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# Improving Safe Handling and Administration of USP<800> Hazardous Drugs within the Medical-Surgical Unit

Pavlo Karaputa
*University of San Francisco*, pkaraputa@usfca.edu

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Pavlo Karaputa

School of Nursing and Health Sciences

University of San Francisco

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## Section I: Abstract

**Problem:** Nurses comprise the largest proportion of healthcare providers who make contact with Hazardous Drugs (HDs) during multiple types of clinical activities and have a risk of exposure. Hazardous drugs (HDs) are a class of pharmaceuticals that pose serious health risks to individuals who handle them, including organ toxicity, reproductive and developmental defects, infertility, miscarriage, genetic toxicity, cancer, and even death.

**Context:** This project was implemented in a hospital system within Northern California, on two units that serve medical-surgical, oncology, geriatric, and transplant patients. The Medical Surgical microsystem at this hospital comprises a small group of professionals such as registered nurses (RNs), certified nursing assistants (CNAs), pharmacists, pharmacy technicians, and janitorial staff.

**Interventions:** The intended aim of this project was to identify all the patients receiving hazardous drugs and observe the nurses assigned to those patients. Nurses were observed with passive and active observation.

**Measures:** The success of this project was measured by the number of nurses wearing correct PPE, the number of door and bathroom signs, as well as generation of the MAR isolation banners.

**Results:** It was calculated that around 24.8% of patients were on a hazardous drug, yet only 7.5% of the rooms had appropriate door signs and 1.7% of doors had correct bathroom door signage. This result is an alarming discovery since a lot of non-nursing personnel such as CNAs, janitors, dietary, and visitors rely on door signs.

**Conclusion:** More education should be provided to the nurses on the necessity of placement of the door signs for the whole unit to be seen. Isolation carts that are available on the unit are not properly stocked and require a designated member to fill the carts.

## Section II: Introduction

According to National Cancer Institute, in 1975 there were 3.7 million people with cancer and in 2022, there were 18.1 million people with cancer (2022). It is projected that by the year 2040 there will be 26 million people diagmosed with cancer. With advances in technology and medicine, more people survive cancer and live past 10 – 20 years since the diagnosis of cancer. Chemotherapy agents play a big role in cancer treatment and are prescribed to the most patients battling cancer. Chemotherapy medications belong to the class of antineoplastic agents and are often classified as hazardous drugs (HDs). National Institute for Occupational Safety and Health classifies a medication as a hazardous drug if it is identified as a carcinogenic hazard, developmental hazard, reproductive hazard, genotoxic hazard, or other health hazard to the human body (2020). Chemotherapy medications are not the only drugs that are classified as hazardous drugs. Medications, such as anticoagulant coumadin, and valproic acid used for seizure management are also classified as reproductive toxins and belong to the hazardous drug criteria (National Institute for Occupational Safety and Health, 2020).

## Problem Description

In February 2016, the United States Pharmacopeial Convention released a new chapter of compounding standards that was named "United States Pharmacopeia (USP) chapter 800" or USP <800>. These standards went into effect as of December 1, 2019, and all the organization staff members handling HD preparations including pharmacists, pharmacy technicians, nurses, physicians, physician assistants, and home healthcare workers must follow the regulations. All of the medical centers and organizations were required to provide Personal Protective Equipment (PPE), training and education about the handling of HDs, and utilize closed transfer systems to minimize exposure for all staff members.

Hazardous drugs (HDs) are a class of pharmaceuticals that pose serious health risks to individuals who handle them, including organ toxicity, reproductive and developmental defects, infertility, miscarriage, genetic toxicity, cancer, and even death (Banihani et al., 2022). Nurses comprise the largest proportion of healthcare providers who make contact with HDs during multiple types of clinical activities. Nurses can protect themselves by wearing correct PPE, wiping surfaces routinely, using closed transfer systems, disposing of HD correctly, and calling for HD spill cleanup, yet many nurses are not following the latest guidelines. The United States Pharmacopeial Convention estimates that more than 8 million US healthcare workers are exposed to hazardous drugs (HDs) in the workplace each year. (VelocityEHS, 2019). From September 2022 to November 2022, a project was conducted by CNL students in two East Bay hospitals' medical-surgical microsystems, to improve the safe handling of HDs on the units.

