Project Title: Improving the Consenting and Education Process for Patients Starting on Oral Oncology Medications

Presenter’s Name: Lauren Zatarain, MD
Institution: Mary Bird Perkins – Our Lady of the Lake Cancer Center, Baton Rouge, LA

Date: October 8, 2015
Institutional Overview

- Baton Rouge population 230,000

- Community Hospital in Southeast Louisiana
  - Mary Bird Perkins-Our Lady of the Lake Cancer Center
  - National Community Cancer Centers Program (NCCCP) site since 2007
  - Medical Oncology: 6 MDs, 2 NPs
  - Recent loss of NP (6/2015) who previously coordinated all oral oncology medications

- Average: 13 Oral oncology patients initiated per month
Problem Statement

Oral oncology medication prescribing is on the rise within the Mary Bird Perkins - Our Lady of the Lake Cancer Center Medical Oncology Clinic. Given that these medications are self-administered, drug compliance is a concern. Appropriate patient education directly impacts drug adherence. Currently, there is implied consent while educating patients on side effects and written informed consent is obtained 0% of the time. This creates a patient safety and risk management problem.
Team Members

Team Leader:
- Lauren Zatarain, MD

Team Members:
- Nursing – Jessica Ashford, RN
- Providers – Dustin Denicola, NP
- Administration – BJ Billeaudreau, Michelle Hyatt
- IT – Erin Wallace

Project Sponsor:
- LaDonna Green, NFA, MPA, Assistant Vice President at Our Lady of the Lake Physician Group

Improvement Coach:
- David Bivens, MS, CQE, CSSBB, CPIM
Initial Process Map

Decision to Start New Oral Oncology Medication

- Review baseline labs/tests
- Chemo education, Side effects discussed
- Administration reviewed
- Review schedule, dosing, cycles, start/stop date

Rx written in Mosaq by MD/NP/RN

- Provider note documented in chart

Rx sent to specialty pharmacy

- Prior Authorization
- Copay assistance
- Communication to patient

Phone contact, side effect documentation at 1 week

1st visit after chemo start at 2 weeks

- Review labs
- Assess compliance
- Review schedule, dosing, cycles, start/stop date
- Side effect management

Dose Adjusted ???

- Specialty pharmacy contacted
- Notify RN, new Rx written

Yes

MD  Nurse
Patient Adherence
To Prescribed Oral
Oncology Medications

Communication
1. Provider ↔ Patient Education
   Not taking drug correctly
   Appropriate start/end of chemo cycle
2. Provider/Nurse ↔ Pharmacy communication
   Dose changes
   Automatic refill after drug d/c
3. Nurse ↔ MD communication

Procedure
1. Inadequate lab monitoring
2. Drug compliance not assessed
3. Appropriate baseline tests forgotten

Financial
1. Delay in MD note for prior authorization submission
2. Delay with insurance approvals
3. Financial toxicity co-pay
4. No communication to providers about patient’s responsibility for drug cost

Documentation Processes
1. Written informed consent
2. Side Effect & Toxicity Management
3. Patient education handout on drug and side effects
4. Documented phone contact for toxicity check
5. Chemo start date not recorded
6. Medication list not updated at start or with updated doses
7. Medication compliance not documented

Patient Adherence
To Prescribed Oral Oncology Medications
Patient Adherence to Prescribed Oral Oncology Medications

Environment

1. Delays in acquiring drug
2. Transition outpatient ↔ inpatient
3. Less experienced RN learning about oral oncology medications that will be invested in patient education process
4. Down 1 NP who previously managed most aspects of this clinic

Equipment

1. Need dedicated chemo nurse
2. Physical space for nurse education visit
3. No drug samples
4. Mosaiq electronic record care plan or flowsheets

Policy

1. Formal chemo education visit
   - In office initial dispense of meds
   - Review of patient folders to reinforce education
2. Direct number needed for patient to reach NP/RN handling their chemo and side effect checks
3. Timely f/u visit for side effect check

Other

1. MD forgets to give adjunct prescriptions for symptom management
2. Drugs just aren't good enough
Diagnostic Data

Provider Perception of Oral Oncology Prescribing Barriers

- Financial Toxicity
- Drug Adherence
- Inadequate Monitoring
- Side Effect Education
- Delay in Drug Start
- Medication List Updates
- Pharmacy Communication
- Internal Communication
- Phone Contacts
- Need Dedicated Chemo Nurse

ASCO Quality Training Program
Aim Statement

By October 1, 2015, 75% of all patients enrolled in oral oncology clinic will provide written informed consent at Mary Bird Perkins – Our Lady of the Lake Cancer Center.
## Measures

