STANDARDIZING THE ORAL CHEMOTHERAPY PRESCRIPTION AND ADMINISTRATION PROCESS IN THE INPATIENT SETTING

A DOCTOR OF NURSING PRACTICE PROJECT SUBMITTED TO THE OFFICE OF GRADUATE EDUCATION OF THE UNIVERSITY OF HAWAI'I AT MĀNOA IN PARTIAL FULFILLMENT OF THE REQUIREMENTS FOR THE DEGREE OF DOCTOR OF NURSING PRACTICE

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ABSTRACT

Introduction

Varying practices for oral chemotherapy prescription and administration in the inpatient setting led to a need for a standardized process. The Iowa Model of Evidenced-Based Practice to Improve Quality Care was used as a framework to guide the project and establish a standardized process. Thus, the purpose of this project was to standardize the prescription and administration of oral chemotherapy throughout the Hawai`i Pacific Health (HPH) healthcare system in a manner that complies with the American Society of Clinical Oncology (ASCO) and the Oncology Nursing Society (ONS) Chemotherapy Administration standards.

Methods

The practice change included an algorithm that standardized the process for oral chemotherapy prescription by requiring orders to be prescribed by an appropriate specialty prescriber. Non-specialty prescribers were considered appropriate prescribers when ordering antiandrogens, aromatase inhibitors, and selective estrogen receptor modulators that meet specific criteria and are screened by a pharmacist. The administration process included the integration of a chemotherapy-competent nurse for the first dose administration to ensure patient and staff education. Additionally, a SMART phase was created for standardized nursing documentation.

Results

The new oral chemotherapy prescription and administration process was successfully implemented. The average monthly volume of oral chemotherapy orders decreased during the implementation phase although the overall volume for oncology services remained consistent. At baseline, the average number of doses was 13 per month. After implementation, the average

decreased by 70% to four per month. Appropriate specialty-provider prescribing of oral chemotherapy increased from 7% to 64%, administration by a chemotherapy-competent nurse increased from 5% to 64%, and patient education at first administration increased from 9% to 55%.

Discussion

Implementation of the project to standardize the process oral chemotherapy prescription and administration resulted in and higher quality care for patients receiving oral chemotherapy in the inpatient setting at SMC. Results revealed project objectives were met with an increased compliance in prescription, administration, and education for oral chemotherapy orders.

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List of Abbreviations

ASCO – American Society of Clinical Oncology
AEs – adverse events
AGREE II – Appraisal of Guidelines for Research and Evaluation
BPA – best practice advisory
CPOE – computerized provider order entry
DAR – data/action/response note
EB – evidence-based
EMR – electronic medical record
HPH – Hawai`i Pacific Health
KMC – Kapi`olani Medical Center
MAR – medication administration record
NIOSH – National Institute for Occupational Safety and Health
ONS – Oncology Nursing Society
OPA – Oncology Physician Assistant
OPC – Oncology Practice Council
PICO – population, intervention, comparison, outcome
SMC – Straub Medical Center

CHAPTER 1. EXECUTIVE SUMMARY

Introduction

Over the last decade, the use of oral chemotherapy for the treatment of cancer has dramatically increased, with more than 25% of new antineoplastic drugs being developed for oral administration (Bourmaud et al., 2014). Oral chemotherapies have similar toxicities to their parenteral counterparts; however, standards of safety and monitoring are less rigorous, despite many of the same safety concerns. Although most institutions have strict guidelines for the administration of parenteral chemotherapy, similar protocols generally do not exist for oral chemotherapy (Shah et al., 2016). The purpose of this evidence-based (EB) project is to standardize the process for prescribing and administering oral chemotherapy in a manner that complies with the American Society of Clinical Oncology (ASCO) and with the Oncology Nursing Society (ONS) Chemotherapy Administration at Hawai`i Pacific Health (HPH) healthcare system.

Conceptual Framework

The Iowa Model of Evidence-Based Practice was used as a framework for this EB practice change, aiming to standardize the process for inpatient oral chemotherapy prescription and administration at Straub Medical Center (SMC), a facility within the HPH healthcare system. The Iowa Model involves a systematic stepwise process that guides program development though: 1) Identifying triggers, 2) Forming a team, 3) Assembling research, 4) Critiquing and synthesize research, 5) Piloting an EB practice change, 6) Implementing an EB practice change, 7) Monitoring and analyzing structure, process, and outcome data (Titler et al., 2001).

Literature Review and Synthesis

An electronic search of the literature was completed using CINAHL with Full Text, PubMed, the Cochrane Library, and the National Guideline Clearinghouse databases. The majority of applicable results were obtained from CINAHL and PubMed. Some key search terms included “oral chemotherapy”, “neoplasms/drug therapy”, "administration, oral”, "antineoplastic protocols", “electronic prescribing”, “computerized provider order entry”, and “inpatients”. This project included 25 journal articles and three clinical practice guidelines. While overall adoption is currently lagging for oral chemotherapy, evaluation of the literature indicated that the ASCO/ONS guidelines should be followed and implemented at all facilities.

Innovations & Objectives

Based on the literature, an EB project was developed to standardize the process of oral chemotherapy prescription and administration by implementing a process algorithm. The practice change included an algorithm that standardized the process for oral chemotherapy prescription by requiring orders to be prescribed by an appropriate specialty prescriber. Non-specialty prescribers were considered appropriate prescribers when ordering antiandrogens, aromatase inhibitors, and selective estrogen receptor modulators that met specific criteria and were screened by a pharmacist. The administration process included the integration of a chemotherapy-competent nurse for the first dose administration to ensure patient and staff education. Additionally, a SMART phrase was created for standardized nursing documentation.

Methods

The HPH healthcare system includes four major hospitals: SMC Kapi`olani, Pali Momi, and Wilcox. The standardized process aimed for system wide implementation, but was initially implemented at SMC due to its high volume of oral chemotherapy orders and low compliance

with chemotherapy prescribing and administration policy. Baseline data was collected from June 2016 to December 2016. The sample was oral chemotherapy orders prescribed to inpatients on the 3rd, 4th, and 5th, floors at SMC from October 2017 to December 2017. Data was collected monthly via the EMR system and a retrospective chart review was completed.

Results

The oral chemotherapy prescription and administration process was successfully implemented at SMC. The average monthly volume of oral chemotherapy orders decreased during the implementation phase although the overall volume for oncology services remained consistent. At baseline, the average number of doses was 13 per month. At post implementation, the average decreased by 70% to four per month. Appropriate specialty-provider prescribing of oral chemotherapy increased from 7% to 64%; administration by a chemotherapy-competent nurse increased from 5% to 64%; and patient education at first administration increased from 9% to 55%.

Discussion

Implementing an algorithm to standardize the process of oral chemotherapy prescribing and administration resulted in higher quality care for patients receiving oral chemotherapy in the inpatient setting at SMC. Results revealed project objectives were met with an increase in prescribing and administering oral chemotherapy that complies with facility policy, and ASCO/ONS Chemotherapy. Implementing the algorithm decreased the volume of orders, increased the number prescribed by an appropriate specialty, increased the number administered by a chemotherapy-competent nurse, and increased the number of patients that received education.

CHAPTER TWO. PROBLEM

Introduction

Oral chemotherapy is fast becoming a common treatment option, with more than 25% of new antineoplastic drugs being developed for oral administration (Bourmaud et al., 2014). Although oral chemotherapy carries several benefits and conveniences, the rapid increase has created a unique set of challenges as the safeguards that have evolved over time for parenteral chemotherapy are lacking for orals. The purpose of this EB project is to standardize the process for prescribing and administering oral chemotherapy in a manner that complies with facility policy, with the ASCO/ONS standards Chemotherapy Administration standards in the inpatient setting at the SMC, a facility within the HPH system. This chapter will present the background of the problem, a conceptual model, and a literature review.

Background and Problem

Although traditional oncology treatments have mainly focused on the parenteral administration of chemotherapy, oral chemotherapy is fast becoming a viable option for cancer treatment. Oral chemotherapy drugs have been available for decades and the number of oral chemotherapy agents approved by the United States (US) Food and Drug Administration has increased significantly in recent years (Weingart et al., 2012). In 2013 alone, five of eight newly approved cancer therapies were in an oral formulation and the use of oral chemotherapy agents will continue to increase as more agents enter the market (Anders, Shillingburg, & Newton, 2015). Experts predict that this trend will continue, with the National Comprehensive Cancer Network task force (NCCN) estimating that more than a quarter of the approximately 400 antineoplastic agents in development will be administered orally (Weingart et al., 2012).

As oral chemotherapy is emerging as a new treatment option for well-selected patients, it is shifting the paradigm in cancer care. Oral chemotherapy can be self-administered at home, allowing for convenience, however home therapy also transfers responsibility for the management and monitoring to patients, their caregivers, and healthcare professionals who may not have the appropriate training to take on these new tasks (The Institute for Safe Medication Practices Canada, 2015).

Medication errors are a long-standing concern with regard to the administration of chemotherapy. In recent years, a rigorous set of checks and balances has been implemented for ordering and administrating parenteral chemotherapy to include templated orders, electronic order-entry systems, clinician double-checks, and review by at least three or four licensed health care providers. To date, however, fewer controls are integrated into oral chemotherapy protocols (Weingart et al., 2008).

A 2007 survey, conducted by Weingart and colleagues, reviewed 54 US comprehensive cancer centers' safety practices, finding that, in comparison to parenteral chemotherapy, fewer safety standards for oral chemotherapy agents had been adopted. Only one in four centers had standard prescribing safeguards in place for oral chemotherapies, and fewer than one in five had measures to ensure safe administration and monitoring. Additionally, oral chemotherapy lacked guidelines and standards for prescription, education, and the assessment of patient compliance. This is a major concern because, while many categories of oral chemotherapies have similar levels of toxicity to their infusion counterparts, the levels of safety and monitoring for prescription and administration are less rigorous than those for parenteral chemotherapy (Birner, 2003; Weingart et al., 2007).

Oral chemotherapy may present a particular problem if a patient receiving the therapy is admitted to an inpatient setting for an acute episode. In this situation, the admitting provider must determine how to continue the oral chemotherapy, frequently without the requisite expertise in the medication or the condition in which the oral chemotherapy is prescribed. The ASCO/ONS administrative guidelines require that orders for oral chemotherapy be written and signed by licensed practitioners who are determined to be qualified by the prescribing institution according to its policies, procedures, and/or guidelines (Weingart et al., 2012). Additionally, each facility has bylaws which determine which specialties are authorized to prescribe chemotherapy.

Although many institutions have dedicated oncology units, patients on oral chemotherapy may be hospitalized for an unrelated issue and placed on a non-oncology floor. Nurses outside of oncology may not be aware that a particular drug is an oral chemotherapy that requires additional verifications, safeguards, and special handling, thereby placing themselves and their patients at risk. They also may lack the confidence to administer, care for, and educate patients receiving oral chemotherapy because of their unfamiliarity with the medications and safe administration standards. Specific safety standards for the administration of chemotherapy have been identified by ASCO/ONS and require that each institution have a comprehensive educational program to include monitoring nursing competency and safe handling and that all patient receive education (Jacobsen et al., 2012).

Theoretical and Conceptual Framework

The Iowa Model of Evidence-Based Practice can help nurses and other healthcare providers translate evidence-based practice into clinical practice while improving outcomes for patients (Brown, 2014). The Iowa Model involves a systematic process that can be described as a

progressive series of activities to identify a problem and initiate the need for a change (Titler et al., 2001). Currently, the Iowa Model is used by HPH (HPH, 2015; HSCN, 2014) to guide all EB projects. The Iowa Model incorporates the following seven steps:

1. Problem and knowledge focused triggers;
2. Form a Team;
3. Assemble Relevant Research and Related Literature;
4. Critique and Synthesize Research;
5. Pilot the Evidence-Based Practice Change;
6. Implement the Evidence-Based Practice Change;
7. Monitor and Analyze Structure, Process and Outcome Data;

Problem-focused triggers. Problem-based triggers that initiated this project included prescriptions for oral chemotherapy by non-specialty providers which have led to inappropriate continuation in the inpatient setting, administration of oral chemotherapy by untrained staff nurses, and a lack of nursing patient education.

The current system wide policy and procedure at HPH for the administration of chemotherapy was updated in 2015 to ensure system wide alignment with ASCO/ONS standards (Blasiak, 2016). The current policy clearly defines who is qualified to prescribe oral chemotherapy, gives oncologists the privilege to prescribe chemotherapy, and specifies that non-oncologists may prescribe chemotherapy only within their specialty and scope of practice. Residents are not permitted to prescribe chemotherapy (Straub Medical Center, 2015). Although oncologists have the expertise and specialized training to safely prescribe oral chemotherapy, they oftentimes are not consulted in the inpatient setting. Oral chemotherapy is

prescribed by non-specialty providers who fail to communicate with the original prescribers to determine the appropriate course of treatment in the inpatient setting.

From June 2016 to December 2016, a total of 332 oral chemotherapy medications were ordered across the HPH's four hospitals (see Figure 1). Of the 332, 137 of the orders were for megestrol acetate. Megestrol is an antineoplastic agent and appetite stimulant that is used for weight loss related to certain conditions and there is limited evidence for its use as an appetite stimulant outside of these conditions. Currently, megestrol is being used at HPH facilities for appetite stimulation outside of labeled indications and for this reason was excluded from the data leaving a total of 195 oral chemotherapy orders. Of the remaining 195 orders, only 44, or 22.56%, were ordered by an appropriate specialty prescriber.

Although a system wide prescribing policy is in place, compliance rates varied among the four hospital sites. Overall, Kapi`olani Medical Center (KMC) had the best compliance with 36 of 39 oral chemotherapy orders prescribed by an approved provider, while the remaining three sites had notably low compliance. KMC's high compliance rate was thought to be associated with patient population as KMC treats pediatric oncology while the other three sites treat adult oncology. Pediatric oncology is typically delivered in the inpatient setting, while adult oncology has a heavier outpatient emphasis which places a greater dependence on non-oncologist in the inpatient setting.

