ASCO’s Quality Training Program

Project Title: Implementation of a Written Chemotherapy Consent - from Zero to Compliant in 6 Months

Presenter’s Name: Brendan Curley DO, MPH
Institution: West Virginia University & Mary Babb Randolph Cancer Center

Date: March 6th, 2014
In-Service Question

- Your fellowship participates in QOPI. Program and fellows are noted to routinely fail to obtain written consent for chemotherapy. Based on this finding, you as a group should:
  A) Refer to Legal
  B) Determine if it is appropriate to obtain chemotherapy consent
  C) Develop a plan to obtain consent and assess its effectiveness
  D) Meet with faculty and determine if this is something that fails to meet local standards of care
Institutional Overview

- West Virginia University & Mary Babb Randolph Cancer Center is the largest Academic Cancer Center in the state, and the only Bone Marrow Transplant Center in the state.
- Currently have 12 oncologists while actively recruiting faculty members, 5 full time pharmacists, 7 mid-level providers, and 8 hematology/oncology fellows.
- Serve a large geographic area including all of West Virginia, western Maryland, eastern Ohio and southwestern Pennsylvania.
- Large portion of patients are from a rural and underserved population with limited resources and education.
- Have the most clinical trials available in the state.
- 2012 - 37,957 unique patient visits.
- 2013 - 40,996 unique patient visits.
Problem Statement

- Original consent process: Recording of verbal acknowledgement of patient consent in clinic note
- Not in an easily retrievable location in the medical record.
- Inconsistencies in communication of risk / benefit between clinicians
- Lack of documentation of communication of treatment goals
- Lack of written chemotherapy consent may lead to patient dissatisfaction in care, poor communication and other adverse events.

Patients at WVU/MBRCC do not have written chemotherapy consent in the medical record prior to the start of therapy. Implementation of written consent will result in improved patient safety, education, understanding, and ensure proper communication.

3) Michels D, Cahill, M. Informed Consent and Chemotherapy: JOP September 2005
Team Members

Example
Team Leader:
- Brendan Curley, DO Chief Hematology/Oncology Fellow PGY-6

Team Members:
- Pharmacy - Michael Newton, PharmD, BCOP
- Oncology - Mohammed Almubarak MD
- Scot Remick MD - Project Sponsor

Improvement Coach:
- David Bivens
• Process Map Creation-
  – We did use the post-its!
  – Thought through the steps and issues that may arise
  – Discussed with multiple members of the oncology team, including the attending staff, fellows, pharmacists, nurses, mid-levels, and social workers
  – Identified areas where we had encountered issues in the past
  – Purpose: to visually display the various steps, events, and operations that constitute a process.

• Lessons Learned
  – Harder and more time consuming than we anticipated
  – Having more “cooks in the kitchen” helped with the creative process and identifying issues
  – Working with post-its was like working with pencil- was easier for us to adapt
Chemo Consent - typically done in clinic prior to infusion center visit
Poor written chemotherapy consent documentation

- Patients not properly educated
  - Oncologists not clearly explaining safety and goal of care
  - Lack of understanding from patients
  - No consistent process to document consent for chemotherapy

- Written materials may either be too basic or too advanced depending on patient population

- Patients under informed
  - Patient volume and education requirements leave minimal time to completely educate patients

- Consent process

- Logistics
  - Busy clinic!!!
  - Short time between physician appointment and start of chemotherapy in infusion center
  - Preauthorization of chemotherapy delays treatment
  - Physician compliance

- When consent needs to be done?
  - Lack of coordination between infusion center and clinic
  - Chemotherapy consent is new process, and no “hard stop” like blood consent

