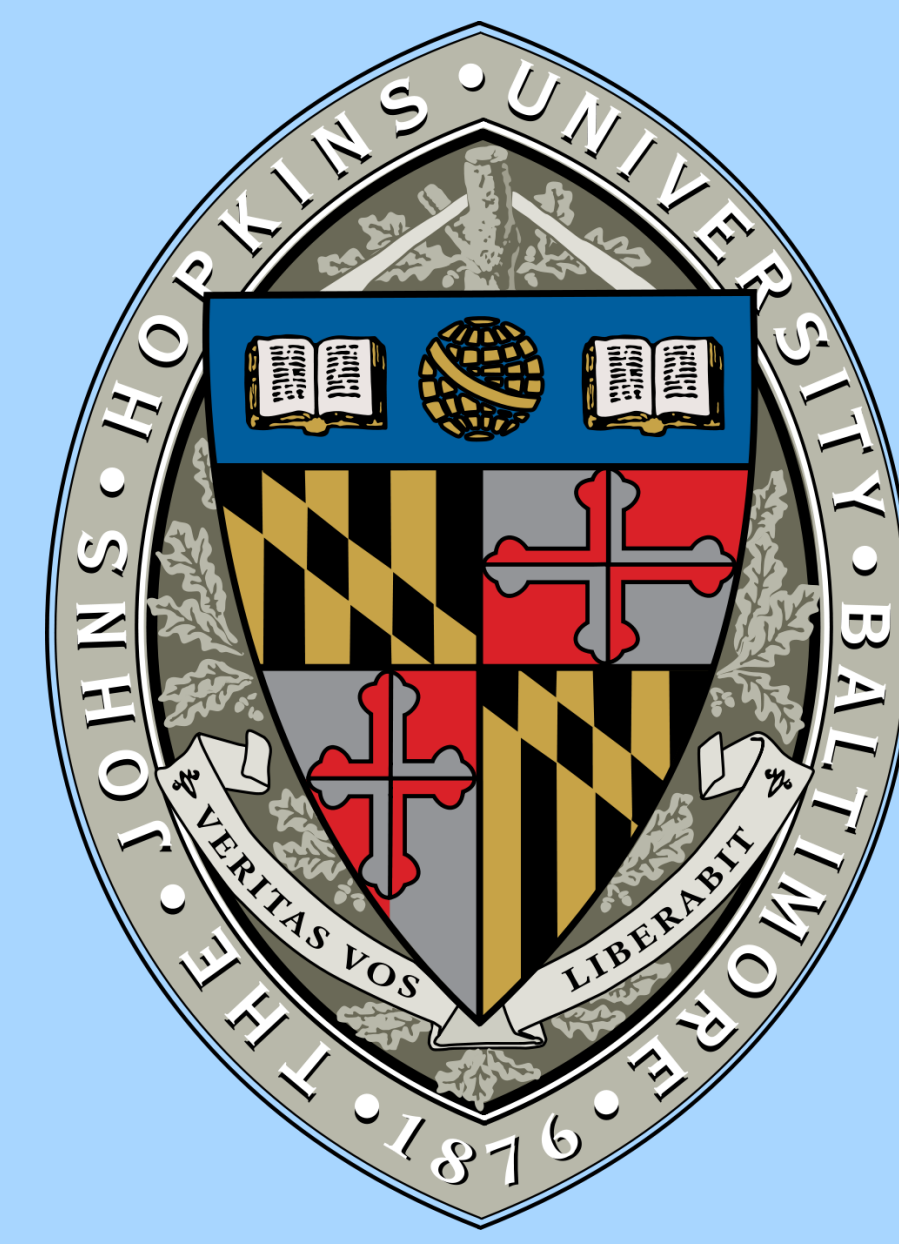


Oral Anticancer Medication Patient Safety Project



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1 Background

- The use of oral anticancer medications has dramatically risen over the past few years.
- Patients receiving IV chemotherapy are closely monitored for adverse effects, efficacy, and adherence. Nurses provide chemotherapy double check at the time of administration; this does not occur with patients on oral anticancer agents who are self administering their medications.
- Patients on oral anticancer medications must practice the same level of adherence as supervised IV chemotherapy regimens. This includes and is not limited to taking the medication at the right time, taking the right dose, promptly reporting toxicities, safe handling of the medications, and knowing what to do if a dose is missed.
- Patients perceive oral anticancer medications as convenient with decreased adverse effects but oral anticancer regimens are often complex and are not free from toxicities.
- Risks of nonadherence increases when a patient is on oral anticancer medication and can lead to adverse consequences that can affect therapeutic outcomes and patient safety.
- The July 17, 2014 ISMP Medication Safety Alert describes the death of a patient due to oral chemotherapy overdose and is indicative of the need for more attention and efforts in ensuring patient safety for those on oral anticancer medication.
- The 2013 ONS/ASCO Chemotherapy Administration Safety Standards updated their guidelines to address the use of oral anticancer medications, including patient education on storage, handling, preparation, administration, and disposal of oral anticancer medications

