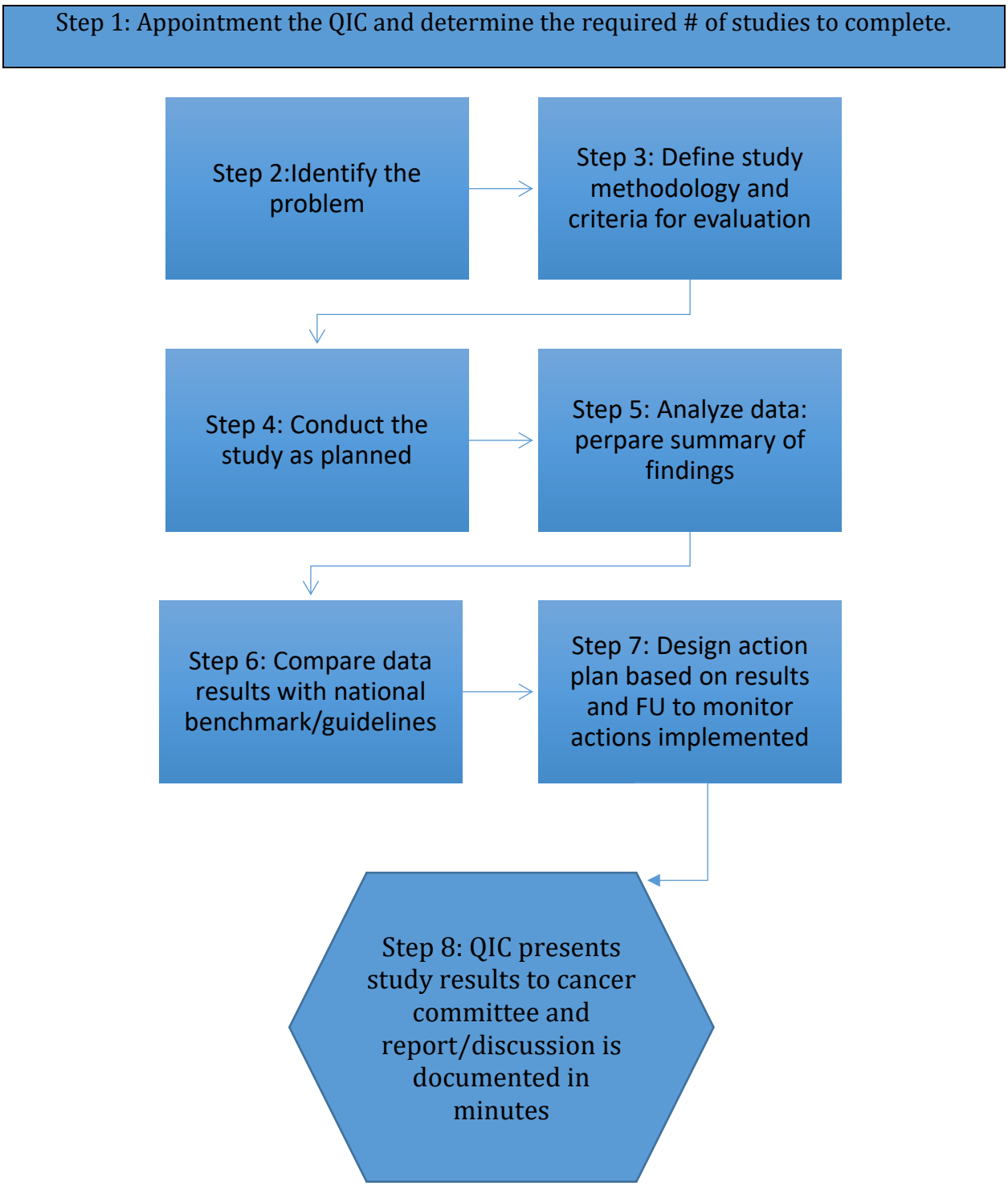
RATING COMPLIANCE

(1) Compliance: Each calendar year, the program fulfills all of the compliance criteria:

1. The cancer committee, under the guidance of the Quality Improvement Coordinator, implements one cancer care improvement based on the results of a completed quality study.
2. The cancer committee, under the guidance of the Quality Improvement Coordinator implements one cancer care improvement based on any study or data source.
3. The quality improvements are reviewed by the cancer committee and documented in the minutes.
4. The quality improvements are shared with medical staff and administration.

(5) Noncompliance: The program does not fulfill one or more of the compliance criteria each calendar year.

Appendix C: Basic Steps of Compliance Flow Chart



Appendix D: Signed Statement of Non-Research Determination

Student Name: Cynthia D. Huff

Title of Project: USP <800> Compliance: A Hazardous Drug Safe-Handling PPE Toolkit for Infusion Nurses

Brief Description of Project: Hazardous drug (HD) residues pose a real threat to the health of staff, patients and families, and the environment when uncontrolled or mismanaged, especially in Cancer Centers (Hon, Teschke, Shen, Demers, & Venners, 20150. Lack of diligent organizational and personal responsibility, and oversight in HD management have caused irreversible harm in some cases, and are well documented (Connor, Lawson, Polovich, & McDiarmid, 2014; Yuki, Sekine, Takase, Ishida, & Sessink, 2013). Scientific evidence has demonstrated that harmful residues can contaminate commonly shared surfaces where HDs are administered, and patients may expose family members, pets, and their homes to residues for several days to weeks after chemotherapy treatment (Bohlandt, Sverdel, & Schierl, 2017; Yuki, et al., 2013).