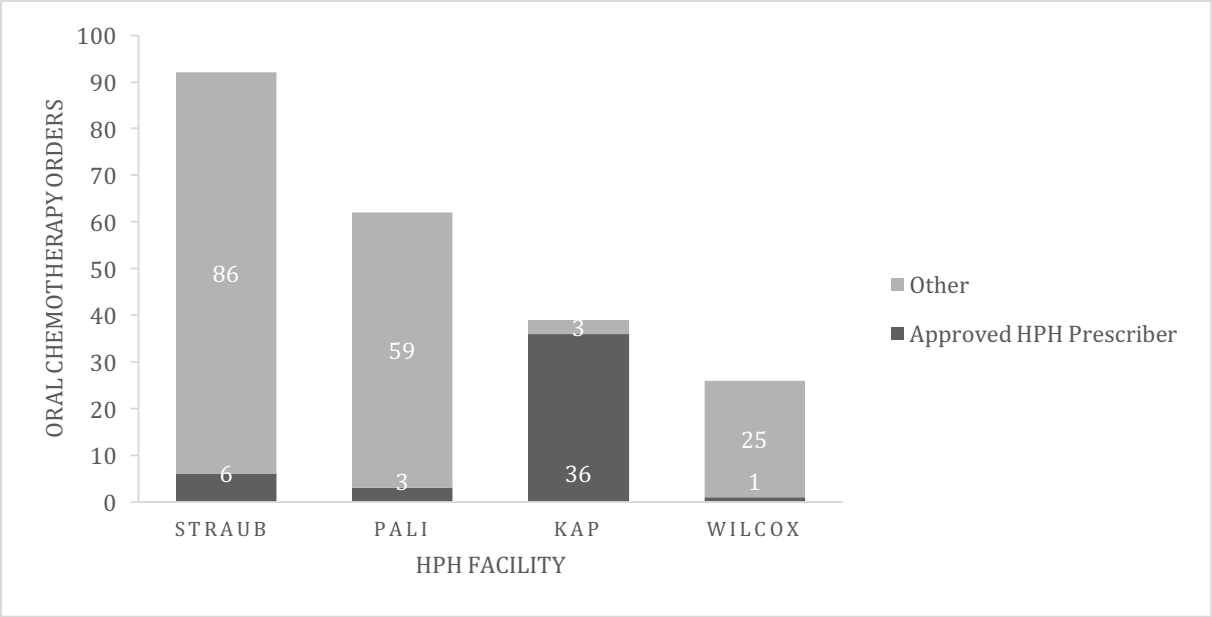


Figure 1. Oral chemotherapy orders prescribed by an appropriate prescriber at Hawai`i Pacific Health from June 2016 – December 2016.

At SMC, there were a total 92 oral chemotherapy orders (See Appendix A). Of the 92 only 7% were prescribed by an appropriate specialty provider. Hospitalist prescribed 61% of all oral chemotherapy orders (see Figure 2). Additionally, only 5% of orders were administered by a chemotherapy competent nurse, and only 9% of patients received education about oral chemotherapy at first dose administration.

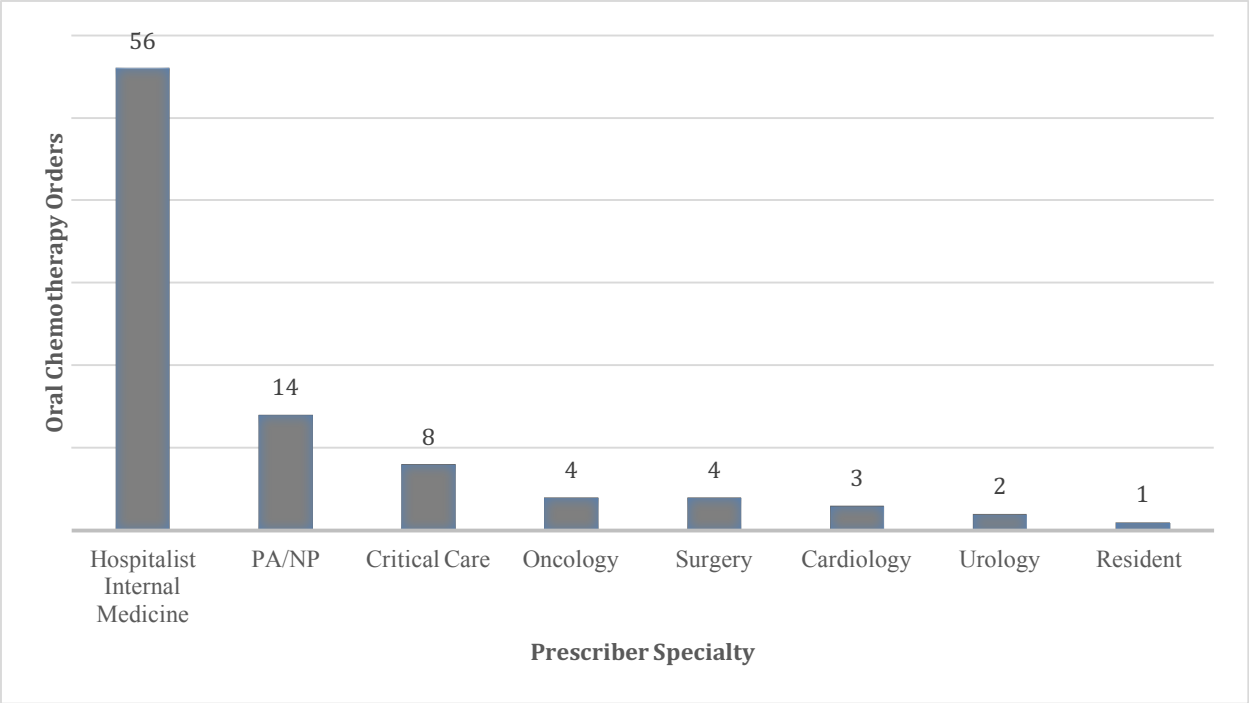


Figure 2. Oral chemotherapy prescriber specialties from June 2016 – December 2016.

Knowledge-focused triggers. The ASCO and ONS provide well known published standards and guidelines for oral chemotherapy prescription and administration (Neuss et al., 2013). The current facility policy at SMC align with these standards by indicating who is authorized to order oral chemotherapy and the steps required for safe administration (Straub Medical Center, 2015). However, gaps in physician knowledge inevitably result in different degrees of physician appropriateness for prescribing oral chemotherapy. Additionally, gaps in nurse knowledge result in variation in the safe handling, administration and education process.

Oncologists have the requisite training and expertise to order oral chemotherapy, yet they infrequently prescribe oral chemotherapy in the inpatient setting at SMC. This calls into question the experience and knowledge of physicians in other specialties to appropriately apply oral chemotherapy medications and to account for their drug interactions and unique side effects.

A recent patient case highlighted this knowledge gap: patient presented to SMC with fever, fatigue, and lab results indicating blood culture positive for gram negative rods. This patient was on an oral chemotherapy treatment at home, and after lab review and evaluation, the patient was admitted with a diagnosis of sepsis. The admitting physician (hospitalist) continued all home medications including an oral chemotherapy drug that is a known neutropenia causing agent. After two days, it was discovered that the patient was erroneously continued on the medication, which was causing neutropenia and triggering the sepsis. In this example, the hospitalist was unaware of the appropriate application of the oral chemotherapy medication and there was inadequate communication between the hospitalist, original prescriber, and oncology specialty.

In another case, a patient on active oral chemotherapy treatment for chronic myeloid leukemia had a mechanical fall at home that required an acute hospitalization, unrelated to the cancer diagnosis. The admitting physician (hospitalist) continued the patient on the oral chemotherapy without a referral to oncology services or communication with the original prescriber. The patient was found to have a gangrenous foot ulcer and severe peripheral arterial occlusive disease, which the oral chemotherapy medication is known to exacerbate. In this situation, the hospitalist lacked the expertise and knowledge that the oral chemotherapy medication was making the patient's peripheral arterial occlusive disease worse. The medication was changed immediately when evaluated by an oncology specialist, but not until days after the admission.

Form a Team

An interdisciplinary team was established to determine appropriate interventions and standardize the process for oral chemotherapy prescription and administration. The team

consisted of the Director of Oncology Services, Oncology Physician Assistant (OPA), Oncology Practice Counsel (OPC), inpatient pharmacy managers, and nursing managers.

Assemble Relevant Research & Related Literature

A thorough review of the literature began by searching the literature for determining strategies that could be used to standardize procedures for oral chemotherapy ordering and administration. An electronic search was completed using CINAHL, PubMed, the Cochrane Library, and the National Guideline Clearinghouse databases. The majority of applicable results were obtained from CINAHL and PubMed. Search terms included “oral chemotherapy”, “neoplasms/drug therapy”, “oral adherence”, "administration, oral”, "drug therapy/administration and dosage", "antineoplastic protocols", “safety standards”, "medication errors", “administration and dosage”, “electronic prescribing”, “computerized provider order entry”, “prescriptions”, “patient education”, and “inpatients”. Parameters in both PubMed and CINAHL, such as subject headings, Boolean operators, and truncation, were utilized to limit and expand search results as needed. Abstracts, full text articles, and bibliographies for related articles were reviewed.

The search results produced 108 articles and relevant publications that matched the established criteria. Filters eliminated duplicate articles and those that were exclusive to parenteral chemotherapy. Inclusion criteria included human subjects over the age of 18, English language publications, and inpatient settings. Year limits were set to the past 10 years to ensure current research was evaluated, the oldest reviewed study being from 2007. After reviewing articles according to the inclusion and exclusion criteria, a total of 25 journal articles and three practice guidelines were utilized for this project.

Critique & Synthesize Research for Use in Practice

A review of the literature revealed a lack of studies examining adherence to ASCO/ONS guideline standards for oral chemotherapy in the inpatient setting. Inappropriate prescribing by providers without oncology training was identified as a concern, but there was little to no evidence to help refine the standard. The majority of the studies reviewed identified gaps in oral chemotherapy safety standards, such as variable practices in prescribing oral chemotherapy, administering the drugs, and educating patients, but few offered solutions outside of following ASCO/ONS standards.

The majority of the literature found was Level VI, descriptive studies. Overall, the publications were deemed to have fair to good internal validity. No Level I, Level II, or Level III research studies were identified, due to the nature of the project topic. Study designs where a subject may not receive an intervention, such as randomized controlled trials, are not suitable due to ethical concerns that all patients should safely receive medication.

The 25 articles were evaluated and ranked in terms of their position on an eight-level scale based on the Mosby Research Critique Tool (2004), as presented in Table 1. The three practice guidelines were critiqued using the Appraisal of Guidelines for Research & Evaluation II (AGREE II) tool, as shown in Table 2. The Mosby Research Critique Tool (2004) has eight levels of evidence including a seven-level grading system, with Level I, meta-analyses, being the highest level of research. The AGREE II tool is designed to assess the quality of practice guidelines and was used to grade performance, usefulness, and areas for improvement. The AGREE II tool has a maximum possible score of seven and minimum of one (Brouwers et al., 2010).

Table 1

Search Results Categorized by Mosby's Level of Evidence

Mosby's Level of Evidence		**Search Results**
Level I	Meta-analysis	0
Level II	Experimental design aka Randomized Controlled Trial (RCT)	0
Level III	Quasi-experimental design	0
Level IV	Case controlled, cohort studies, longitudinal studies	0
Level V	Correlation studies	1
Level VI	Descriptive studies including: • Surveys • Cross sectional design • Developmental design • Qualitative studies	16
Level VII	Authority Opinion or expert committee reports	4
Other:	Quality Improvement Project (QI)	4
TOTAL:		**25**

Table 2

Clinical Practice Guideline AGREE II Score

Reference	**Score**
America Society of Health-System Pharmacists, 2014	5
Neuss et al., 2013	6
Neuss et al., 2017	6

Clinical Practice Guidelines. In order to assist facilities in developing policies and procedures ensuring safe administration of chemotherapy, guidelines related to chemotherapy preparation, handling, and administration have been released by ONS (Brown et al., 2001; Level VII), Infusion Nurses Society (2000; Level VII), and the ASHP (ASHP, 2002; Level VII). In 2008, the ASCO and the ONS initiated a collaborative project to develop standards for safe chemotherapy administration to adult patients with cancer. The scope of the project included patient safety with chemotherapy regimens across the treatment course, but did not specifically address oral chemotherapy (Jacobson et al., 2009; Level VII). This prompted, another ASCO/ONS workgroup to address the challenges surfacing around oral chemotherapy treatments. In 2013 the guidelines were updated to specifically address the unique complications associated with the use of oral chemotherapy (Neuss et al., 2013; Level VII). The most current guidelines were recently updated in 2016 (Neuss et al., 2017; Level VII). In addition, ASHP released revised standards in 2014 that included oral chemotherapy (ASHP, 2014; Level VII).

While overall adoption is currently lagging for oral chemotherapy, multiple studies have concluded that the ASCO/ONS guidelines should be implemented by all facilities, and that oral chemotherapy should be subject to the same safety procedures as parenteral chemotherapy (Levy et al., 2011, Level VII; Roop & Wu, 2013 - Level VI; Vioral & Kennihan, 2012 - Performance Improvement; Weingart et al., 2012 – Level VI). Two studies similarly recognized that the administration of oral chemotherapy often lacks not only safeguards similar to those required for parenteral chemotherapy, but also standards for ensuring order accuracy, thus giving rise to safety concerns (Johnson, Chambers, & Vaida, 2008 – Level VI, Roop & Wu, 2013). In addition, Weingart et al. (2012) assessed the overall implementation of the 2009 standards and concluded that only four of the 55 National Cancer Institute designated cancer centers were compliant with

all 31 safety standards. These studies and the variable implementation of the ASCO/ONS chemotherapy safety standards reflect the need for standardized procedures and further evaluation of strategies to ensure adherence to standards.

