United States Pharmacopeia (USP) <800> Standards: Increasing Compliance of Safe Handling and Proper Administration of USP General Chapter <800> Drugs

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United States Pharmacopeia (USP) <800> Standards: Increasing Compliance of Safe Handling and Proper Administration of USP General Chapter <800> Drugs

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TABLE OF CONTENTS

Section I. Title and Abstract
Title .................................................................................................................. 1
Abstract ......................................................................................................... 4

Section II. Introduction
Problem Description ..................................................................................... 6
Available Knowledge ................................................................................... 9
PICOT Question ............................................................................................ 9
Literature Review ......................................................................................... 9
Summary of Evidence .................................................................................. 10
Rationale ........................................................................................................ 12
Specific Aim .................................................................................................. 13

Section III. Methods
Context ......................................................................................................... 14
Microsystem Assessment ............................................................................. 14
5P Framework ............................................................................................. 14
SWOT Analysis ........................................................................................... 16
PDSA ........................................................................................................... 18
Interventions ............................................................................................... 20
Study of Interventions ............................................................................... 21
Measures ..................................................................................................... 22
Ethical Considerations ............................................................................... 23

Section IV. Results
Results ................................................................. 24

Section V. Discussion

Summary .............................................................. 26
Limitations ........................................................... 27
Conclusion ............................................................. 27

Section VI. References

References ........................................................... 30

Section VII. Appendices

Appendix A. Evidence-Based Literature Review ..................... 35
Appendix B. PPE Work Flow Diagram .................................. 40
Appendix C. Tip Sheet for Donning and Doffing ....................... 41
Appendix D. Precaution Sign for Patient Room Door .................. 42
Appendix E. Precaution Sign for Bathroom Door ....................... 43
Appendix F. SWOT Analysis ........................................... 44
Appendix G. PDSA Cycle ............................................... 45
Appendix H. Gantt Chart ............................................... 46
Appendix I. Ishikawa (Fishbone) Diagram ............................. 47
Appendix J. Nurse ‘Elbow-to-Elbow’ Questionnaire Form .......... 48
Appendix K. Statement of Determination ................................ 49
Appendix L. Number of Patient’s on USP <800> Chart ............. 52
Appendix M. Average Number of Cart Supplies Chart ............... 53
Appendix N. Nurse Questionnaire Results ............................ 54
Appendix O. Cost-Benefit Analysis .................................... 55
USP <800> Hazardous Drug Compliance

Abstract

Problem: United States Pharmacopeia (USP) developed a set of standards to minimize exposure risks to patients, healthcare workers, and the environment when preparing, handling, and administering hazardous drugs (HDs) known as USP <800> HDs. The guidelines became effective December 1, 2019, but additional information is needed to ensure healthcare personnel are complying with the standards.

Context: Two medical surgical units from Hospital A were included in this project. Currently mandatory online modules about USP <800> standards are provided annually to every healthcare worker, but it is unknown if the policies and procedures are being followed appropriately.

Interventions: Active and passive observations as well as inspections were used to compile data regarding the compliance of USP <800> standards of both healthcare workers and within the hospital setting. Surveys were conducted through informal ‘elbow-to-elbow’ interviews with hospital employees, primarily nurses, to collect subjective evidence.

Measures: The measures can be divided into two categories: personnel and atmosphere compliance. Measures to determine personnel compliance include determining a current level of knowledge and comfortability, collecting self-reported compliance to the standards, and observing personal protective equipment (PPE) donning and doffing techniques. Atmosphere compliances are measured by calculating the total number of patients taking USP <800> HDs, evaluating the accuracy and efficiency of notifications in the electronic health record (EHR), documenting the frequency of correctly displayed signage on patient doors, and assessing supplies located on USP <800> carts.
Results: Nurses self-reported a high level of knowledge and comfortability regarding safe handling and administration practices of USP <800> HDs. However, despite over a quarter of the patients being on at least one USP <800> drug, compliance with proper PPE recommendations, signage, and accessibility of supplies was low.

Conclusions: This project determined that healthcare employees at Hospital A are not consistently following the recommended USP <800> standards. It also provided a baseline knowledge for future education to ensure safety of patients, healthcare employees, and the environment.

Keywords: USP <800> policy, hazardous drugs, hazardous medication, nursing, safety standards, and personal protection equipment (PPE)
Section II: Introduction

Problem Description

The United States Pharmacopeia (USP) organization began over 200 years ago in 1820 with a goal to improve public health specifically overseeing poor-quality European drugs deemed “good enough for America” (USP Timeline: Building trust for over 200 years: A timeline of USP, n.d.). It also regulated medications and doses given by local apothecary’s and other nonconventional medical healers (From Guesswork to Standards: The History of Medicine Quality, n.d.). This non-profit organization consisted of a small group of physicians who established the first set of medication standards (From Guesswork to Standards: The History of Medicine Quality, n.d.) providing reliable information about proper high-quality care for sick and wounded patients (USP Timeline: Building trust for over 200 years: A timeline of USP, n.d.). The Pure Food and Drug Act of 1906 declared USP guidelines as standard regarding the purity, strength, and quality of medical drugs and as such, all medicines were expected meet the appropriate standards (USP Timeline: Building trust for over 200 years: A timeline of USP, n.d.). By 1969, the USP organization had begun to collaborate with other countries around the world and today 140 countries follow USP standards (USP Timeline: Building trust for over 200 years: A timeline of USP, n.d.).

In 1970, two U.S. federal agencies were established to endorse safe and healthy work environments and to eliminate occupational-related health risks: the National Institute for Occupational Safety and Health (NIOSH) created as part of the Centers for Disease Control and Prevention (CDC) and the Occupational Safety and Health Administration (OSHA) formed under the U.S. Department of Labor (About NIOSH, 2022). In 1981, NIOSH released an article cautioning about the exposure risks of certain antineoplastic drugs with recommendations that...
the medications be prepared in a safety cabinet to reduce risks (Zimmerman et al., 1981). Later in 1995, OSHA expanded the definition of this class of medications to “hazardous drug” to include a greater range of medications with potentially harmful effects and released guidelines but not mandatory standards including proper personal protective equipment (PPE) usage (Zhao & Radwick, 2020). It was not until 2004 that NIOSH advised about the importance of hazardous drug (HD) safe handling from preparation to administration as well as the potential exposure risk to the patient, healthcare workers, and the environment including medication waste and the patient’s waste (Zhao & Radwick, 2020). Eventually in 2010 the first list of HDs was released which has been updated five times in 2012, 2014, 2016, 2018, and 2020 (Zhao & Radwick, 2020).

Despite multiple government and private agencies acknowledging and researching the risk of HDs to the patient, the healthcare workers, and the environment, it was not until 2014 that USP proposed a distinct set of guidelines (Zhao & Radwick, 2020). This quality standard became known as USP General Chapter <800> and encompasses healthcare professional responsibilities including PPE; facility obligations such as personnel training requirements; a set hazard procedure for spill mitigation including neutralizing and cleaning protocols; and appropriate documentation (USP 800 | USP, n.d.). The goal of USP <800> guidelines is to protect those who may have access or exposure to HDs including the patient and those who store, prepare, transport, and administer the medications (USP 800 | USP, n.d.) and to promote a safe work atmosphere for the patient, the worker, and the environment (Gabay, 2014). Healthcare personnel includes (but is not limited to) physicians, physician assistants, home health workers, nurses, nursing assistants, technicians, pharmacists, specialists such as physical therapists, housekeeping, and maintenance workers.
NIOSH continues to update the HD list as new information about drugs are available. There are currently over 200 drugs on the USP <800> list (Hazardous Drugs- Handling in Healthcare, n.d.). These drugs can cause acute symptoms like nausea, vomiting, and hair loss or can pose a chronic threat with potential to cause one or more of the following with exposure: carcinogenicity, genotoxicity, mutagenicity, teratogenicity, organ toxicity, reproductive toxicity, or other harmful effects (Andrews & Dill, 2018). The USP <800> drugs are categorized based on type of risk: hazardous, hazardous: limited risk, or reproductive toxin depending on the medication, route, and dose administered. Most of the HDs alter or damage DNA (such as chemotherapy agents) but some HDs change the DNA synthesis process (such as antivirals or antibiotics) changing the growth or proliferation of healthy cells in a patient or offspring (Connor et al., 2016). The type of medication and possible risk, dosage, drug form, and packaging play a role in the assessment of the risk as well as the approach that should be taken with exposure.