Healthcare organizations are preparing for the implementation of USP <800> (United States Pharmacopeial Chapter 800: Hazardous Drugs-Handling in Health Care Settings which imposes strict regulatory standards intended to protect health care workers from HD exposure beginning December 1, 2019. As USP <800> changes how HDs are handled, timely education and acceptance from health care personnel, especially pharmacists and nurses, will drive the long-anticipated worker protections (Andrews & Dill, 2018). The purpose of an Ambulatory Care Hazardous Drug Safe-Handling PPE Toolkit for Infusion Nurses is to provide a resource toolkit that will improve nurses' adherence to personal protective equipment (PPE) use, increase compliance with USP <800> Standards, and adhere to hospital policies and procedures for safe-handling. Better risk education is needed to ensure employers and health care workers are fully aware of the processes required to minimize exposure to these toxic drugs (Boiano, Steege, & Sweeney, 2014). There are six steps in the safe handling process for HDs: (1) Transport, (2) Receipt, (3) Storage, (4) Preparation, (5) Administration, and (6) Disposal of contaminated waste.

A) Aim Statement: By February 1, 2020, develop, implement, and evaluate a HD resource toolkit to improve adherence to personal protective equipment (PPE) use to 90% or higher with hazardous drug administration and with current hospital and USP <800> policies and procedures.

B) Description of Interventions:

1. September, 2019 – Confidential observations of infusion nurses preparing, administering, and discarding HD waste will be completed by the DNP student (to determine the baseline level of adherence using an established tool called the "PPE Observation Tool" (Hennessy & Dynan, 2014). A survey to obtain nurses' self-assessments of adherence to policies and USP <800> will be provided to the AIC

nurses via Qualtrics.

2. October, 2019 – An expert panel will introduce the Hazardous Drug Safe-Handling PPE Toolkit to staff and bring awareness of the health risks with HD exposure, and explore barriers for self-adherence in the practice environment. Ambulatory Infusion Center (AIC) nurses will attend a two-hour skills session to introduce them to the proper donning and doffing of PPE and the policies and procedure changes related to mandatory requirements imposed by USP <800>.

3. November, 2019 – Individual nurse observations will be performed to assess for PPE adherence and compared to the self-assessment survey results to reinforce USP <800> standards and hospital policies and procedures for safe-handling and protections using the "Safe-Handling Adherence Between Observation and Self-Assessment tool." A "Hazardous Drug Administration Safe Handling Checklist" (Peer-to-Peer Feedback tool) will be utilized to educate and reinforce goal 90% PPE compliance for all nurses handling HDs (Polovich & Olsen, 2017).

4. December, 2019 – Data will be collected pre-and-post intervention, analyzed, and displayed for staff on the performance dashboard as a quality improvement project.

5. January and February, 2020 – DNP student will present results to the respective committees and enter the results in the Cancer Committee's minutes to fulfill the COC Standard 4.8 requirements.

C) How will this intervention change practice?

The Hazardous Drug Safe-Handling PPE Toolkit intervention is expected to improve nurses' access to USP <800> PPE requirements and improve adherence and compliance with the organization's policy and procedures for HD safe-handling.

D) Outcome measurements:

1. Monthly peer-to-peer audit tool and real-time feedback indicate 90% or higher adherence and compliance with PPE use during hazardous drug administration processes.

2. Pre-and-post intervention analysis posted on performance dashboard for staff review and comments.

3. 100% compliance with USP <800> PPE expectations during hazardous drug administration as evidenced by internal audit from oncology infusion nurses, quality and risk management department managers, and nursing education audits annually.

To qualify as an Evidence-based Change in Practice Project, rather than a Research Project, the criteria outlined in federal guidelines will be used: (http://answers.hhs.gov/ohrp/categories/1569)

x This project meets the guidelines for an Evidence-based Change in Practice Project as outlined in the Project Checklist (attached). Student may proceed with implementation.

☐This project involves research with human subjects and must be submitted for IRB approval before project activity can commence.

Comments:

EVIDENCE-BASED CHANGE OF PRACTICE PROJECT CHECKLIST *

Instructions: Answer YES or NO to each of the following statements:

Project Title: **USP <800> Compliance: Hazardous Drug Safe-Handling Toolkit for Infusion Nurses**	**YES**	**NO**
The aim of the project is to improve the process or delivery of care with established/ accepted standards, or to implement evidence-based change. There is no intention of using the data for research purposes.	**X**	
The specific aim is to improve performance on a specific service or program and **is a part of usual care**. ALL participants will receive standard of care.	**X**	
The project is **NOT** designed to follow a research design, e.g., hypothesis testing or group comparison, randomization, control groups, prospective comparison groups, cross-sectional, case control). The project does **NOT** follow a protocol that overrides clinical decision-making.	**X**	
The project involves implementation of established and tested quality standards and/or systematic monitoring, assessment or evaluation of the organization to ensure that existing quality standards are being met. The project does **NOT** develop paradigms or untested methods or new untested standards.	**X**	
The project involves implementation of care practices and interventions that are consensus-based or evidence-based. The project does **NOT** seek to test an intervention that is beyond current science and experience.	**X**	
The project is conducted by staff where the project will take place and involves staff who are working at an agency that has an agreement with USF SONHP.	**X**	
The project has **NO** funding from federal agencies or research-focused organizations and is not receiving funding for implementation research.	**X**	
The agency or clinical practice unit agrees that this is a project that will be implemented to improve the process or delivery of care, i.e., **not** a personal research project that is dependent upon the voluntary participation of colleagues, students and/ or patients.	**X**	
If there is an intent to, or possibility of publishing your work, you and supervising faculty and the agency oversight committee are comfortable with the following statement in your methods section: *"This project was undertaken as an Evidence-based change of practice project at X hospital or agency and as such was not formally supervised by the Institutional Review Board."*	**X**	

ANSWER KEY: If the answer to **ALL** of these items is yes, the project can be considered an Evidence-based activity that does NOT meet the definition of research. **IRB review is not required. Keep a copy of this checklist in your files.** If the answer to ANY of these questions is **NO**, you must submit for IRB approval.

*Adapted with permission of Elizabeth L. Hohmann, MD, Director and Chair, Partners Human Research Committee, Partners Health System, Boston, MA.

