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Hazardous Drug Administration in the Home:

Reducing Exposure Risks

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Hazardous Drug Administration in the Home: Reducing Exposure Risks

A serious health threat may be looming over patients and families fighting cancer as antineoplastic drug administration shifts from conventional healthcare centers to the home setting. Without safe handling, storage, and proper waste disposal, hazardous drug (HD) residues can expose not only family members, but also visitors and the environment (Crickman & Finnell, 2016). Hazardous drug exposure can potentially alter DNA, impose reproductive harm, and is toxic to the body's natural defenses. According to Graeve, McGovern, Arnold and Polovich (2017), toxic residues may cause acute allergic reactions and other unintended adverse side effects to caregivers.

Widespread hazardous drug exposure in the home setting has been well-documented through many years of studying chemotherapy patients and families (Bohlandt, Sverdel, & Schierl, 2017; Connor, Zock, & Snow, 2016; Rudnitzki & McMahon, 2015; Yuki, Ishida, & Sekine, 2015). However, safeguards to prevent home residue exposure are lagging, and patient and family safety in the home remains unmonitored and less understood (Carpenter, Famolaro, Hassell, Reefer, Robins, & Siegel, 2017). Contributing to the shift in hazardous drug administration include the rising numbers of patients receiving oral chemotherapy (Polovich & Olsen, 2018). Oral chemotherapy is effective and may be considered a more desirable route by patients over other similar cancer treatment options, but these drugs require the same safe handling as HDs in other formulations (Lester, 2012).

This large not-for-profit home care agency is located in Northern California and is an extension of a large hospital system serving the Sacramento region. Services include home health, palliative care, hospice care, and infusion (IV) therapy. The microsystem provides short-

term acute and chronic disease management for patients recently discharged from a hospital for a myriad of health issues. The project will focus on providing home care nurses with the training and tools required to minimize personal exposure to hazardous drugs in a home setting.

The home health care (HHC) industry is adjusting to the influx of patients receiving oral and IV hazardous drug agents in the home and recognize the growing need to address employee occupational safety and health risks. The population in this microsystem include patients who are receiving infusion therapies such as antibiotics, blood products, chemotherapy, total parenteral nutrition (TPN), hydration, inotropes, and intravenous pain management. Cancer patients may require some or all of these infusions during the course of cancer treatment. Oral chemotherapy adds to the complexity of caring for patients who have additional comorbidities that complicate care. Home care infusion nurses are struggling to comprehend the importance of their increasing role and responsibility regarding HD identification, education, and personal safety precautions required for themselves and families of cancer patients.

The team consists of one team leader, two home infusion coordinators, and 10 to 12 registered nurses. Each nurse has a caseload of up to 20 patients, visiting four to five patients per day. Six nurses are Certified Registered Nurses in Infusion Therapy (CRNI). Nursing experience ranges from 4 years to 25 years. The average patient census for the team ranges from 100 to 150, and the average patient age ranges from 45 to 75 years.

Clinical Leadership Theme

The project aims to improve the confidence, competence, and compliance of home care nurses' use of personal protective equipment (PPE) when administering HDs in the home. The clinical nurse leadership theme that correlates to this project is safety with HD PPE practice. According to the American Association of Colleges of Nursing (2013), the CNL role of

“Educator” uses the most current, evidence-based research to teach those persons within the microsystem. The CNL role of “Systems Analyst/Risk Anticipator” monitors the microsystem’s operations in order to anticipate potential problems and make corrections to improve processes that put nurses and families at risk.

Statement of the Problem

The U.S. Bureau of Labor Statistics (2015) reported over eight million health care workers in the United States are potentially exposed to HD residues, emphasizing current safe handling precautions and oversight are inadequate. Safe-handling procedures were structured for application in controlled healthcare environments and are sometimes not realistic in the home setting. The commonality is that both settings struggle with environmental exposure, non-compliance with PPE, and waste disposal practices (He, Mendelsohn-Victor, McCullagh, & Friese, 2017). In response to increasing pressures from healthcare professionals, the U.S. Pharmacopeia Convention (USP, [2016]) General Chapter <800> Standards for hazardous drug handling and enforcement were developed and will be enforced beginning December 1, 2019. The standards will require all health care organizations to have hazardous drug management programs in place or suffer imposed fines or suspended licensure consequences.

Little emphasis has been placed on self-protection strategies for nurses in the home setting, and most are unaware of the increasing dangers of exposure. One major concern is the unavailability of hazardous drug PPE for home care nurses. Other issues include (1) fragmented patient health information, (2) incomplete medication records, (3) work productivity pressures, (4) and outdated policies. Evidence-based HD education and innovative learning activities are lacking because of budgetary constraints and access to oncology content experts. However, safe

drug handling should be a top priority because any level of HD exposure is unacceptable (Diamond, 2017).

Project Overview

Safety and advocacy are important core values of the CNL's role and are the basis for this evidence-based project. With organizational support, home care nurses will become better safety advocates, not only for patients and families, but for their colleagues that follow. The CNL's objectives aim to (1) improve nurses' knowledge of hazardous drugs, (2) improve compliance with PPE use in the home, (3) provide nurses with HD PPE and (4) develop a quick reference guide for reporting an exposure. Finally, a "Hazardous Drug Safe Handling Guide" for patients and families will describe actions to minimize personal and home exposure.

To accomplish best practices, the global project aims to improve safe handling from 39% to 95% by implementing two home care nurse educational sessions; (1) recognizing and responding to HD exposure in the home, and (2) providing a hands-on PPE competency training no later than March 15, 2018. The specific aim is aligned with the global aim of providing a residue-free home environment for everyone. The global and specific aims are united and both create a sense of urgency with a definite purpose, expected outcomes, and time frame for sustaining results.

The project begins with (1) surveying home care nurses to determine knowledge, beliefs, and attitudes about hazardous drug exposure risks, and (2) understanding current comfort levels and experience with personal protective equipment (PPE), with the aim of minimizing hazardous drug exposure during a home visit. The process ends with enhanced organizational support for home care nurses by providing HD education and supplying the necessary PPE by March 15, 2018. It is important to work on this project now because the known adverse health and

environmental risks are valid, and new hazardous drug regulations mandate and support an efficient, standardized approach.

