ASCO’s Quality Training Program

Project Title: Improving oral chemotherapy fulfillment processes and implementation of a pharmacist-managed oral chemotherapy follow-up program

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Firas Shadad, MD

Institution: Cone Health Cancer Center at Alamance Regional

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Institutional Overview

Cone Health Cancer Center at Alamance Regional Medical Center, Burlington, NC

– Community Hospital Comprehensive Cancer Center
– 4 Hematologists/Oncologists
– 3 Oncology Pharmacists
– 631 cases in 2014
Problem Statement

Development of oral chemotherapy agents is expanding
  – Concerns regarding access and adherence to oral chemotherapy treatment have arisen

Process of initiating a patient on oral chemotherapy varies significantly among institutions
  – Hospital vs. specialty pharmacy
  – Delay in prescription fulfillment affects treatment adherence and potentially patient outcomes if treatment is postponed for days to weeks
Team Members

Project Sponsors: Cindy Johnson, RN, MSN, OCN; Director of Oncology Nursing, Cone Health Cancer Center

Team Leader: Firas Shadad, MD
Medical Oncologist, Cone Health Cancer Center

Team Members:
• Sonja Jacobsen, PharmD; PGY1 Pharmacy Resident, Cone Health at ARMC
• Adam Peele, PharmD, BCPS, BCOP; System Oncology Pharmacy Manager, Cone Health Cancer Center
• Chris Elder, PharmD, BCOP; Cone Health Cancer Center

QTP Improvement Coach: Amy Guthrie, MSN, ACHPN
Current Process Map

Physician writes new Rx for oral chemotherapy

Nurse faxes Rx to specialty pharmacy

Specialty pharmacy coordinates fill & delivers to pt; Notifies CC of shipment

Transfers Rx to other specialty pharmacy if out-of-network

Physician follow-up for treatment efficacy
Why Does Oral Chemotherapy Treatment Get Delayed?

Routing of Prescription
- Specialty pharmacy use
- Oral chemo not filled on-site
  - Transfer to other pharmacy within network

Affordability
- High cost of oral chemo drugs
  - Prior authorizations

Third-party processing
- Co-pay assistance enrollment
- Insurance denial
  - Specialty pharmacy not contacting provider
  - Lack of patient education of treatment
  - Patient not contacting provider

Communication Issues
- Specialty pharmacy unable to contact patient
- Uncertainty of who is responsible for oral chemo (provider, nurse, pharmacist)

Lack of Patient Involvement
- Lack of education
- Lack of understanding of treatment
- Patient not involved in prescription process
Overall patient self-reported adherence was calculated to be 92.5% mean adherence. Overall mean adherence reported from the outpatient pharmacy refill reports was 86%.

Implementation of pharmacist oral chemotherapy follow-up program produced good overall adherence rates at the Cone Health Cancer Center – GSO site.

AIM Statement

By October 1, 2015, collect and analyze data regarding oral chemotherapy fulfillment processes in order to understand the problem and get an idea of the magnitude of the problem at our site:

• Time delay (# of days) of patient started on new oral chemotherapy
• Identify reasons for delay
Process Measure

• **Measure**: Time delay from date oral chemotherapy prescription written to date patient began therapy; reasons for delay.

• **Patient population**: Adult cancer patients starting a new oral chemotherapy medication

• **Calculation methodology**: Difference in days from date oral chemotherapy prescription written to date patient began therapy

• **Data source**: Cone Health Cancer Center at Alamance Regional

• **Data collection frequency**: Daily

• **Data quality (any limitations)**: Limited access to prescription data due to utilization of specialty pharmacies; unable to reach some patients by telephone.
Balance Measure

• **Time spent:**
  – Tracking prescriptions
  – Calling patient’s for follow-up and medication counseling
  – Calling other specialty pharmacies
  – Cost
  – Documentation
Oral Chemotherapy Initiation Process Map

Physician writes new Rx for oral chemotherapy

Nurse faxes Rx to specialty pharmacy

Specialty pharmacy coordinates fill & delivers to pt; Notifies CC of shipment

Nurse places Rx in folder to notify pharmacist of new oral chemotherapy

Transfers Rx to other specialty pharmacy if out-of-network

Pharmacist tracks Rx and performs follow-up within 3-5 days of patient receiving drug; documents in EMR

Physician follow-up for treatment efficacy
## PDSA Plan (Tests of Change)