STUDENT NAME (Please print):
Cynthia Huff
Signature of Student:

_____DATE_____

SUPERVISING FACULTY MEMBER (CHAIR) NAME (Please print):

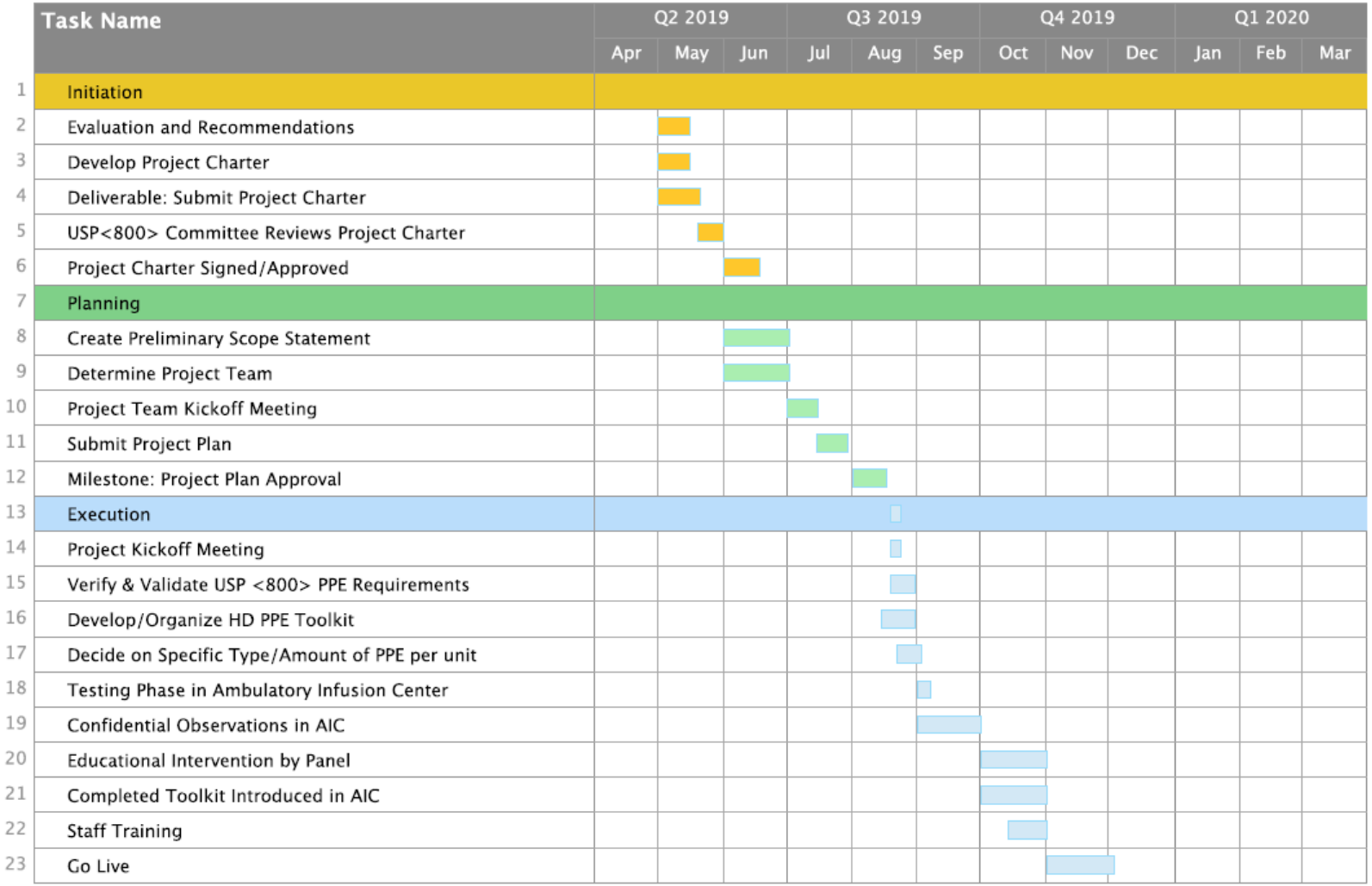
_____
Signature of Supervising Faculty Member (Chair):

_____DATE_____

Appendix E: Gap Analysis

1.	The physical layout of the treatment areas lend difficulty with hazardous drug (HD) administration.
2.	The AIC is not set up for moderate HD disposal; there are gaps in pharmaceutical waste management (i.e. PPE).
3.	Policies and procedures do not reflect USP <800> requirements for HD processes and require modifications for AIC compliance with PPE management and waste disposal.
4.	The cost impact for meeting the USP <800> Standards are unknown because the nurses in the AIC are not wearing required PPE except for one pair of nitrile gloves.
5.	There is no standard work for HD administration in the AIC.
6.	There are gaps in pharmaceutical delivery of HDs to the nurses (need to be delivered in specific HD bins and stored in cabinets in the medication rooms, not on countertops in patient areas).
7.	There is no system-defined comprehensive list of HDs for the AIC (NIOSH List of Hazardous Drugs is the default), and there is no risk assessment for all HDs.
8.	No annual PPE training or learning modules for HD administration.
9.	There are space limitations within the treatment area for donning and doffing PPE in the designated patient threshold areas.
10.	Adherence and compliance with PPE have been ignored for several years in the AIC, and nurses' beliefs and attitudes that exposure risks are minimal and do not warrant changing behavior with HD administration.
11.	Scheduling demands and workload pressures do not reflect the appropriate acuity levels of patient appointment times and unique situations.
12.	There are inconsistent HD labeling on medications delivered by the pharmacy.
13.	Tools needed to assess for PPE compliance, such as observation tools or Standard work for "HD Safe Handling" are unavailable in the AIC.
14.	No staff champions to promote best practice with PPE use.

