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

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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 it's 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 a 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.

1) Storm C, et al. Informed Consent for Chemotherapy: ASCO Member Resources: JOP November 2008
2) Treleaven J, et al. Obtaining Consent for Chemotherapy: British Society for Haematology 2005.
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:

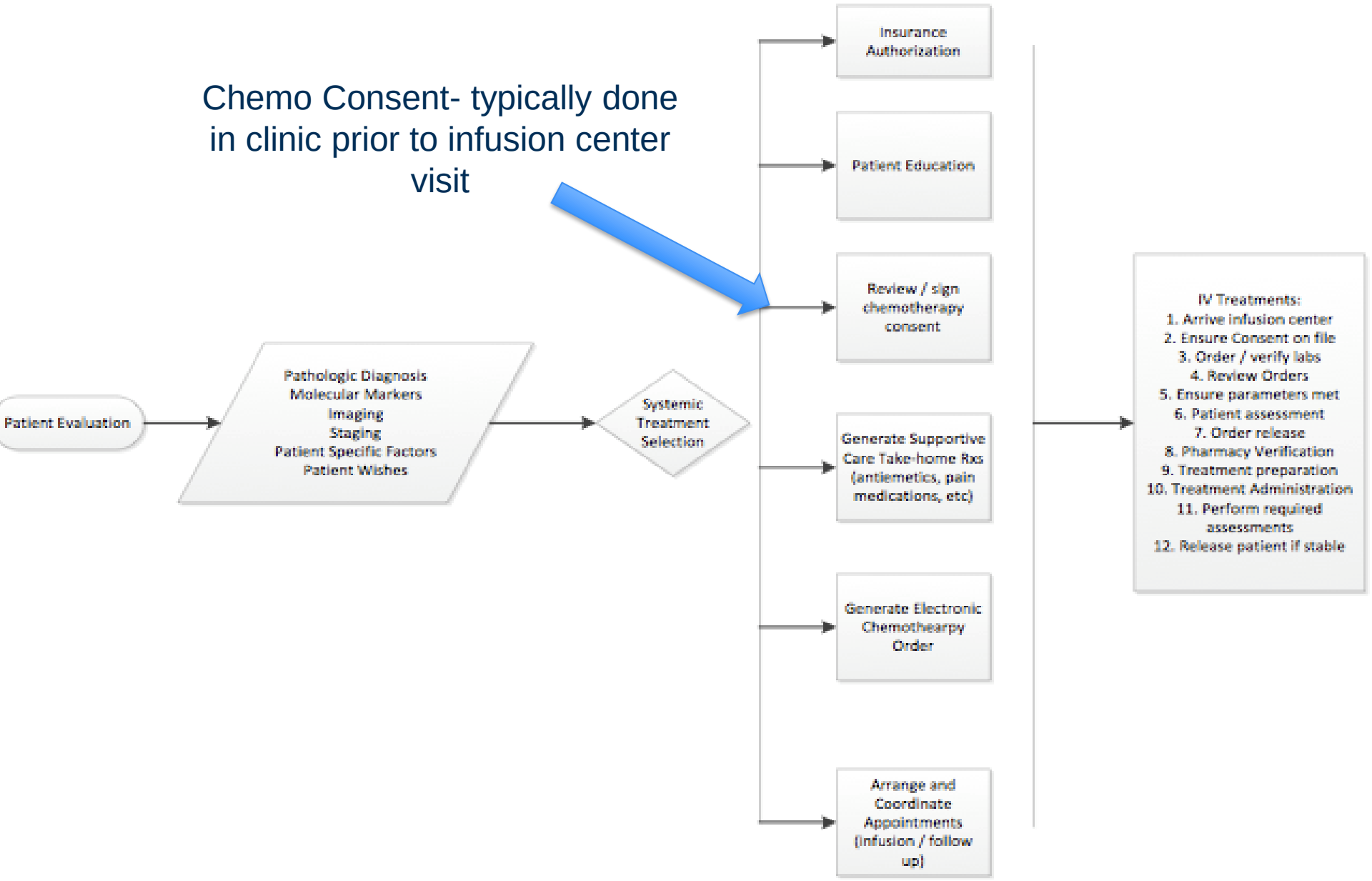
- David Bivens

Process Map- WVU

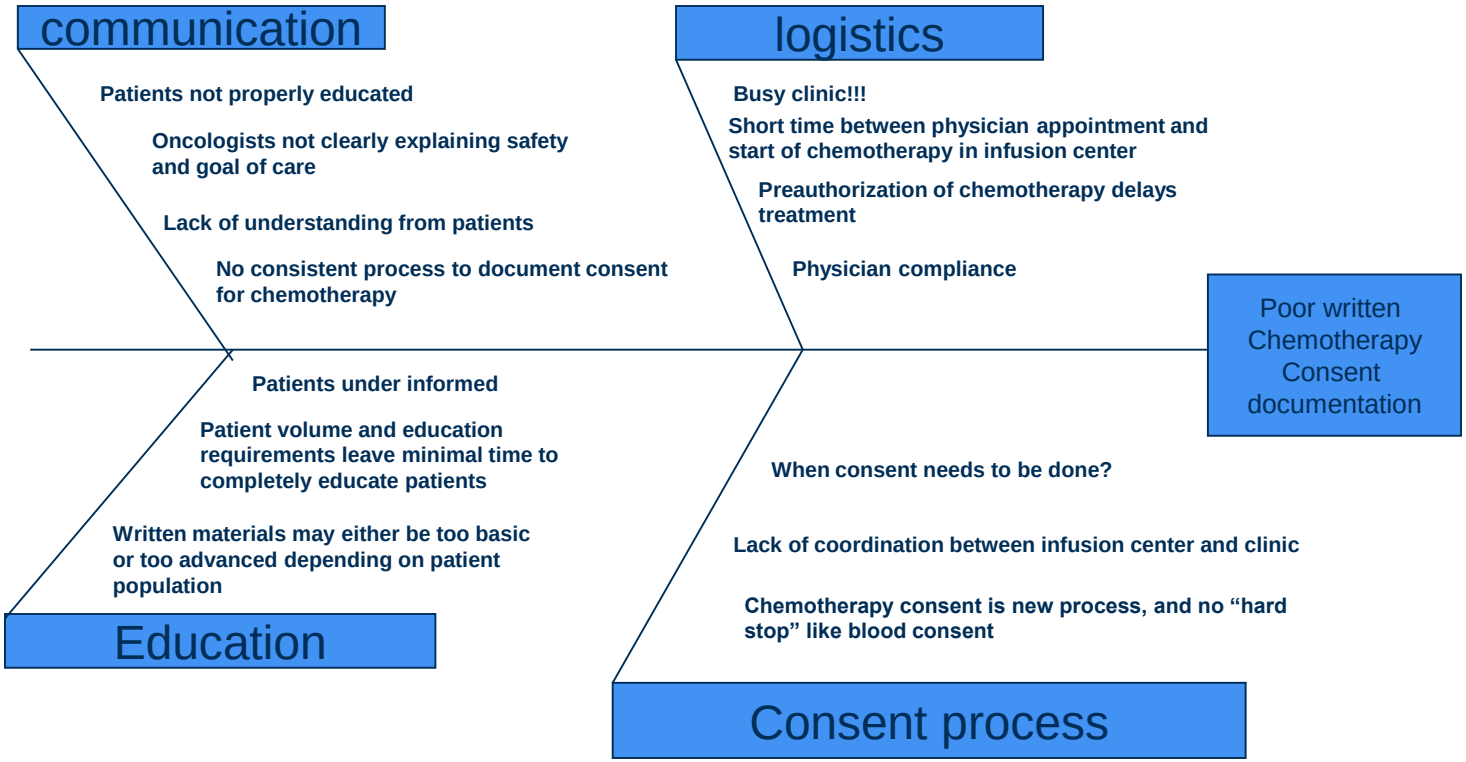
- Process Map Creation-
  - We did use the post-its!
  - Thought through the steps and issues that may arise
  - Discussed with multiple members of the oncology team, including the attending staff, fellows, pharmacists, nurses, mid-levels, and social workers
  - Identified areas where we had encountered 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



Cause & Effect Diagram- WVU



- 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 individuals ideas

Diagnostic Data- WVU

- 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

West Virginia University
Office of Research Integrity and Compliance

Acknowledgement Letter Exempt Initial Protocol Review

To	Brendan Curley
From	WVU Office of Research Integrity and Compliance
Approval Period	12/09/2013 **Expiration Date** 12/08/2016
Subject	**Acknowledgement Letter Exempt Initial Protocol Review**
Protocol Tracking	1311136785
Title	Implementation of Written Chemotherapy consent in a University Based Practice- A Quality Improvement Initiative

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 1st 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