<table>
<thead>
<tr>
<th>Date of PDSA cycle</th>
<th>Description of intervention</th>
<th>Results</th>
<th>Action steps</th>
</tr>
</thead>
</table>
| **PDSA Cycle 1**  
June-July 2015     | Folders placed in nursing stations for oral chemo Rx collection  
Resident began data collection and patient follow-up calls | Inconsistent collection of prescriptions  
Inconsistent data collection due to inconsistent collection of prescriptions | Staff educated to place oral chemotherapy prescriptions in folder |
| **PDSA Cycle 2**  
July-Aug 2015      | Oral chemotherapy data collection & patient follow-up | Inconsistent data collection/missing information if unable to contact patient | Revise data collection strategy/contact specialty pharmacies directly |
| **PDSA Cycle 3**  
Aug-Sept 2015      | Revised data collection and contacted specialty pharmacies directly for information | Data collection/notification of prescription status improved | Continue data collection strategy |
### Prioritized List of Changes (Priority/Pay-Off Matrix)

<table>
<thead>
<tr>
<th>Impact</th>
<th>Ease of Implementation</th>
</tr>
</thead>
<tbody>
<tr>
<td>Low</td>
<td></td>
</tr>
<tr>
<td></td>
<td>PDSA #1</td>
</tr>
<tr>
<td></td>
<td>Folders placed in nursing stations for oral chemo Rx collection</td>
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<tr>
<td>High</td>
<td></td>
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<td></td>
<td>PDSA #2</td>
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<tr>
<td></td>
<td>Oral chemotherapy data collection &amp; patient follow-up</td>
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<tr>
<td></td>
<td>PDSA #3</td>
</tr>
<tr>
<td></td>
<td>Revised data collection plan and contacted specialty pharmacies directly for information</td>
</tr>
</tbody>
</table>

**Remarks:**

- PDSA stands for Plan-Do-Study-Act.
- The table categorizes changes by impact and ease of implementation.
# Oral Chemotherapy Agents Prescribed

<table>
<thead>
<tr>
<th>Agent</th>
<th># of Prescriptions</th>
</tr>
</thead>
<tbody>
<tr>
<td>Eltrombopag</td>
<td>1</td>
</tr>
<tr>
<td>Ruxolitinib</td>
<td>1</td>
</tr>
<tr>
<td>Imatinib</td>
<td>1</td>
</tr>
<tr>
<td>Everolimus</td>
<td>1</td>
</tr>
<tr>
<td>Ibrutinib</td>
<td>2</td>
</tr>
<tr>
<td>Vemurafenib</td>
<td>1</td>
</tr>
<tr>
<td>Palbociclib</td>
<td>5</td>
</tr>
<tr>
<td>Erlotinib</td>
<td>1</td>
</tr>
<tr>
<td>Abiraterone</td>
<td>1</td>
</tr>
<tr>
<td>Pomalidomide</td>
<td>2</td>
</tr>
<tr>
<td>Capecitabine</td>
<td>3</td>
</tr>
<tr>
<td>Sunitinib</td>
<td>2</td>
</tr>
<tr>
<td>Lenalidomide</td>
<td>1</td>
</tr>
</tbody>
</table>

# of Prescriptions (N=22)
Delay from Date Rx Written to Date of Drug Shipment

- **Less than or equal to 5 days:** 5 prescriptions
- **6 to 10 days:** 7 prescriptions
- **11 to 15 days:** 4 prescriptions
- **16 to 20 days:** 0 prescriptions
- **21 to 25 days:** 0 prescriptions
- **Greater than 26 or never received:** 2 prescriptions

Avg delay (N=17): 9.06 days
Longest delay: 38 days; Shortest delay: 2 days
Delay (in days) from Date Rx Written to Date Patient Began Treatment

- # of Prescriptions:
  - Less than or equal to 5: 2
  - 6 to 10: 3
  - 11 to 15: 3
  - 16 to 20: 1
  - 21 to 25: 1
  - Greater than 26 or never received: 2

- Days:
  - Avg delay (N=11): 13.18 days
  - Avg delay (N=12, incl. pt that never received drug): 14.25 days
  - Longest delay: 38 days; Shortest delay: 3 days
Delay Based on Oral Chemotherapy Agent Prescribed

Days

Drug Prescribed (N=17)
Reason for Delay in Oral Chemo Rx Fulfillment

- Rx Transferred, 5
- Prior Authorization, 5
- Insurance Denial, 2
- Patient Assistance Program, 4
- Disease Progression, 2
- Other, 3
- Denial, 5
- Non-Patient Specific, 5
Conclusions