Appendix F: Gantt Chart



Appendix G: Work Breakdown Structure

LEVEL 1	LEVEL 2	LEVEL 3
1 PPE Toolkit Implementation in Ambulatory Care	1.1 Initiation	1.1.1 Evaluation and Recommendations 1.1.2 Develop Project Charter 1.1.3 Deliverable: Submit Project Charter 1.1.4 USP <800> Committee Reviews Project Charter 1.1.5 Project Charter Signed/Approved
	1.2 Planning	1.2.1 Create Preliminary Scope Statement 1.2.2 Determine Project Team 1.2.3 Project Team Kickoff Meeting 1.2.4 Develop Project Plan 1.2.5 Submit Project Plan 1.2.6 Milestone: Project Plan Approval
	1.3 Execution	1.3.1 Project Kickoff Meeting 1.3.2 Verify & Validate USP <800> PPE Requirements 1.3.3 Develop/Organize HD PPE Toolkit 1.3.4 Decide on Specific Type/Amount of PPE per unit 1.3.5 Testing Phase in Ambulatory Infusion Center (AIC) 1.3.6 Completed Toolkit Introduced in AIC 1.3.7 Staff Training 1.3.8 Go Live
	1.4 Control	1.4.1 Project Management 1.4.2 Project Status Meetings 1.4.3 Risk Management 1.4.4 Update Project Management Plan
	1.5 Closeout	1.5.1 Audit Procurement 1.5.2 Document Lessons Learned 1.5.3 Update Files/Records 1.5.4 Gain Formal Acceptance 1.5.5 Archive Files/Documents

Appendix H: Work Breakdown Structure Dictionary

Level	WBS Code	Element Name	Definition
1	1	Personal Protective Equipment (PPE) Toolkit Implementation in Ambulatory Care	All work to implement the new toolkit in Ambulatory Care Setting.
2	1.1	Initiation	The work to initiate the project.
3	1.1.1	Evaluation and Recommendations	Working group to evaluate USP <800> General Chapter PPE requirements and make recommendations for the Ambulatory Care Setting.
3	1.1.2	Develop Project Charter	Project Manager to develop the Project Charter.
3	1.1.3	Deliverable: Submit Project Charter	Project Charter is delivered to USP <800> Committee designee.
3	1.1.4	USP <800> Committee Reviews Project Charter	USP <800> Committee Reviews Project Charter.
3	1.1.5	Project Charter Signed/Approved	The USP <800> Committee signs the Project Charter which authorizes the Project Manager to move to the Planning Process.
2	1.2	Planning	The work for the planning process for the project.
3	1.2.1	Create Preliminary Scope Statement	Project Manager creates a Preliminary Scope Statement.
3	1.2.2	Determine Project Team	The Project Manager determines the project team and requests the resources.
3	1.2.3	Project Kickoff Meeting	The planning process is officially started with a project kickoff meeting which includes the Project Manager, Project Team and USP <800> Committee designee.
3	1.2.4	Develop Project Plan	Under the direction of the Project manager, the team develops the project plan.
3	1.2.5	Submit Project Plan	Project Manager submits the project plan for approval.
3	1.2.6	Milestone: Project Plan Approval	The project plan is approved and the Project Manager has permission to proceed to execute the project according to the project plan.
2	1.3	Execution	Work involved to execute the project.
3	1.3.1	Project Kickoff Meeting	Project Manager conducts a formal kickoff meeting with the project team, project stakeholders, and USP <800> Committee designee.
3	1.3.2	Verify & Validate USP <800> PPE Requirements	The original USP <800> General Chapter requirements for personal protective equipment (PPE) use with hazardous drug agents is reviewed by the Project Manager and team, then validated with the

			stakeholders. This is where additional clarification may be needed.
3	1.3.3	Develop/Organize HD PPE Toolkit	The resources to design the new PPE toolkit will be assembled.
3	1.3.4	Decide on Specific Type/Amount of PPE per Unit	The procurement of all PPE required for the project.
3	1.3.5	Testing Phase in Ambulatory Infusion Center	Team creates a system for testing PPE adherence and customizations of user interfaces (Low, Moderate, High Risk) with hazardous drug handling.
3	1.3.6	Completed PPE Toolkit introduced into Ambulatory Infusion Center setting	The actual PPE Toolkit is introduced into the Ambulatory Infusion Center's workflow processes.
3	1.3.7	Staff Training	All staff are provided with a one-hour training on donning and doffing of PPE. Additionally, managers are provided with a two-hour class to cover advanced reporting.
3	1.3.8	Go Live	System goes live with all Ambulatory Infusion Center (AIC) staff.
2	1.4	Control	The work involved for the control process of the project.
3	1.4.1	Project Management	Overall project management for the project.
3	1.4.2	Project Status Meetings	Weekly team status meetings.
3	1.4.3	Risk Management	Risk management efforts as defined in the Risk Management Plan.
3	1.4.4	Update Project Management Plan	Project Manager updates the Project Management Plan as the project progresses.
2	1.5	Closeout	The work to close out the project.
3	1.5.1	Audit Procurement	An audit of all measurement tools and management plans procured for the project, ensure that all procured products are accounted for and in the asset management system.
3	1.5.2	Document Lessons Learned	Project Manager along with the project team performs a "lessons learned" meeting and documents the lessons learned from the project.
3	1.5.3	Update Files/Records	All files, data, and adherence monitoring tools are updated to reflect the completed PPE Toolkit intervention.
3	1.5.4	Gain Formal Acceptance	The USP <800> Committee formally accepts the project by signing the acceptance document included in the project plan.
3	1.5.5	Archive Files/Documents	All project related files and documents are formally archived.