It is estimated that over eight million healthcare workers have potential exposures to hazardous medications each year (Gabay, 2014) and studies continue to find worsening health affects due to these exposures (Tocco, 2015). A 2017 study found that there was a significant amount of HD residue left on surfaces after chemotherapy treatment (Böhlandt et al., 2017) indicating an increased risk of exposure though dermal uptake. While this study focused on outpatient chemotherapy treatments and collected data from the patient’s home, the same concepts of surface contamination can be applied in the hospital setting. In fact, a 2015 Canadian study found that many healthcare workers still have considerable amounts of HDs in urine samples indicating a significant risk of exposure to HDs despite strict protocols (Hon et al., 2015). It was concluded that personnel who frequently handle HDs and those who do not receive...
proper handling/administration training or do not follow precautions regularly have a higher level of urine HD concentration, leading to a greater health risk (Hon et al., 2015).

USP <800> standards became effective on December 1, 2019, but many hospital organizations had difficulty implementing, educating, and maintaining the minimum standards due to the COVID-19 pandemic that began a few months later in 2020. Not only did the entire healthcare system shift their focus and efforts to the pandemic, but the PPE shortage also limited the amount of PPE available to healthcare workers. Now that PPE resources are more readily available, hospitals are beginning to shift their focus to the implementation of USP <800> policy and standards. The primary reason for implementing this evidence-based quality improvement (QI) project was to identify current awareness and compliance of the USP <800> policy in Hospital A. The QI intervention’s aim was to provide up-to-date knowledge of existing compliance through active and passive observation and provide proposed recommendations to Hospital A’s USP <800> Committee on ways to improve compliance.

Available Knowledge

**PICOT Question**

The following PICOT question was created to guide a literature research strategy for evidence-based solutions: Among nurses who administer USP<800> HDs, does active observation with a supplemental questionnaire compared to passive observation with no direct intervention increase compliance with safe handling of USP <800> HD over thirteen weeks?

**Literature Review**

An exhaustive search of literature was completed to discover relevant information related to the PICOT question of this QI project. Databases including Cumulative Index to Nursing and Allied Health Literature (CINAHL) and PubMed were searched frequently between August 2022
and November 2022. Keywords utilized in the search included *USP <800> policy, hazardous drugs, hazardous medication, nursing, safety standards, and personal protection equipment (PPE)*. A total of 63 articles were found ranging from 2014 to current (2022). Inclusion criteria was added to include articles in English resulting in 49 articles remaining. The abstracts of the articles were reviewed, and articles were chosen based on relevance to the project. Eight articles were evaluated using the John Hopkins Nursing Evidence-Based Practice Research Evidence Appraisal Tool (Dang, Dearholt, & Ascenzi, 2022), and are included in Appendix A: Evidence-Based Literature Review Table. The eight articles were appraised resulting in three articles as Level I (Quality A), two articles as Level III (Quality A and B, respectively), and three articles as Level V (one as Quality A/B and two as Quality C) (Dang, Dearholt, & Ascenzi, 2022).

**Summary of Evidence**

The recent development of formal guidelines and official standards regarding safe practices when handling and/or administering USP <800> HDs is due to decades of research and advancements. Andrews & Dill (2018) report that research on potential hazards of modern medications began in the 1930s but it was not until 1970 that a medical resident requested a list of hazards and precautions to use after becoming concerned about toxicity while administering chemotherapy drugs. After nearly 90 years since first administering HDs like chemotherapy, standards created by USP became official in 2019 (Andrews & Dill, 2018). The defining criteria of USP <800> HDs was updated by NIOSH to include any drugs that have the following negative health effects: carcinogenicity, reproductive toxicity, genotoxicity, teratogenicity, organ toxicity, or a new medication that has a similar structure of an existing hazardous medication (Andrews & Dill, 2018). Today there is a wide range of known side effects if exposed to HDs
including dizziness/lightheadedness, abdominal pain, nausea, vomiting, dermal injury/sore, infertility, and/or miscarriages (Eisenberg, 2018).

Andrews & Dill (2018) describe the difficulty of accurately identifying exposures as it can occur anytime between manufacturing the medication to administration. A study by Böhlandt, Sverdel, and Schierl (2017) inspected the home of thirteen patients for three days after receiving outpatient chemotherapy and found HD residue on several surfaces in the home leading to an increased exposure risk to others in the household. A Canadian study by Hon et al. (2015) analyzed two sets of 24-hour urine samples from 103 employees with eight job titles including unit clerk, pharmacist, pharmacy receiver, pharmacy technician, porter, nurse, transport, and “other” encompassing several other professions like volunteers, oncologists, and dieticians. It was found that even after following proper protocols around HDs, levels of non-metabolized cyclophosphamide (CP) were found in urine samples of these healthcare workers (Hon et al., 2015). Even with no known contact to HDs on shift, the unit clerk was found to have a high level of CP in their urine sample (Hon et al., 2015) indicating that unexpected yet significant exposure risk can occur from commonly touched surfaces. Hon et al. (2015) also noted that while there was no correlation discovered between urine CP concentrations and known HD contact. Healthcare workers who handled HDs regularly or who reported not receiving proper HD training were found to have a substantially higher CP urine concentration (Hon et al., 2015). This and several findings suggest that better communication, increased education, and improved organization management of USP <800> HD standards and protocols would improve compliance of safe handling and administration and reduce unnecessary exposures to healthcare workers (Boiano et al., 2014; DeJoy et al., 2017).
Even when guidelines are established and well-known to hospital staff, standards are not always followed. Boiano, Steege, and Sweeney (2014) assessed 2069 anonymous surveys and discovered nearly 1 of every 7 participants did not always wear gloves when administering HDs despite 95% of the participants reporting they have received HD training in the past. Per this report, the most common excuse to not wearing proper PPE included “skin exposure was minimal” and “exposures are inconsequential or so rare that they do not justify their use [of PPE]” (Boiano et al., 2014). An additional mixed-method study compared subjective and objective nursing behaviors to determine compliance of HD protocols. Nurses reported a higher subjective compliance with recommended PPE compared to objective observation by the observer (Colvin et al., 2016) thus believing nurses are complying with protocols more often than they actually are (Boiano et al., 2014; DeJoy et al., 2017).

Rationale

The Lewin’s Change Model is known for influencing change both within an individual and in a group or organization and involves unlearning and relearning behaviors without losing self-identity (Harris et al., 2018). This model is comprised of three phases: unfreezing, change, and refreezing (Harris et al., 2018). Unfreezing involves recognizing the issue, ensuring management support for change, and raising awareness of the concerns among the staff (Hussain et al., 2018). In this QI project, a lack of compliance of USP standards was noted by Hospital A’s Quality Improvement Team and presented to the USP <800> committee to increase understanding of the gap in care. The next step in Lewin’s model is change. This was done using active and passive observations to detect compliance levels of USP standards and educate staff about proper techniques as necessary. The final step in the Lewin’s model is refreezing which entails incorporating the desired change into everyday practice (Hussain et al., 2018). In this
project, this phase is established once all healthcare workers consistently follow the USP standards.

The Orem’s Self-Care Deficit Nursing theory was also used to direct this project. Orem’s Model of Nursing was developed by nurse theorist, Dorothea Orem, who believed fulfilling self-care behaviors would be the most successful approach to improving larger health outcomes (Potter et al., 2021). The model was intended to encourage nurses to assist patients in improving self-care skills with the goal that the patient’s would eventually be able to do it on their own (Wilkinson et al., 2020) to better the patient’s overall health. However, the theory can be expanded and used in this QI project. It is the healthcare worker’s duty to protect themselves and others from unnecessary HD exposures using health promoting behaviors like always wearing appropriate PPE. A clinical nurse leader (CNL) within the microsystem can help educate and encourage the proper self-care activities as seen in this QI project.