	Process Measure	Outcome Measure	Balance Measure
What is your measure?	**% of patients with written chemotherapy consent**	**% of patients with written chemotherapy consent**	**Change in % of patients with written chemotherapy consent after implementation**
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

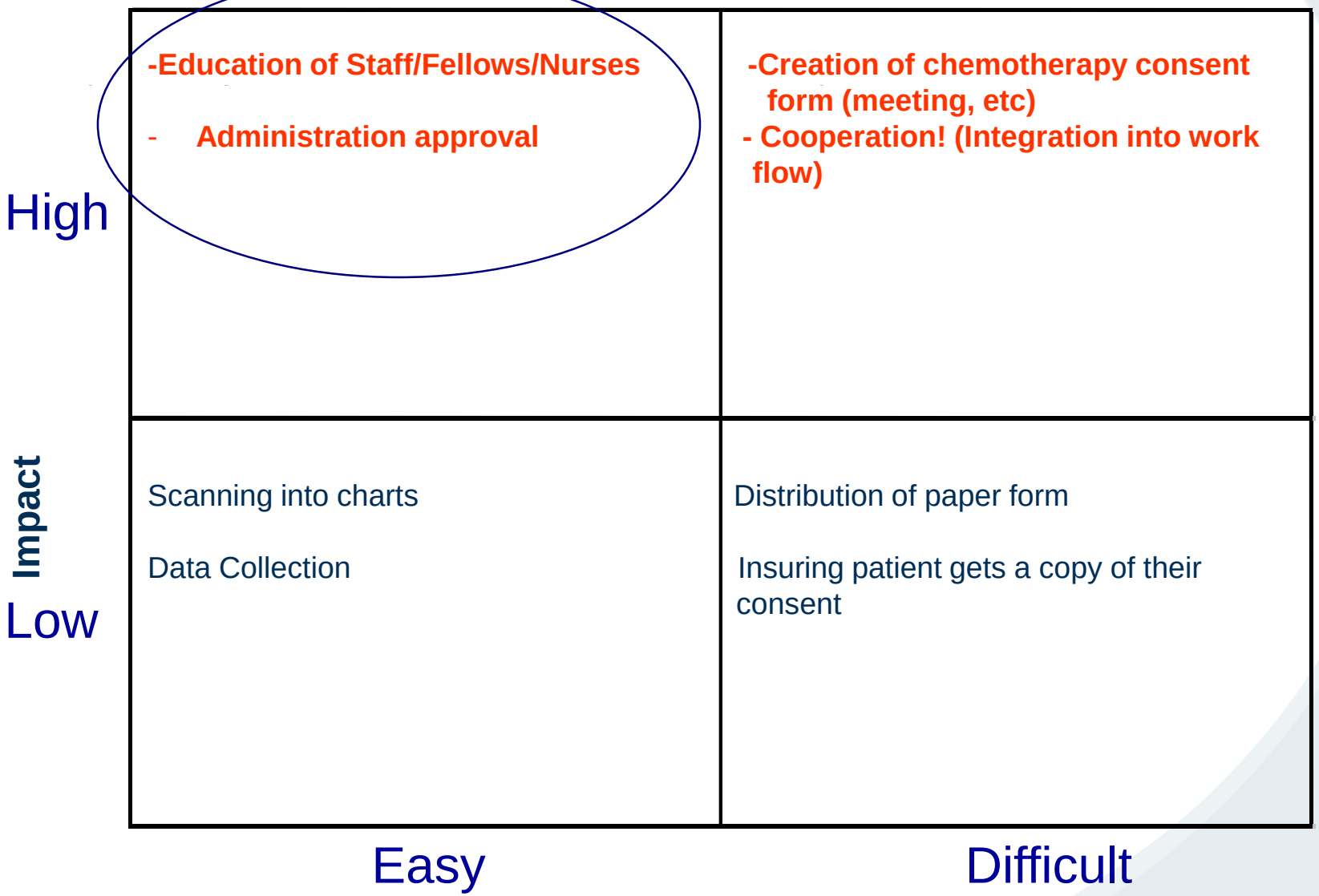
Baseline Data

- 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)



PDSA Plan (Tests of Change)

Date of PDSA cycle	Description of intervention	Results	Action steps
7/1/13-12/1/13	Implement chemotherapy consent process	Went from 0% written documentation to 52%, and drastic increase in documented goals of care	Presentation of data, reminder to all clinical staff
1/1/14-6/30/14	Continue to improve chemotherapy consent process by addressing issues noted during first intervention (access to form, confusion with form, etc)	TBD- Hopefully will hit 80% of new start chemotherapy patients with consent form	TBD- based on results of secondary look