Methodology

The organization uses a performance improvement real-time data collection program called Strategic Healthcare Programs (SHP). This program provides analytics, benchmarks, and dashboards for home care agencies across the country. The data collection is intended as a guide to help improve quality and optimize performance for home health care agencies, hospices and home infusion pharmacies. The data also helps the organization maximize reimbursement for patient care and helps improve compliance with the Centers for Medicare and Medicaid (CMS) requirements specific to home health care participation. This program is a good resource for CNL's because SHP reports highlight areas where staff education and professional oversight should be focused to improve patient satisfaction and health outcome scores.

Strategic Health Programs (SHP) data identified that from January 1, 2017 through December 2017, 440 patients were admitted with a primary or secondary cancer diagnosis to the microsystem. However, data mining for information was cumbersome and incomplete in determining the current census of patients receiving hazardous drugs. Without the ability to accurately identify patients on service who are prescribed these medications, the risk of exposure is even more alarming. More work needs to be done with internal and external informatics specialists to capture this population's data, perhaps through specific ICD-10 coding or HD medication list alerts in the future.

Rationale

Several methods of evaluating information to identify the specific needs of the project included (1) performing a root cause analysis, (2) home care nurse surveys at the annual skills

day competency fair, and (3) completing a SWOT (Strengths, Weaknesses, Opportunities, and Threats) analysis. The root cause analysis (see Appendix A) identified outdated policies addressing HD management, inadequate and unavailable PPE, and a lack of evidence-based resources to support clinicians in teaching families how to minimize exposure with HD administration.

The nurse surveys from the competency fair in January 2018 provided good data on several fronts (see Appendix B). When nurses were asked about the risks associated with hazardous drug administration to test for “knowledge of the hazard”, 25% felt that oral chemotherapy was safer to administer than other routes. Fifty-one percent of nurses perceived personal home exposure risks as highly likely, but over 30% felt it was unlikely. When evaluating workplace safety, 79% of nurses assumed that the organization had a HD policy which was not the case (see Appendix B).

When assessing knowledge and experience with PPE use in the home, 75% of nurses admitted to having little to none. Nurses expressed hesitation to don PPE because it may cause patient or family anxiety. Nurses rationalized that it would take longer to don PPE than it would to “hand a pill to the patient”. While this may be true, unsafe handling place everyone at risk and sets the stage for potential adverse results. With new advances in science and technology, patients are performing tasks originally done by trained nurses. However, it does not negate the responsibility of nurses to supervise and support patients performing those tasks.

The SWOT analysis (see Appendix C) clarified the overwhelming need for the organization to address HD exposure now to prepare for upcoming enforceable worker protection regulations by federal, CMS, state and other credentialing entities expected in 2019. The analysis also highlighted the weaknesses and vulnerabilities of home care clinicians in

regards to the lack of knowledge about antineoplastic administration and the beliefs that exposure risks were low or non-existent in the home setting. Other weaknesses identified were operational issues with informatics and application software used by nurses to access and document patient care. Opportunities to improve family and home care nurse safety through the application of best practices with safe handling and PPE use are within reach and are worthy goals of this CNL project.

Cost Analysis

The project required a solid organizational hazardous drug program framework that was missing. As a consequence, it took the senior management team six months to initiate a few temporary fixes to protect nurses until a comprehensive HD program could be implemented. Portions of the USP <800> Standards were chosen as the developing framework in the microsystem (see Appendix D). Budget projections (see Appendix E) lists the items and estimates required to comply with those standards. A CNL will be essential in developing each piece of the framework to ensure effective use of resources and minimize costs. It will take 12 months for the program to be fully integrated into the microsystem. After the program is fully sustainable, the CNL could refocus on other important safety and quality issues.

An education module would be added to new hire and annual competency training through the “HealthStream” on-line learning system. A customized PPE kit would be available in the office for nursing to obtain for patients requiring these items. A personal PPE kit for car stock would cost the organization around \$16.00 per nurse, however, individual items such as gloves and plastic-backed pads, could be restocked separately. The overall costs over two years is around \$300,000. By implementing competency training and providing PPE, this project will improve the safety of nurses and families by 95% no later than March 30, 2018.

The risk to the organization will also be reduced in regards to occupational health claims due to HD exposure. According to the Worker's Compensation Insurance Rating Board, the 2017 average California indemnity claim averaged \$37,054 which was the 5th highest-reported claims cost in the United States (WCIRB, 2017). This average claim is 40% higher than the median average nationwide. With this cost risk in mind, and applying it to ten exposed nurses, the cost for one year would be over \$370,540 per year. The average California claim is reported as paid over three years at a cost of \$1.1 million dollars for 10 potential nurse exposures.

Change Theory

Kotter's change theory will be used to implement an evidence-based quality improvement project that addresses HD safety for home care nurses as described in Appendix F (Kotter & Cohen, 2002). The model was chosen because it intends to promote behavioral change (Frieson, Foote, & Wagner, 2012). The 8-step model will help the microsystem and organization complete the changes necessary to provide nurses, and patients and families, with a safer work and home environment with hazardous drug administration. This is the perfect time to implement this project because healthcare organizations are preparing for the 2019 enforcement deadline, and home care agencies will not be exempt from the USP <800> Standards and regulations outlined for patient and worker safety.

Kotter's 8-step change theory stresses when people connect emotions with a desired change, the change is more apt to be effective and sustainable. With improved knowledge and awareness of exposure hazards, nurses are more apt to practice safe handling to protect themselves, patients and families. The steps to accomplish the desired change include; (1) assuring everyone understands the sense of urgency, (2) forming a powerful, interdisciplinary, guiding coalition, (3) creating a common vision, (4) communicating the vision of what the future

would look like, (5) empowering others to share the vision, (6) planning for, and creating short-term wins that create momentum, (7) removing the negative resistance, not letting up, and (8) making it stick.

Data Source/Literature Review

The PICO statement used to find literature to support the project was “With the increasing risk of HD exposure to (P) home care nurses, patients and families, and the environment, what is the effect of a (I) hands-on PPE nursing in-service compared to (C) no in-service on the level of (O) nursing compliance with PPE use?” Key words for the PICO question included hazardous drug, health care workers, personal protective equipment, safe-handling, and chemotherapy. Numerous articles were available to support the PICO question regarding healthcare workers (those employed in controlled-health settings) but few specific to home care workers.