• AIM Statement met:
  – Average delay in oral chemotherapy treatment ~13 days
  – Delays mostly due to third-party processing issues and affordability

• Benefit from designated pharmacist at our site responsible for oral chemotherapy follow-up?
  → will test in next phase
Lessons Learned

• Multiple barriers identified in oral chemotherapy prescription fulfillment which led to delays in treatment

• Pharmacists are able to provide patient education and monitoring of medication; track prescription fulfillment
Next Steps/Plan for Sustainability

• Continue to track patients started on new oral chemotherapy medication

• Begin second phase of study to assess patient adherence to oral chemotherapy:
  – Pharmacist follow-up/education with patient weekly for first 4 weeks, then monthly
  – Validate that improvements are successful
    • % adherence rates, patient and physician satisfaction rating to pharmacist-driven oral chemotherapy follow-up
Improving oral chemotherapy fulfillment processes and implementation of a pharmacist-managed oral chemotherapy follow-up program

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BACKGROUND
Oral chemotherapy has significantly increased in the treatment of patients with cancer. Of the 750 new therapeutics currently being tested for oncology, 30 to 50 percent are in oral form. Historically, administration of chemotherapy has not been a concern as the majority of chemotherapy is administered intravenously at an infusion center. In contrast, oral chemotherapy is often delivered to the patient's home, where the patient becomes responsible for administration. As the use of oral chemotherapy has grown, concerns regarding access and adherence to treatment have arisen.

Prescriptions for oral chemotherapy can be filled in a variety of ways, often at hospital and specialty pharmacies. The process of initiating a patient on oral chemotherapy varies significantly among institutions and is largely dependent upon the ability to fill prescriptions internally versus utilizing a specialty pharmacy. A number of issues arise when involving a specialty pharmacy due to routing of the prescription, high cost, complex reimbursement, and a lack of communication between pharmacies and healthcare providers. Without proper coordination from all persons involved, confusion may arise resulting in delay of distribution of oral chemotherapy, non-adherence to treatment, and frustration among physicians and patients. Delay in medication delivery may potentially affect patient outcomes as treatment is postponed for days to weeks. Few published studies have focused on the complex issue of oral chemotherapy fulfillment. One study by Mancini et al. has shown that a pharmacist-managed oral chemotherapy program can successfully collaborate with patient financial advocates to prevent high rates of “nonfulfillment” (i.e., failure to obtain a prescribed medication).

PURPOSE
A quality improvement project was created to evaluate and improve the current oral chemotherapy process at CHCC-ARMC, and to implement a pharmacist-driven oral chemotherapy program in the future. The purpose of the first phase of this study is to delineate the timeline of a patient prescribed a new oral chemotherapy agent. The second phase of the study aims to determine whether continued follow-up by a pharmacist increases patient adherence to oral chemotherapy, as well as increase patient and physician satisfaction, at CHCC-ARMC.

METHODS
Cone Health Cancer Center at Alamance Regional is a designated Community Hospital Comprehensive Cancer Center located in Burlington, North Carolina. The center features oncology offices, radiation therapy, chemotherapy infusion area, cancer specialty clinics, pharmacy, and support services. At this time, our pharmacy does not fill prescriptions for oral chemotherapy.

The process of tracking the fulfillment of prescriptions for all patients beginning a new oral chemotherapy medication during the first phase of our study is outlined in the figure above.
- Folders were placed in each nursing station for collection of any documentation relating to oral chemotherapy prescriptions.
- A pharmacist rounded daily on the folders and tracked when the prescription was written to when the patient received the medication and began therapy.
- A pharmacist conducted an interactive patient follow-up within 3 to 6 days of the patient receiving the drug from the specialty pharmacy, which included dosage, schedule, administration, possible side effects, drug interactions, and to answer any patient questions.
- Data was collected on a continual basis for each patient beginning a new oral chemotherapy medication including the drug prescribed, dosage, date prescribed, date patient began therapy, and any reasons for delay in fulfillment of the oral chemotherapy prescription.

CONCLUSION
Overall, areas for improvement include documentation in the patient's electronic medical record regarding oral chemotherapy, utilization of resources to develop a pharmacist navigator position for coordinating oral chemotherapy, and increased patient education and monitoring to increase adherence to oral chemotherapy. We aim to implement these improvements in the next phase of our study.

REFERENCES