## Available Knowledge/ Literature Review

The PICOT question used for the literature search and synthesis of evidence for the Improving Safe Handling and Administration of USP<800> Hazardous project asks: Among hospital staff who administer USP<800> Hazardous Drugs (HD) (P), does active and passive observation (I) increase HD (USP <800>) signage compliance (O), compared with no observation CAN, in one month (T)? Data were synthesized after completing a comprehensive literature search using the following databases: Cochrane Database of Systematic Reviews, CINAHL Complete, and PubMed. The databases were searched using the main topics and themes from the PICOT question and included the following search terms: *hazardous drugs, reproductive toxin, chemotherapy, medication handling, adverse effects, antineoplastic, and USP 800.* Limitations were set to include English-only and peer-reviewed articles, with publication dates no earlier than 2016.

Six articles were selected and rated using the Johns Hopkins Nursing Evidence-Based Practice Research Evidence Appraisal tool (Dang & Dearholt, 2018). As outlined in the Evidence table (Appendix A), one systematic review of RCTs was appraised at the level I revealed that Some of the factors that prevented nurses from using proper PPE included lack of supplies, not enough education, being confident and proficient in administration, and discomfort (Lin et al., 2019). Two randomized control trials were appraised at level II and concluded that nurses' PPE use during hazardous drug administration was suboptimal, and gloves were the most connected to nonadherence (Colvin et al., 2016).

## Rationale

Health Belief Model (HBM) will form the conceptual framework for this prospectus as it focuses on individual perceptions of threats and interventions necessary to change a person's behavior (Washburn, 2020). The Health Belief Model was developed in the 1950s by social psychologists at the U.S. Public Health Service to better understand the widespread failure of screening programs for tuberculosis and has become one of the widely used theories in health behavior research (Urich, 2017). The Health Belief Model posits that six constructs predict health behavior: risk susceptibility, risk severity, benefits to action, barriers to action, self-efficacy, and cues to action.

Perceived severity refers to the subjective assessment of the severity of a health problem and its potential consequences (Rural Health Information Hub, 2018). Individuals must understand that there will be health problems if they do not follow certain behavior. For this prospectus, the nurses must understand that exposure to HDs will lead to negative health outcomes. Perceived susceptibility refers to the subjective assessment of the risk of developing a health problem. Nurses that realized that they are at increased risk of being exposed to HDs will

attempt to minimize that risk. Perceived benefits refer to an individual's assessment of the value or efficacy of engaging in a health-promoting behavior to decrease the risk of disease (Rural Health Information Hub, 2018). Staff members must realize that personal protective equipment (PPE) is one of the most effective strategies to reduce exposure to hazardous drugs.

Perceived barriers refer to an individual's assessment of the obstacles to behavior change. Nurses must identify barriers and obstacles that prevent them from following the policy and not wearing proper PPE. Some of the barriers may include not having enough PPE available and not knowing where to locate necessary PPE. While some individual characteristics such as age, race, and ethnicity as non-modifiable, other variables such as education and staffing can be modified. The health belief model suggests that modifying variables affect health-related behaviors indirectly by affecting perceived seriousness, susceptibility, benefits, and barriers.

## Specific AIM

We aim to improve nurse compliance with the safe handling of Hazardous Drugs (USP <800>) on the Medical-Surgical floors by 10/28/22. We expect a 50% increase in: the use of USP <800> carts, PPE, and door and bathroom signs correctly filled out. This increase will be measured by passive and active observation and questionnaires.

## Section III: Methods

### Context

The first step was to conduct a microsystem assessment using the 5Ps model that focuses on purpose, patients, professionals, processes, and patterns. The hospital's mission statement is dedicated to improving the health of the communities they serve with quality and compassion. The purpose of this project plan as CNL students is to provide education to nurses in the hematology/oncology units to increase the use of personal protection equipment (PPE) when

handling USP 800 hazardous drugs and following the latest guidelines. In this QI project, we aim to further the hospital's mission by improving patient safety outcomes by increasing the use of USP 800 carts. The patient population at the hospital's medical-surgical unit consists mostly of elderly patients. Our target population for this project primarily focuses on patient receiving hazardous drugs (HDs) including chemotherapy and reproductive toxins.