<table>
<thead>
<tr>
<th>What is your measure?</th>
<th>Outcome Measure</th>
<th>Outcome Measure</th>
<th>Measure</th>
</tr>
</thead>
<tbody>
<tr>
<td>% of patients with written consent in EHR</td>
<td>% of patients given patient education materials</td>
<td>% of patients for whom the provider notified the RN of drug start</td>
<td></td>
</tr>
</tbody>
</table>

### Patient population (exclusions if any)

- All oral oncology patients started on drug since 2/2015
- All oral oncology patients started on drug since 2/2015
- All oral oncology patients started on drug since 2/2015

### Calculation methodology

- Numerator: # of patients with written consent in EHR
- Denominator: # of patients on oral oncology medications
- Numerator: # of patients with patient education in EHR
- Denominator: # of patients on oral oncology medications
- Numerator: # of patients for whom the provider notified the RN of drug start prior to patient leaving clinic
- Denominator: # of patients on oral oncology medications

### Data source

- EHR; excel tracking sheet
- EHR
- Oral oncology RN tally sheet

### Data collection frequency

- Data will be entered into an excel spreadsheet on a biweekly basis or IT creates biweekly report
- Data will be entered into an excel spreadsheet on a biweekly basis or IT creates biweekly report
- Data will be collected as new patients are started on oral oncology medications

### Data Quality

- Requires provider to remember to consent patients; requires oncology RN to scan in written consent form
- Requires provider to remember to give handout to patients; requires oncology RN to scan in patient education document
- Requires RN to recall which patients she was notified about drug start prior to leaving clinic
Baseline Data

Written Informed Consent Obtained Prior to Oral Oncology Drug Start (p chart, 3 sigma)

Creation of consent form

Weeks

Percentage

Baseline Mean, LCL, UCL
Baseline Data

Patient Education Handouts Given to Patient Prior to Oral Oncology Drug Start

p chart, 3 sigma

Percentage

Weeks

100%
90%
80%
70%
60%
50%
40%
30%
20%
10%
0%

1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22

baseline mean  LCL  UCL
## Prioritized List of Changes (Priority/Pay-Off Matrix)

<table>
<thead>
<tr>
<th>Impact</th>
<th>Ease of Implementation</th>
</tr>
</thead>
<tbody>
<tr>
<td>High</td>
<td></td>
</tr>
<tr>
<td></td>
<td>1) Creation of written consent form</td>
</tr>
<tr>
<td></td>
<td>2) RN Phone Education</td>
</tr>
<tr>
<td></td>
<td>3) MD Reminder Checklist</td>
</tr>
<tr>
<td></td>
<td>4) Creation of education powerpoint</td>
</tr>
<tr>
<td></td>
<td>1) Automatic order generation for common care plans</td>
</tr>
<tr>
<td></td>
<td>2) Formal RN education visit</td>
</tr>
<tr>
<td></td>
<td>3) RN notification while patient in clinic</td>
</tr>
<tr>
<td></td>
<td>4) 1st shipment of drug to MD office</td>
</tr>
<tr>
<td>Low</td>
<td></td>
</tr>
<tr>
<td></td>
<td>1) Relocation of patient education folders and consent forms to central office location</td>
</tr>
<tr>
<td></td>
<td>1) Streamline use of specialty pharmacies</td>
</tr>
<tr>
<td></td>
<td>2) Create drug favorites for ease of prescribing</td>
</tr>
</tbody>
</table>

**Ease of Implementation**

- **Easy**
- **Difficult**
## 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>
<tbody>
<tr>
<td>4/29/15-5/26/15</td>
<td>Pilot of RN education visit with 1st drug shipment to MD office</td>
<td>Delays in drug start</td>
<td>Reverted back to drug shipment to patient home</td>
</tr>
<tr>
<td>8/3/15-</td>
<td>Reminder checklist in exam rooms</td>
<td>Providers report the reminder sticker is somewhat helpful.</td>
<td>Continue with data collection</td>
</tr>
<tr>
<td>8/17/15-</td>
<td>Re-pilot RN education visit with earlier scheduling prior to drug shipment to patient home</td>
<td>No delays in drug start</td>
<td>Continue with data collection</td>
</tr>
</tbody>
</table>
# 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>
<tbody>
<tr>
<td>8/7/15-</td>
<td>Centralize consent forms in office</td>
<td>Coincided with new policy to obtain written consent for IV chemotherapy</td>
<td>Continue with data collection</td>
</tr>
</tbody>
</table>
Materials Developed