After careful literature review, and advanced searches in CINAHL and PubMed databases, 11 articles with dates that ranged from 2012 to 2017 were selected for review. The articles in the review were evaluated for evidence and quality using the Johns Hopkins Nursing Evidence-Based practice tool. Four of the 11 articles chosen were rated Level IV and good quality. The results of the studies selected provided consistent evidence related to HD exposure risks and PPE requirements. The strengths and limitations of the Level IV literature indicated the need for further research on home environmental contamination and long-term health effects with chronic residue exposure.

Bohlandt, Sverdel, and Schierl (2017) conducted an environmental and biological study with the aim of confirming HD residues on common household surfaces inside 13 homes of ambulatory patients receiving outpatient chemotherapy and determine whether HD levels could

be detected in the urine of persons residing in the home. There were 13 study participants who received intravenous chemotherapy in an outpatient clinic. Two-hundred and sixty-five wipe test samples were taken from home surfaces, including toilet, bathroom, and kitchen, and 62 urine specimens from patients and families were collected. Every surface tested had significant levels of HD residues. However, there were no traceable residues found in the urine of family members. This research study concluded that strict hand hygiene measures and PPE are necessary to ensure a safer home environment, free from hazardous drug residues. The research also confirmed that the patient's urine post-chemotherapy was the main source of contamination inside the home. The evidence presented in the article was a Level IV and of good quality.

Another study by Yuki, Ishida, and Sekine (2015) measured urinary hazardous drug excretion by patients and family members at home. Eight patients treated with cyclophosphamide (CP), 10 family members, and ten control patients provided urine samples over seven days. One hundred twelve of 276 urine samples from patients detected CP five days after treatment. Fifty-two of 243 urine specimens from family members had detectable levels of CP. The long-term effects of low-dose HD exposure are not well-understood. Furthermore, the researchers stressed the need to develop consistent home safety measures to protect patients and families. Even though the study was limited in size, the results were significant and confirmed through scientific analysis. The evidence presented was also a Level IV and of good quality.

Eisenberg (2015) argued the need to change workplace culture regarding HD safety precautions, implement current guidelines, and resolve misunderstandings that exposure risks are minimal. The author asserts that current guidelines and research to support stronger prevention programs, including enforcement, will lead to better results. The USP <800> Standards were reviewed as it relates to state legislative involvement and The Joint Commission (TJC)

enforcement implications on healthcare organizations, however, home care enforcement was not mentioned.

Dike, Ogunmakin, Pokluda, Shank, Yates, and Payne (2014) argue that while home HD self-administration might be convenient for patients and families, these drugs require the same safe handling to avoid secondary exposure. Home care nurses will require PPE and access to chemotherapy spill kits. However, kits may need to be modified to apply to some unique home exposure situations. The CNL project has addressed this issue and intends to ensure that nurses have the proper PPE and training necessary to provide better barrier protection and safer care.

An international pharmacy panel collaboratively acknowledged the increase in oral chemotherapy practices and the issues surrounding safe handling and waste disposal of toxic medications outside of a controlled environment. Patients and families are now preparing and administering HDs and potential exposure risks have increased. The panel expressed concerns that the attitudes and beliefs of healthcare workers may influence the behaviors of families by downplaying exposure risk to oral HDs by indicating that personal protection is unnecessary. International roundtables led to discussions about storage, handling, patient and worker safety, and the need to standardize practices specific to each organization's need to protect healthcare workers and the public (Goodin, Griffith, Chen, Chuk, Daouphars, Doreau, C., . . . Meier, 2011).

Likewise, Lester (2012) provided an overview of evidenced-based literature that supports the importance of ensuring that all healthcare workers are educated on applying the same principles of HD management with oral agents as with other methods of administration. The author recommended that healthcare workers should be instructed to monitor patients for adherence and compliance to safe administration practices to ensure they receive the optimal

benefits. The author recommended that proper education and competencies with PPE include patients and families.

Rudnitzki and McMahon (2015) conducted a systematic review of the literature from 2003 to 2014 with the aim of understanding the implications for nursing practice related to the shift in responsibility to patients and families regarding hazardous drug administration.

Unintentional exposure to family members, medication errors, and unaddressed toxicity concerns and environmental pollution were among some of the identified risks associated with HD self-administration without professional oversight. The false impression of safety with oral chemotherapy versus intravenous routes indicates that patients may not understand the potential hazards of oral hazardous drugs. Overall, the authors' review confirmed patient education and training were essential to ensure the safety of others.

One prospective-controlled study compared routine instruction to innovative instruction in nursing students and discovered that more knowledge and practical application skills were acquired and retained better using an innovative teaching approach. The researchers found that nursing students lacked understanding that oral chemotherapy was as dangerous as other routes of HDs and were less inclined to use PPE during administration. A decrease in environmental contamination was a result of improving nurses' understanding and skills. When considering the best method for instruction, this study revealed innovative instruction could be applied to this project (Zimmer, Hartl, Standfuls, Mohn, Bertsche, Frontini, . . . Bersche, 2016).

Crickman and Finnell's (2015) literature review asserts healthcare workers in multiple settings may be at risk for HD residue exposure that could lead to adverse health consequences. Evidence-based PPE and safe-handling recommendations were presented acknowledging modifications would have to be considered for the home setting. Recommendations ranged from

improving PPE competency and access, increasing professional oversight and medical monitoring, standardizing HD identification processes, and implementing a comprehensive HD program for all home care workers.

Hennessy and Dynan (2014) reported on a PPE initiative conducted at Dana-Farber Cancer Institute in the ambulatory infusion center. Observations of oncology infusion nurses revealed a 30-40% compliance rate with PPE use while caring for patients. The project used the framework for the Model for Improvement which is a continuous process of testing change, assessing performance, and providing feedback. The importance of this observational study is that compliance dramatically improved by implementing staff audits, peer review and innovative learning activities.