A quality improvement project conducted at Gibbs Cancer Center & Research Institution assessed standardizing the consenting, ordering, and documenting for oral chemotherapy in compliance with ASCO/ONS Chemotherapy Administration standards for inpatient oral chemotherapy administration via an algorithm (Hegedus, 2016 – Quality Improvement Project).

Oral Chemotherapy Prescribing. Due to the narrow therapeutic index, oral chemotherapy agents are often associated with a greater risk of adverse events (AEs) than other medications. An even greater incidence of AEs may result when used in combination with other medications (Goodin et al., 2011, level VII). In 2010, Weingart et al. analyzed over 500 reports of medication errors involving oral chemotherapies and found the majority of incidents resulted in, or had the potential for, significant harm. Errors were identified at every stage of the medication process (Weingart et al., 2010; Level VI). Two quality improvement projects found that by requiring oncology-trained pharmacists to review oral chemotherapy prescriptions prior to dispensing prescribing errors for oral chemotherapy were reduced (Battis, Clifford, Huq, Pejoro, & Mambourg, 2016 – Quality Improvement Project; Shah et al., 2016 – Quality Improvement Project).

Oral Chemotherapy Administration. Although no publications compare chemotherapy errors that occur with oral administration versus intravenous administration, known issues with oral administration include incorrect dosing and limited monitoring. These can lead to overdosing, serious toxicity, morbidity, and mortality (Goodin et al., 2011). In one study of 199 registered nurses working in oncology wards, 26% demonstrated compliance with them during

administration even though 73% of them reported knowing the guidelines for safe handling of chemotherapy agents. (Kampitsi et al., 2012; Level VI).

Oral chemotherapy administration is guided by the ASCO/ONS standards and indicates that two independent checks must be completed prior to administration (Neuss et al., 2013). An independent double check requires two people to check separately each component of the medication order to reduce the risk of bias that occurs when a single person prepares and checks a medication (Institute for Safe Medication Practices, 2013). A study that investigated the practice of double-checking procedures in chemotherapy administration found that 25% of responders reported that one or more serious medication errors had taken place in their unit during the past 12 months. A majority of those surveyed believed it could have been prevented with a thorough double-check (Schwappach, Pfeiffer, & Taxis, 2016 – Level VI).

Computerized Provider Order Entry Systems. Communication from physicians to other members of the treatment team takes place primarily through the ordering process, which can be complex due to the need for precision with regard to the drug, dose, and scheduling, and duration of oral chemotherapy (Meisenberg, Wright, & Brady-Copertino, 2013). Oral chemotherapy medications often have narrow therapeutic ranges and complicated dosing schedules, which can lead to prescribing errors. Computerized Provider Order Entry (CPOE) systems have the potential to prevent oral chemotherapy errors and to improve the quality of care for patients receiving oral chemotherapy (Brown et al., 2002 – Level VII; Collins & Elsaid, 2010 – Level VII).

In a study that evaluated the ability of a CPOE system to reduce the probability of oral chemotherapy errors during the review and administration process (Collins & Elsaid, 2010), CPOE resulted in an approximately 69% reduction in the risk of oral chemotherapy prescribing

errors. Prior to the implementation of a CPOE, errors of drug dose and/or schedule comprised 33% of total prescribing errors. After the CPOE implementation, this type of prescribing error was completely eliminated over a 6-month period. This study demonstrates the ability of a CPOE system to reduce prescribing errors and potentially eliminate certain error types that can cause patient harm (Collins & Elsaid, 2010).

A similar study investigated the effects of instituting a CPOE system for chemotherapy ordering and administration in an academic teaching institution that admits approximately 1,300 patients for chemotherapy administration annually (Martin, Kaemingk, Frieze, Hendrie, & Payne, 2015 – Level VII). They concluded that the CPOE system for ordering chemotherapy was successfully and safely implemented, with staff reporting a decrease in adverse safety events, particularly in the areas of prescribing and transcribing. The ASHP Guidelines on Preventing Medication Errors with Chemotherapy and Biotherapy (2002) recommend that a CPOE should be implemented to further enhance the safety of the chemotherapy ordering process. The CPOE system and electronic health record should allow for an electronic check and documentation of the independent checks by the pharmacist, nurse, and any others involved in the chemotherapy use process.

Several studies validated the positive impact CPOE can have on the reduction of oral chemotherapy medication errors (ASHP, 2002; Brown et all., 2002; Collins & Elsaid, 2010; Gandhi, Tyono, Pasetka, & Trudeau, 2013; Martin, Kaemingk, Frieze, Hendrie, & Payne, 2015; Meisenberg, Wright, & Brady-Copertino, 2013). Advantages include providing alerts for missing orders, incorrect doses and wrong route, time, and schedule. In addition, CPOE systems provide increased communication among healthcare providers and easy access to pertinent patient data related to oral chemotherapy ordering and administration (Levy et al., 2011 – Level VII). Several

studies identified successful integration strategies to identify safety gaps with input from interdisciplinary teams consisting of clinicians, pharmacists, information technology specialists, and nurses (Gandhi, Tyono, Pasetka, & Trudeau, 2013; Martin, Kaemingk, Frieze, Hendrie, & Payne, 2015).

Innovation in Practice

Standardization of Chemotherapy Prescription and Administration. Currently, the gold standard guiding oral chemotherapy safety is from the ASCO/ONS, which is the most highly cited guideline in the literature. These standards require the oral chemotherapy process to include prescription by a qualified provider with documented specialized training, preparation by a licensed pharmacist with documented chemotherapy preparation education, three independent verifications by a second licensed pharmacist, and at least two independent nursing checks prior to administration (Neuss et al., 2016). Recommendations for avoiding chemotherapy administration errors calls for standardized approaches, development of policies and procedures for system improvement, and review of errors by interdisciplinary professional staff (Jacobson et al., 2009). The use of an oral chemotherapy prescribing and administration algorithm was shown to be an effective approach to standardize the process to align with ASCO/ONS guidelines (Hegedus, 2016). The current policy and procedure at SMC was evaluated to expand upon and standardize the process for ordering and administering oral chemotherapy, ensuring compliance with ASCO/ONS guidelines.

Education and Training. Nurses play a vital role in the safe administration of oral chemotherapy. In order to ensure alignment with the ASCO/ONS safety standards, it is critical to ensure that all staff involved in the oral chemotherapy process have the training necessary to ensure safe prescription and administration of oral chemotherapy. The ASCO/ONS updated

(2017) safety standards indicate that every healthcare setting must have a policy to document the qualifications of clinical staff that order, prepare, and administer chemotherapy. In addition, the healthcare setting must use a comprehensive education program providing initial and ongoing educational requirements for all staff that prepare and administer chemotherapy. The guideline makes clear that patient safety is paramount, and proper training of all staff involved with oral chemotherapy must align with current safety standards.

Summary

The purpose of this EB project was to standardize the process for prescription and administration oral chemotherapy in compliance with facility policy, ASCO/ONS Chemotherapy Administration standards in the inpatient setting at HPH's SMC. A comprehensive literature review identified key principles and guidelines to follow in order to ensure safe prescription and administration of oral chemotherapy. These principles include standardizing the process for prescribing and verifying oral chemotherapy, ensuring proper training and education for staff, and providing patient education for oral chemotherapy. Based on the evidence reviewed, interventions will be incorporated into a practice change to be implemented and evaluated.

CHAPTER THREE. METHODS

Objectives

While there is a clearly outlined prescribing policy for oral chemotherapy at SMC, patients admitted to the inpatient setting were found to have oral chemotherapy agents prescribed (and continued from home) by inappropriate specialty prescribers. Additionally, oral chemotherapy was being administered by nurses unfamiliar with the treatment and failing to provide patient education. The project used the PICO format to frame its underlying clinical question in terms of Population, Intervention, Comparison, and Outcome. Each aspect of the clinical question are discussed below.

P - Population: Adult patients admitted to a 4th, 5th, and 6th floors at SMC and prescribed oral chemotherapy.

I - Intervention: Initiation of an oral chemotherapy algorithm addressing prescribing, administering, and educating.

C - Historical data with current practice.

O - Increased compliance with facility policy for prescribing and administering oral chemotherapy orders and thereby increased compliance with the ASCO/ONS Chemotherapy standards in the inpatient setting at SMC.

The primary clinical question for this project is “Will the initiation of an inpatient oral chemotherapy prescription and administration algorithm increase the number of oral chemotherapy orders that comply with ASCO/ONS guidelines by having orders placed by an appropriate specialty prescriber and having the first dose administered by a chemotherapy-competent nurse?

The Practice Change

This EB project aimed to standardize the process of oral chemotherapy prescription and administration by implementing a system wide process that includes an algorithm to standardize the process for prescription and administration of oral chemotherapy (see Appendix B) that includes a nursing standardized documentation process for oral chemotherapy. The algorithm for prescribing and administering requires the following: 1) a consult is requested for the appropriate prescribing specialty, 2) pharmacy reviews and releases oral chemotherapy orders only when the order is written by an oncologist or approved specialty prescriber, 3) the first dose of every oral chemotherapy order is administered by a chemotherapy-competent nurse who provides essential staff and patient teaching that is documented via SMART phrase in the electronic medical record (EMR) algorithm (see Appendix C).

Components such as education for physicians, pharmacists, and nurses were performed in small groups to clarify the existing prescribing and administration oral chemotherapy policy, as well as the standardization of the prescription and administration process by integrating the algorithm and SMART phrases. The algorithm was designed to incorporate EB literature recommendations and SMC and ASCO/ONS guidelines. The algorithm's development included contributions from key stakeholders including the Director of Oncology Services, OPC, OPA, inpatient nurse managers, and pharmacy leadership.

Characteristics of the Innovation

In order to increase adoption of the proposed practice change, five perceived attributes of the innovation were examined. These attributes included relative advantage, compatibility, complexity, trialability, and observability (Rogers, 2003). The following section identifies

features of the practice changes proposed by the current project that correspond to the five perceived attributes of innovation.

Relative advantage. Relative advantage, as explained by Rogers (2003), is the degree to which an idea or innovation is superior to the existing idea. The foremost advantage of this project addresses patient and staff safety. Unlike parenteral chemotherapy, oral chemotherapy medications were not ordered or administered via a standardized process, leaving gaps in patient and staff safety. With successful implementation, this project intends to decrease the number of inappropriate specialty prescribers ordering oral chemotherapy. It also aims to increase staff and patient safety by ensuring that nurses were aware of safety precautions necessary for handling hazardous drugs and the unique side effect profile associated with the medications. Additionally, it ensured that oral chemotherapy education for patients is completed and documented.

Compatibility. Rogers (2003) describes compatibility as the degree to which an idea or innovation is in line with the present values, experiences, and needs of likely adopters. The HPH organization recently addressed the lack of standardization for verification and administration of parenteral chemotherapy and successfully implemented a system wide policy that is currently in use (Blasiak, 2016). This policy included guidance on oral chemotherapy; however, project baseline data indicated a lack of compliance at three of the four hospitals triggering this project. This project was highly compatible with the current parenteral chemotherapy process and utilized similar procedures to develop interventions that have been proven successful and that complement the existing policy.

Complexity. Complexity is described by Rogers (2003) as the degree to which an idea or innovation is understood as difficult to comprehend and use. This project would implement an algorithm to decrease complexity and create a clear and defined process for ordering and

administering oral chemotherapy. The algorithm will provide a step-by-step, easy to follow guide that observes system policy and ASCO/ONS guidelines.

Trialability. Every inpatient oral chemotherapy order was an opportunity to test the new standardized process. With each order, evaluation of individual parts could be assessed and modified as needed. Furthermore, the process would only be piloted at SMC before HPH system wide implementation, which allowed for further reevaluation as necessary.

Observability. Observability is defined by Rogers (2003) as the degree to which the results of an innovation are observable to others. Results can be observed by approved specialty prescribers and pharmacy staff through an increase in communication for verification of oral chemotherapy orders and pharmacy. In addition, nursing staff will see an increase in patient education in oral chemotherapy orders administered by a chemotherapy-competent nurse for the initial dose. Although not directly visible to leadership, review of data will show increased use of SMART phrases that standardize the process of oral chemotherapy prescription and administration and provide a way to track the data.

Sampling Plan

Setting

HPH is a not-for-profit health care system of medical centers, clinics, physicians and other care providers throughout the state of Hawai`i. The health care system includes four major hospitals: Straub, Kapi`olani, Pali Momi, and Wilcox. (HPH, 2015). The new standardized process aimed for system wide implementation, but initial implementation took place at SMC due to its high volume of oral chemotherapy orders and low compliance with chemotherapy prescribing and administration policy. SMC is a fully integrated medical center with 159-beds located in Honolulu, Hawai`i and offers more than 32 medical specialties, including oncology

(HPH, 2015). SMC is currently accredited by the Commission on Cancer as a Community Cancer Care Center and passed reaccreditation requirements in 2015. In addition, SMC is fully accredited by the Joint Commission on the Accreditation of Healthcare Organizations.

At SMC, the 6th floor serves as the oncology unit, but many patients on oral chemotherapy regimens are admitted to other non-oncology units for acute issues. Baseline data, from June 2016 – December 2016, indicated that the 4th, and 5th floors have the highest volume of oral chemotherapy orders and served as the setting for the interventions along with the 6th floor oncology unit.

Oral chemotherapy sample. The sample for the project included all oral chemotherapy orders prescribed to inpatients on the 4th, 5th, and 6th, floors at SMC from October 2017 to December 2017. Inclusion criteria included all oral chemotherapy orders with the exception of megestrol. All intravenous, subcutaneous, or intermuscular chemotherapy was excluded from the project.

Recruitment and marketing plan. Frequent and effective communication is essential for successful implementation of a change in practice. There are many channels of communication that can be used to transmit the information within a social system. Rogers (2003) identifies two methods in which communication can be applied: mass media and interpersonal channels.