Professionals in a microsystem refer to any member who either contributes to patient care or directly provides care to the patients on HDs. Therefore, the Medical-Surgical microsystem at this hospital comprises a small group of professionals such as registered nurses (RNs), certified nursing assistants (CNAs), pharmacists, pharmacy technicians, and janitorial staff. It is expected that every staff member and professional that participates in patient care applies correct PPE and adheres to the guidelines to decrease their exposure to hazardous drugs. Several processes can be done to decrease the incidence of hazardous drug exposure on the Medical Surgical floor. First, a closed transfer system needs to be utilized so that none of the medication will be exposed. Next, the nurses need to place all appropriate door signs to notify all other care members that enhanced precautions are needed when performing patient care. Finally, all staff members need to apply appropriate personal protective equipment (PPE) when entering the patient room. There are frequent administrations of USP 800 medications on Hematology/Oncology floors and not all staff members are following the designated protocols. A microsystem assessment revealed that nurses do not place the door signs at all times as well as occasionally do not wear the right PPE.

A root cause analysis that is displayed by a fishbone diagram (Appendix B ) was performed to determine areas of impact on hazardous medication handling. Some of the factors included patient volume, availability of the carts, and the unit being too large to walk back and forth for the carts.

A gap analysis was initially performed by the CNL students for this project to determine the root cause leading to suboptimal usage of hazardous drugs protocol and USP 800 carts within the unit. Using the Strengths, Weakness, Opportunities, and Treats (SWOT) analysis (Appendix C), it was identified that there was no priority in placing the door signs in the unit. Although there were many identified strengths in the unit, several weaknesses were indicating that staff had a lack of understanding regarding HD exposure and some of the adverse effects. Some of the strengths included an available cart on the unit as well as warning chemotherapy banners for each of the patients receiving hazardous drugs. Some of the weaknesses were related to staff not using the USP 800 carts, no one being responsible for refilling and restocking the carts regularly, and the warning banners firing the alerts improperly.

The opportunities that were found include assigning a responsible person such as a unit secretary to check and refill USP 800 carts as necessary. This will make the RNs more willing to use the carts and not have to gather PPE all over the unit floor. Another opportunity is for the nurses to make a habit of placing the door signs and having the charge RN check door signage during shift rounding. A few threats that were identified included a lack of sustainability related to not being able to refill the carts and maintenance and replacement of the carts if one starts to malfunction in the future. Another threat that can limit the success of the project is the training of the new personnel and staff members on the hazardous drugs protocol and usage of the USP 800. A Gannt timeline (Appendix D) was developed to plan the project for every week and provide recommendations to the hospital staff by the end of the semester. The initial actions of the timeline included the identification of the issue and the development of the PICOT and AIM statements as a literature review. Next, there was data collection and data analysis, followed by a presentation of the results and future recommendations to the hospital administration.

## Intervention

The intervention was created based on research of evidence-based practice, hospital policy and procedures, analysis of microsystem assessment, and collaboration HD (USP <800>) quality improvement team. The first step of the intervention was to identify all the patients on the floor that were receiving hazardous medications by opening patient charts and looking at the MAR banners. After generating a list of all the patients we were able to locate the nurses that took care of those patients. We were able to observe the nurses through passive and active observation and talk with the non-nursing staff afterward.

The data collection itself was the intervention because the expected outcome is that the act of being observed increased nurse compliance with protocol over time. The hospital USP <800> team requested students to gather data related to the effectiveness of this model of leader standard work in implementing education on the units as an additional research goal. Recommendations based on the data collection and observations were presented to the hospital pharmacy team at the end of the school term.

## Study of the intervention

The PDSA cycle for this project focused on analyzing the microsystems, conducting the SWOT analysis, and data collection by passive and active observations (Appendix E). The CNL nursing student team performed the passive observatio to collect data about the current understanding and compliance with HD administration in medical-surgical units (Appendix F). Next, active observations were conducted with open discussion and an in-person questionnaire on HD (Appendix G). We measured the nurses' knowledge and comfort level with USP <800> administration of the self-reported questionnaire. Another study of the intervention included the interview of non-nursing staff and their experience with hazardous medications and precautions.

The next step of the PDSA cycle included analyzing the data from the observations and questionnaires. The team reviewed results and grouped data based on nurses' feedback.