The CNL project includes mandatory in-services to improve knowledge and awareness of HD safety. The process consists of observations of individual nurse competency and compliance with PPE standards, immediate feedback to encourage best practices, and real-time measurable performance postings. A safe handling awareness campaign along with conscience raising activities (lectures and interdisciplinary discussions) will hope to improve PPE competency and compliance to 95%. Kotter's change theory will incorporate much of what was done to improve and sustain the Dana-Farber initiative, as it is more relevant to this project.

Timeline

The project will be completed in phases. "Phase 1" began in September 2017 and will conclude in April, 2018, however, future phases will continue within the organization through December 1, 2019 to ensure compliance with the USP <800> Standards. Senior leadership recognized the need to begin the project in September 2017. From September 2017 to December 15, 2017, organizational processes such as policy review and revisions, education module

program development, and home PPE items were agreed upon. The Gantt chart (Appendix G) defined a step-by-step timeline to complete this phase, however, for the purposes of this project, the timeline began on January 15, 2018 and will end on April 6, 2018.

The first step began with providing an initial survey of 61 homecare and infusion team (HIT) nurses at the annual skills day competency fair on January 15th, 2018. The purpose of the survey was to gather data to determine current knowledge, beliefs, attitudes, and behaviors associated with HD precautions and administration, and on January 16th, the data was reviewed. Second, a team of oncology nurses began developing several health literacy tools that included an HD oral administration protocol from January 20st through February 25th. The Oncology Certified Nurse (OCN) worked with the team as a content expert for the home health division to create a “Hazardous Drug Home Safety Guide” (see Appendix H) for families and a “Quick PPE Choice Guide” (see Appendix I) for home care clinicians. Third, a nursing in-service with half of the home infusion team was done on personal protective equipment training on March 3rd. Fourth, a home visit was completed with a nurse on March 6th. Fifth, a second in-service was completed on March 15th with the other half of the nurses. Again, a home visit was arranged with a nurse on March 18th. Sixth, the microsystem was rewarded for its contribution to developing a culture of safety in the patients’ homes. Seventh, the results were shared with both nursing groups on March 30th. Eighth, results for phase 1 will be presented to senior leadership with recommendations to include all homecare divisions in future plans.

Expected Results

With the implementation of a hazardous drug administration program, the leadership team expects the organization will be compliant with the USP <800> Standards ahead of the projected mandate of December 1, 2019. Home care clinicians will be more competent and

inclined to practice safe handling and waste disposal. Personal protection strategies will improve as 95% of homecare nurses will utilize proper PPE when exposure risk is present. Survey results from the annual skills day held in January 2018 will be compared to survey results on March 30th when the nurses regroup, and data will be compared to see if improvements have been realized.

Providing nurses with the education and training with PPE will improve safe handling of HDs in the home. In addition to improving safety, an HD kit will ultimately be more cost-effective to the organization as nurses will be protected from toxic exposure. Patients and caregivers will feel more confident in managing potential HD spills. The success of this change process affirms efficient lateral integration and improved patient-nurse partnerships that promote safe patient-centered care for those requiring hazardous drug administration at home.

As more evidence becomes available on the acute and long-term effects of HD exposure in the home, nurses will need to take a more proactive approach in reviewing the institutional policies and workplace environment to ensure feasible evidence-based solutions. Themes that may emerge from this project include (1) tracking exposed healthcare workers through an organizational database that is reportable to OSHA, and (2) increasing efforts to enforce regulations at every level of government. According to Polovich and Olsen (2018), thirty years of studying the issue has not solved the problem of occupational HD exposure.

Nursing Relevance

The unique nature of providing hazardous drug administration to patients in the home has posed a new dilemma; keeping clinicians, patients and families, and the environment safe. The recommendations for safe-handling have remained consistent through the years, nonetheless, suboptimal PPE use and HD exposure continue to plague the workplace. The home environment is more complex for HD administration because each home has its own limitations. Personal

protective equipment, including the recommended type of gloves for oral administration, have not been available to homecare nurses. This issue underscored the need for organizations to standardize PPE and ensure nurses are protected when providing patient care in the home.

Furthermore, the Occupational Safety and Health Administration (OSHA) recommends using a hierarchy of controls to address potential hazardous drug exposures (see Appendix J). Some of the controls are not feasible in the home. For example, the first control in the hierarchy is eliminating the source. Patients are prescribed these medications to treat disease, thus, elimination is impossible. The second control is to replace the HD with an alternative. This too, would have to be the physician's decision. The third control would be to isolate persons from the hazard. This can be done in the home by limiting the number of persons assisting the patient with drug administration. Nurses could instruct the patient to store and administer the agent in one area of the home to avoid cross-contamination to surfaces in the home setting. The fourth control, "changing the way people work", is an important and practical solution because nurses can educate and train patients and caregivers to practice good hand hygiene before and after administration, how to clean-up exposed areas, dispose of hazardous waste, and reporting of personal contact with agents that have the potential to cause adverse acute and long-term side effects. The final control in the hierarchy includes protecting workers and families by using barriers and PPE. This critical step minimizes risks associated with contact. However, PPE needs to be readily available not only for clinicians, but for families too.

Summary Report

The aim of this evidence-based project "Hazardous Drug Administration in the Home: Reducing Exposure Risks" was to improve home care nurses' knowledge and competency regarding hazardous drug administration and the use of personal protective equipment (PPE) in a

home setting. The project began in January 2018 and continued through April 6, 2018 in a home health microsystem of a large community hospital system. The expectations after didactic and hands-on demonstration sessions geared toward nurses proposed to increase knowledge and competence from 39% in January 2018 to 95% in April 2015. However, management only allowed 15 of the 61 homecare nurses to participate in the project. After instruction, only 10 of 15 home infusion nurses expressed comfort with using a chemotherapy spill kit, and 11 of 15 stated they were now familiar with the steps involved in managing a chemotherapy exposure in the home setting. It is clear that home care nurses will need joint supervisory visits and regular PPE competency training over time to reach the goal of 95% compliance with PPE. A Hazardous Drug Administration Safe Handling Checklist will be needed to document initial and annual compliance, and competency tracking (see Appendix H).