Mass media. Rogers (2003) explains that mass media can enable rapid communication to a large audience, create knowledge, spread information, and change weakly held attitudes. The mass media channels used for this project included e-mails and the SMC's hospital intranet communication. E-mail was utilized to initiate mass communication and provide information about the standardized oral chemotherapy prescription and administration process along with the

algorithm. Although e-mail generates the ability to reach a large audience, it does not itself provide the level of communication necessary for implementation of the project and was combined with interpersonal channels.

Interpersonal channels. Interpersonal channels of communication can be more effective than mass media in convincing individuals to change practices (Rogers, 2003). Due to possible resistance to a change of process for the prescription and administration of oral chemotherapy, face-to-face meetings were arranged to provide information about the new process and algorithm. Monthly face-to-face meetings were conducted with key stakeholders which include the Oncology Practice Council, nurse managers of the inpatient floors, and inpatient pharmacy.

Opinion leaders are effective in changing behaviors and facilitating the diffusion of innovation. These individuals are viewed as a respected source of influence, considered by colleagues as technically competent, and trusted to judge the fit between the innovation and the local situation (Titler, 2001). The opinion leader, Director of Oncology Service Line, was involved in developing the communication strategies to fit the culture of SMC. A series of face-to-face educational in-services were presented to key stakeholders, oral chemotherapy prescribers, clinical pharmacist, and all inpatient nursing managers.

Data Collection

Data Management Plan

A data management plan establishes how project data would be collected, managed, and analyzed while ensuring creditability. The following subsection will describe the data sources, collection procedures and plan for data analysis.

Data sources. Currently, the only data source for tracking oral chemotherapy orders is electronic drug orders from the pharmacy. Data elements that will would collected from the pharmacy are listed in Table 3.

Table 3

Data Source

Data Source	Elements
All oral chemotherapy orders pulled from pharmacy	1. Date ordered 2. Medication 3. Ordering provider and specialty 4. Nursing Unit 5. First dose administration 6. Verification user
SMART phrase	1. Nursing patient and staff teaching during first dose administration from chemotherapy-competent nurse

Data collection procedures. Data was collected monthly via the EMR system by a key stakeholder from the pharmacy and electronically transmitted in a Microsoft Excel file for evaluation. The data was aggregated without identifiers and securely exchanged to ensure confidentiality. Both baseline and implementation data were collected using the same method. At baseline, oral chemotherapy orders were abstracted once a month for 7 months (June 2016-December 2016) and post implementation records were abstracted once for three month beginning October 2017, with final data from December 2017.

Data analysis. Data was analyzed on a monthly basis and included all oral chemotherapy orders to determine if there was a change from the baseline. Specifically, all oral chemotherapy orders were analyzed to determine if 1) the appropriate specialty prescribed the oral chemotherapy order, 2) a chemotherapy-competent nurse administered the first does of oral chemotherapy and provided education to staff and patients documenting via SMART phrase.

Evaluation Plan

The evaluation design is an impact evaluation that uses an observational T1-T2 test to determine the impact of a new algorithm on the number of oral chemotherapy orders that comply with facility policy and ASCO/ONS guidelines. The evaluation measures the impact of the algorithm on prescriber specialty, first dose administration by a chemotherapy-competent nurse, and patient education. T1 will include baseline data from June 2016 – December 2016 and T2 will be January 2017 – December 2017. The following section will describe and operational definitions necessary for this analysis.

Additional Operational Definitions

1. Approved Oral Chemotherapy Prescriber: Licensed independent practitioner as determined by state law and the facility who prescribes chemotherapy and/or biotherapy (ONS, 2014).
2. Chemotherapy-competent Nurse: A nurse who has been trained to administer chemotherapy with evidence of completing the ONS chemotherapy and biotherapy certificate course, chemotherapy skills course, initial on-unit competency, and ongoing education as evidence by annual competencies. Documents first dose administration of oral chemotherapy patient and staff education with SMART phrase
3. SMART phrase: Standardized documenting method in the EMR.

Timeframe

Development of a project timeline is an essential part of coordinating an EB practice change. Initial stages of the project began in June 2016 and included team development and discussions with facility and site leadership. Implementation of the interventions began in

October 2017. Data collection for the implementation took place between October and December 2017 (see Appendix F).

Resources

Although program funding is often one of the most vital resources for the successful implementation of a program, this project did not require a financial outlay. The resources utilized were both time and human. The project required time from the Director of Oncology Services, OPA, nursing managers, and pharmacy staff to give input about developing and implementing the new process and to provide education and training on the new process. Additionally, time was necessary from the key stakeholders during the process of modifying the process and interpreting the results.

Human Subjects Considerations

The guiding principles of autonomy, non-malfeasance, beneficence, and justice were upheld when designing this quality improvement project. All data collected was in aggregate form, without identifiable information related to personnel. Vulnerable populations were not included; participants were not randomized; and all patients received the same standard of care. The project did not involve the administration of medical procedures; therefore, informed consent was unnecessary and was not collected. The principles of non-malfeasance and beneficence were upheld as the proposed interventions for standardizing the oral chemotherapy prescription and administration process included no additional patient and staff risk, outside of standard practice. The overarching goal of this project was to improve upon patient and staff safety, achieve the best possible patient outcomes, and ensure the rights, welfare, and greater benefit of all patients and staff who participated.

Limitations

Many limitations were identified despite efforts to minimize them. Time was a considerable factor as the project was only implemented and evaluated over a period of 3 months. Design limitations included variability in the practice setting and inability to control for variables and create constant conditions. There was a lack of high-level evidence guiding implementation selection, and the algorithm and chart audits utilized non-validated methods. Additionally, a small sample size limited the generalizability and applicability of the project.

Summary

This chapter presented a description of the practice change, sampling plan, data management plan, resources, and human subject considerations. The purpose of this project was to standardize the process for prescribing and administering oral chemotherapy that complies with facility policy and the ASCO/ONS Chemotherapy Administration standards in the inpatient setting at at SMC.

CHAPTER FOUR. RESULTS

Description of the Sample

Oral Chemotherapy Doses

The sample for the project was oral chemotherapy orders prescribed to inpatients on the 3rd, 4th, and 5th floors from October 2017 to December 2017. The sample size was 11 doses and the average was four per month (see Figure 3). At baseline from June 2016 to December 2016, the average number of doses was 13 per month. During the algorithm implementation from October 2017 to December 2017, the average monthly volume trended down and decreased 70 percent from baseline.

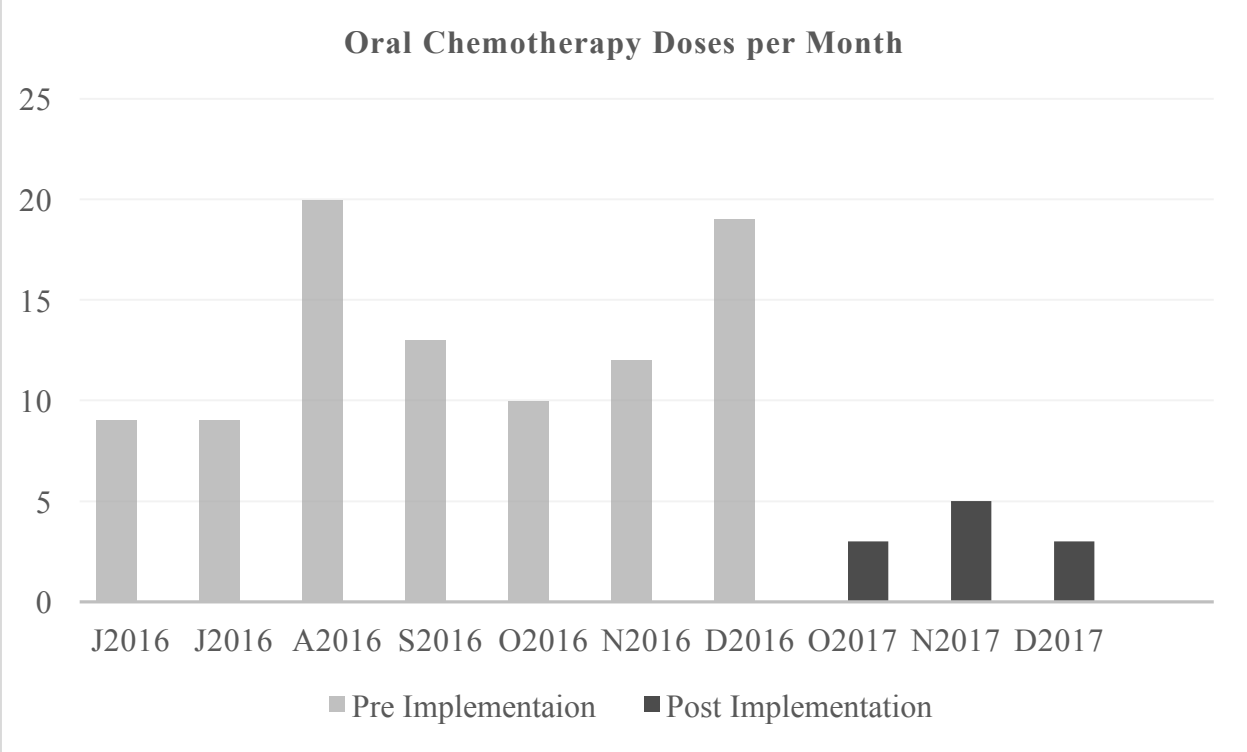


Figure 3. Oral Chemotherapy Doses per Month

Trend Analysis

The T1 and T2 impact evaluation measured the percentage change for the following measures at baseline and post implementation: (1) percentage of oral chemotherapy orders

prescribed by an appropriate specialty, (2) percentage of oral chemotherapy orders administered by a chemotherapy-competent nurse, and (3) percentage of patients who received oral chemotherapy education at first dose administration (see Table 4).

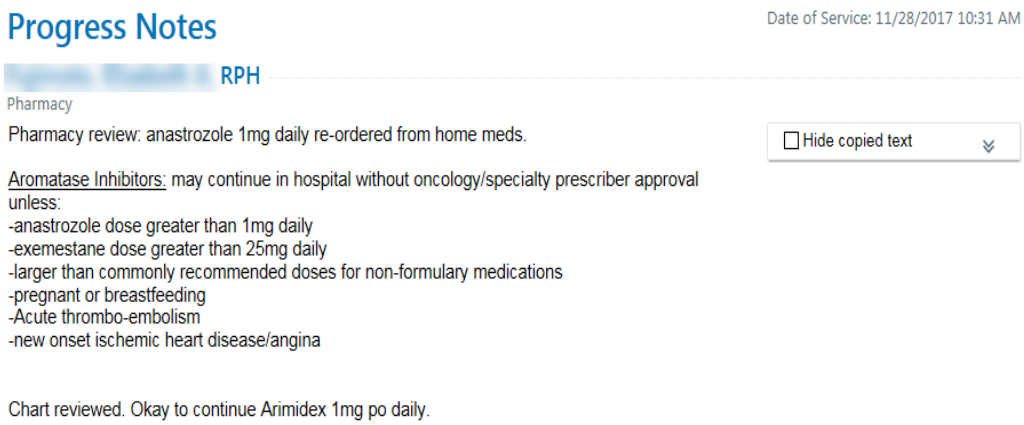
Table 4

T1-T2 Impact Evaluation: General Findings

	% Oral chemo prescribed by appropriate specialty	% Oral chemo administered by Chemo-competent RN	% Patients received oral chemo education
Baseline (T1)	7%	5%	9%
Comparison (T2)	64%	64%	55%
Change **Δ**	+57%	+59%	+46%

Oral Chemotherapy Prescriber

Based on feedback, the prescribing component of the algorithm was modified and delayed implementation (see Appendix G). Pharmacy staff recommended a prescribing carve out for hormonal agents since they are not categorized as hazardous drugs per the National Institute for Occupational Safety and Health (NIOSH). This modification categorized non-specialty prescribers as appropriate prescribers when ordering antiandrogens, aromatase inhibitors, and selective estrogen receptor modulators that meet specific criteria and must be screened by a pharmacist (see Appendix H). Pharmacy review and documentation of the carve out process during implementation was captured and is presented in Figure 4. After implementation of the updated algorithm with the hormonal carve out, 64% of orders were prescribed by an appropriate specialty prescriber compared to 7% at baseline (see Figure 5).



Progress Notes

Date of Service: 11/28/2017 10:31 AM

[redacted] RPH

Pharmacy

Pharmacy review: anastrozole 1mg daily re-ordered from home meds.

Hide copied text

Aromatase Inhibitors: may continue in hospital without oncology/specialty prescriber approval unless:
-anastrozole dose greater than 1mg daily
-exemestane dose greater than 25mg daily
-larger than commonly recommended doses for non-formulary medications
-pregnant or breastfeeding
-Acute thrombo-embolism
-new onset ischemic heart disease/angina

Chart reviewed. Okay to continue Arimidex 1mg po daily.