Appendix I: Work Breakdown Structure Glossary

Ambulatory Care Settings	Ambulatory Care refers to medical services performed on an outpatient basis, without admission to a hospital or other facility. Ambulatory care is provided in settings such as dialysis clinics, ambulatory infusion centers, ambulatory surgical centers, hospital outpatient departments, and the offices of physicians and other health professionals.
Hazardous Drug Agents (HDs)	In pharmacology, hazardous drugs are drugs that are known to cause harm, which may or may not include genotoxicity (the ability to cause a change or mutation in genetic material). These drugs can be classified as antineoplastic, cytotoxic agents, biologic agents, antiviral agents and immunosuppressive agents. The NIOSH criteria include: carcinogenicity, teratogenicity, reproductive toxicity, genotoxicity, organ toxicity at low doses, and drugs that mimic existing drugs in structure or toxicity.
Level of Effort	Level of Effort (LOE) is how much work is required to complete a task.
Personal Protective Equipment (PPE)	Personal protective equipment is protective clothing, headwear, goggles, gloves, shoe covers, respirators, or other garments or equipment designed to protect the wearer's body from injury, infection, or exposure to hazardous agents. The hazards addressed by protective equipment include physical, electrical, heat, chemicals, biohazards, and airborne particulate matter.
PPE Toolkit	A set of resources, interventions, and skills required to ensure staff adherence to hazardous drug safe-handling and compliance with USP General Chapter <800> requirements for PPE selection and use during transport, receivership, storage, preparation, administration, and disposal.
USP General Chapter <800> Scope (USP <800>)	Protects any worker in contact with hazardous drugs or the patient environment and includes, but not limited to; pharmacists; technicians, nurses, physicians, physician assistants, nurse practitioners, home health care, environmental services workers, engineering, anyone entering a patient treatment area, pharmacies, hospitals, and other healthcare institutions, patient treatment clinics, physician practices, and the public.
WBS Code	A unique identifier assigned to each element in a Work Breakdown Structure for the purpose of designating the elements hierarchical location within the WBS.
WBS Component	A component of a WBS which is located at any level. It can be a Work Package or a WBS Element as there's no restriction on what a WBS Component is.
WBS Element	A WBS element is a single WBS component and its associated attributes located anywhere within a WBS. A WBS Element can contain work, or it can contain other WBS Elements or Work Packages.
Work Package	A Work Package is a deliverable or work component at the lowest level of its WBS branch.

Appendix J: Responsibility/Communication Matrix

Who	What	How
Cancer Committee Members	Evaluation and Recommendations	Monthly at Cancer Committee meeting
Assistant Unit Manager (AUM) AIC	Develop Project Charter	Discuss project with leadership and ask for recommendations of persons interested in working on the PPE Project Team
Assistant Unit Manager (AUM) AIC	Submit Project Charter	Meet with interested people and gain buy-in and have them help finalize the Charter and AUM will send completed Charter to USP <800. Committee
USP <800> Committee	USP <800> Committee Reviews Project Charter	Present at USP <800> Committee meeting and request approval from Project Sponsor
USP <800> Committee/Cancer Committee	Project Charter Approved	Committee will approve Charter and report back to DNP team
Cancer Committee NPs/Pharmacy/AUM/Clinical Nurse Educator	Create Preliminary Scope Statement	Meeting with the group to discuss the needs of the Cancer Center related to physician practices/specialties
Assistant Unit Manager	Determine Project Team	AUM to meet with interested persons and select based on knowledge and skills related to HD management and PPE knowledge
Project Charter Team Members	Project Team Kickoff Meeting	Arrange for meeting with group once Charter has been approved via Skype or Zoom sessions
Assistant Unit Manager (AUM)	Submit Project Plan	AUM to assist team with project plan and submit to USP<800> committee
Cancer Committee Members/ Executive Director Cancer Center	Milestone: Project Plan Approval	Report back to Cancer Committee and gain approval at next meeting
USP <800> PPE Group	Project Kickoff Meeting	Notify PPE group of plans to set up meeting by email and personal telephone calls
Clinical Nurse Educator Pharmacy Department USP <800> Committee Representative	Verify & Validate USP <800> Requirements	Check with OSHA, NIOSH, and USP<800> Committee to confirm requirements for PPE
Clinical Nurse Educator/ DNP Student (AUM in AIC)	Develop/Organize HD PPE Toolkit	Review current evidence regarding toolkit resources for HD PPE/select tools/request permission from owners of tools to use

Clinical Nurse Educator/ DNP Student Relief Charge Nurses in AIC/Central Supply Department	Decide on Specific Type/Amount of PPE per unit	Request items used for PPE and bring to unit for evaluation by nurses/discuss preferences and select type and amount needed for test phase
Clinical Nurse Educator/DNP Student	Testing Phase in AIC	Preliminary testing with one RC to determine feasibility of project and to demonstrate "Observation of PPE Tool" purpose and planned confidential use
NPs, Pharmacist, AUM	Confidential Observations in AIC	Audits over 2 weeks at random intervals by practitioners, pharmacy, and AUM during routine rounding in AIC
Oncology MD, NPs, Pharmacist, OCN Nurse, Oncology Nurse Educator, AUM	Educational Intervention by Panel	Select panel of experts to introduce HD education and need for PPE/invite to informational meeting about project
DNP Student/ Clinical Nurse Educator	Completed Toolkit introduced in AIC	Review final Tools for the toolkit and get approval from Executive Director and expert panel members to proceed with printing/preparing for intervention
RN Staff in AIC	Staff Training-Peer-to-Peer Review	Provide inservice during monthly staff meeting to teach use of peer-to-peer review tool for PPE during administration
All Staff in AIC	Go Live	Use huddle boards, email, and text reminders of Go Live with PPE date