### Measures

One of the measures collected during this project was the nurses' knowledge and comfort level with PPE and isolation carts. The nurses were given questionnaires and were asked to rank their knowledge of the hazardous drugs and their comfort level with HD administration. The nurses were also asked to rate how often they administer medications and if they are follow the PPE guidelines. Another measure that was being collected was related to the door signage. The CNL students observed if the appropriate door signs were placed at the patient door and the bathroom door. Finally, the last measure was related to the MAR banner alerts. The students looked at patient charts to identify the number of charts with current isolation banners and those that had missing banners or banners that were placed by accident.

### Ethical Considerations

This project has been approved as a quality improvement project by the school faculty and does not require IRB approval.

## Section IV: Results

Analysis of data collected during this project showed that around 24.8% of patients were on a hazardous drug, including reproductive toxins. The MAR Banner did not load PPE recommendations 100% of the time which placed nursing staff at risk for not wearing proper PPE. It was also calculated that a misfire occurred 53 times or for 30.6% of the patients on precautions. A misfire is when a precautionary banner occurs, but the patient is not receiving chemotherapy or hazardous agents and therefore does not require special isolation.

The results also revealed that only 7.5% of the rooms had appropriate door signs and

1.7% of doors had correct bathroom door signage. This result is an alarming discovery since a lot of non-nursing personnel such as CNAs, janitors, dietary, and visitors rely on door signs. Missing signs place these staff members at risk for hazardous exposure and health complications. While observing the RNs donning PPE only one staff member was not following the protocol and wearing PPE incorrectly.

## Section: V Discussion

### Summary

One of the key findings was that only 7.5% of the doors had appropriate signs which were far below expectations. During an interview with non-nursing staff, it was noted that they rely on signage for knowing what PPE to wear. Many of the complaints included that nurses sometimes do not put up the sign and janitorial or CAN staff finds out after cleaning or being with the patient that they should have worn PPE. Nurses on the contrary explain that they rarely post signs because nurses like to rely on the MAR for when to use PPE. A lot of nurses did not realize that other staff members rely on signs, and it is the nurse's job to not only protect themselves but also their coworkers. Not everyone has time to open each patient chart and a simple door sign makes the job easier for everyone.

Some of the limitations included a small interview sample size, guests not observed during donning and doffing of PPE, and hesitancy to participate in the interview. Some members were afraid of retaliation and were uncomfortable expressing their opinion and giving honest feedback. The Clinical Nurse Leader (CNL) role can apply changes and recommendations within the microsystem by following the competencies listed by the American Association of Colleges of Nursing (2007). For this QI project, the CNL served as the team leader, advocate, educator, and information manager for the hospital unit. The CNL is an invaluable resource for the

healthcare system since they act as a patient advocate, and educators for staff, improve patient outcomes and serve as team leaders.

## Conclusion

Some of the recommendations include fixing the MAR banner to include which PPE nurses should wear when administering each hazardous medication. The current MAR banner had a lot of false banners that added to the confusion and made it hard for the nurses to follow the guidelines. It is also advised to include a length of time medication will remain in the system if medication is no longer being given. Even if the patients are no longer receiving chemotherapy medications, precautions should still be taken to prevent possible exposure. A few staff members complained that the hazardous carts are not readily available and often do not have all of the required PPE supplies. A unit secretary should re-stock carts weekly and each floor needs to have a designated space for the carts to be visible and available at all times.

Another recommendation is for the charge nurses to check for door signage during shift rounding. Since the charge nurses are already performing rounds on regular basis, it will not be a new task but an additional step to verify that all signs are properly displayed. If the sign is not posted on the door, the charge nurse should fill out and post signage and generate a list of patients on HD for janitorial staff since they rely on nursing staff to keep them protected. A final recommendation includes providing yearly training or a refresher course on USP 800 and hazardous drug precautions. Many nurses mentioned that everyone receives hazardous training during initial orientation but very limited training afterward. Since some of the precautions change over time it is crucial to provide the latest information and evidence to all of the staff members handling hazardous medications.