Specific Aims

The objectives of this project were to determine current practices and nurse understanding of USP <800> drug handling and administration. The specific aim included improving nurse compliance among the medical surgical units with safe handling of HDs as outlined in the Hospital A 2022 HD Safe Handling and Management Updates Training. The process began with an initial assessment of the microsystem, review of Hospital A’s HD policy and procedures, and investigation of current and relevant evidence-based nursing research. The process ended with the implementation of recommendations based on the assessment of the microsystem, Hospital A's policy and procedures, data collected during the project through questionnaires and observational data, and feedback from the medical-surgical staff. By working on this process, it is expected that an increase in compliance of USP <800> HD standards will
occur including an increased use of USP carts and PPE by 50%, and an increased number of correctly filled out door signs. This increase is measured by the questionnaires and observation data collection. It is important to work on this now because:

1. USP <800> HDs pose a health risk to nurses. Therefore, nurses should be trained to understand the risks and proper techniques to fully protect themselves.
2. Not following or meeting current USP <800> standards of safe handling became an enforceable regulation in 2019.
3. Nurses who become ill from repeated exposure to HDs will contribute to the nursing shortage and may increase costs in paid time off or extra hiring.
4. Adequate PPE is now available following the PPE shortage during the COVID-19 pandemic removing this barrier to comply with USP<800> HD recommendations.

Section III. Methods

Context

Microsystem Assessment

According to Harris et al. (2018), change begins within a microsystem and starts with a microsystem assessment to identify areas of improvement. The first microsystem analysis used in this project was the 5P Framework (King & Gerard, 2016). A Plan-Do-Study-Act (PDSA) cycle was then created and initiated to begin a continuous process for improvement (King & Gerard, 2016).

5 P Framework.

Purpose. The mission statement of a healthcare organization is a formal declaration of the hospital’s values, morals, and beliefs. Hospital A’s mission statement includes being committed to better the health of the community using a high level of safe, compassionate,
patient-centered care (Hospital A, n.d.). A CNL can support the hospital’s mission statement by identifying processes or patterns within a microsystem that needs amending and assist in creating and implementing a plan to make appropriate improvements. It was observed at Hospital A that the hospital staff did not consistently follow the proper protocol when administering HDs. As such, the purpose of this plan is to determine a baseline of the current understanding and knowledge of safe handling and administration of USP <800> drugs to limit unnecessary exposures to the patient and visitors, the healthcare worker, and the environment. This QI project aims to further Hospital A’s mission of improving patient safety outcomes by increasing the understanding and standard compliance of USP <800> hazardous medications and improving the use of USP <800> carts and door signage.

**Patients.** This project took place on two medical-surgical units that were determined, by the pharmacy team of the USP <800> hospital committee, to have the highest concentration of HD administration behind the hematology/oncology units. The hematology/oncology units require nurses to have additional certifications for medication administration and therefore were excluded from the project. Both medical-surgical units cared for a range of 28 to 36 patients at a time. The patients were found to have a wide range of medical diagnoses including active cancer diagnoses, history of cancers, and infections.

**Professionals.** The professionals involved in this project primarily included nurses on the units that care for patients on UPS <800> HDs and are responsible for handling and administering the medications. Other healthcare workers such as physicians and housekeeping were also observed or interviewed as additional perspectives in this study.

**Process.** The processes involved in caring for patient’s on USP <800> HDs require additional safety precautions depending on the medication. A workflow diagram of the existing
process can be seen in Appendix B. The nurse first checks the patient’s medication administration record (MAR) tab in the electronic health record (EHR) and determines the appropriate medication to administer. The nurse prepares, handles, administers, and discards the medication using appropriate PPE noted in the MAR and on the medication label using proper donning and doffing practices (see Appendix C). To ensure all staff and visitors know about the extra precautions needed to reduce the potential risk of HD exposure, it is protocol to place identification signs on the patient’s room door (see Appendix D) and bathroom door (see Appendix E) containing information about what PPE is required for safety. Finally, the supplies used in this process are stored in a specific USP <800> cart located on each unit. The supplies must be restocked frequently to ensure proper use of the cart.

**Patterns.** Despite the additional PPE requirements, each patient is cared for with high-quality patient-centered care. Although nurses reported a high understanding and knowledge of proper HD safety and administration practices, it was observed using active and passive observation that proper PPE protocols were not consistently being followed by hospital staff. It was also found that USP <800> carts were not stocked with appropriate supplies and appeared to not be used during the data collection period.

**Strengths, Weaknesses, Opportunities, and Threats (SWOT) Analysis.** After thoroughly assessing the microsystem using the 5 P’s framework, it is important to determine various objective factors that can cause positive or negative effects on the project (King et al., 2021, p 179). This can be done using a SWOT analysis which helps with strategic planning for possible solutions to existing threats within the microsystem (King et al., 2021, p 179). See Appendix E for the full SWOT Analysis diagram.
**Strengths and Weaknesses.** Practices already implemented and used within the microsystem that contribute to the desired goal are considered “strengths” and can be used to help further facilitate positive changes (King et al., 2021). In this project, each unit already contains USP <800> carts to be used when handling and administering HDs. Additionally, each staff member on these units is required to complete an online module on safe handling and administration of USP <800> HDs annually, that is frequently updated by Hospital A’s Quality Improvement Team to ensure the most up-to-date information is being shared. Finally, Hospital A’s EHR is already equipped with the technology to identify USP <800> HDs. Warning banners both on the summary page of the patient’s chart and in the MAR are used to notify medical staff about the medication and recommended PPE to use. The system can also monitor other local EHR systems and will notify the staff member if the patient is on a HD, even if documented outside Hospital A’s records. These strengths are a positive step in making change happen.

Weaknesses in this analysis include areas that may cause negative effects on the process and delay the desired change (King et al., 2021). While USP <800> carts are available on each unit, they are not utilized due to decreased knowledge of the cart, stocking inconsistencies, and no personnel responsible for maintenance or upkeep. Additionally, the warning banners in the EHR and MAR were found to fire but not list specific PPE recommended or the concerning medication making it difficult to eliminate risks. Finally, although available on the unit, room and bathroom door signs are rarely utilized or posted.

**Opportunities and Threats.** Opportunities involve future areas of improvement that are achievable within the microsystem (King et al., 2021, p 179). In this project, the opportunities should increase compliance of USP <800> guidelines. Appointing a responsible staff member to regularly check and restock USP carts can increase accessibility and the likelihood that nurses
will use the carts regularly. Finally, future opportunities exist for door signage such as reviewing signage during shift rounding or by a responsible staff member like a unit secretary or charge nurse.

Threats in the SWOT analysis take into consideration the potential risks or hazards that may arise within the facility while implementing the project (King et al., 2021). It was anticipated that factors such as lack of time or sustainability of cart maintenance or sign verification could impede the change project. Additionally, hiring and training new staff members may require extra resources that will be taken away with the implementation of the project. Finally, as USP <800> standards and policy change, personnel will be needed to identify, implement, and educate the staff about the new change.

**Plan-Do-Study-Act (PDSA) Cycle.** The PDSA cycle is a tool used in improvement projects to evaluate the effectiveness of the change and determine if the anticipated objective is met or if the plan must be altered to achieve the goal (Finkelman, 2019, p.84) and can be viewed in Appendix G. The cycle is cyclical, easily allowing for changes to be made to obtain the best outcome possible. The PDSA cycle in this improvement project occurred over 13 weeks as seen in the Gantt chart in Appendix H.

**Plan.** The initial “plan” phase begins the first day of the project and involves creating a global and specific AIM statement. After several meetings with Hospital A’s staff, a PICOT question was developed, and a plan of action was constructed. Research was completed to determine the current standard practice for safe handling and administration of HDs. Data collection forms and questionnaires were created based on standard practice and current protocols at Hospital A. The microsystem was analyzed using the 5 P’s framework to determine the purpose of the microsystem, typical patient population, the involved medical professionals,
and the current processes and patterns within the Microsystems (King & Gerard, 2016). Once the microsystem is assessed and the possible concerns were identified, a SWOT analysis and a root cause analysis (RCA) are conducted to evaluate the possible causes (King & Gerard, 2016). Specifically in this project an Ishikawa (fishbone) diagram was created to determine a list of potential sources that could lead to decreased compliance of safe handling and administration of USP <800> HDs (seen in Appendix I). This process took seven weeks.