Appendix K: SWOT Analysis

Strengths	Weaknesses
• Expert Oncology Staff Resources • Infusion-Trained Chemotherapy Certified RN Team • Supportive Leadership • Long-term Employees at the facility committed to quality improvement at all levels • Teamwork between various divisions/pharmacy/physician offices and ambulatory infusion centers through focused workgroups	• Room design and waste management not practical for effective safe-handling • Employee and environmental surveillance inconsistently performed and costly • Policies and procedures reflect guidance for PPE use, not mandatory (open to interpretation by staff nurses) • Unknown cost impact for meeting the USP <800> Standards for PPE use • No system-defined comprehensive list of HDs, and no risk assessment for all HDs • No standard work process for PPE utilization with HD administration • Beliefs and attitudes of nurses that PPE is a personal choice • No audit tools to measure compliance with USP <800> Standards for PPE use
Opportunities	**Threats**
• Increase in demand for ambulatory infusion services across the country requires more oncology-infusion trained nurses/may need to partner with nursing schools to provide exposure/hiring pool for future needs • Decrease the gap between leadership and frontline infusion nurses to improve care delivery and patient/nurse safety in the AIC • Increase in the ageing population with baby boomers at Medicare age • Increase all infusion nurses training on chemotherapy/biotherapy/infusion therapy for future growth needs	• Unknown costs associated with PPE equipment, environmental testing for residues, and health monitoring of staff for HD exposure/no known HD limits like radiation oncology practice • Maintaining and recruiting nurses to work in high-risk exposure environment • Decrease in funding for infusion services with 21st Century Cures Act. Political climate related to healthcare structural changes within the political parties as to what changes will be implemented • Deadline extended for implementation of USP <800> regulations

Appendix L: Proposed Budget

Type of Expense	Cost
Staff Training on "Observation of PPE Use Tool" (NP, CNL, Clinical Nurse Educator, Pharmacist) – 1 hour discussion	$75/hr. x 7 persons = $525
Staff Training on "Hazardous Drug Administration Safe-Handling Checklist Tool" (1 Clinical Nurse Educator, 2 Relief Charge Nurses, 2 Nurse Practitioners, 2 Pharmacists)	$75/hr. x 7 persons = $525
Expert Panel Discussion for Staff	Complimentary Time from Cancer Committee Budget ($1,200 in kind)
Staff training estimate based on $75 (15 nurses) 2-hour training	$2,250
USP <800> Compliance: Hazardous Drug Toolkit for Infusion Nursing (printing)	$1,000
DNP Project Manager = 30 hrs.	$75/hr. x 30 hrs. = $2,250
PPE Supplies including White Preparation trays in Medication Rooms Average 5 RNs per day x 10 hrs. = 50 hrs. Average nurse # PPE changes per patient (5) x 15 PPE changes per day	$15 per PPE Kit x 15 changes/per nurse/per shift = $210 x 5 nurses/per day = $1,050 per day x 7 days/week = $7,350 per week
Hazardous Waste Bins for PPE and Medical Waste Disposal per cubicle (35)	$35 per waste bin x 35 cubicles = $1,225 per week
Additional Workers Compensation Funds for medical monitoring, HD exposure treatment, and long-term medical management	Currently under review/organization is self-insured and committed to employee safety measures to manage risk.
Estimated Total	$16,385 + ($1200 in kind)

Appendix M: IRB Approval

To ensure Internal Review Board (IRB) approval is not required for implementation of the QI project, I will submit the DNP Statement of Non-Research Determination form to my DNP Committee (see Appendix D), as well as submit a request for project review to the healthcare systems' IRB committee.

Appendix N: Letter of Support from Organization

MemorialCare
Long Beach Medical Center

Appendix N

Letter of Approval from Immersion Site

June 26, 2019

To: University of San Francisco

RE: Approval of Cynthia Huff Dissertation Project

To Whom It May Concern:

The University of San Francisco may rely on the MemorialCare Long Beach Medical Center/ Todd Cancer Institute for the review and implementation of:

Name: **"USP <800> Compliance: A Hazardous Drug Safe-Handling PPE Toolkit for Infusion Nurses."**

Author: Cynthia Huff

The University of San Francisco will perform initial review, continuing review, amendments or decision of whether project is exempt from IRB approval. In addition, the DNP student will submit the proposal to Long Beach Memorial Care's IRB Committee to gain approval that this will be a Quality Improvement project.

Cathy Kopy

Cathy Kopy
Executive Director, Todd Cancer Institute

Appendix O: Proposed CQI Method and Data Collection Tools

Variable Name	Brief Description	Data Source	Tools/Analyzing Data	Measurement Type	Time Frame
Nursing Skills	Pre-Intervention Assessment for Adherence by trained observers in the Cancer Center	Tool	PPE Observation Tool (Hennessey & Dynan, 2014)	Medians and quartiles of counts and percentages	Four weeks
Adherence to PPE use with HD administration	Observation Adherence	Tool	Observations of Chemotherapy Safe-Handling Adherence (Colvin, Karius & Albert, 2016)	Median and quartiles of counts and percentages	Two weeks
Nurses' Self-Assessment of Adherence to PPE use	Nurses evaluate their own perception of adherence and compliance to PPE use with HD-handling at their current state	Survey	Safe Handling between Observation and Self-Assessment (Colvin, Karius, & Albert, 2016)	Qualtrics Survey Nine-item questionnaire that uses a five-point Liker-type response set ranging from 0 (never) to 4 (always), plus a "not applicable" option.	Two weeks

Appendix P: Dummy Tables

Table 1: PPE Observation Tool

Location: Month/ Year: _____ Observer: _____										
Observation: Compliant with USP <800> Hospital Policy Observation type (check box)	**#1** **Yes** **No**	**#2** **Yes** **No**	**#3** **Yes** **No**	**#4** **Yes** **No**	**#5** **Yes** **No**	**#6** **Yes** **No**	**#7** **Yes** **No**	**#8** **Yes** **No**	**#9** **Yes** **No**	**#10** **Yes** **No**
Pre-Administration • Handling bags or syringes outside the leak-proof transport bag requires gloves and gowns • Handling the closed, zipped leak-proof bag does not require gown (gloves are optional).										
Administration • Hanging bags, attaching tubing, administering IVP, IM, and SC requires gloves and gown.										
Discard • Take down of bags and tubing that contain or contained chemotherapy and discarding syringes after IVP, IM, and SC requires gown gloves and gown.										
Description of Non-Compliance										
Wore no gloves										
Wore non-chemotherapy gloves										
Wore no gown										
Reused gown										