Methods and teaching aides used to implement the project were (1) a power point presentation on hazardous drug administration, (2) hands-on PPE training session, (3) hazardous drug administration checklist for clinicians, (4) quick PPE choice guide for clinicians and (5) a patient and family tool about hazardous drug safety in the home. All of the tools were developed by the CNL student with the assistance of a health literacy team, oncology nurse experts, and interprofessional collaboration between hospital nurses, oncology clinic nurses, outpatient and home infusion pharmacists, and the home health care nursing team. The Chief Nurse Executive (CNE) was instrumental in streamlining communication with the various home health directors who provided guidance that influenced the outcomes of the project. However, this expanded the project well beyond the plans associated with this phase of implementation.

The baseline data collected through nurse questionnaires provided opportunities for future improvement projects within the microsystem. The data also revealed a serious gap in

knowledge that places homecare nurses, patients and families, and the environment at risk for HD exposure. Kotter's 8-step change theory provided a methodical approach to completing a small piece of a much larger project that the organization is implementing and was an efficient way to keep the momentum moving forward when there were unexpected obstacles impeding progress.

The interdisciplinary coordination and collaboration between hospital oncology nurses, oncology clinic nurses, and home care nurses during this project provided an excellent learning opportunity for each professional group. It was important that patient education be consistent throughout the continuum of care and that all nurses follow the same hazardous drug precautions in every patient encounter, no matter the site. Moreover, the project demonstrated a need for greater understanding of the complexities of HD administration in the home and the need to provide training and education to reduce risk from exposure to hazardous drug residues.

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Appendix A Nurse Questionnaire Responses

61 nurses participated in the survey at the Annual Skills Day and Competency Fair at the Sacramento Homecare Branch.

Question 1: (Knowledge of the hazard)

1. Do you think that oral chemotherapy/hazardous drug administration (HDs) is safer than intravenous (IV) administration of chemotherapy/HDs for nurses in the home?
 - A. Yes, oral chemotherapy administration is safer than intravenous (IV) chemotherapy administration for nurses in the home. (25%)
 - B. No, I think oral chemotherapy administration is just as unsafe as IV chemotherapy. (39%)
 - C. I don't know which method of administration is safer for nurses in the home. (36%)

Response: 15 nurses answered "A". 24 nurses answered "B". 22 nurses answered "C". The majority of nurses know that oral chemotherapy is as unsafe as IV administration in the home, but they don't know which method would be safer. (Actually, both routes require the same safe-handling requirements to protect themselves, patients and families, and the environment. Although it may be simpler to administer oral chemotherapy, personal protection considerations are warranted).

Question 2: (Perceived Risk)

2. How likely are you to be exposed to someone in the home receiving oral or IV chemotherapy?
 - A. Never (3%)
 - B. Unlikely (30%)
 - C. Likely (16%)
 - D. Highly Likely (51%)

Response: 2 nurses answered "A", 18 nurses answered "B". 31 nurses answered "C", and 10 nurses answered "D". (Nurses perceptions are that it is likely that someone in the home could be receiving or IV chemo and that they could be potentially exposed in the home setting. Widespread contamination of HD residues in the home have been well-documented inside the patient homes who receive chemotherapy or other non-oncology hazardous drugs through environmental contamination, although oral chemotherapy contamination is less understood).

Question 3: (Workplace safety climate)

3. Do you know where to find information at work about hazardous drug precautions?
 - A. Yes (79%)
 - B. No (21%)

Response: 48 nurses answered "Yes". 13 nurses answered "No". (The organization does not have a policy in place for hazardous drug precautions, but nurses have been informed on where to find such policies in the past. A new policy is being created now for oral chemotherapy administration in the home setting, and a Hazardous Drug Management program will be rolled-out to address the issues).

Question 4: (Interpersonal influence)

4. When you do a medication reconciliation, do you ask patients/family members if they are taking any chemotherapy/HD via oral, IV, topical, subcutaneous or g-tube routes?
 - A. Never (16%)

- B. Sometimes (36%)
- C. Always (43%)
- D. I don't feel like this question is important to my role in home care. (5%)

Response: 10 nurses answered "A". 22 nurses answered "B". 26 nurses answered "C". 3 nurses answered "D". (The Electronic Health Record (HomeCare/HomeBase (HCHB) does not prompt the nurse to ask questions pertaining to chemotherapy/HD medication and does not alert nurses who enter these drugs in the patient's medication record. Efforts are underway with the help of the HCHB team and the Informatics team to address these problems).

Question 5: (Perceived conflict of interest)

5. How comfortable are you with using a hazardous drug spill kit?
- A. Uncomfortable (17%)
 - B. Comfortable (8%)
 - C. I have never had the opportunity to demonstrate competency with a hazardous drug spill kit. (75%)

Response: 10 nurses answered "A". 5 nurses answered "B". 46 nurses answered "C". (This finding creates an opportunity to teach nurses how to properly apply PPE to prevent personal and environmental exposure. In addition, a new oral chemotherapy administration kit is being considered for inclusion into the homecare nurses' car stock).

Question 6: (Knowledge of the hazard)

6. How familiar are you with the steps involved in managing a chemotherapy exposure in the home setting?
- A. Not familiar (66%)
 - B. Familiar (18%)
 - C. I don't think I would ever need to manage a chemotherapy exposure in the home setting. (16%)

Response: 40 nurses answered "A". 11 nurses answered "B". 10 nurses answered "C". (Again, this is an opportunity to educate nurses on the steps required to manage a hazardous drug exposure, including; safe handling, containment, storage and waste disposal of contaminated surfaces, and reporting process).

Question 7: (Self-efficacy)

7. I am familiar with the NIOSH List of antineoplastic and other hazardous drugs (2016) reference tool.
- A. No (51%)
 - B. Yes (19%)
 - C. I have no idea what the list is or how it relates to my role in the home. (29%)

Response: 31 nurses answered "A". 12 nurses answered "B". 18 nurses answered "C". (The NIOSH list has the most recent hazardous drug list and the required personal protective equipment required to protect healthcare workers. This list may be added to the homecare nurses' tablet for quick reference).