2 Methods

- Conducted a literature review on oral anticancer adherence and patient education which showed that patients receiving oral anticancer medications have more responsibility and that a collaborative communication effort between patients and health care providers best promotes adherence. Additionally, providing education and repeated teaching to patients on oral anticancer medications improves patient safety.
- Developed educational materials to meet the needs of patients receiving oral anticancer medications in accordance with the 2013 ONS/ASCO standards.
- Incorporated suggested revisions by the members of the oral anticancer patient safety committee, patient education committee, and CUSP team at the Sidney Kimmel Cancer Center to the patient education materials.
- Reviewed and proposed changes to the Johns Hopkins chemotherapy, education and medication administration policies to meet the 2013 ONS/ASCO standards.
- Conducted a medical review for eight different oncology providers to analyze how they document monitoring/adherence for patients on oral anticancer medications.

Figure 1. Oral Anticancer Medicine Fact Sheet

The Johns Hopkins Hospital Patient Information		Original Date: 1/31/15
Oral Anticancer Medicine		Chemistry Revised/Reviewed
What are oral anticancer medicines?	Oral anticancer medicines work like IV chemotherapy. They slow or stop the growth of cancer cells or directly kill cancer cells. They can be in the form of a tablet, capsule, or liquid.	
What tests need to be done?	Blood tests and radiology scans may be done before starting and throughout the treatment. This will allow your care team to check how your body and the cancer are responding to the oral anticancer treatment.	
What should I expect with an oral anticancer medicine?	Before you start oral anticancer medicine be sure that your health care team answers all of your questions. Some patients find it helpful to make a list of questions and bring them to their visit with the care team. Even though you will take oral anticancer medicines at home, you will still need to see your health care team.	
What are safety measures that I have to follow with oral anticancer medicine?	You should never crush tablets or empty capsules before taking them. Do not dissolve your medicine in liquids unless told to do so. Pregnant women, children, and pets should not touch your medicine and you should store it where children and pets cannot reach. Your body waste and fluids, such as urine, stool, vomit, blood, sweat, semen and vaginal fluids, may contain some of the medicine and it could be harmful to others. You should always separately wash items that have been soiled with body fluids and close the toilet lid and flush twice every time you go to the bathroom. Be sure to wear gloves when handling and washing the items. If you have unused medicine, you can usually bring it to your doctor or pharmacist for safe disposal. Do not throw it away in the trash or by flushing it down the toilet.	
What are possible side effects of oral anticancer medicine?	Side effects can vary depending on the drug and the patient. Your health care team will give you an idea of what to expect, however it is important to contact them if you feel ill. Telling your health care team about side effects as soon as they happen can help make sure that the problem does not become dangerous. You should make sure that you have your team's phone number handy at all times.	
References / Resources	http://www.cancer.org/treatment/treatmentsandsideeffects/treatmentpegs/chemotherapy/oral-chemotherapy Microencodes	

3 Results

- Developed a general oral anticancer brochure, fact sheet and complimentary patient education video which describes what oral anticancer medications are, how to safely handle them, and how to manage side effects (see Figure 1. below).
- Hopkins chemotherapy policies do not address three guidelines that are outlined in the 2013 ASCO/ONS guidelines (see Table 1. below).
- Oncology attendings are not consistently documenting patient education, monitoring, and adherence for patients on oral anticancer medications in their treatment notes (see Table 2. below).
- Location of documentation of patient education, monitoring, and adherence varies between attendings and is not standardized (see Table 2. below).