**Do.** The next step is the “do” phase where implementation of the plan occurs. Data collection occurred over a two-week period on two units at Hospital A’s two campus locations using both active and passive observation techniques. The EHR was initially assessed to determine the HD and recommended precautions. Next, observations about signage were gathered and the location and supplies in the USP <800> carts were noted. On each day of data collection, at least one nurse from each unit was surveyed using an ‘elbow-to-elbow’ technique to determine a baseline of understanding and knowledge of HD administration (questionnaire in Appendix J). Finally, passive observations about PPE donning and doffing procedures were noted if witnessed during data collection.

**Study.** The third step of the PDSA cycle is “study” which entails analyzing the collected data and reviewing the results. The analysis of the data can be seen in the Results section. This step of the cycle took three weeks to complete.

**Act.** The fourth and final step is the ‘act’ phase where the findings are compared with the expected results to see if the change achieved the desired goal. If the goal is not accomplished or a better outcome is wanted, the plan of the PDSA cycle will be changed and the cycle will be repeated until the anticipated objective is obtained. Due to the time constraints of this project, only one PDSA cycle was completed and the recommendations about future changes were
presented to Hospital A’s USP <800> Committee. The act phase took less than 2 weeks to complete.

**Intervention**

The project took place on two medical-surgical units at an acute care hospital, Hospital A, in the Greater Bay Area of Northern California. One unit is located at each of the hospital’s two locations and historically had the highest number of patients given USP <800> HDs behind the oncology units per an internal report produced by Hospital A’s pharmacy department. The project started August 2022 and ended December 2022 with a data collection period between October 17, 2022 and October 28, 2022. An International Review Board (IRB) evaluation was completed (see Appendix K) but pre-approval was not required due to the nature of the QI project.

Hospital A’s two units were visited once daily Monday through Friday during the data collection period. The EHR was first evaluated for the number of patients on USP <800> HDs using a preprogrammed icon on the patient dashboard. Each chart was opened and reviewed for the name of the hazardous medication, type of risk associated with the medication, and description of the precautions necessary. The bedroom and bathroom doors in these patient’s rooms were examined to determine if proper signage was posted and completed per Hospital A’s policy (see Appendix D & Appendix E).

All units at Hospital A contain at least one HD cart that contains the necessary materials to handle and administer the medications as well as clean spills and bodily fluids. The carts should contain the following ten items: medication crush, gloves, isolation gowns, chemotherapy gowns, goggles, face shield, bleach wipes, Sani-Wipes, a spill kit, and laminated HD PPE chart
resource guide. The carts were examined daily for the number of correct items on each cart and the location of the cart(s) were noted.

Due to increasing survey fatigue in the workplace, a survey was performed by an informal ‘elbow to elbow’ conversation where the data collectors asked at least one nurse on each unit during the daily visits questions to analyze the current understanding and proper compliance of safe handling and administration of HDs. Results were recorded on a previously created form (see Appendix J). Finally, during each visit, passive observation of PPE donning and doffing techniques were assessed following Hospital A’s tip sheet in Appendix C.

The CNL and team then analyzed the quantitative and qualitative data collected from the observations and the anonymous questionnaires to determine the knowledge of current standards performed on the units. The findings of the project will be presented to Hospital A’s USP <800> Committee including recommendations on how to improve compliance and limit future risks.

Study of Intervention

The measurement strategies in this QI project included observation and surveys using an informal interview approach. Active observation, also known as active participation, occurs when an observer is openly involved in the recipient’s situation and uses tactics like watching, listening, clarifying, and instructing to improve the behavior or outcome (KU School of Medicine, n.d.). Passive observation is when the observer does not interact to the situation with the goal of observing the recipient’s true behaviors. Active observation was utilized when interviewing the nurses about their understanding and compliance with USP standards. Passive observation was the most frequent method used such as to determine if the door signs were appropriately posted and while watching the donning and doffing of PPE.
To assess the quantitative data including the number of patients on HDs and the average number of supplies on the USP cart, a Google Form was created using various question types such as checklists and fill-in-the-blanks to collect the pertinent data. Qualitative data was also collected on the Google Form through an open-ended long answer text format.

Finally, a separate questionnaire was completed on a Google Form to document the answers to the questions from ‘elbow-to-elbow’ discussions with nurses (see Appendix J). Question types included rating processes or knowledge on a scale of one to ten (identifying what the number sequence on the scale represents), quantitative questions like estimating the number of times one administers HDs weekly, qualitative questions like knowing the location of specific items, and utilization of the Likert Scale for frequency estimations.

**Measures**

According to Harris et al. (2018), the basis for quality improvement involves choosing clear and well thought out measurements and metrics to properly identify change. The outcome measure in this project is improvement in overall compliance of the USP <800> protocols. Various factors need to be considered including calculating percentages of correct door signage, averaging the correct number of supplies in each unit’s USP cart, assessing the number of correct PPE donning and doffing occurrences, evaluating the accessibility and practicality of the EHR, and determining the current knowledge and understanding of Hospital A’s USP <800> policy and procedures.

The number of accurate door signs was calculated by finding the percentage of appropriate signage for each unit and combining them to find Hospital A’s overall compliance rate. During each day of data collection, the number of correct supplies on each PPE cart were counted and documented. Since each cart should have ten different supplies, the number of
correct supplies was divided by ten. The averages for each unit were calculated depending on the number of carts present and multiplied by 100 indicating the percentage of accurate supplies on the carts. Donning and doffing occurrence were documented as either “Yes” indicating a correct procedure or “No” meaning it was done incorrectly. The “Yes” findings were divided by the total number of occurrences observed to find the percentage of times the procedure was done correctly. Accessibility and practicality of the EHR was determined by assessing how often the banner PPE recommendations matched the medication listed in the MAR. Finally, the staff’s current knowledge of USP <800> was determined using a survey seen in Appendix J.

**Ethical Considerations**

This project is classified as a QI project (Dang et al., 2021). It was approved by the School of Nursing and Health Professions faculty at the University of San Francisco and is associated with the master’s level CNL curriculum. Per the *Statement of Determination* and *Institutional Review Board (IRB) Statement of Non-Research Determination Form* located in Appendix K, this QI project does not meet the criteria needed for IRB pre-approval. Participation during any portion of the data collection was voluntary and expectations were discussed and acknowledged by participant prior to collecting data. Patient safety and confidentiality were top priorities throughout the project. Healthcare workers who participated in surveys were asked to participate prior to beginning the survey. Anonymity, confidentiality, transparency, and respect were upheld during the entire project. This QI project did not receive any funding and no conflicts of interests were detected.

The QI project was inspired by the Jesuit value of *cura personalis*, a highly respected value of the Jesuit community and of the University of San Francisco (*Our Mission and Values*, n.d.). This value emphasizes the importance of caring for all portions of the body equally.
Including the body, mind, and spirit with respect and dignity (Our Mission and Values, n.d.). Ensuring healthcare professionals and patients are properly protecting themselves and reducing the risk of exposures to others parallels with this value. Furthermore, the American Nurses Association’s (ANA) Code of Ethics (COE) helped guide this project by providing the ethical responsibilities of nurses within the healthcare system. The ANA COE Provision 7.2 states it is essential for nurses to “establish, maintain, and promote conditions of employment that enable nurses to practice according to accepted standards” (Association & Hegge, 2015). This emphasizes the importance of supporting the safety protocols and guidelines established by USP to maintain a safe work environment. Not only does ANA COE state that nurses must “promote, advocate, and protect the rights, health, and safety of the patient” in Provision Three, but also acknowledges the importance of protecting the “health, safety, and well-being” of oneself in ANA COE Provision Five (Association & Hegge, 2015). Overall, the nurse has the ethical responsibility to promote a safe environment for all involved including the patient, visitors, all healthcare workers including oneself, and the environment.