Lessons learned from the process - No idea was a bad idea
- Items were thought of individually and shared as a group
- Areas of focus were primarily those that were repeated in each individual's ideas
Largest branch of issue is communication and logistics
Largest specific issue is no “written chemotherapy consent” - that was extensively researched, developed and approved and is now being utilized in our cancer center
Our data collection was over the entire year of 2013
Data collected was divided into a PRE written chemotherapy consent (prior to June 30th) and a POST written chemotherapy consent (July 1st and after)
Only new starts were included
Oral chemotherapy was excluded
Clinical trial patients were excluded, as they have written consent with their trial consent
We also collected documentation of intent of treatment (curative, palliative, etc)
Data was a retrospective chart review
<table>
<thead>
<tr>
<th>To</th>
<th>Brendan Curley</th>
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<tbody>
<tr>
<td>From</td>
<td>WVU Office of Research Integrity and Compliance</td>
</tr>
<tr>
<td>Approval Period</td>
<td>12/09/2013 Expiration Date 12/08/2016</td>
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<tr>
<td>Subject</td>
<td>Acknowledgement Letter Exempt Initial Protocol Review</td>
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<td>Protocol Tracking</td>
<td>1311136785</td>
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<td>Title</td>
<td>Implementation of Written Chemotherapy consent in a University Based Practice- A Quality Improvement Initiative</td>
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The above-referenced study was reviewed by the West Virginia University Institutional Review Board IRB and was granted exemption in accordance with 45 CFR 46.101.

- Data collection completed!
RESULTS

• Data was collected from 546 patients, with 224 in the pre-intervention group and 322 in the post-intervention group. Documentation of chemotherapy consent decreased from 63% to 52% ($p = 0.011$) when written consent was required.

• Why did it go down?
GOALS OF CARE

• However, documentation of goals of care improved dramatically with 95% of patients having explicit goals of care documented with written chemotherapy consent, compared to 48% of those that consented orally (p<0.0001).

• Drastic increase- so why do we care?

Expectations About the Effectiveness of Radiation Therapy Among Patients with Incurable Lung Cancer, JCO, Jul 20, 2013: 2730-2735
Aim Statement

- By March 1\textsuperscript{st} 2014, 80\% of patients initiated on chemotherapy (oral or IV) or a change in chemotherapy at West Virginia University/Mary Babb Randolph Cancer Center will have a documented written consent in the medical record prior to initiation of therapy.
# Measures

<table>
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<tr>
<th>Process Measure</th>
<th>Outcome Measure</th>
<th>Balance Measure</th>
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<tbody>
<tr>
<td>% of patients with written chemotherapy consent</td>
<td>% of patients with written chemotherapy consent</td>
<td>Change in % of patients with written chemotherapy consent after implementation</td>
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</table>

## What is your measure?

- All adult patients undergoing chemotherapy
- All adult patients undergoing chemotherapy
- All adult patients undergoing chemotherapy

## Patient population (exclusions if any)

- All adult patients undergoing chemotherapy
- All adult patients undergoing chemotherapy
- All adult patients undergoing chemotherapy

## Calculation methodology

- Pre and post implementation with multiple factors will be gathered and analyzed by biostats
- Pre and post implementation with multiple factors will be gathered and analyzed by biostats
- Pre and post implementation with multiple factors will be gathered and analyzed by biostats

## Data source

- Medical Records
- Medical Records
- Medical Records

## Data collection frequency

- One time data collection analyzing a set time period
- One time data collection analyzing a set time period
- One time data collection analyzing a set time period

## Data Quality

- Retrospective chart review, experienced physician researchers
- Retrospective chart review, experienced physician researchers
- Retrospective chart review, experienced physician researchers
Baseline Data

- Data was retrospectively collected to see if our chemotherapy documentation has improved.
- Our “pre” period is 6 months prior to implementation of consent.
- “Post” period is the following with 6 months after the implementation.

Data was collected from 546 patients, with 224 in the pre-intervention group and 322 in the post-intervention group. Documentation of chemotherapy consent decreased from 63% to 52% (p =0.011) when written consent was required.

Documentation of goals of care improved dramatically with 95% of patients having explicit goals of care documented with written chemotherapy consent, compared to 48% of those that consented orally (p<0.0001).
Prioritized List of Changes (Priority/Pay-Off Matrix)

<table>
<thead>
<tr>
<th>High Impact</th>
<th>Easy</th>
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<tbody>
<tr>
<td>Scanning into charts</td>
<td>- Education of Staff/Fellows/Nurses</td>
</tr>
<tr>
<td>Data Collection</td>
<td>- Administration approval</td>
</tr>
<tr>
<td>- Creation of chemotherapy consent form (meeting, etc)</td>
<td>- Cooperation! (Integration into workflow)</td>
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<table>
<thead>
<tr>
<th>Low Impact</th>
<th>Difficult</th>
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<tr>
<td>Distribution of paper form</td>
<td>Insuring patient gets a copy of their consent</td>
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</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>7/1/13-12/1/13</td>
<td>Implement chemotherapy consent process</td>
<td>Went from 0% written documentation to 52%, and drastic increase in documented goals of care</td>
<td>Presentation of data, reminder to all clinical staff</td>
</tr>
<tr>
<td>1/1/14-6/30/14</td>
<td>Continue to improve chemotherapy consent process by addressing issues noted during first intervention (access to form, confusion with form, etc)</td>
<td>TBD- Hopefully will hit 80% of new start chemotherapy patients with consent form</td>
<td>TBD- based on results of secondary look</td>
</tr>
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Informed Consent For Antineoplastic Chemotherapy