Figure 4. Pharmacy Progress Note for Oral Chemotherapy Review

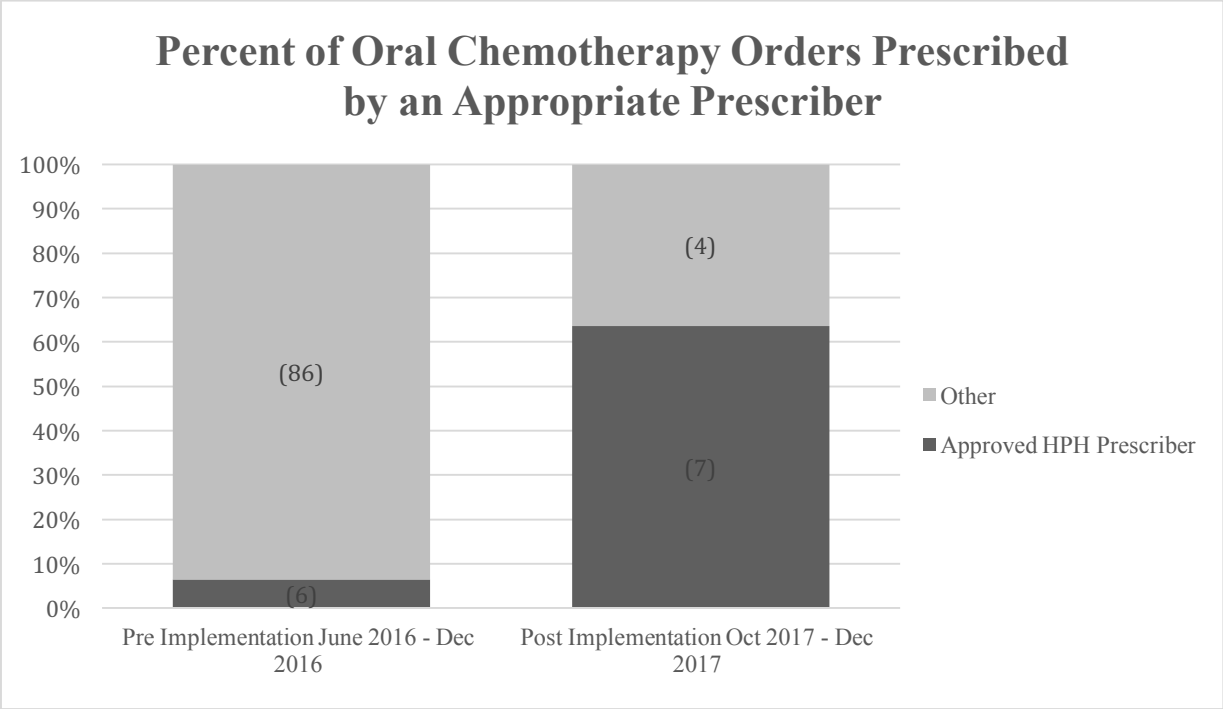


Figure 5. Percent of Oral Chemotherapy Prescribed by Appropriate Specialty with updated algorithm

Oral Chemotherapy Administration

The administration process did not undergo any changes during the implementation period. At baseline, 5% of oral chemotherapy orders were administered by a chemotherapy-

competent nurse. After implementation, 64% were administered by a chemotherapy competent nurse (see Figure 6).

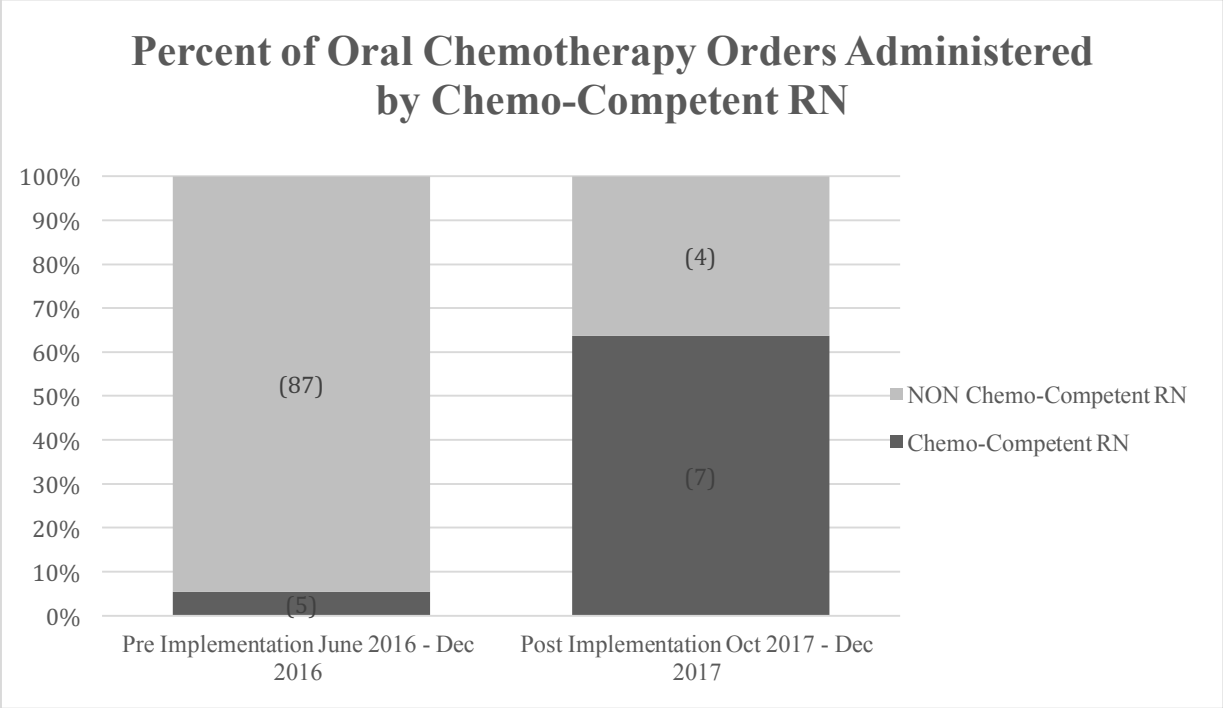


Figure 6. Percent of Oral Chemotherapy Orders Administered by a Chemotherapy-Competent Nurse

Patient Education

The patient education piece of the process was not modified also remained unchanged during the implementation period. At baseline, patient education was provided to 9% of patients. Post implementation, 55% of patients received education (see Figure 7). Documentation was reviewed related to three primary sources: the SMART phrase, the DAR (Data/Action/Response Note), and the Plan of Care. An example of the SMART phrase captured during chart review for documentation appears in Figure 8.

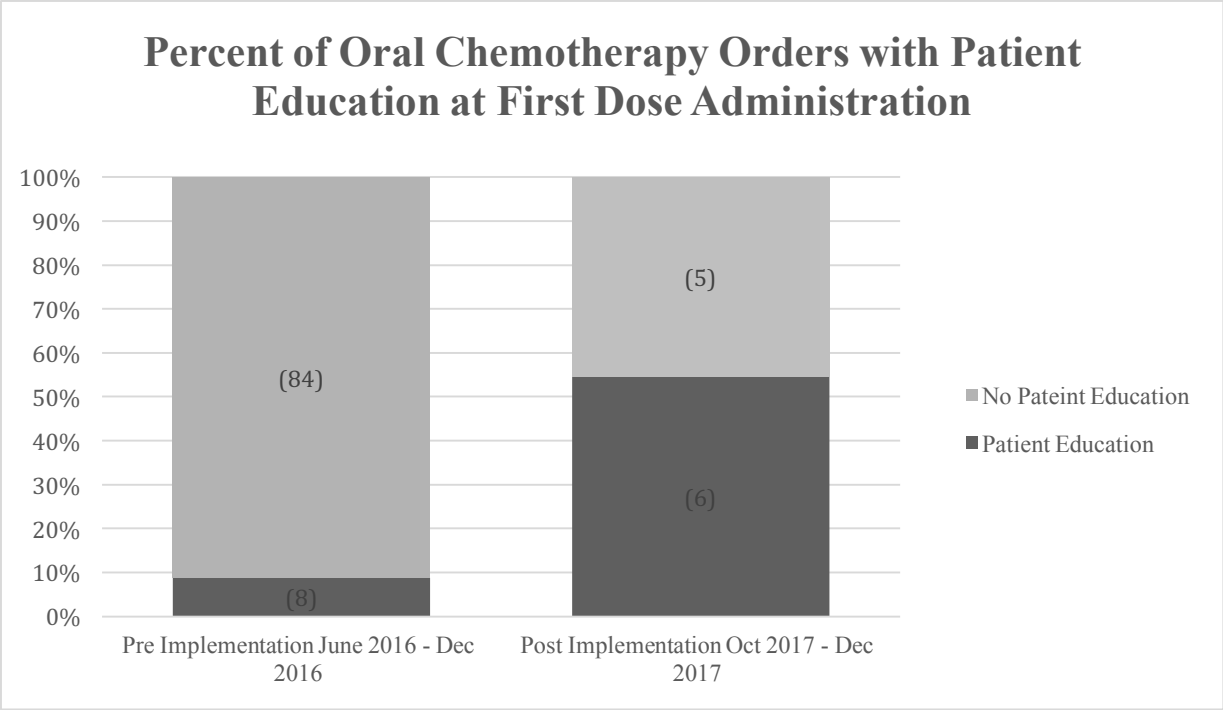


Figure 7. Percent of Oral Chemotherapy Orders and Patient Education

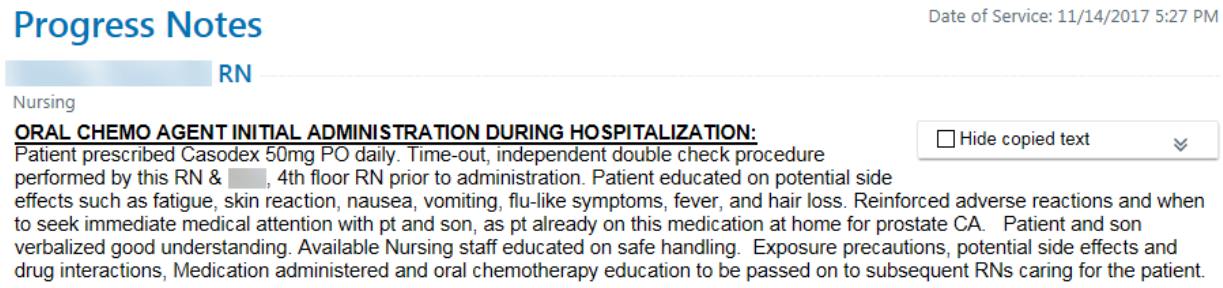


Figure 8. Oral Chemotherapy Patient Education SMART Phrase Documentation

Hospital Event Reports

At baseline there were no event reports related to oral chemotherapy. Integrating a chemotherapy-competent nurse into first dose administration led to two separate event reports. In one of the reports, an oral chemotherapy medication was ordered by a prescriber, dispensed by a pharmacist, but held at the bedside when the chemotherapy-competent nurse reviewed the order with the patient prior to administration and discovered that the patient was no longer on that medication. In the second event report, a chemotherapy-competent nurse discovered that a

patient required an oral chemotherapy medication, was able to verify with prescribing doctor from Louisiana, and ordered the medication.

Evolution of Project

Since this project served as a form of quality improvement, continuing assessment and modifications were anticipated throughout process. The project was evaluated and modified before and during the implementation phase based on feedback from hospitalists, pharmacy staff, and nursing mangers. The original implementation period was expected to begin in August 2017, but was delayed due to modifications to the process.

In the original algorithm (see Appendix B), before hospitalists prescribed an oral chemotherapy they would consult the original prescriber of the medication or a SMC specialty provider. Feedback from the hospitalist indicated the process for consulting a specialist is done by telephone and not electronically, thereby creating additional work. The feedback suggestion was that pharmacy should be involved in the process. Pharmacy was consulted and agreed to modify the process and review all oral chemotherapy orders. The algorithm was modified by adding the following steps:

- Hospitalist will enter a pharmacist consult to evaluate oral cytotoxic medication – but will not enter medication order.
- If consult received in the eve/night, pharmacist will leave for follow up the next day.
- 6^{th} floor pharmacist will follow up with provider and document brief note.
- If specialist is a provider outside of HPH, pharmacist will discuss with outside provider and document a note and discuss with hospitalist.
- If hospitalist does not feel comfortable with ordering, the hospitalist will be directed to contact outside specialist to discuss specific clinical situation.

- If oncology patient, OPA will be consulted to provide assessment /documentation of plan.
- Once order is entered, 6th floor charge will be notified to provide 1st dose administration, patient education, and documentation.

The updated algorithm was presented to the hospitalist group. While they were receptive to the new updated process, they asked for the following except for the following change:

- If the specialist is a provider outside of HPH, the pharmacist will discuss with the outside provider, document note, and order under the hospitalist if therapy continues.

The algorithm was further modified to eliminate this component. Instead the pharmacist would evaluate the medication but the specialty prescriber would be responsible for ordering the medication, not the hospitalist (see Appendix I). This version on the algorithm was implemented on October 1, 2017.

During the implementation, pharmacy suggested a prescribing carve out for hormonal agents (antiandrogens, aromatase inhibitors, selective estrogen receptor modulators) since they do not fall under the NIOSH 2016 Hazardous Drug List. The exception allows non-specialty prescribers to order selected hormonal drugs that meet criteria and are screened by a pharmacist to meet criteria (see Appendix G). The algorithm was modified a final time to reflect the new process (see Appendix H). There were no changes to the administration or education parts of the algorithm.

Near the end of the implementation period, the pharmacy captured three patient examples that highlighted some challenges and opportunities for additional modifications in (see Table 5).

Table 5

Patient Examples of Challenges for Oral Chemotherapy Prescription

Example	**Challenge**
Patient 1	Pt was admitted for surgery for colon cancer and takes mercaptopurine for crohns prescribed by Straub GI. Medication reordered on admission by surgery resident: **Day 1**: Pharmacist does not verify. Order left in queue. **Day 2**: Patients GI not working. Called on call GI. Did not want to order, deferred to Oncology. Patient has not seen outside oncologist yet and medication is not for oncology indication. Oncology declines to order. Order left in queue to attempt follow-up with patient's own GI next day. **Day 3**: Patients GI not working. Called GI again. Staff in clinic updated on situation. They follow-up with Dr. XX. Per Dr. XX, ok to hold medication for the next few days, resume upon discharge or when patient's GI is back in office (in 2 more days). Patient upset because the patient brought in own supply and wants to take it.
Patient 2	Pt admitted with respiratory issues. Takes Ofev (nintedanib) for pulmonary fibrosis order by Straub Pulmonary: **Day 1**: Pharmacist does not verify. Order left in queue. Admitting doctors note said he already consulted doctor 1. Tried to page doctor 1, page operator would not page doctor 1 because it's the weekend and doctor 2 is on call. Sent in basket to doctor 1 and doctor 2. No order entered. **Day 2**: Pharmacist discussed with Dr. YY, verified order in queue from attending and made a med note. Concerns that missed doses may have caused harm. Confusion regarding if this medication would fall under our protocol.
Patient 3	Patient admitted with polycythemia vera. Takes hydrea ordered by Straub Oncologist. **Day 1**: Pharmacist does not verify. Order left in queue. **Day 2**: Pharmacist speaks with Oncology PA. In baskets patient's oncologist to re-enter order. Oncology PA will also ask him to order. No order entered. **Day 3**: No order entered. Patient discharged.