Section IV. Results

Results from this project showed that over a quarter (27.7%) of the patients on the units at Hospital A were on at least one USP <800> HD over the data collection period (see Appendix L). Each chart was evaluated for a MAR banner notifying staff which precautions to take. It was found that the banner did not load any precautions 100% of the time. This result was reported to the hospital’s IT department immediately for further investigation. In addition to noting the MAR banner, each chart was inspected for the name and type of USP <800> medication. If the USP icon and banner fired in the chart but the specific medication was not listed in the MAR, it was considered a “misfire” of the icon. A “misfire” occurred 53 times meaning 30.6% of the
patients did not have a known HD listed in the chart and therefore staff did not know what precautions were necessary to reduce health risks.

Next, USP signage was observed and analyzed. It was determined that 13 of the 173 patients (7.5%) on the two units at Hospital A had correctly posted door signage on their room door while only 3 of the 173 patients (1.7%) had a correctly posted bathroom door sign.

While gathering data on the two units, donning and doffing of PPE by various healthcare workers was witnessed. Out of the 37 times donning and doffing was passively observed, 36 occurrences were done following proper protocol as seen in Appendix C. This means that 97% of the time that PPE is worn, it is put on and taken off following the correct steps.

The USP <800> supply carts were also located and inspected daily on each unit. One unit had a total of three carts located in a supply closet and the other unit had two carts with one cart in each medication room. It was found that none of the carts were stocked properly at each hospital. An average of the number of correctly located items were documented daily and the trends can be seen in Appendix M. Additionally, some carts were also noted to have random medical supplies like needles and syringes that do not need to be stocked in the carts. It was noted that the carts appeared to be in the same locations each daily visit and therefore it was hypothesized that the carts were never moved or were even utilized during the collection period. When asked who restocks the carts or orders the supplies, various healthcare workers on the units did not know.

Finally, an ‘elbow-to-elbow’ discussion was conducted with on-duty nurses and the questionnaire (seen in Appendix J) was completed by the research team at the end of the conversation. A total of 27 nurses were surveyed on the units of Hospital A and to limit bias, each nurse was assured the questionnaire answers and the conversations would be kept
completely confidential. The questions and answers to the questionnaire are displayed in Appendix N. Nurses reported an average knowledge of USP <800> HDs as 7.15 on a scale from one to ten (one indicating no knowledge and ten indicating a high level of knowledge). On a similar scale from one to ten (one indicating not feeling comfortable and ten indicating very comfortable), it was reported that nurses have an average of 8.45 of comfortability with handling USP <800> HDs. When asked how often they administer HDs per week, there was a large range of answers from zero times per week up to fifteen times per week but overall reported an average of 3.44 times per week. In terms of locations of USP <800> carts and waste receptables, fifteen nurses reported knowing their locations while ten reported not knowing where they were located on the unit. Using another scale from one to ten (one indicating very difficult with ten indicating very easy), nurses were asked to rate how easy they felt it was to identify proper signage and recommended PPE and an average of 8.39 was reported. Finally, nurses were asked about how often they followed the recommended PPE while handing and administering USP <800> HDs: Twelve nurses reported ‘always’ wearing the correct PPE, ten reported ‘sometimes’ wearing correct PPE, four nurses reported ‘most of the time’, and one nurse reported ‘never’ wearing the recommended PPE.

**Section V. Discussion**

**Summary**

Due to updates in current standards, improvements in care, and advances in technology, the healthcare community is constantly changing and adapting to provide high-quality, evidence-based care to all patients. To effectively endorse change, a current standard of practice must be established before changes can be made. This QI project used observation, surveys, and assessments to establish a baseline of current knowledge and compliance of USP <800> HD
standards in two units at Hospital A. It was determined that while nurses had a strong understanding of safe practice, the techniques and procedures were not always followed for a variety of reasons creating a frequent and unnecessary health risk to the patient, visitors, healthcare workers, and the environment.

**Limitations**

This QI project had several limitations. First, the data collection period was only two weeks long and data was only collected from day-time nurses. Due to the high demand and busy workflow of the on-duty nurses, only a limited number of nurses were surveyed leading to few data points to analyze. Next, the surveys were self-reported meaning the findings are based on a nurse’s subjective understanding and knowledge of the USP <800> standards. As found in many research studies like Colvin (2016), self-reported survey responses often express a higher level of adherence to a policy compared to the action being observed. This likely means compliance and knowledge is lower than survey results found. Some of the survey questions also required qualitative answers which can be difficult to effectively analyze. Finally, although over a quarter of the patients on the two units were on USP <800> HD precautions, the medications were generally not administered daily so observation of physical administration of a HD was infrequent.

**Conclusion**

This QI project sets the groundwork for many future projects at Hospital A. The findings showed that while nurses report an understanding of USP <800> HD safety, healthcare personnel are not always following the appropriate precautions to reduce risk to themselves, the patient, other healthcare workers, and the environment. The following three recommendations were made to Hospital A to improve hazardous risks.
First, repairing and improving technological glitches can help increase awareness among the healthcare team. Although a warning banner was attached to the appropriate charts, due to a technical error the banner did not give appropriate PPE recommendations. Additionally, 31% of the charts did not list an active USP <800> medication leading to confusion about what precautions to take. Fixing these technological issues will likely encourage compliance.

The second recommendation involves restocking USP <800> carts. Currently there is no set person to do this task leading to it not being done. A staff member noted that a centralized location with signs, a checklist, and all supplies needed for proper handling and administration of USP <800> medications would simplify the current barriers and promote safe techniques by acting as a “grab and go” area. Since the unit secretary at Hospital A already has the responsibility of maintaining the supply stock and ordering supplies as needed, this would be a good assignment to add to this role.

The third and final recommendation includes establishing a method to routinely assess door signage for each patient on a USP <800> HD. On admission to the unit or when the HD is ordered, the chart should add a section to report if proper PPE signage is posted on the patient’s bedroom and bathroom doors similar to documenting if the bed is in the lowest position and if suction devices are present in the room. It is recommended to assign responsibility to the charge nurse who will check if signs are posted and contain the correct information each day. The questionnaire revealed that nurses felt like they did not have enough time to create and post the signs but instead relied on the banner in the MAR and medication labels to comply with proper PPE requirements. However, non-nursing staff like housekeeping reported not having the proper signage on the doors makes it impossible for them to know about the risks of the HDs and are therefore unable to protect themselves.
Cost is a major factor and common barrier in implementing QI projects and executing the recommendations. A cost-benefit analysis incorporating the above recommendations reveals even with extra supplies required and additional duties added to current positions, the hospital will save a significant amount of money annually. The detailed cost analysis is available in Appendix O. The average cost for restocking the PPE required is estimated to be $25,000 annually but majority of these costs are already being spent by the hospital as PPE is being worn but is not located in centralized location specifically for HD administration. The above recommendations are also estimated to increase PPE usage causing a rise in the annual PPE budget. Per Glassdoor (2022), the average hourly wages in California for unit secretary is $21.49, for a RN Charge Nurse is $70.32/hour, and for a EHR IT Analyst is $55.00/hour. According to the U.S. Department of Labor, the average workers’ compensation cost for one instance of injury or illness due to hazardous drug exposure is $57,292 (Workers’ Compensation, n.d.). Based on the estimated costs, it was concluded that $8,413.85 would be saved if the proposed recommendations prevented just one workers’ compensation claim annually. Each additional prevented claim would save $57,292 of expenditure annually.