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## Appendix A: Evaluation Table

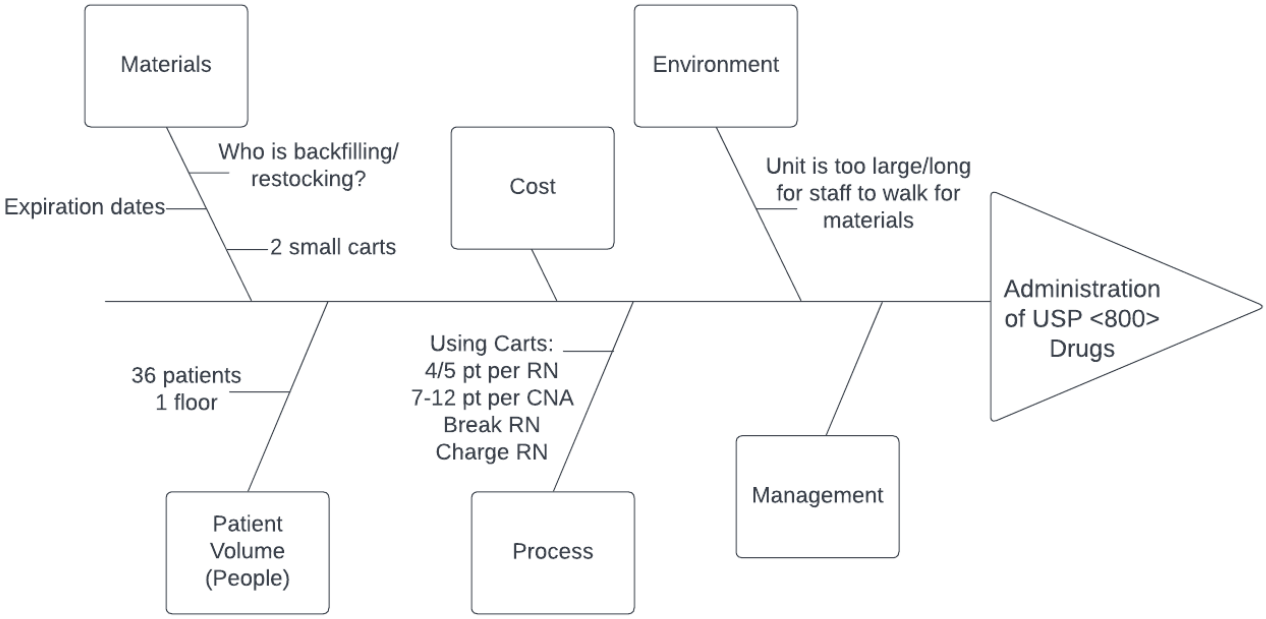
**PICOT Question:**

Among hospital staff who administer USP<800> Hazardous Drugs (HD) (P), does active and passive observation (I) increase HD (USP <800>) signage compliance (O), compared with no observation (C), in one month (T)?