Expected Outcomes versus Actual Outcomes

Table 6 outlines the expected versus actual outcomes in relation to the key aspects of the project. A description of facilitators and barriers will also be discussed.

Table 6

Expected Outcomes versus Actual Outcomes

	Expected outcomes	Actual outcomes
Timeline	• Implementation period Jul 2017 – Dec 2017 (6 months)	• Implementation period Oct 2017 – Dec 2017 (3 months)
Oral Chemotherapy Orders	• Monthly volume of oral chemotherapy would decrease from an average of 13 doses	• 70% decrease in oral chemotherapy orders, average 4 doses per month • Hospitalists now questioning appropriateness of medication and not unnecessarily continuing in acute setting
Prescription	• Increase in oral chemotherapy orders by appropriate specialty	• Integration of crave out for hormonal medications • 64% of orders prescribed by appropriate specialty • Increase in communication between prescriber and appropriate specialist
Administration	• Increase in number of first doses administered by a chemotherapy-competent nurse	• 64% of first doses were administered by chemotherapy-competent nurse • Four orders on 6th floor oncology unit • Three orders on non-oncology unit
Education	• Increase in number of patient who receive education by at first doses administration • SMART phase built October 2017	• 55% of patients received education at the first dose administration • SMART phase built December 2017 • SMART phase for standardize documentation used for one order • DAR documentation used for five orders

Facilitators

There were several facilitators identified for this project. Due to the collaboration necessary to address oral chemotherapy prescription and administration, an interdisciplinary approach was required for successful implementation. The Director of Oncology Services served as the key facilitator of the project objectives and ensured support from hospitalists, pharmacy, nursing, and oncology services. Pharmacy staff and nursing management were additional key facilitators of the project as they were at the center of the prescription and administration process and continually helped to modify and improve the process.

Barriers

A major barrier for implementation of this project was time as the implementation period was reduced from six to three months. It took additional time to modify the prescription process to ensure it was not impeding workflow for hospitalists, pharmacists, and nurses. The SMART phase was not available in the EMR until December 2017. More time might have allowed for a demonstration of increased use. Also, many of the initial interventions suggested for this project included interventions within the EMR, such as pop ups to alert that the medication is an oral chemotherapy, but limited time prevented extensive adjustments to the EMR system. The process was still evolving as of March 2018 and is expected to continue to evolve and improve.

Other barriers associated with data collection played a role. For example, the initial oral chemotherapy education data did not capture education that was within the DAR note, but individual chart review was able to confirm that education was given to patients. Another barrier was a lack of a method for tracking pharmacy interventions in the oral chemotherapy process. Anecdotal findings revealed interventions by pharmacists that resulted in oral chemotherapy

medications being held due to the pharmacy review. Currently, there is no way to quantify this in the results; however, moving forward pharmacy will be working on a tracking method.

Summary

This chapter described the results of the practice change, a comparison of expected versus actual outcomes, and facilitators and barriers that affected the project. Overall, the project objectives were met with an increase in standardizing the process for prescribing and administering oral chemotherapy that complies with facility policy and ASCO/ONS chemotherapy guideline standards.

CHAPTER 5. DISCUSSION

Interpretation of Findings

Oral Chemotherapy Prescription

Volume. The average monthly volume of oral chemotherapy orders significantly decreased during the implementation phase even though the overall volume for oncology services remained consistent. At baseline, the average number of doses was 13 per month. After implementation, the average decreased to four per month. The decline is thought to be attributed to educating the hospitalist staff about the oral chemotherapy prescribing policy and encouraging them to critically evaluate and question whether a medication should be continued in the acute inpatient setting. The data shows a significant decrease in orders beginning in October 2017. This might be attributed to the influence of two presentations about the project given to the hospitalist staff in September 2017 along with implementation of the algorithm. It was thought that an increase in communication between the original prescriber and hospitalist also contributed to the decline. Figure 9 captures EMR documentation communication with the original prescriber in which the urologist was contacted and verified the continuation in the inpatient setting. At baseline, during medication reconciliation, oral chemotherapy was being continued without questioning and often times despite the need to discontinue.

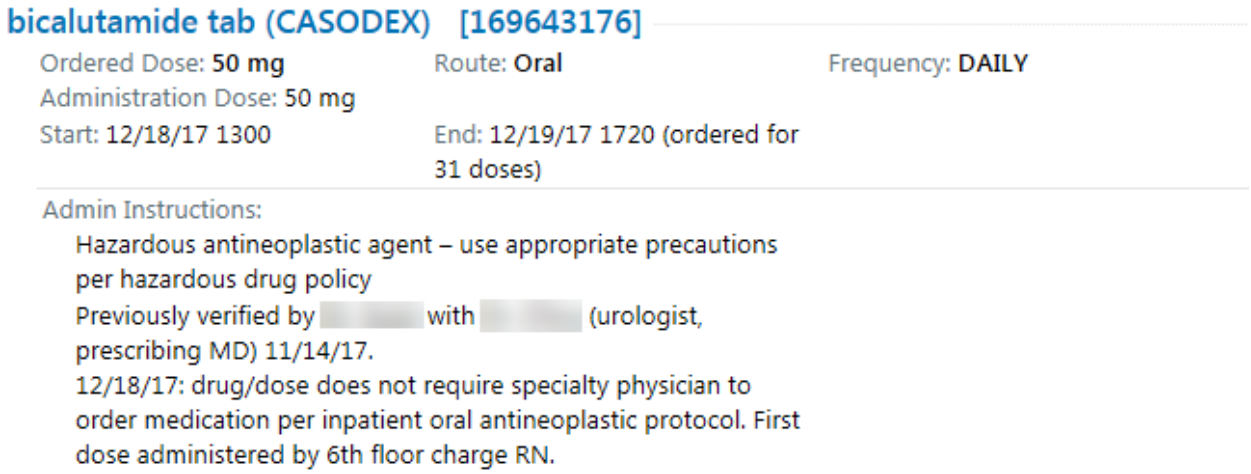


Figure 9. Oral Chemotherapy BPA alert

Pharmacy. Pharmacy collaboration was essential to the project and contributed to the positive outcomes of the process. The integration of the hormonal carve out into the algorithm had a positive impact and increased the percent of appropriate prescribing. Going forward, the hormonal carve out will continue as part of the process change.

Pharmacy leadership expressed the value of the project and its impact on improving pharmacy's internal process for screening oral chemotherapy orders, which was updated after the completion of the data collection (see Appendix J). In January 2018, pharmacy requested a Best Practice Advisory (BPA) alert in the EMR for order verification to prompt the pharmacist to review all oral chemotherapy orders (see Figure 10). On February 1, 2018 the BPA alert and process was implemented (see Appendix K).

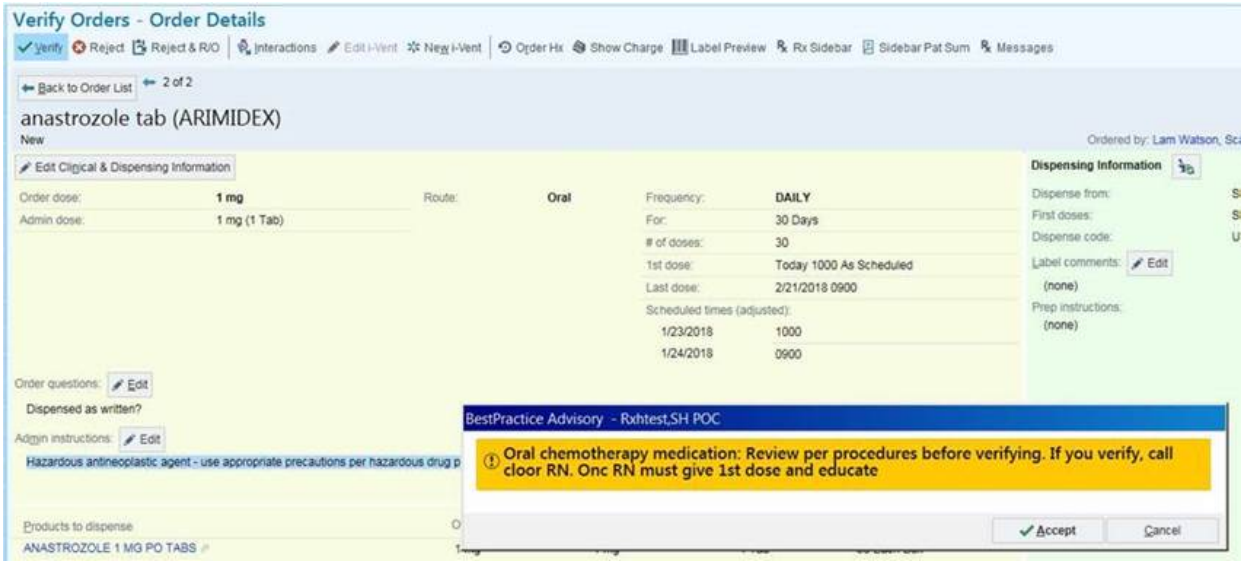


Figure 10. Oral Chemotherapy BPA alert

The three case study examples provided by pharmacy in Table 5 offered an opportunity to improve the process. Patients one and two were both prescribed oral chemotherapy for a non-oncology indication and would follow the process to have the appropriate specialty prescriber order the medication, in these cases gastrointestinal and pulmonary. These two examples highlight the need to educate the non-oncology specialty prescribers and ensure they are aware of the process change and expectations for ordering medications, that non-specialty prescribers are unapproved to order.

The project continues to develop even after the completion of the implementation period. In January 2018, it was suggested that all oral chemotherapy medications be delivered to the 6th West oncology floor. A yellow medication bin in the chemotherapy drawer would be labeled "ORAL CHEMO" to alert the nurses that there is a first dose to be administered on another floor to help to prevent the other floors from administering without a chemotherapy-competent nurse, the proper verification, and education. In response, pharmacy labeled all oral chemotherapy capsules and tablets with yellow stickers but the challenge will be to maintain this process since

hundreds of drugs are affected. Pharmacy will also label the outer bag to always say "hazardous" to match the label on the medication administration record (MAR). Additionally, pharmacy is trying to implement a first dose sticker and paper notification for oral chemotherapy. Nursing leadership will need to continue educating nurses on all units to review the MAR, look for stickers, and continue following the algorithm by contacting the the 6th floor nursing unit for first dose.

Oral Chemotherapy Administration

The project increased the number of oral chemotherapy orders administered by a chemotherapy-competent nurse and improved compliance with safety measures for patients receiving oral chemotherapy. There were two event reports directly related to administration that were reported by chemotherapy-competent nurses at the first dose administration. This demonstrates the awareness and critical thinking involved when adding a nurse trained in chemotherapy to the administration process. Integrating chemotherapy-competent nurses into the process not only improves safety but impacts nursing knowledge for non-oncology nurses. Chemotherapy-competent nurses provided nursing education on safe handling, exposure precautions, potential side effects, drug interactions, and adherence to policies and protocols.

Oral Chemotherapy Education

Patient education by nurses is required when administering oral chemotherapy. During project implementation, education was increasingly performed by nursing staff but was documented in a variety of ways. There were instances where oral chemotherapy education was not found on the Plan of Care but was identified during chart review in the DAR note. The SMART phase was expected to be available in October 2017 but was not built in the EMR until December so it was only utilized once. More education is needed to ensure nursing staff is aware

of the SMART phase tool, especially on the non-oncology units, and reinforcing its use and the importance of standardizing documentation.

Implications and Recommendations for Based on DNP Essentials

The eight DNP essentials are foundational skills that doctoral graduate nurses are expected to possess according to the American Association of Colleges of Nursing (2006). Table 7 outlines the foundational competencies in the development, implementation, and evaluation of the EB project.

Table 7

Implications and Recommendations Based on the DNP Essentials

DNP Essentials	Implications & Recommendations
ESSENTAL I: **Scientific Underpinnings for Practice**	1. Evidence based algorithm to standardize the oral chemotherapy prescription and administration process in the inpatient setting. 2. Iowa model of evidence based practice utilized as process framework.
ESSENTIAL II: **Organizational & Systems Leadership for QI & Economics**	1. Collaboration with leadership to create and sustain changes at the organizational levels. 1. 2. Expansion of standardize the oral chemotherapy process from site to system wide.
ESSENTIAL III: **Evidence-Based Practice/Translation Science**	1. Critically evaluated existing literature to determine and implement the best evidence for practice. 2. Designed and implement oral chemotherapy processes and evaluated outcomes of practice
ESSENTIAL IV: **Information Systems/Technology**	1. Literature review utilizing electronic databases. 2. SMART phase created for standardized nursing documentation 3. Requesting to build in EMR for order verification for pharmacy
ESSENTIAL V: **Health Care Policy & Ethics**	1. Analyzed HPH's policy process for future review and update of chemotherapy policy.

ESSENTIAL VI: **Inter-professional Collaboration**	1. Communication between nursing, pharmacy, physicians, and leadership related to oral chemotherapy prescription and administration in the inpatient setting. 2. Collaboration with pharmacy, nursing, and physicians to modify algorithm process.
ESSENTIAL VII: **Prevention and Population Health**	1. Standardized oral chemotherapy process addressed risk reduction of inappropriate medication continuation in the inpatient setting 2. Staff risk reduction addressed for improper handling of hazardous medication.
ESSENTIAL VIII: **Advanced Nursing Practice & Education**	1. Designed, implemented, and evaluated standardized process for oral chemotherapy prescription and administration.