As the USP <800> list continues to grow with more awareness and advances in medicine, appropriate healthcare staff education about proper compliance will be needed to ensure the safety of patients, healthcare employees, and the environment. This clinical intervention reveals the importance of observation and frequent assessments to help identify and mitigate barriers within the microsystem and the importance of complying with USP <800> standards to reduce unnecessary and preventable risk of HD exposures.
References


### Evidence-Based Literature Review Table

<table>
<thead>
<tr>
<th>Study / Citation</th>
<th>Design / Method</th>
<th>Sample / Setting</th>
<th>Outcome / Feasibility</th>
<th>Evidence Rating</th>
</tr>
</thead>
<tbody>
<tr>
<td>Böhlundt, A., Sverdel, Y., &amp; Schierl, R. (2017). Antineoplastic drug residues inside homes of chemotherapy patients. <em>International Journal of Hygiene and Environmental Health</em>, 220(4), 757-765. 10.1016/j.ijheh.2017.03.005</td>
<td>Quasi-Experimental • Used wipe samples and urine drug concentrations of the patient and families to determine exposure</td>
<td>• n = 13 home settings of chemotherapy patients • 3 days of data collection</td>
<td>Found evidence of contamination of HD on several surfaces in home Further protective measures and hygiene recommendations and education should be provided to patients and families</td>
<td>JHNEBP: Level I A <strong>Limitation:</strong> Samples only taken for 3 days and do not reflect duration of potential risk</td>
</tr>
</tbody>
</table>
• 2069 surveys completed; 98% were nurses  
• Found guidelines not always followed  
• Most frequent excuse for not wearing proper PPE include “skin exposure was minimal” and “exposures are inconsequential or so rare that they do not justice their use [of PPE].”  
• Despite self-reported surveys (a limitation), a large number of participants reported regularly not following safe working policies and procedures  
• Recommendations for greater education and better communication to inform employees of risk and measures to reduce the exposures |
| --- | --- | --- |
• Compares objective and subjective nursing behaviors via micro-ethnography (observational) and questionnaires  
• Cleveland Clinic  
• Observe oncology nurses with two or more years of experience handle and administer HDs  
• Observations occurred first  
• 22 observations were made on HD handling and administration  
• 12 nurses completed questionnaires  
• Observations were compared to questionnaire results  
• Adherence to recommended PPE was higher per survey results compared to observation  
• Not wearing gloves or gowns were the most observed noncompliance | JHNEBP:  
Level III  
A  
Limitation:  
Small sample size  
To encourage honest participation on the questionnaires, surveys were anonymous so observed nurses may be different than RN who
<table>
<thead>
<tr>
<th>Study</th>
<th>Study Design</th>
<th>Study Methods</th>
<th>Findings</th>
<th>JHNEBP:</th>
</tr>
</thead>
</table>
• Understanding and organization policy of engineering control and PPE requirements varied  
• The greater number of risks per week (greater number of HD treatments administered) led to a higher number of experienced adverse symptoms  
• Increased communication, education, and management of the organization showed fewer rates of adverse effects reported | Level III B  
Limitation: Anonymous survey  
Survey data is self-reported and was not confirmed with observation |
| Eisenberg, S. (2018). USP and Strategies to Promote Hazardous Drug Safety. *Journal of Infusion Nursing, 41*(1), 12-23. 10.1097/NAN.0000000000000257 | Nonexperimental | N/A | Discusses USP <800> history, NIOSH HD list including categories of HDs and potential side effects, contamination/risk potentials, reducing exposures including proper PPE and protocol implementation, and importance of annual education and training.  
Recommends organizations develop a | Level V C |
<table>
<thead>
<tr>
<th>Gabay, M. (2014). USP: Handling Hazardous Drugs. <em>Hospital Pharmacy</em>, 49(9), 811-812. 10.1310/hpj4909-811</th>
<th>Non-experimental</th>
<th>N/A</th>
<th>multidisciplinary team to analyze current standard practice and implement changes as needed</th>
<th>USP &lt;800&gt; creates a standard for the safe handling of hazardous drugs in all stages of administration including transport, storage, preparation, and administration. Goal of USP &lt;800&gt; standards is to reduce harmful exposures to the patient, healthcare workers, and environment. USP &lt;800&gt; guidelines are not regulated by USP but can be enforced by federal or state agencies.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Hon, C., Teschke, K., Demers, P. A., &amp; Venners, S. (2015). Antineoplastic drug contamination in the urine of Canadian healthcare workers. <em>88</em>(7), 933-41. 10.1007/s00420-015-1026-1</td>
<td>Quasi-Experimental</td>
<td>n = 103 healthcare employees Canadian Healthcare System: five acute care sites and one cancer treatment center 8 job categories evaluated: unit clerk, pharmacist, pharmacy receiver, pharmacy</td>
<td>Despite protocols to reduce risk, healthcare workers are still exposed regularly to HD. No correlation found between urine concentrations of CP and known contact during shift. Workers who do not have direct exposure to handling HDs were found to have the highest level of CP in urine samples.</td>
<td></td>
</tr>
<tr>
<td><strong>JHNEBP:</strong> Level V C</td>
<td><strong>JHNEBP:</strong> Level I A</td>
<td><strong>Limitation:</strong> Study did not include housekeeping who may have the greatest potential exposure risk. Surveys were self-reported and not verified for accuracy.</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
| known contact of HD on shift       | technician, porter, nurse, transport, other (volunteer, oncologist, dietician) | Two factors associated with substantial CP:
1. Worker who handling HDs regularly as job
2. Workers without proper HD training |
Appendix B

PPE Workflow Diagram
Appendix C

Hospital A’s Tip Sheet for Proper Donning & Doffing Techniques

Hazardous Drug Tip Sheet: PPE Donning and Doffing

Proper donning and doffing of PPE is an important way to maximize protection and minimize exposure to hazardous materials. Take a moment to review the correct donning and doffing order. These instructions are also posted on the hub.

<table>
<thead>
<tr>
<th>Hazardous Medications</th>
<th>Reproductive Toxins</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Donning</strong></td>
<td><strong>Doffing</strong></td>
</tr>
<tr>
<td>1. Perform hand hygiene</td>
<td>1. Outer gloves</td>
</tr>
<tr>
<td>2. First pair gloves</td>
<td>2. Face shield</td>
</tr>
<tr>
<td>3. Chemo gown</td>
<td>3. Goggles</td>
</tr>
<tr>
<td>5. Face shield (if high splash risk)</td>
<td>5. Inner gloves</td>
</tr>
<tr>
<td>6. Second pair gloves</td>
<td>6. Wash hands with soap and water (do not use gel)</td>
</tr>
<tr>
<td><em>Dispose of soiled PPE in regular or large yellow bin</em></td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th><strong>Donning</strong></th>
<th><strong>Doffing</strong></th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Perform hand hygiene</td>
<td>1. Outer gloves</td>
</tr>
<tr>
<td>2. First pair gloves</td>
<td>2. Face shield</td>
</tr>
<tr>
<td>4. Face shield (if high splash risk)</td>
<td>4. Inner gloves</td>
</tr>
<tr>
<td>5. Second pair gloves</td>
<td>5. Wash hands with soap and water (do not use gel)</td>
</tr>
</tbody>
</table>

*Dispose of soiled PPE in regular trash bin*

Tip Sheet sourced from John Muir Health
## Appendix D
### Precaution Sign for Patient’s Room Door

**HAZARDOUS DRUG PRECAUTIONS**

Start Date __________  End Date __________

<table>
<thead>
<tr>
<th>Precaution Level (circle one)</th>
<th>Red</th>
<th>Green</th>
<th>Yellow</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>HAZARDOUS</strong> RED</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Intravenous, Intramuscular, Subcutaneous, Intrathecal</td>
<td>Double Glove</td>
<td>Chemo</td>
<td>If high splash risk</td>
</tr>
<tr>
<td>-Oral: Risk of spitting, splash, splatter, or spray</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Topical dosage form</td>
<td>Double Glove</td>
<td>Chemo</td>
<td>If high splash risk</td>
</tr>
<tr>
<td>Body Fluids/Waste containing trace medication or metabolites (e.g. emesis, urine, stool)</td>
<td>Double Glove</td>
<td>Chemo</td>
<td>Yes</td>
</tr>
<tr>
<td>Intravascular, Intraperitoneal, Irrigation, Aerosol Inhalation</td>
<td>Double Glove</td>
<td>Chemo</td>
<td>Yes</td>
</tr>
<tr>
<td>-Spill of hazardous medication: Contact Veolia when &gt;5 mL</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

| HAZARDOUS: LIMITED RISK GREEN | | | |
| Oral: Limited to NO RISK of spitting, splash, splatter, or spray | Single Glove | None | None | None |
| Oral: Risk of spitting, splash, splatter, or spray | Double Glove | Chemo | If high splash risk | None |
| Body Fluids/Waste Containing trace medication or metabolites (e.g. emesis, urine, stool) | Double Glove | Chemo | Yes | None |

| REPRODUCTIVE TOXIN (Only applies to personnel with reproductive concerns) YELLOW | | | |
| Oral: Limited to NO RISK of spitting, splash, splatter, or spray | Single Glove | None | None | None |
| Crushing | Double Glove | Standard Isolation | None | None | (If ENFit Punch is unavailable use N95) |
| Intravascular, Intraperitoneal, Irrigation, Aerosol Inhalation | Double Glove | Standard Isolation | Only face shield | N95 |
| -Spill of reproductive toxin medication | | | | |
| Topical dosage form | Double Glove | Standard Isolation | If high splash risk | Only face shield | N95 | (If Inhalation potential) |
| Body Fluids/Waste Containing trace medication or metabolites (e.g. emesis, urine, stool) | Double Glove | Standard Isolation | If high splash risk | Only face shield | None |