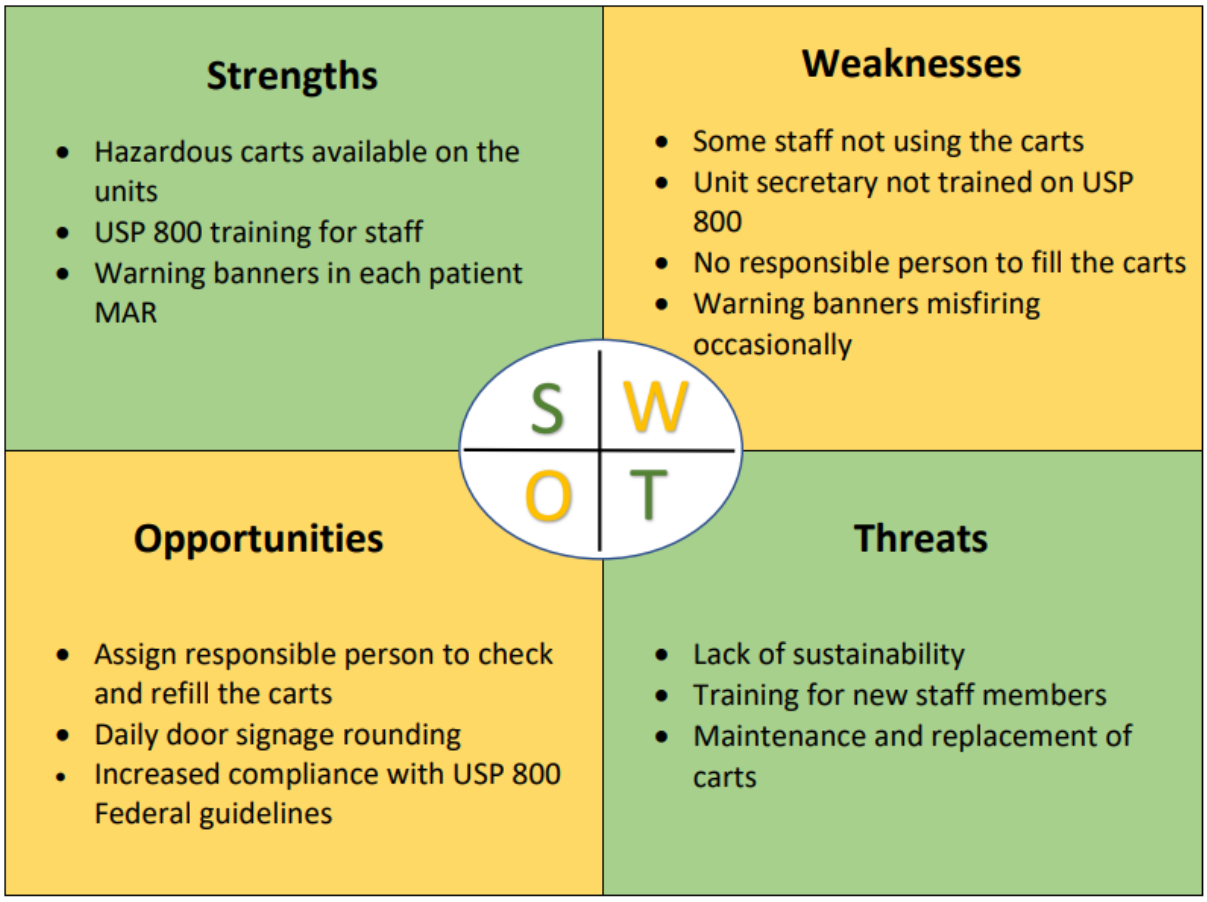
| Study | Design | Sample | Outcome/Feasibility | Level of Evidence |
|---|---|---|---|---|
| Colvin et al. (2016) | Cross-sectional study | Twenty-two cases of chemotherapy handling were observed, and 12 of 33 nurses completed self-assessments at the Cleveland Clinic | Nurses may have failed to follow policies if they focused on delivering treatment to patients rather than on protecting themselves and the environment. Gloves and gowns were most often involved in non-adherence. | Level II |
| Friese et al. (2019) | Cluster randomized controlled trial | 136 nurses in a control group, and 121 nurses in treatment settings, both received 1-hour training and the experimental received tailored messages | Control and intervention sites had suboptimal PPE use before and after the intervention. Oncology nurses have shown low perceived risk from hazardous drug exposure and need more education on adverse effects and health impacts from hazardous exposure. | Level II |
| Friese et al. (2020) | Case report analysis from a prospective, multisite study | Twelve academic-affiliated cancer centers with high-volume ambulatory infusion practices in the United States. | Individual nurses' spill response was suboptimal; nurses rarely wore PPE as recommended. During most spills, PPE use did not conform to professional organizations' recommendations, and closed system transfer devices often | Level IV |

| | | | | |
|---|---|---|---|---|
| | | | had a malfunction that resulted in a spill. | |
| He et al. (2017) | Cross-sectional mailed survey. | 252 Oncology Nursing Society in Michigan, Georgia, or California members who administer hazardous drugs. | Only 25 of the respondents expressed that they were somewhat or strongly concerned about the spill. The findings showed that lower nursing workloads and more favorable manager support are correlated with fewer reported drug spills. | Level IV |
| Lin et al. (2019) | A systematic review of 10 RCTs and 2 qualitative studies | The number of study participants ranged from 15 to 1,954 with a majority of participants from the US | Some of the factors that prevented the nurse from using proper PPE included lack of supplies, not enough education, being confident and proficient in administration, and discomfort. It is important to consider nurses' opinions on PPE use and to purchase PPE that complies with safety standards and is comfortable to use. | Level I |
| Topcu et al. (2017) | Qualitative study | 15 registered nurses at 2 major hospitals in Turkey | Results showed barriers (overworking, understaffing, and insufficient equipment and support) to using safe handling precautions. There are a lot of knowledge deficits regarding adverse effects and a lot of staff already had health issues. | Level VI |