Table 1. Hopkins Chemotherapy Policy Compared to ASCO/ONS Standards

ASCO/ONS Standard	Hopkins Policy	Reference Location	Comments
2E: Documentation of patient comprehension of chemotherapy regimen	Patient and family education is documented in the medical record using worksheets or note	Chemotherapy: Prescribing, Dispensing, and Administering, pg. 9, section C	Suggested revision is to include another section explicitly addressing patient education for oral anticancer
2H: Documentation of treatment plan includes the frequency of office visits and monitoring for oral chemo	Treatment notes will include the indication for chemotherapy, the agent, dose basis, schedule, and anticipated duration of treatment	Chemotherapy: Prescribing, Dispensing, and Administering, pg. 2 section B	Revise policy to include "oral anticancer" and the frequency of visits and monitoring
2I: Documentation of an assessment of patient's ability to obtain drug and administer it according to plan as well as plan to address any identified issues	NOT ADDRESSED	Chemotherapy: Prescribing, Dispensing, and Administering, pg. 2 section Aa	Revise the "Responsibility of Authorized Prescribers" section to include this standard in the treatment plan, not prescriber.
9: Documentation of new orders or changes to orders for oral chemotherapy, including changes to regimen and dose adjustment communication to patient	An additional treatment plan note is required for changes in the original treatment plan	Chemotherapy: Prescribing, Dispensing, and Administering, pg. 2 section Aa	Revise section to include "oral anticancer agents" and communication of dose adjustment to patient
12A: Complete prescriptions for oral chemotherapy includes....	NOT ADDRESSED	Chemotherapy: Prescribing, Dispensing, and Administering, pg. 4 section A.	Revise prescribing section guidelines for chemotherapy with separate guidelines for oral anticancer
13: Order for parenteral/oral chemotherapy are written with a time limitation to ensure appropriate evaluation at predetermined intervals.	Orders for multiple chemotherapy regimens are written for one cycle at a time	Chemotherapy: Prescribing, Dispensing, and Administering, pg. 4 section A2.	Revise section to include oral anticancer agents
14: Institution maintains procedures for communicating discontinuation of oral chemotherapy, including patient education of time to stop and disposal of remaining medication	NOT ADDRESSED	Chemotherapy: Prescribing, Dispensing, and Administering, pg. 5 section Bc and "Documentation" section D.	Disposal guidelines revisions should include instructions of how to dispose of remaining oral anticancer agents, the modification forms for discontinuing oral anticancer or use a prescriber order? Revision should also include documentation of patient education for discontinuing oral anticancer.
20A: Written or electronic patient education materials are provided before or at the time of prescription of oral anticancer medication	Patients and families will receive education related to their illness, treatment, etc.	Multidisciplinary Patient Education Standard, pg. 1, objective A and pg. 5 section B.	Regimen standards do not specify when educational materials regarding medication are provided. Patient education is not included in the chemotherapy policy at all.
25: Institution maintains written policy/procedure for assessment of patient adherence to oral anticancer medication	The frequency and intensity of monitoring shall be based on the condition of the patient and the specific properties of the medication	Medication Administration Management pg. 7 Section 10.	"Adherence/monitoring" for oral anticancer medication. Suggested revision would be to include a "Monitoring" section in the Chemotherapy policy
35: Institution maintains plan for ongoing and regimen-specific assessment of each patient's oral anticancer medication adherence and toxicity	The frequency and intensity of monitoring shall be based on the condition of the patient and the specific properties of the medication.	Medication Administration Management pg. 7 Section 10.	Include specific plan for monitoring/adherence and toxicity assessment in the proposed "Monitoring" section of the chemotherapy policy

Key
 Pink: Documentation
 Blue: Prescription
 Peach: Patient Education
 Purple: Adherence/Monitoring

Table 2. Treatment Note Documentation Audit for Patients on Oral Anticancer Medication