A) Consent: I understand that I have been diagnosed with ____________________, and that treatment with chemotherapy has been recommended. I voluntarily authorize Dr. ____________________, as my physician and other health care providers at West Virginia University Healthcare, to provide chemotherapy to treat my diagnosis.

B) Goals of Therapy: I agree that a physician has explained to me the purpose of, duration of, and details related to the chemotherapy I am to receive. I have been explained the risks of receiving and NOT receiving the chemotherapy. I understand that there are benefits of this treatment if it is successful. I also understand that chemotherapy affects different people differently and that there is no way to be certain that the treatment will help me. The goal(s) of chemotherapy has also been explained to me and includes:

- Attempt to cure my cancer
- Prepare my blood prior to transplant
- Slow the growth / progression of my cancer
- Improve my quality of life / control symptoms
- Decrease risk of recurrence of my cancer
- Other: ____________________

C) Chemotherapy Regimen: I understand the following drugs will be used to treat my cancer:

________________________________________________________

D) Risks and Side Effects: While not receiving chemotherapy has risks, I understand that the chemotherapy medications recommended by my doctor can have short-term and long-term side effects. Reasonable alternatives to chemotherapy have been explained to me and include, but are not limited to, surgery, hormonal therapy, immunotherapy, other chemotherapy, radiation therapy, and/or experimental therapies if I meet certain criteria. I also understand that I may stop this treatment at any time. My doctor talked to me about the complications and side effects of chemotherapy, which may include, but are not limited to:

- Nausea / vomiting
- Hair loss
- Anemia
- Fatigue
- Infection
- Bleeding
- Mouth / throat sores
- Constipation
- Diarrhea
- Nerve effects
- Skin effects
- Muscle / bone effects
- Heart effects
- Kidney / bladder effects
- Sexual effects
- Irritation or tissue
- Lung effects
- Fertility effects
- Second cancers
- Allergic reaction
- Damage at infusion site
- Other: __________________________
Conclusions

- Implementation of written consent that is reviewed and signed by the patient may initially reduce compliance with the consent process when compared to documenting an oral consent in the patient’s chart.
- Improvement is in the eye of the beholder - we either went from 0-52% or decreased from 63%-52%.
- Written consent appears to drastically improve documentation of treatment goals.
- Have not yet reached our aim of 80% written consent in chart.
Next Steps/Plan for Sustainability

- Continue to measure post intervention data to monitor adherence.
- Presentation at Cancer Center Committee Meeting of data.
- Submission to National Meetings (ASCO)
- Discussions amongst providers (Nurse Clinicians and Physicians)
- Peer Pressure!
Implementation of a Written Chemotherapy Consent Form In a University Center - The West Virginia University/Mary Babb Randolph Cancer Center Experience

**AIM:** By March 1st 2014, 80% of patients initiated on chemotherapy or a change in chemotherapy at West Virginia University/Mary Babb Randolph Cancer Center will have a documented written consent in the medical record prior to initiation of therapy.

**INTERVENTION:**
- Developed and fine-tuned a consent form that will fit all oncology patients.
- Implementation of a new chemotherapy consent form.
- Educated staff on importance of chemotherapy consent form and how to complete it.
- Educated nursing staff to review chemotherapy consent prior to new start.

**RESULTS:**

- Baseline includes weeks ending 9/15, 9/22 & 9/29
- Average run rate is 64.1%

**CONCLUSIONS:**
- Implementation of written may initially reduce compliance with the consent process when compared to documenting an oral consent in the patient’s chart.
- Documentation of goals of care improved dramatically with written chemotherapy consent.

**NEXT STEPS:**
- Continue to measure post intervention data to monitor adherence.
- Presentation at Cancer Center Committee Meeting of data.
- Discussions amongst providers (Nurse Clinicians and Physicians)