Home Visit #1

Patient Information: 69 y/o male with history of acute on chronic respiratory failure due to recurrent aspiration pneumonia (pseudomonas), malnutrition with tube feeding, history of non-Hodgkin's lymphoma in 2001, head and neck cancer with dysphagia requiring PEG tube feeding, CAD with stroke, chronic stridor, advanced lung cancer, admitted to homecare services with IV needs (Zosyn 4.5grams every 6 hours via CADD SOLIS infusion pump for 5 days).

Assessment: CNL student, also an Oncology Certified Nurse (OCN), assisted home RN with medication review and noted that patient was taking an oral antineoplastic medication daily (Tagrisso/Osimertinib) for the treatment of advanced lung cancer. Patient's wife stated that she was dissolving the tablet in a small cup and pouring the liquid into a 60 mL syringe to drain into the PEG tube. Patient has chronic diarrhea, and the linens were visibly soiled. RN notified the MD office that patient was unable to swallow and was ingesting the medication via PEG and had diarrhea, which may be a side effect of the oral chemotherapy drug. The CNL student informed the physician that the medication should be administered via a closed-system transfer device that fits into the PEG tube but these are not available outside of a hospital setting. The physician did not suggest an alternative route for safe drug delivery. The CNL student called the Astra Zeneca Pharmaceutical Company (manufacturer of Tagrisso) to inquire about alternative routes and PPE requirements with administration. We were instructed to consult our own organization's policy for hazardous oral drug administration. The patient's wife did not have any PPE, including gloves, for safe handling. Home nurse was not able to provide any instructions about safe handling and did not have proper PPE to prevent personal exposure. The CNL spent some time educating the patient's wife and provided her with several options for self-protection, such as

gloves, zip-lock bags, and plastic-backed barriers to reduce personal and environmental contamination.

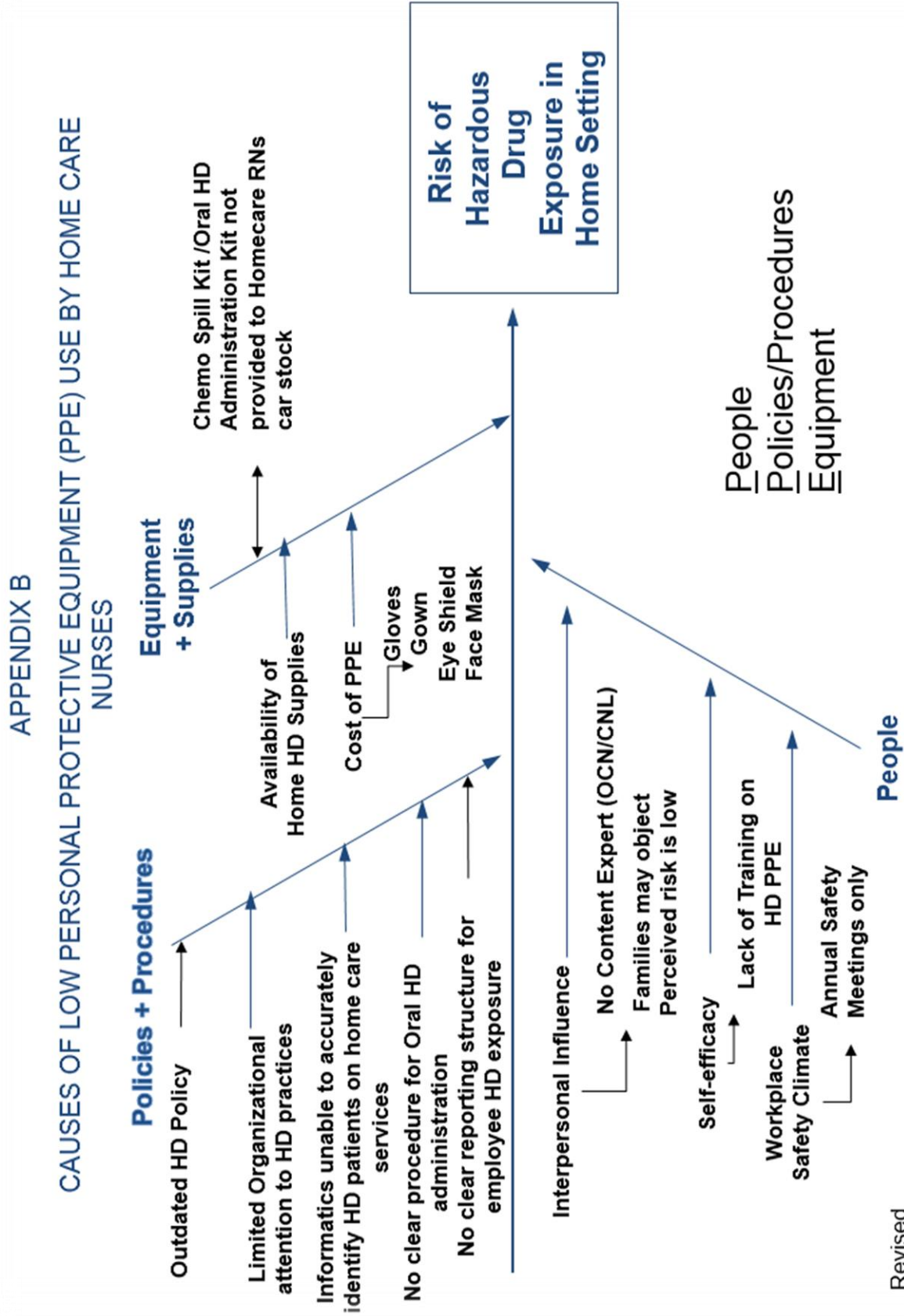
Outcome: The CNL student called a meeting with the Sutter Health Oncology Nurse Chapter (SHON) to share concerns about home administration by untrained caregivers. Several oncology nurse practitioners and one oncology pharmacist agreed to help push the agenda forward with the organization. The CNL student also suggested to Astra Zeneca that they place hazardous drug precautions on their website for patients and families to reference, and remove the statement that allows the medication to be dissolved in water at home. The rationale given by the manufacturer was that if the medication were aerosolized with crushing, it may pose a greater danger than allowing it to dissolve in the water. More needs to be done to ensure safe handling of these HD agents in the home.