PPE gown worn in non-patient care area										
Chemotherapy at desk or in the non-patient care area										

Additional Comments: Observation #	**Comment**

IM – Intramuscular; IVP – Intravenous Push; PPE – personal protective equipment; SC – subcutaneous
Note: For each observation, please indicate “yes” for compliant with safe-handling policy or “no” if not compliant. If “no”, check the corresponding box for a description of the failure to comply. More than one description may apply to one observation. (Hennessey & Dynan, 2014)

Table 2: Observations of Chemotherapy Safe-Handling Adherence in Number of Events

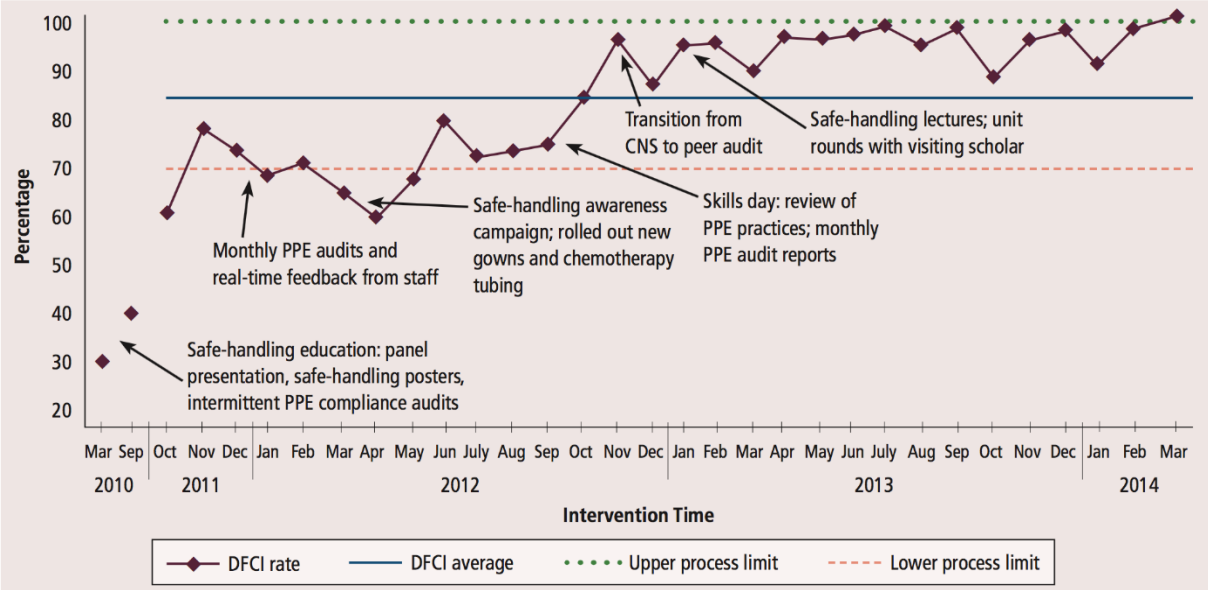
Behavior	Adherence (n)	Observation (n)
Handling		
Uses absorbent pad on work surface for chemotherapy agents		
Wears one pair of chemotherapy-approved gloves to remove chemotherapy agents from transport bag		
Wears two pairs of chemotherapy-approved gloves to remove chemotherapy agents from transport bag		
Removes outer gloves prior to programming pump		
Washes hands		
Wears second pair of chemotherapy-approved gloves over ribbed cuff of gown		
Removes gown prior to leaving room		
Wears chemotherapy-approved gown, with first pair of approved gloves under ribbed cuff of gown		
Disposes of gloves in a chemotherapy-approved container after initiating chemotherapy		
Disconnecting and discarding		
Removes gown prior to leaving room		
Wears two pairs of chemotherapy-approved gloves and chemotherapy-approved gown when handling chemotherapy		
Wraps gauze pad around connection site (CSTD) when disconnecting chemotherapy tubing, leaving chemotherapy bag attached		
Disposes of gloves in a chemotherapy-approved container		
Washes hands		
Discards the chemotherapy bag and attached secondary tubing in chemotherapy-approved waste container		

(Colvin, Karius, & Albert, 2016)

Table 3: Safe-Handling Adherence between Observation and Self-Assessment

Behavior	Observation Adherence			Self-Assessment Adherence			
	N	N	%		N	%	p
Double gloved during administration							
Removed outer gloves prior to programming pump							
Washed hands after glove removal post-administration							
Double gloved during disconnect							
Wrapped gauze pad around connection site							
Removed gown prior to leaving room at disconnect							

Table 4: Safe Handling: PPE Compliance/Visibility Board



CNS—clinical nurse specialist; DFCI—Dana-Farber Cancer Institute; PPE—personal protective equipment

Note. Process limits exclude baseline data from 2010.

FIGURE 1. Safe Handling: PPE Compliance

Table 5: Hazardous Drug Administration Safe Handling Checklist (Peer-to-Peer Feedback Tool)