Plans for Dissemination and Sustainment

Dissemination of the project results will be shared though multiple channels. First, the project will be defended at the University of Hawai`i at Mānoa. Organizational dissemination of results will be shared onsite with project stakeholders involved in the process. The results of the project will be presented to the HPH Cancer Committee as a quality improvement project. If the project receives approval by the Cancer Committee, it be implemented throughout the HPH system providing ongoing sustainment. Additionally, a manuscript will be prepared for submission to a peer-reviewed nursing journal as the process has potential for adoption in other facilities.

Summary

In conclusion, this EB project to standardize oral chemotherapy prescription and administration in the inpatient setting improved the overall process. Results revealed project objectives met with an increase in prescribing and administering oral chemotherapy that complies with facility policy, and ASCO/ONS Chemotherapy. Implementing the algorithm

decreased the volume of orders, increased the number prescribed by an appropriate specialty, increased the number administered by a chemotherapy-competent nurse, and increased the number of patients that received education. The process continues to improve and evolve with input from key stakeholders. The project will be presented to the HPH Cancer Committee for consideration of system wide adoption to deliver quality care to patients.

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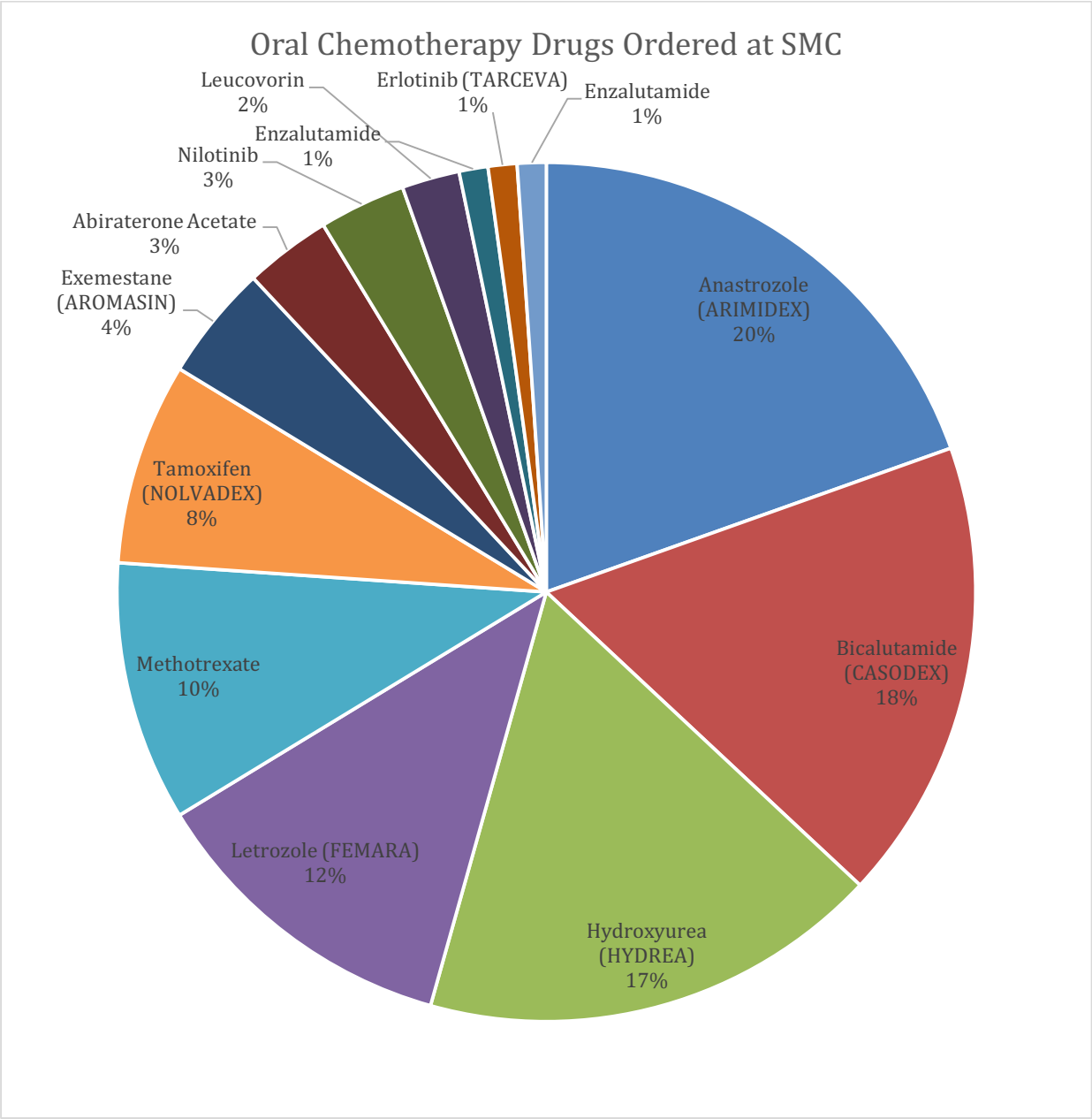
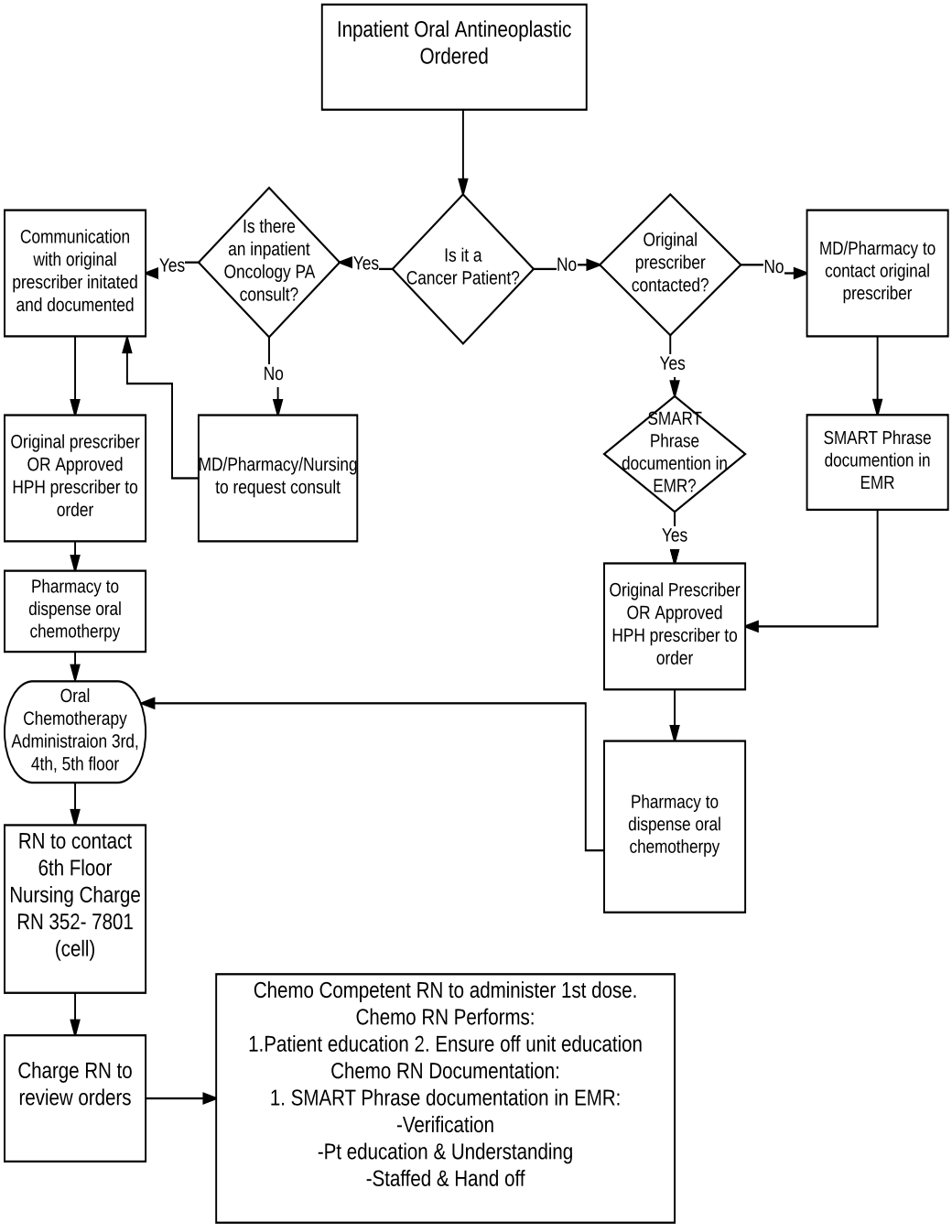
Appendix A

Inpatient Oral Antineoplastic Medications Prescribed June 2016- December 2016



Appendix B

Inpatient Oral Antineoplastic Prescribing and Administering Algorithm (Version 1)



Appendix C

Nursing SMART Phrase Documentation for Oral Chemotherapy

Patient prescribed ___(Oral Chemo)____. Time-out, independent double check procedure performed by ____(Autofill with RN name)_____ & _____(floor RN)_____ prior to administration. Patient educated on potential side effects such as fatigue, skin reaction, nausea, vomiting, flu-like symptoms, fever, and hair loss. Educated on symptoms of adverse reactions and when to seek immediate medical attention. Patient verbalized understanding. Available Nursing staff educated on safe handling, exposure precautions, potential side effects and drug interactions. Medication administered and oral chemotherapy education to be passed on to subsequent RNs caring for the patient.

Appendix D

Hawai`i Pacific Health Chemotherapy Prescribing and Administration Policy

A. Prescribing:

1. Oncologist will have the knowledge which has been provided through the documented training program, that includes but is not limited to the following: chemotherapy pharmacokinetics; the side effect profiles of chemotherapeutics agents and appropriate treatments; appropriate routes of administration; use of personal protective equipment; appropriate disposal. In addition, oncologist who prescribe chemotherapy shall have been trained as part of an accredited fellowship or equivalent in the specific skills required to administer chemotherapy. Those so credentialed will be listed.
2. Non-Oncologist will be allowed to prescribe anti-neoplastic agents only within their specialty and scope of practice (HPH, 2015).

Appendix E

American Society of Clinical Oncology and the Oncology Nursing Society Chemotherapy Administration Standards (Selected Excerpts)

ASCO/ONS guidelines section 1.1. The health care setting has a policy to document the qualifications of clinical staff who order, prepare, and administer chemotherapy and documents:

1. Description of initial education (1.1.1).
2. Description of at least annual ongoing continuing education requirements (1.1.2).
3. Description of credentialing process and how credentialing is documented (1.1.3).
4. The health care setting uses a comprehensive education for initial and ongoing education requirements for all staff who prepare and administer chemotherapy (1.1.4).

The ASCO/ONS guidelines section 2.3. Patients are provided with verbal and written or electronic information as part of an education process before the first administration of treatment of each treatment plan. The content of this educational material will be documented. Educational information includes the following at a minimum:

1. Patient diagnosis (2.3.1).
2. Treatment objectives (2.3.2).
3. Planned duration of treatment and schedule (2.3.3).
4. Potential long-term and short term side effects of therapy (2.3.4).
5. Symptoms or adverse effects that require the patient to contact the healthcare facility (2.3.5).
6. Symptoms of events that require immediate discontinuation or oral chemotherapy (2.3.6).
7. Procedures for handling medications in the home (2.3.7).

8. Procedures for handling body secretions and waste in the home (2.3.8).

All of the above standards are ASCO/ONS guidelines unless otherwise indicated (Neuss et al., 2017).

ASCO/ONS guidelines sections 3.3. Identify the steps for proper verification prior to dispensing and administering:

1. Orders for chemotherapy are signed by approved, licensed independent practitioners who are determined to be qualified by the health care facility (3.3).

2. A licensed pharmacist verifies all orders before administration or dispensing of chemotherapy (3.10).

3. A second person- a practitioner approved by health care facility to prepare or administer chemotherapy - performs three independent verifications (3.11).

4. Before preparation, a second person - practitioner approved by the healthcare facility to prepare or administer chemotherapy - independently verifies (3.11.1).

Appendix F

Timeline

Task	2017									2018				
	A	M	J	J	A	S	O	N	D	J	F	M	A	M
Engage Staff														
Project Approval														
Submit Ch 1-3 to Project Chair														
Submit Ch. 1-3 to committee														
Proposal Defense														
Ongoing Education: MD, PA, RN, PharmD														
Briefing Key Leaders & Staff														
Develop Data Base														
Intervention: Implement at SMC (10/1/2017)														
Collect Data														
Enter Data														
Analyze Data														
Interpret Data														
Final defense (3/16/2018)														
Graduation														
Prepare & Submit Dissemination Findings														

Appendix G

SMC Pharmacy Hormonal Exclusion Process

Oral Antineoplastic Cytotoxic Chemotherapy Process

Straub Medical Center oral antineoplastic cytotoxic chemotherapy process requires the oncologist or specialist review prior to continuation of therapy in the hospital

Hawai‘i Pacific Health categorizes hazardous drugs into three categories per NIOSH:
1. Hazardous cytotoxic
2. Hazardous non-cytotoxic
3. Reproductive risk

At this time, the oral chemotherapy process applies only to hazardous cytotoxic antineoplastic agents.

Pharmacists will refer to the HPH Hazardous Drug List and/or the NIOSH 2016 Hazardous Drug List (posted on the Pharmacy intranet) to categorize the oral agent

- If the oral medication was recently approved by the FDA, the pharmacist will refer to UptoDate (Lexicomp) and AHFS (links available on the Pharmacy Intranet)

- If categorized as “antineoplastic” or AHFS category 10:00 Antineoplastic, the oral agent will follow the Oral Antineoplastic Chemotherapy workflow http://ahfs.ashp.org/drug-assignments.aspx

Oral Hormonal Agents: Guidelines

Hormonal agents (Antiandrogens, Aromatase Inhibitors, Selective Estrogen Receptor Modulators) will be excluded from the oral chemotherapy physician (oncologist or specialist) approval process with the exceptions below.