Home Visit #2

Patient Information: 83 y/o female with history of colon cancer with mets to the liver and lungs. Has ileostomy with generous output/primary caregiver is spouse. Currently receiving TPN for failure to thrive and ostomy output issues.

Assessment: Joint visit with RN to perform medication reconciliation and provide spouse with information on the safe handling of Megace. Spouse has been administering this medication without gloves or other PPE and does not feel the need to start doing it now. He has filled a cup with the medication at the bedside and has her sip on it every 6 hours. Patient has dementia and is unable to follow commands but spouse wants to try everything to keep her comfortable.

Outcome: RN notified the office of the potential risks and contamination of the home environment to this toxic medication and asked patient's spouse to wear gloves. Information left for spouse to consider regarding safe storage, administration, and waste disposal.



Appendix C

SWOT ANALYSIS

<p style="text-align: center;">Strengths</p> <ul style="list-style-type: none"> • Federal mandate to comply with Chapter USP <800> standards by December 1, 2019, or face fines or penalties. • Other state and credentialing agencies such as the Centers for Medicare and Medicaid (CMS) and The Joint Commission (TJC) will begin enforcing the requirements. • Corporate support from Chief Nursing Executive, Directors of Quality/Risk management, Informatics, Accreditation/Licensure, Credentialing, Educations, and Pharmacy. • Proactive Culture of Safety 	<p style="text-align: center;">Weaknesses</p> <ul style="list-style-type: none"> • NIOSH List of antineoplastic and other hazardous drugs (2016), not available for reference for clinicians. • HomeCare/HomeBase (HCHB) application issues. • Unable to gather reliable data that identifies current patients receiving hazardous drugs. • International Classification of Diseases (ICD-10) coding for oncology patients lengthy and cumbersome. • Home care OSHA data limited regarding HD exposure rates.
<p style="text-align: center;">Opportunities</p> <ul style="list-style-type: none"> • Improve patient and healthcare personnel safety with the use of PPE. • Improve staff and patient education regarding safety related to HD administration in the home setting. • Prevent the risk of HD exposure to the patient, caregiver, family members, and the environment with health literacy tools. • Reduce exposure/sick days of all frontline staff. • Identify oncology patients at SOC. 	<p style="text-align: center;">Threats</p> <ul style="list-style-type: none"> • Attitudes and beliefs of nurses that exposure risk is low or non-existent in home care setting. • Difficulty with obtaining HD information consistently from other health care providers. • Increased visit time to accommodate patient education regarding HDs. • Reduction in staff due to concerns about being exposed to HD residues. • Budget limits on time spent on staff education.

Appendix D

USP <800> Requirements

Hazardous Drug Reference List	Training	Hazardous Drug Communication Program
<p>Requirement:</p> <p>Create a facility-specific list of hazardous drugs that is accessible by all staff (i.e. NIOSH list of antineoplastic and other hazardous drugs, 2016).</p> <p>List must be:</p> <ol style="list-style-type: none"> 1. Reviewed annually. 2. Updated when newly approved hazardous drugs are incorporated into the practice setting. 	<p>Requirement:</p> <p>Training must be provided to all staff who may have contact with hazardous drugs prior to initial work assignment, and annually, thereafter.</p> <ol style="list-style-type: none"> 1. Summary of policies and procedures. 2. Proper use of PPE and other equipment. 3. Exposure response. 4. Managing exposures. 5. Disposal of bags, tubing, syringes, and PPE. 6. Include oral chemotherapy medication administration, monitoring, procurement, and waste disposal. 	<p>Requirement:</p> <ol style="list-style-type: none"> 1. Establish policies and procedures to ensure worker safety. 2. Describe in writing how the standard will be implemented. 3. Provide training for all personnel who may be exposed to hazardous drugs prior to handling. 4. Obtain written confirmation that all personnel of reproductive capability (includes men and women of childbearing age), and understand the risks associated with hazardous drugs.

Appendix E

Budget Estimates for Project Implementation

Two Year Projections 2017-2019	Year 1	Year 2
Oncology Clinical Nurse Leader 1.0 FTE for 12 months	\$90,000	0
Health Stream Education Module Development and update revisions	\$1500	\$1500
Staff nurse training/competency testing @ \$50.00 per individual x 15 nurses (Home Infusion Team Champions)	\$750	\$750
Staff In-service- Hazardous Drug Management in the Home/ 15 Home Infusion Team Champions	\$750	\$750
Hazardous Drug Administration and Spill Kits (\$30 + \$16 each, respectively for RN car stock)	\$108,790	\$108,790
Staff replacement during training (rule: 1 staff in training = 1 less patient /visit=1 hour of service)	\$750	\$750
NIOSH List of antineoplastic and other hazardous drugs 2016 reference guide for clinicians	Free	Free
	\$202,540	\$112,540

Cost Benefit Analysis compared to Worker's Compensation Claims in California 2017

Potential Worker's Compensation Claims for HD Exposure for 10 nurses @ \$37,054 per year	\$370,540	\$370,540
Cost of HD management start-up for 15 nurses in homecare	\$202,540	\$112,540
Cost Savings due to reducing risk of exposure	\$168,000	\$258,000

Appendix F

Implementation of Kotter's 8-Step Change Model

Step 1- Establish a sense of urgency/ Why change now?
Hold convincing conversations about the rising trends in home chemotherapy administration. Share credible research data on home environmental exposure studies within the last 5 years. Regulatory enforcement is required by December 1, 2019 through USP <800> standards.
Step 2- Form a powerful guiding coalition/ Who really cares?
Seek out directors of the organizations (i.e. Chief Nursing Executive, Licensure/Accreditation, Education, Risk Management/Safety, Quality Management, Informatics, Nursing Team Leaders in Home Health, Infusion, Hospice, Palliative Care programs. Recruit staff that are invested in the health outcomes of patients and staff.
Step 3- Create a vision and a Strategy/ How do we get there?
Education modules regarding hazardous drug precautions, oral chemo administration at hire, annually. Staff training on use of PPE, waste disposal, and reporting exposure in the home
Step 4- Communicate the vision of change/How do we share what we know?
Regular safety meetings (quarterly), placing reference tools in Clinical Connect Employee newsletter, senior leadership push to get the word out in their meetings, email strategies
Step 5- Empower others to act on a vision/ What do we do?
Share ideas throughout the implementation process, and post communication/ideas on boards.
Step 6- Plan for and create short-term wins/ How do we reward successes?
Acknowledgement by senior leadership for great ideas. Provide CEU's for learning modules.
Step 7- Consolidate improvement plans and produce more change/How do we work together?
Use SMART objectives to address gaps and barriers, and implement strategies for improvement.
Step 8- Institutionalize new approaches in the culture/ Make it a culture of safety.
Mandatory learning modules at hire, and annually. PPE competencies for all healthcare workers.