Oral Oncology Medication Patient Consent

Patient Name_________________________ Date of Birth ________________
Oral Medication________________________ Diagnosis____________________
Physician________________________ Oral Oncology Nurse___________________
Specialty Pharmacy ____________________________________________________________
Specialty Pharmacy Phone________________________ Fax __________________________
_____ Patient can swallow pills.
_____ Patient understands that this is an oral oncology medication.
_____ Patient understands instructions in self-administering oral oncology medications.
_____ Patient understands safe handling of oral oncology medication.
_____ Patient understands potential side effects of oral oncology medication and when office should be notified of concerns.
_____ Office contact information and phone numbers have been given to patient.
_____ Patient has been advised to contact office if there are problems with prescription fulfillment.
_____ Follow up Doctors’ visits and lab visits were scheduled/discussed.

By my signature below, I attest that I have been taught about the oral oncology medication that my doctor has prescribed for me. I understand the goal of this oral oncology medication and that the success of this treatment weigh largely upon my compliance in taking the medication and informing my doctor of any issues that I may have. I understand that this prescription will be delivered to my home and it is imperative that I call my Doctors’ office with any questions, issues, or concerns.

Patient Signature________________________________________ Date__________

• New Consent Forms
• Patient Drug Education Folders
• MD Reminder Checklists
• Electronic Assessment Forms
Revised Process Map

Start New Oral Oncology Medication
- Review baseline labs/tests
- Chemo education, Side effects discussed

Write RX in Mosaic

1st Visit After Chemo Started (2 weeks)
- Review Labs
- Assess Compliance

Dose Adjustment?
- Yes
  - Notify RN, New Rx Written

- No
  - Specialty Pharmacy Contacted

Rx Sent to Specialty Pharmacy
- Prior Authorization
- Co-pay Assistance
- Communication to Patient

RN Visit w/ 1st Dispense
- Written Consent
- Chemo Education, Provide Handout
- Administration Reviewed
- Clarify Sched., Dosing, Cycles, Start/Stop Date

Contact Patient via Phone (Week 1)
- Assess for Side Effects and Document
Change Data

Written Informed Consent Obtained Prior to Drug Start (p chart, 3 sigma)

Consent Form Created

22%

75%

Provider In-Service

Weeks

Percentage

0% 10% 20% 30% 40% 50% 60% 70% 80% 90% 100%

1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23 24 25 26 27 28 29 30 31 32

mean LCL UCL
Change Data

Patient Education Handouts Provided Prior to Drug Start
(p chart, 3 sigma)

Percent

Week

0% 10% 20% 30% 40% 50% 60% 70% 80% 90% 100%

1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23 24 25 26 27 28 29 30 31

Provider In-Service

80%

37%

mean LCL UCL
Elapsed Days from Provider Decision to Initiate Drug Until Patient Acquires Oral Oncology Medication (xMr chart, 3 sigma)

Initial Trial Of Drug Shipment to Office

2nd Trial of RN chemo Education visit; drug ships to patient home
Conclusions

• Providers found the new process of notifying the RN about drug start while patients were still in clinic to be an easy step.
• Significant improvement in obtaining written informed consent.
• Signal of significant improvement after implementation with 7 points above the baseline mean.
• Achieved our goal of 75%.
Next Steps/Plan for Sustainability

• Continue to measure post intervention data to monitor adherence
• Continue to show blinded provider data at staff meeting to encourage healthy competition
**Improving Consenting and Education Process for Patients Initiating Oral Oncology Medication**

**AIM:** By October 1, 2015, 75% of all patients enrolled in oral oncology clinic will provide written informed consent at Mary Bird Perkins – Our Lady of the Lake Cancer Center.

**INTERVENTION:**
- Creation of written informed consent form
- Pilot of in-house RN oral oncology education visit
- Educated providers on importance of consenting and patient education process
- Creation of provider reminder checklist

**RESULTS:**

**Written Informed Consent Obtained Prior to Drug Start**

(p chart, 3 sigma)

**CONCLUSIONS:**
- Exceeded target goal of 75%
- Interventions improved the acquisition of written consent forms

**NEXT STEPS:**
- Continue post-intervention data collection
- Encourage healthy competition among providers with blinded data

**TEAM:** OLOL-MBP Cancer Center
- **Oncology Provider:** Dustin Denicola, NP
- **Administration:** Michelle Hyatt, BJ Billeaudeau
- **Information Technology:** Erin Wallace
- **Coach:** David Bivens, MS

**PROJECT SPONSORS:**
- LaDonna Green, NFA, MPA