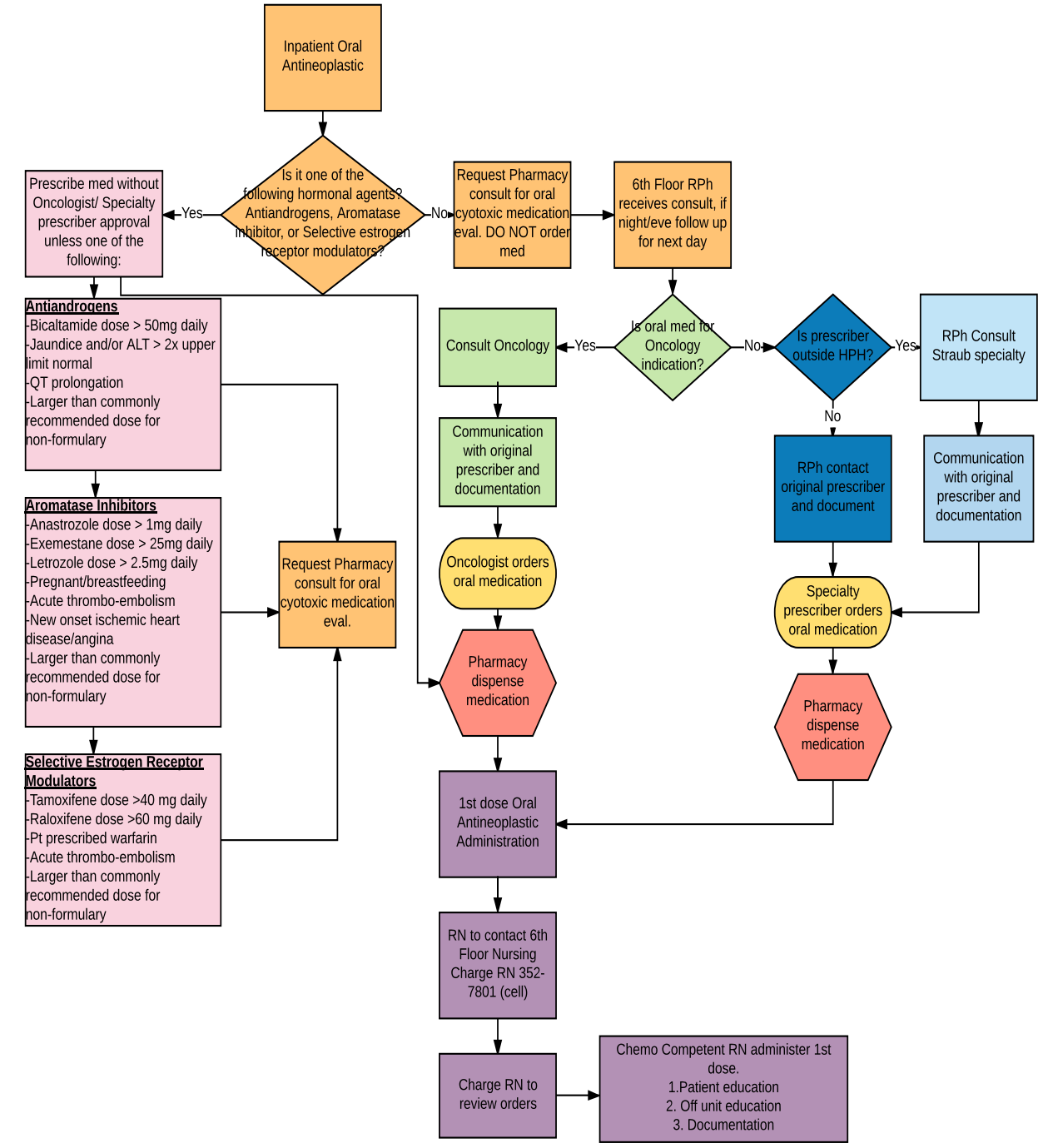
- The pharmacist will screen for criteria and follow the oral chemotherapy workflow process
- No change to the oral chemotherapy medication administration process and notification to 6th floor RN

Class	Criteria
Antiandrogens	May continue in hospital without oncologist/specialty prescriber approval unless: -Bicalutamide dose greater than 50mg daily • Larger than commonly recommended doses for non-formulary medications • Jaundice and/or ALT greater than 2 times the upper limit of normal • QT prolongation
Aromatase Inhibitors	May continue in hospital without oncology/specialty prescriber approval unless: -Anastrozole dose greater than 1mg daily -Exemestane dose greater than 25mg daily

	-Letrozole doses greater than 2.5mg daily • Larger than commonly recommended doses for non-formulary medications • Pregnant or breastfeeding • Acute thrombo-embolism • New onset ischemic heart disease/angina
Selective Estrogen Receptor Modulators	May continue in hospital without oncology/specialty prescriber approval unless: -Tamoxifene dose greater than 40mg daily -Raloxifene dose greater than 60mg daily • Patient prescribed warfarin • Acute thrombo-embolism • Larger than commonly recommended doses for non-formulary medications

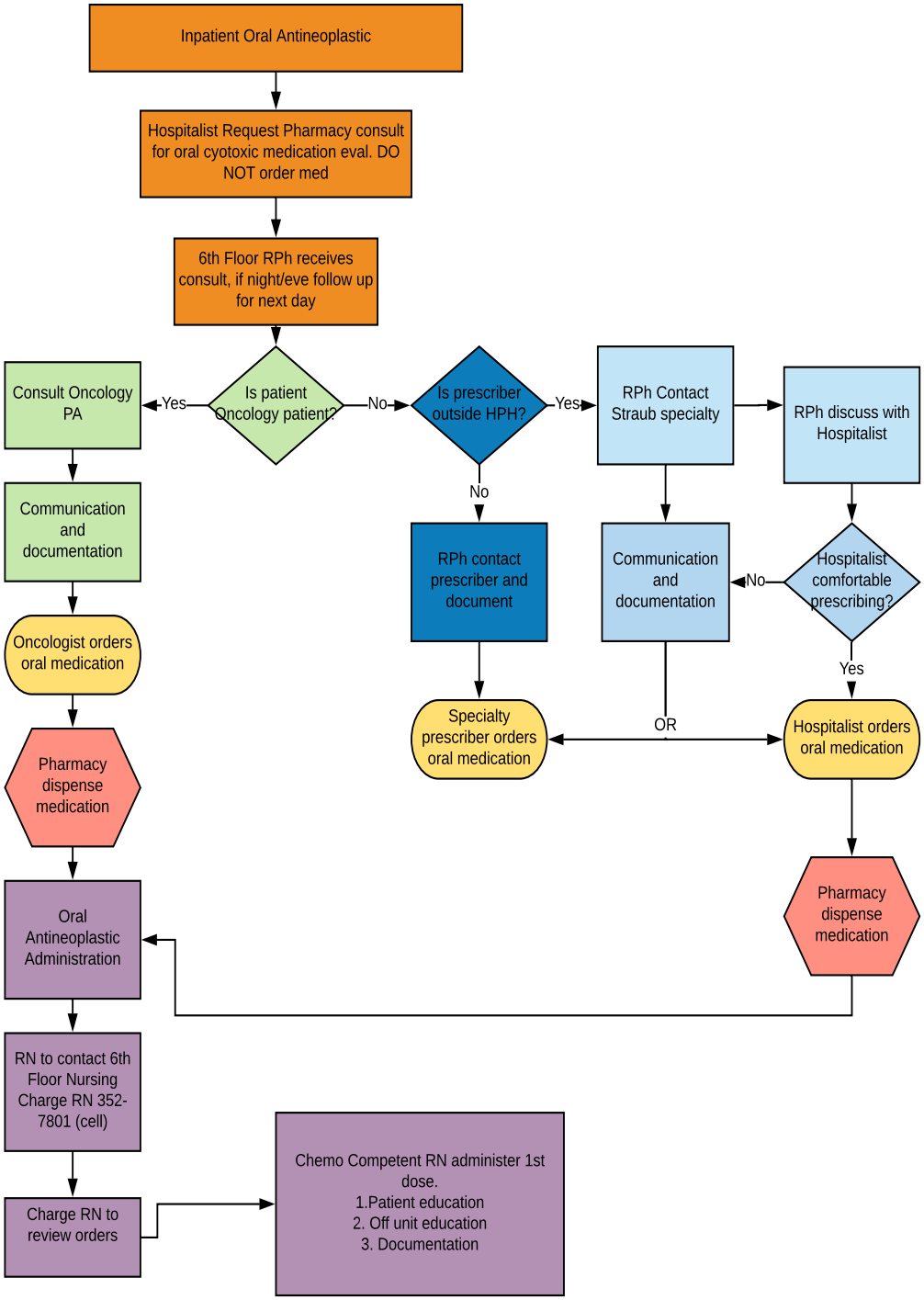
Appendix H

Updated Algorithm with Hormonal Carve Out (Final Version)



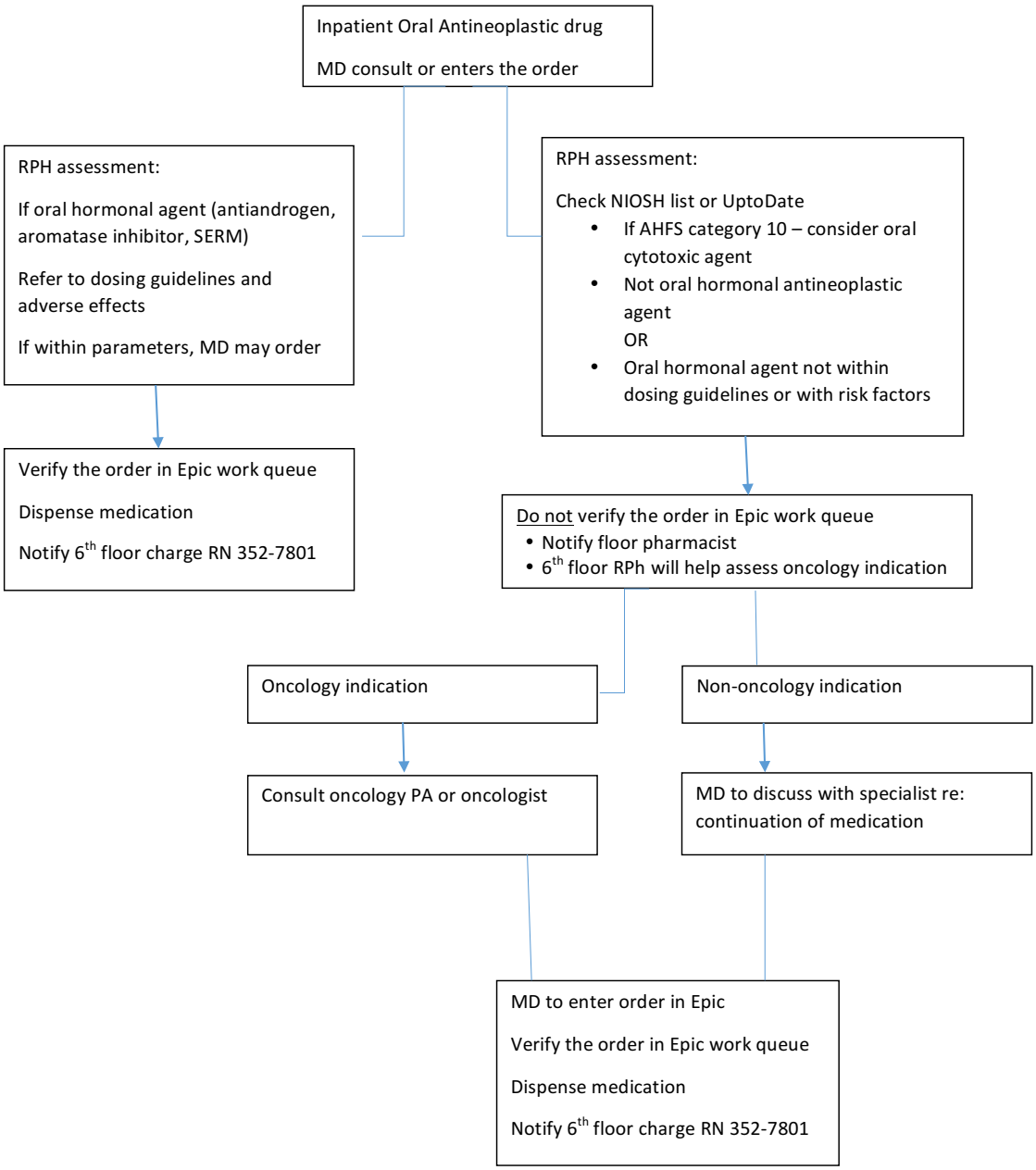
Appendix I

Updated Algorithm with Pharmacy Review (Version 2)



Appendix J

SMC Pharmacy Internal Oral Chemotherapy Process



Appendix K

Oral Chemotherapy EMR BPA Process

- A BPA alert will fire when the pharmacist verifies an oral antineoplastic order as a reminder (AHFS class 10.00 - antineoplastic agents).
- This alert should not fire for non-cytotoxic hazardous or reproductive risk hazardous drugs.
- The BPA should trigger the pharmacist to verify the proper oral chemotherapy procedures (posted on pharmacy intranet).
- If hormonal agent: review carve out guidelines - verify order if within guidelines, then notify the nurse that 6th chemotherapy-competent nurse must administer 1st dose.
- If oral cytotoxic drug - leave in work queue with follow up for floor pharmacist.
- All oral cytotoxic medication tablet/capsules should be labeled with "chemotherapy" sticker as well as a sticker on the outer bag.
- Floor pharmacist assisting with facilitating, clarifying, and communicating oral chemo process will document short note in EMR record. Working on developing a note template to communicate with all providers.