Provider	Chemotherapy Note Documented?	Location	Common Oral Anticancer Agent	Patient Education	Monitoring	Adherence	Comments
A.D., MD	Sometimes	Assessment/Plan	Ibrutinib	Occasionally Addressed	Occasionally Addressed	Occasionally Addressed	Documentation of adherence only. Issues arise (e.g. pt. not taking or taking incorrectly) but not documented. 1/2 pt charts reviewed had chemo tx notes. A lot of 2nd opinion patients that come in already on treatment. Monitoring-office. Suggested revision would be to include a "Monitoring" section in the Chemotherapy policy
D.A., MD	No	Assessment/Plan	Tamoxifen	Occasionally Addressed	Occasionally Addressed	Not Addressed	Documentation of adherence only. Issues arise (e.g. pt. not taking or taking incorrectly) but not documented. 1/2 pt charts reviewed had chemo tx notes.
F.D., MD	Sometimes	Impression/Plan and Interventions	Everolimus, Eribulin, Sunitinib	Not Addressed	Occasionally Addressed	Not Addressed	Addressed toxicity checks through clinic visit and labs and addressed in Interventions. 1/2 pt charts reviewed had chemo tx notes. Changed to plan from 4 table/days and NO documentation of patient education/adherence.
K.G., MD	Sometimes	Assessment/Plan	Brukinib, Etoposide	Not Addressed	Not Addressed	Not Addressed	1/2 pt charts reviewed had chemo tx notes. List of med not complete with notes. Specifics in plan missing how medication should be taken. SE, monitoring through visits and labs, and how pt will tolerate medication. 1/2 pt charts reviewed had chemo tx notes.
R.M., MD	Sometimes	Assessment/Plan	Ibrutinib	Occasionally Addressed	Occasionally Addressed	Not Addressed	Documentation of adherence only. Issues arise (e.g. pt. not taking or taking incorrectly) but not documented. 1/2 pt charts reviewed had chemo tx notes.
*S., MD	Sometimes	Assessment/Plan, Internal Hx, Problem/Dx	Ibrutinib	Occasionally Addressed	Occasionally Addressed	Not Addressed	Documentation of adherence only. Issues arise (e.g. pt. not taking or taking incorrectly) but not documented. 1/2 pt charts reviewed had chemo tx notes.
*A.G., CRNP	No	Internal Hx, Problem/Dx	Ibrutinib	Addressed	Addressed	Not Addressed	Documentation of adherence only. Issues arise (e.g. pt. not taking or taking incorrectly) but not documented. 1/2 pt charts reviewed had chemo tx notes.
*T.J., RN	No	N/A	Ibrutinib	Addressed	Addressed	Partially Addressed	Documentation when pt presents for toxicities and monitoring SE. Also when pt calls medication (time of day and when to take, instructions/education are given. Documents "understanding"

4 Conclusions

- As the number of oral anticancer medications rise, cancer centers need to ensure patient safety and quality of care through patient education, side effects and efficacy monitoring, and adherence.
- The Oral Anticancer Patient Safety Committee at Johns Hopkins has taken the initiative to address the 2013 ASCO/ONS guidelines in regards to patient education and documentation for oral anticancer medications.
- As an interdisciplinary team, the committee has developed and implemented additional patient education resources for oral anticancer medications. However, the committee needs to continue to work to meet the documentation and monitoring guidelines outlined by ASCO/ONS.

5 Future Directions

- Develop additional patient education brochures, fact sheets, etc. for more specific oral anticancer medications.
- Update Hopkins' Chemotherapy Policy to address oral anticancer medication administration and documentation as outlined by the 2013 ASCO/ONS updated standards.
- Standardize treatment notes so that patient education, monitoring, and adherence are all documented in the same location.

6 References

Bosley, C. (2012). What Affects Patient Adherence to Oral Chemotherapy. ONS Connect. Retrieved from <http://connect.ons.org/issue/april-2012/a-closer-look/what-affects-patient-adherence-to-oral-chemotherapy>.

Institute for Safe Medication Practices. (2014). With oral anticancer medication, we simply must do better. *Acute Care ISMP Safety Alert*, 19 (14).

Nuess, M., Polovich, M., McNiff, K., Esper, P., Gilmore, T., LeFebvre, K., Schulmeister, L., and Jacobson, J. (2013). 2013 Updated American Society of Clinical Oncology/ Oncology Nursing Society Chemotherapy Administration Safety Standards Including Standards for the Safe Administration and Management of Oral Chemotherapy. *Journal of Oncology Practice*, 9 (2s), 5s-13s.

Oakley, C., Johnson, J. & Ream, E. (2010). Developing an intervention for cancer patients prescribed oral chemo: a generic patient diary. *European Journal of Cancer Care* 19, 21-28.

Roop, J.C., & Wu, H. (2014). Current Practice Patterns for oral anticancer medication: Results of a National Survey. *Oncology Nursing Forum*, 41(2), 185-193.

Siden, R., Kem, R., Ostrenga, A., Nicky, D., Bernhardt, B., & Bartholomew, J. (2014). Templates of patient brochures for the preparation, administration and safe handling of oral anticancer medication. *Journal of Oncology Pharmacy Practice*, 20 (3), 217-224.

Wong, S., Bounthavong, M., Nguyen, C., & Hernandez, E. (2014). Implementation and preliminary outcomes of a comprehensive oral chemo management clinic. *Am J Health-Syst Pharm* 71, 960-965.

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