**NOTE:** For all activities that are not designated high splash risk, wear eye and face protection if desired. Observe Precautions PO Drugs 7 days and ALL OTHER ROUTES 48 hours

Sign sourced from John Muir Health
Appendix E

Precaution Sign for Bathroom Door

HAZARDOUS DRUG PRECAUTIONS
POST ON BATHROOM DOOR

<table>
<thead>
<tr>
<th>Precaution Level</th>
<th>Red/Green</th>
<th>Yellow</th>
</tr>
</thead>
<tbody>
<tr>
<td>Reproductive Toxin (For staff with reproductive concerns only)</td>
<td>Hazardous/Limited Hazardous</td>
<td></td>
</tr>
<tr>
<td>Double glove</td>
<td>Double glove</td>
<td></td>
</tr>
<tr>
<td>Standard isolation gown</td>
<td>Chemo gown</td>
<td></td>
</tr>
<tr>
<td>If high splash risk, face shield</td>
<td>If high splash risk, goggle and face shield</td>
<td></td>
</tr>
<tr>
<td>All PPE disposed of in Regular Trash Bin</td>
<td>All PPE and saturated or flaking linens disposed of in Regular or Large Yellow Bin</td>
<td></td>
</tr>
<tr>
<td>All linens follow routine management</td>
<td>Linen which is not saturated or flaking with bodily fluids is to be placed in yellow linen bag</td>
<td></td>
</tr>
<tr>
<td>Toilet is to be double flushed after any bodily fluid disposal, place chux over toilet while flushing.</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Sign sourced from John Muir Health
### SWOT Analysis

<table>
<thead>
<tr>
<th>S</th>
<th>W</th>
</tr>
</thead>
<tbody>
<tr>
<td>Strengths</td>
<td>Weaknesses</td>
</tr>
<tr>
<td>Hazardous carts available on the units</td>
<td>Some staff not using the carts</td>
</tr>
<tr>
<td>USP 800 training for staff</td>
<td>Unit secretary not trained on USP 800</td>
</tr>
<tr>
<td>Warning banners in each patient MAR</td>
<td>No responsible person to fill the carts</td>
</tr>
<tr>
<td></td>
<td>Warning banners misfiring occasionally</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>O</th>
<th>T</th>
</tr>
</thead>
<tbody>
<tr>
<td>Opportunities</td>
<td>Threats</td>
</tr>
<tr>
<td>Assign responsible person to check and refill the carts</td>
<td>Lack of sustainability</td>
</tr>
<tr>
<td>Daily door signage rounding</td>
<td>Training for new staff members</td>
</tr>
<tr>
<td>Increased compliance with USP 800 Federal guidelines</td>
<td>Maintenance and replacement of carts</td>
</tr>
</tbody>
</table>
Appendix G

PDSA Cycle

This PDSA is for the first cycle of the change project.

**PLAN**
- Analyze the microsystem using 5Ps framework assessment
- Collaborate with Hospital A
- Develop a Global & Specific AIM
- Develop a PICOT Question
- Create data collection forms & questionnaires
- Conduct a root cause analysis (RCA)
- Conduct a SWOT analysis

**DO**
- Conduct data gathering on Med-Surg units in Hospital A
  - Passive & Active observational data collection
  - Administer ‘elbow-to-elbow’ questionnaires

**STUDY**
- Analyze data gathered from:
  - Passive & Active Observations
  - ‘Elbow-to-Elbow’ Questionnaires
- Review results of data

**ACT**
- Determine if desired goal was achieved
- Develop next steps or recommendations based on results
- Results and Recommendations
  Presented to Hospital A on 11/22/22
## Appendix H

### Gantt Chart

<table>
<thead>
<tr>
<th>Task</th>
<th>Assigned To</th>
<th>Start</th>
<th>End</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Plan</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Meet with Committee</td>
<td>CNL, USPC</td>
<td>Day 1</td>
<td>Day 1</td>
</tr>
<tr>
<td>Identify an issue</td>
<td>CNL</td>
<td>Day 1</td>
<td>Day 14</td>
</tr>
<tr>
<td>Develop a PICO question and AIM statement</td>
<td>CNL</td>
<td>Week 3</td>
<td>Week 4</td>
</tr>
<tr>
<td>Literature Review</td>
<td>CNL</td>
<td>Day 29</td>
<td>Day 47</td>
</tr>
<tr>
<td>Assess the Microsystem (IP Framework)</td>
<td>CNL</td>
<td>Week 6</td>
<td>Week 7</td>
</tr>
<tr>
<td>Conduct a RCA and SWOT Analysis</td>
<td>CNL</td>
<td>Week 6</td>
<td>Week 7</td>
</tr>
<tr>
<td>Create data collection forms and questionnaires</td>
<td>CNL</td>
<td>Week 6</td>
<td>Week 7</td>
</tr>
<tr>
<td><strong>Do</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Implement Change and Assess</td>
<td>CNL</td>
<td>Week 8</td>
<td>Week 9</td>
</tr>
<tr>
<td>Gather Data</td>
<td>CNL</td>
<td>Week 8</td>
<td>Week 9</td>
</tr>
<tr>
<td><strong>Study</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Analyze Data</td>
<td>CNL</td>
<td>Week 10</td>
<td>Week 12</td>
</tr>
<tr>
<td>Review Results</td>
<td>CNL</td>
<td>Week 10</td>
<td>Week 12</td>
</tr>
<tr>
<td><strong>Act</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Determine if Goal was reached</td>
<td>CNL</td>
<td>Week 12</td>
<td>Week 13</td>
</tr>
<tr>
<td>Make Changes</td>
<td>CNL</td>
<td>Week 12</td>
<td>Week 13</td>
</tr>
<tr>
<td>Meet with Committee to discuss findings and recommendations</td>
<td>CNL, USPC, NM</td>
<td>Week 13</td>
<td>Week 13</td>
</tr>
</tbody>
</table>
Appendix I

Ishikawa Diagram (Fishbone Diagram)

- Materials
  - Who is backfilling/restocking?
    - 2 small carts
- Environment
  - Unit is too large/long for staff to walk for materials
- Cost
- Process
- Patient Volume (People)
  - 36 patients
    - 1 floor
- Using Carts:
  - 4/5 pt per RN
  - 7-12 pt per CNA
  - Break RN
  - Charge RN
- Management
- Administration of USP <800> Drugs
Appendix J

Nurse ‘Elbow-to-Elbow’ Questionnaire Forum

1. On a scale of 0-10, how would you rate your knowledge of Hazardous Drugs (USP <800>) (0 indicating no knowledge, 10 indicating a high level of knowledge)?

   0  1  2  3  4  5  6  7  8  9  10

2. On a scale of 0-10, how comfortable do you feel with the handling of Hazardous Drugs (USP <800>) (0 indicating not comfortable at all, 10 indicating very comfortable)?

   0  1  2  3  4  5  6  7  8  9  10

3. How many times per week do you administer Hazardous Drugs (USP <800>)? A numbered estimation is preferred.

4. Do you know where the Hazardous Drug (USP <800>) carts and waste receptacles are located?

5. On a scale of 0-10, how easy do you feel it is to identify Hazardous Drug (USP <800>) signage and recommended PPE for administration of the drugs?