Nurse's Name: _____Date of Review: _____ Pt MR #: _____			
PRIOR TO ADMINISTRATION	**YES**	**NO**	**INITIALS**
1. Gather equipment required for drug administration.			
2. Select appropriate gloves for hazardous drug administration.			
3. Select appropriate gown for hazardous drug administration.			
4. Identify situations when mask and face protection are required.			
5. Locate hazardous drug spill kit.			
6. Obtain hazardous waste container.			
ADMINISTRATION			
1. Wash hands and don personal protective equipment before opening drug delivery bag.			
2. Visually inspect the contents of the delivery bag for leaks.			
3. Gather IV administration supplies including closed-system drug-transfer devices.			
4. For IV infusions • Ensure tubing is primed with a nondrug solution. • Utilize plastic backed absorbent pad under work areas. Remove cap from IV tubing and connect to patient's IV device. • Utilize closed-system drug-transfer device when compatible. • Tighten locking connections. • When complete, don personal protective and discontinue IV bag with tubing intact (do not unspike bag). • Utilize gauze pads when disconnecting from patient's IV device when a closed-system drug-transfer device cannot be used.			
5. For IV push medications • Utilize closed-system drug-transfer device when possible. • Tighten locking connection. • When complete, do not recap needle. • Discard syringe-needle unit in puncture-proof container.			
6. For intramuscular/subcutaneous injections • Utilize closed-system transfer-device when possible. • Attach needle to syringe. • Tighten locking connection. • When complete, do not recap needle. • Discard syringe-needle unit in puncture-proof container.			
7. For oral drugs (tablets/capsules) • If using bar code technology, scan medication prior to removing medication from packaging. • Don gloves. • Open unit-dose package and place into medicine cup (avoid touching drug or inside of package). • Avoid touching tablets/capsules.			
8. For oral drugs in liquid form • Obtain drug in final form in appropriate oral syringe. • Don double gloves, gown, and mask with face protection • Use plastic-backed absorbent pad during administration.			

• Discard syringe in hazardous waste container after administration.			
POST-ADMINISTRATION			
1. Don personal protective equipment.			
2. Seal hazardous drug-contaminated supplies in sealable plastic bag for transport to hazardous waste container.			
3. Place sealed plastic bag in hazardous waste container.			
4. Remove outer gloves.			
5. Close lid on waste container.			
6. Decontaminate equipment in the area appropriately.			
7. Remove and discard inner gloves.			
8. Wash hands thoroughly with soap and water.			

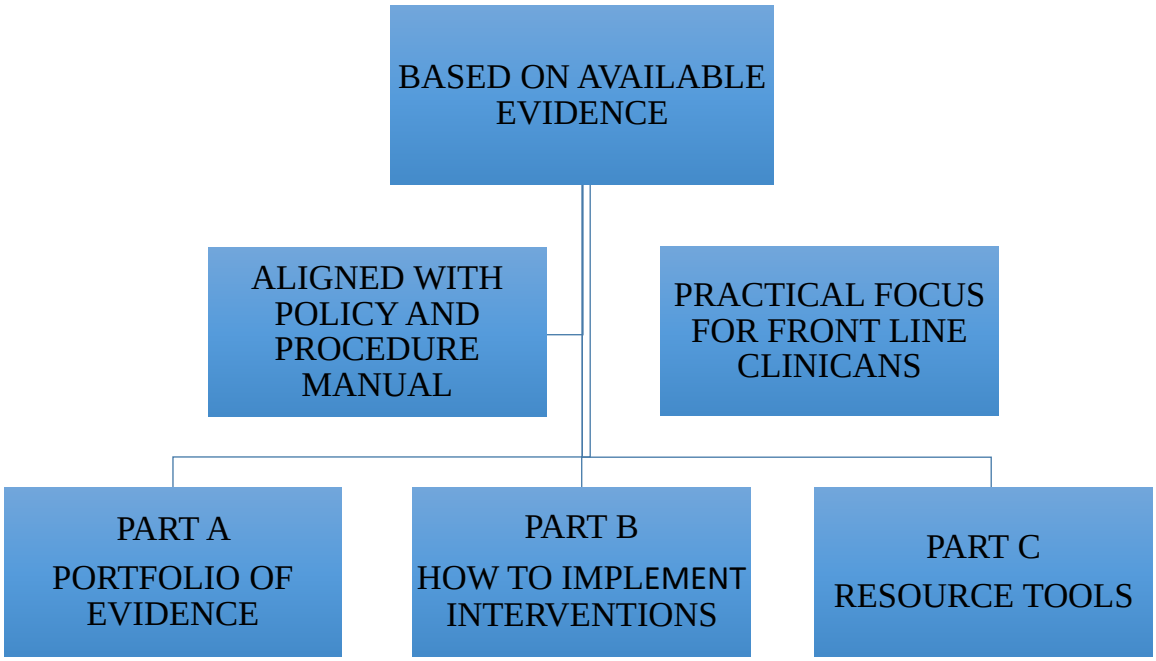
Reviewer Signature: _____ Initials: _____

Comments:

(Polovich & Olsen, 2017)

Appendix Q: Key Elements of the Toolkit

(LAMINATED FLIPCHART FORMAT)



Hazardous Drug Precautions: Antineoplastic

Activity	**Double Gloves** ASTM (D6978) *Wash hands with soap and water after removal.*	**Disposable impervious gown** *Single use, dispose in regular trash unless known contamination..*	**Eye/Face Protection** *Use Plastic face shield when splash is possible*	**Respiratory Protection** *Annual Fit Testing Completed in Employee Health*
Administration PPE by Formulary				
Solid, Intact Tablet/Capsule, Not Manipulated	Single Pair of Gloves only 	n/a	n/a	n/a
Solid, Manipulated **Nursing does not manipulate, all splitting and crushing to be done in the pharmacy**			Yes, if liquid can splash or inhalation	Yes, if inhalation potential
Oral Liquid, Oral Suspensions, Topical, Subcutaneous **Nursing does not manipulate, all suspensions will be created in pharmacy**			Yes, if liquid can splash or inhalation	Yes, if inhalation potential
Parenteral/IV Administration *Medication will be primed and have a closed system transfer device attached by pharmacy. Wear PPE for administration and discontinuation of hazardous medication IV tubing.*			Yes, if liquid can splash or inhalation	Yes, if inhalation potential
Intracavitary *Use closed system devices when available*			Always 	
Aerosolized			Always 	
Use of PPE Outside of Administration				
Touching patient body fluids 48 hours after parenteral meds 5 days after last does of oral meds			Yes, if liquid can splash	Yes, if inhalation potential
Cleaning Trace materials or environments			Yes, if liquid can splash	
Cleaning Minor Spills *For large spills activate Code Orange*			Always