Appendix G

GANTT CHART

Project starts: 01/15/2018 Projects Ends: 04/06/2018	January 2018	Feb 2018	Mar 2018	Apr 2018	May 2018	June 2018
1. Annual Competency Fair Surveys	15 th + 16 th					
2. Learning Module/Health Literacy Tool/PPE Guide Development	20 th to	25 th				
3. RN in-service ½ nursing staff			3 rd			
4. Home Visit with RN			6 th			
5. RN in-service ½ nursing staff			15 th			
6. Home Visit with RN			18 th			
7. Share results with nurses/Post 2 nd survey results			30 th			
8. Share results with Leadership				6 th		

Persons Responsible for tasks (CNL +):

- | | |
|--|--------------------------------|
| 1. Director of Education and Nursing Quality | 5. Team Leader #2/Homecare RNs |
| 2. Oncology Nurse Committee/Health Literacy Team | 6. Homecare RN |
| 3. Team Leader #1/Homecare RNs | 7. All Nurses and Team Leaders |
| 4. Homecare RN | 8. All Directors |

Appendix H

Safe Handling of Hazardous Drugs.

Appendix H Hazardous Drug Administration Safe Handling Checklist			
Name: _____	Date of Review and Exam: _____		
PRIOR TO ADMINISTRATION	Yes	No	Initials
1. Gather equipment required for drug administration.			
2. Select appropriate gloves for hazardous drug administration.			
3. Select appropriate gown for hazardous drug administration.			
4. Identify situations when mask and face protection are required.			
5. Locate hazardous drug spill kit.			
6. Obtain hazardous waste container.			
7. Receive drug(s) from pharmacy in sealed bag.			
ADMINISTRATION			
1. Wash hands and don personal protective equipment before opening drug delivery bag.			
2. Visually inspect the contents of the delivery bag for leaks.			
3. Gather IV administration supplies including closed-system drug-transfer devices.			
4. For IV infusions <ul style="list-style-type: none"> • Ensure tubing is primed with a nondrug solution. • Utilize plastic backed absorbent pad under work area. Remove cap from IV tubing and connect to patient's IV device. • Utilize closed-system drug-transfer device when compatible. • Tighten locking connections. • When complete, don personal protective equipment and discontinue IV bag with tubing intact (do not unspike bag). • Utilize gauze pads when disconnecting from patient's IV device when a closed-system drug-transfer device cannot be used. 			
5. For IV push medications <ul style="list-style-type: none"> • Utilize closed-system drug-transfer device when possible. • Tighten locking connection. • When complete, do not recap needle. • Discard syringe-needle unit in puncture-proof container. 			
6. For intramuscular/subcutaneous injections <ul style="list-style-type: none"> • Utilize closed-system drug-transfer device when possible. • Attach needle to syringe. • Tighten locking connection. • When complete, do not recap needle. • Discard syringe-needle unit in puncture-proof container. 			
7. For oral drugs (tablets/capsules) <ul style="list-style-type: none"> • If using bar code technology, scan medication prior to removing medication from packaging. • Don gloves. • Open unit-dose package and place into medicine cup (avoid touching drug or inside of package). • Avoid touching tablets/capsules. 			
8. For oral drugs in liquid form <ul style="list-style-type: none"> • Obtain drug in final form in appropriate oral syringe. • Don double gloves, gown, and mask with face protection. • Use plastic-backed absorbent pad during administration. • Discard syringe in hazardous waste container after administration. 			
POST-ADMINISTRATION			
1. Don personal protective equipment.			
2. Seal hazardous drug-contaminated supplies in sealable plastic bag for transport to hazardous waste container.			

(Continued on next page)

Safe Handling of Hazardous Drugs

Appendix (A) Hazardous Drug Administration Safe Handling Checklist (Continued)			
POST-ADMINISTRATION (cont.)	Yes	No	Initials
3. Place sealed plastic bag in hazardous waste container.			
4. Remove outer gloves.			
5. Close lid on waste container.			
6. Decontaminate equipment in the area appropriately.			
7. Remove and discard inner gloves.			
8. Wash hands thoroughly with soap and water.			

Appendix I

Quick PPE Choice Guide for Clinicians

Formulation	Activity	Double chemotherapy gloves	Protective gown	Eye/face protection	Respiratory protection
Intact tablets or capsule	Administration from unit-dose package	No (single glove can be used, unless spills occur)	No	No	n/a
Tablets or capsules	Cutting, crushing, or manipulating tablets or capsules; handling uncoated tablets	Yes	Yes	No	Yes, if not done in a control device
	Administration	No (single glove can be used)	No	Yes, if vomit or potential to spit up	No
Oral liquid drug or feeding tube	Administration	Yes	Yes	Yes, if vomit or potential to spit up	No
Topical drug	Administration	Yes	Yes	Yes, if liquid that could splash	Yes, if inhalation potential
Subcutaneous	Administration	Yes	Yes	Yes, if liquid that could splash	No
Inhalation	Administration	Yes	Yes	Yes	Yes
Drugs and metabolites in body fluids	Disposal and Cleaning	Yes	Yes	Yes, if liquid that could splash	Yes, if inhalation potential
Drug-contaminated waste	Disposal and cleaning	Yes	Yes	Yes, if liquid that could splash	Yes, if inhalation potential
Spills	Cleaning	Yes	Yes	Yes	Yes

How to Report a Hazardous Spill or Occupational Exposure

Notify your supervisor, and complete “Electronic Report of Injury” form located on the SCAH Employee Portal.

Employee Health will contact you for follow-up.

Appendix J

Hierarchy of Controls