   0  1  2  3  4  5  6  7  8  9  10

6. How often do you follow the Hazardous Drug (USP <800>) PPE recommendations?

   Never  Sometimes  Most of the time  Always

7. What are your recommendations for improvement?
Appendix K

Statement of Determination

Title of Project: *United States Pharmacopeia* (USP) <800> Standards: Increasing Compliance of Safe Handling and Proper Administration of USP General Chapter <800> Drugs

**Brief Description of Project**

A. **Aim Statement**

To improve nurse compliance with administration and safe handling of Hazardous Drugs (USP <800>) as outlined in the *Hospital A 2022 Hazardous Drugs (HD) Safe Handling and Management Updates Training* through active and passive observation on two medical surgical units by 50% within 1 month.

B. **Description of Intervention**

Interventions will include active and passive observation of hospital personnel and the hospital environment and informal ‘elbow to elbow’ surveys between clinical team and nurses.

C. **How will this Intervention Change Practice?**

This intervention and quality improvement project will determine current level of knowledge and compliance among Hospital A’s staff to ensure safe and proper handling and administration of USP <800> hazardous drugs. The results can be used to establish a current baseline and help develop and shape future staff education.

D. **Outcome Measurements**

- The total number of patient’s on USP <800> hazardous drugs on the units.
- The number of appropriate EHR alert notices.
- The number of currently documented door signs and bathroom door signs.
- The number of currently witnessed PPE donning and doffing occurrences.
- An estimated number of correct supplies located on designated USP <800> PPE carts along with the location of these carts.
- An information ‘elbow-to-elbow’ questionnaire with nurses to determine:
  - Current Knowledge of USP <800>
  - Comfortability with handling and administration of USP <800> HD
  - Number of times per week each nurse administers the drugs
  - Knowledge of location of USP <800> carts and waste receptacles
  - Ease of identification of patients on HDs including documentation of signage and difficulty to determine recommended PPE
  - How often nurses follow recommended PPE

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

Comments:

**IRB Statement of Non-Research Determination Form:**

**EVIDENCE-BASED CHANGE OF PRACTICE PROJECT CHECKLIST** *

<table>
<thead>
<tr>
<th>Project Title:</th>
<th>Y</th>
<th>E</th>
<th>S</th>
<th>N</th>
<th>O</th>
</tr>
</thead>
<tbody>
<tr>
<td>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.</td>
<td></td>
<td></td>
<td></td>
<td>X</td>
<td></td>
</tr>
<tr>
<td>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.</td>
<td></td>
<td></td>
<td></td>
<td>X</td>
<td></td>
</tr>
<tr>
<td>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.</td>
<td></td>
<td></td>
<td></td>
<td>X</td>
<td></td>
</tr>
<tr>
<td>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.</td>
<td></td>
<td></td>
<td></td>
<td>X</td>
<td></td>
</tr>
<tr>
<td>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.</td>
<td></td>
<td></td>
<td></td>
<td>X</td>
<td></td>
</tr>
<tr>
<td>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.</td>
<td></td>
<td></td>
<td></td>
<td>X</td>
<td></td>
</tr>
<tr>
<td>The project has NO funding from federal agencies or research-focused organizations and is not receiving funding for implementation research.</td>
<td></td>
<td></td>
<td></td>
<td>X</td>
<td></td>
</tr>
<tr>
<td>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.</td>
<td></td>
<td></td>
<td></td>
<td>X</td>
<td></td>
</tr>
<tr>
<td>If there is an intent to, or possibility of publishing your work, you and supervising faculty and agency oversight committee are comfortable with the following statement in your methods section.</td>
<td></td>
<td></td>
<td></td>
<td>X</td>
<td></td>
</tr>
</tbody>
</table>

**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, except at Stanford Hospital. 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.

Signature of Supervising Faculty_______________________

Signature of Student: Katelyn Sinclair Date: 10/03/22
Appendix L

Chart with Number of Patients on USP <800> Drugs

Patients of USP <800> Hazardous Drugs

<table>
<thead>
<tr>
<th>Unit</th>
<th>Number of Patients on USP &lt;800&gt;</th>
<th>Number of Patients NOT on USP &lt;800&gt;</th>
</tr>
</thead>
<tbody>
<tr>
<td>Unit A</td>
<td>252</td>
<td>71</td>
</tr>
<tr>
<td>Unit B</td>
<td>200</td>
<td>102</td>
</tr>
<tr>
<td>Combined</td>
<td>452</td>
<td>172</td>
</tr>
</tbody>
</table>
Appendix M

Average Number of Supplies on USP <800> Carts

Average Number of Supplies Per USP <800> Cart

- Total Desired Supplies
- Average Number of Supplies Per Cart - Unit B
- Average Number of Supplies Per Cart - Unit A
### Appendix N

**Nurse Questionnaire Results**

<table>
<thead>
<tr>
<th>Nurse Questionnaire</th>
<th>Hospital A {27 Nurses}</th>
</tr>
</thead>
<tbody>
<tr>
<td>On a scale of 1-10, how would you rate your knowledge of Hazardous Drugs (USP &lt;800&gt;) (1 indicating no knowledge, 10 indicating a high level of knowledge)?</td>
<td>Mean: 7.15</td>
</tr>
<tr>
<td>On a scale of 1-10, how comfortable do you feel with the handling of Hazardous Drugs (USP &lt;800&gt;) (1 indicating not comfortable at all, 10 indicating very comfortable)?</td>
<td>Mean: 8.45</td>
</tr>
<tr>
<td>How many times per week do you administer Hazardous Drugs (USP &lt;800&gt;)?</td>
<td>Mean: 3.44</td>
</tr>
<tr>
<td>Do you know where the Hazardous Drugs (USP &lt;800&gt;) carts and waste receptacles are located?</td>
<td>Yes: 16</td>
</tr>
<tr>
<td></td>
<td>No: 11</td>
</tr>
<tr>
<td>On a scale of 1-10, how easy do you feel it is to identify Hazardous Drugs (USP &lt;800&gt;) signage and recommended PPE for administration of the drugs?</td>
<td>Mean: 8.39</td>
</tr>
<tr>
<td>How often do you follow the Hazardous Drugs (USP &lt;800&gt;) PPE recommendations?</td>
<td>Always: 12</td>
</tr>
<tr>
<td></td>
<td>Sometimes: 10</td>
</tr>
<tr>
<td></td>
<td>Most of the Time: 4</td>
</tr>
<tr>
<td></td>
<td>Never: 1</td>
</tr>
</tbody>
</table>
## Appendix O

### Cost-Benefit Analysis

<table>
<thead>
<tr>
<th>Cost: Items</th>
<th>Annually Cost</th>
<th>Total Cost</th>
</tr>
</thead>
<tbody>
<tr>
<td>Restocking Supplies (PPE)</td>
<td>$25,000</td>
<td>$48,878.15</td>
</tr>
<tr>
<td>USP &lt;800&gt; Signage</td>
<td>$500</td>
<td>$500</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Cost: Duties</th>
<th>Annually Cost</th>
<th>Total Cost</th>
</tr>
</thead>
<tbody>
<tr>
<td>Unit Secretary</td>
<td></td>
<td>$2,234.96</td>
</tr>
<tr>
<td>Salary: $21.49/hour</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Expected Extra Hours Per Week: 2</td>
<td></td>
<td></td>
</tr>
<tr>
<td>$21.49 x 2 = $42.98 / week</td>
<td></td>
<td></td>
</tr>
<tr>
<td>$42.98 x 52 weeks = $2234.96</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

| Charge Nurse             |               | $18,283.20 |
| Salary: $70.32/hour      |               |            |
| Expected Extra Hours Per Week: 5 |
| $70.32 x 5 = $351.60 / week |
| $351.60 x 52 weeks = $18283.20 |

| IT Analyst: EHR         |               | $2,860.00  |
| Salary: $55.00/hour     |               |            |
| Expected Extra Hours Per Week: 1 |
| $55.00 x 52 weeks = $2860 |

<table>
<thead>
<tr>
<th>Worker’s Compensation Claim</th>
<th>Annually Cost</th>
<th>Total Cost</th>
</tr>
</thead>
<tbody>
<tr>
<td>$57,292 per claim</td>
<td></td>
<td>-($57,292)</td>
</tr>
</tbody>
</table>

**Total Saving Annually for One Workers' Compensation Claim:** $8,413.85