## Appendix B: Root Cause Analysis



**Appendix C: SWOT Analysis**



## Appendix D: GANTT Timeline

**Improving Safe Handling and Administration of USP<800> Hazardous Drugs within the Medical-Surgical Unit**

| *WEEK* | 08/28- 09/03 | 09/04 - 09/10 | 09/11 - 09/17 | 09/18 - 09/24 | 09/25 - 10/01 | 10/02 - 10/08 | 10/09 - 10/15 | 10/16 - 10/22 | 10/23 - 10/29 | 10/30 - 11/5 | 11/6 - 11/12 | 11/23 - 11/19 | 11/20 - 11/26 | 11/27 - 12/03 | 12/04 - 12/10 |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| issue | | | | | | | | | | | | | | | |
| Development of PICOT and AIM Statements | | | | | | | | | | | | | | | |
| Literature review | | | | | | | | | | | | | | | |
| Assessment of Microsystem | | | | | | | | | | | | | | | |
| Data Collection | | | | | | | | | | | | | | | |
| Data analysis | | | | | | | | | | | | | | | |
| Present proposal with future recommendations | | | | | | | | | | | | | | | |

## Appendix E: Cost Benefit Analysis

**Cost Benefit Analysis**

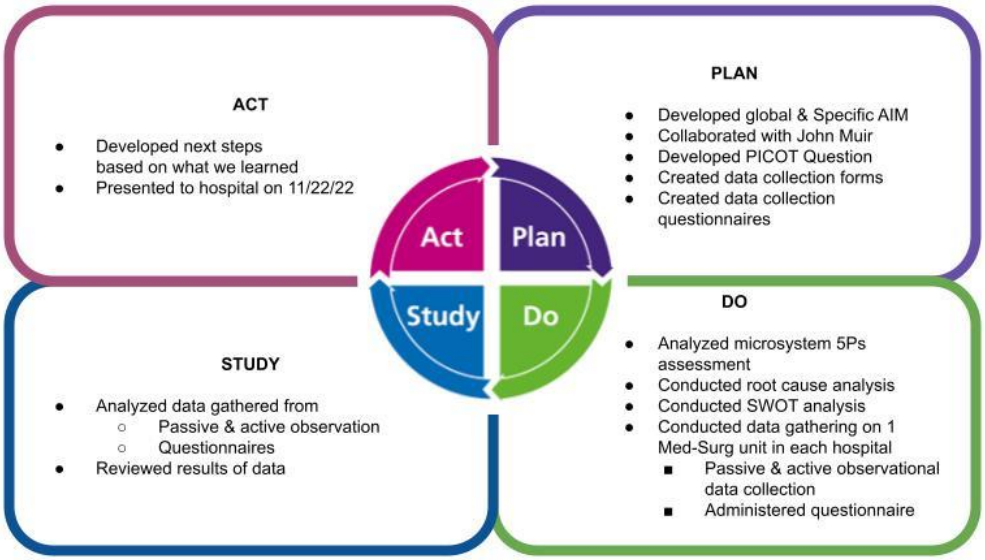
| | |
|---|---|
| Restocking items | $25,000/yr |
| Additional duties | |
| Unit Secretary ($25/hr) x 2hr/week | $2,600/yr |
| Charge Nurse ($80/hr) x 5hr/week | $21,000/yr |
| IT Analyst Epic ($55/hr) x 24hr/week | $1,320/yr |
| USP <800> Signage | $500 |

**Total: $50,420**

Total Average cost 1x worker's compensation for HD exposure-related illness or injury

**$57,292**

## Appendix F: PDSA Cycle



## Appendix G: Nursing Questionnaire

**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 the 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 H: Passive Observation Data Collection Questions

1. Total Number of Nurses in unit
2. Total Number of Patients in unit
3. Total Number Patients on (USP <800>) Hazardous Drug Medications (from Trevor)
4. Number of Signs Used for HD (USP <800>) on Unit

   Number of Signs in the correct place

   Number of Signs Filled Out Appropriately for HD (USP <800>) Administered
5. Location of USP <800> Carts

   Is the USP <800> cart in the appropriate place?

   Is the USP <800> cart visible to all staff members?
6. Observation of Nurses using appropriate PPE

   Proper Donning Steps followed?

   Proper Doffing Steps followed?
7. Are absorbent pads being placed per protocol before medication administration?