Materials Developed

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: _____

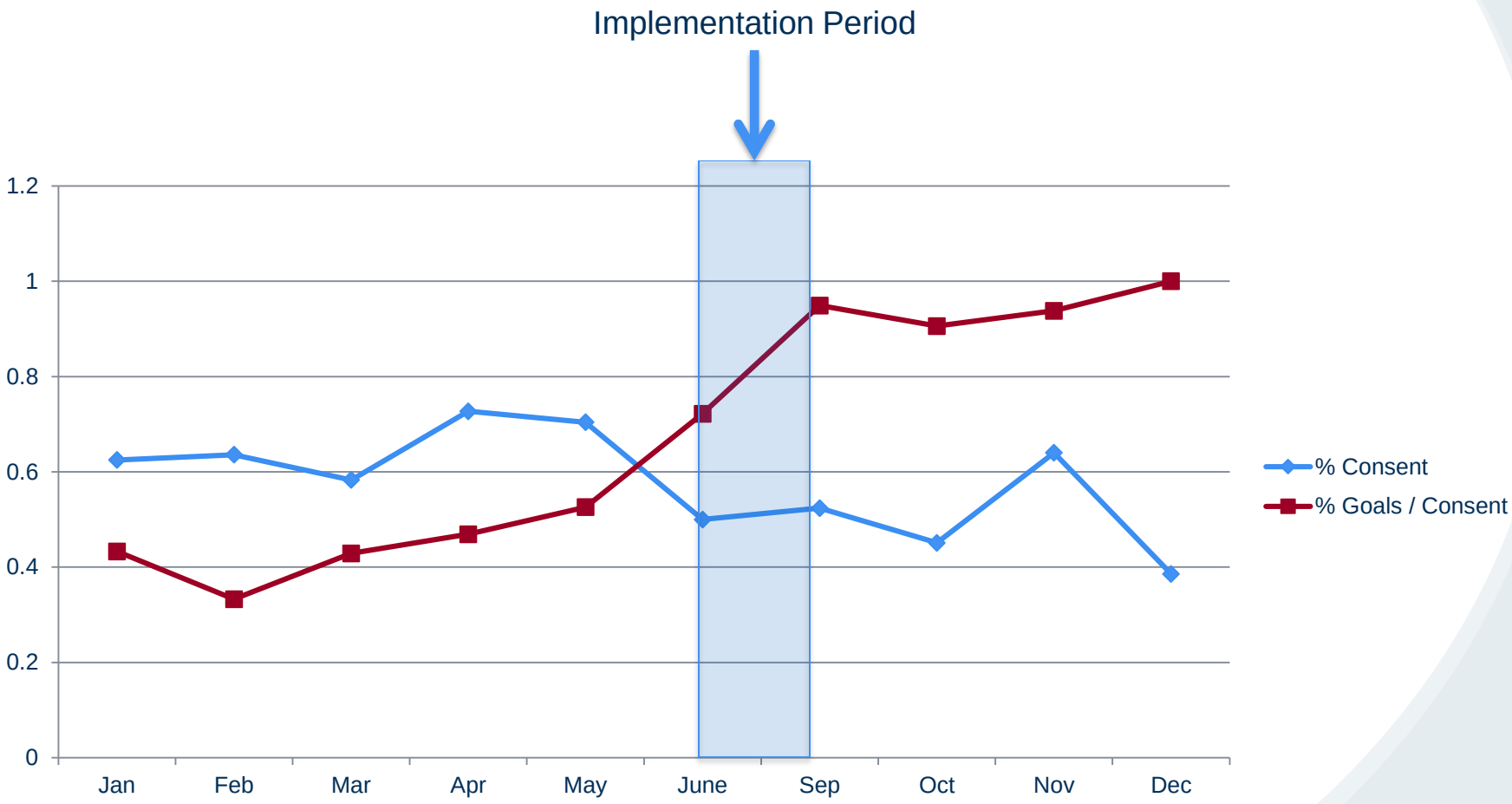
C) Chemotherapy Regimen: I understand the following drugs will be used to treat my cancer:

_____
_____

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

Change Data



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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!

Brendan Curley, DO, MPH- Team Leader
Michael Newton, PharmD, BCOP- Pharmacy Faculty

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.

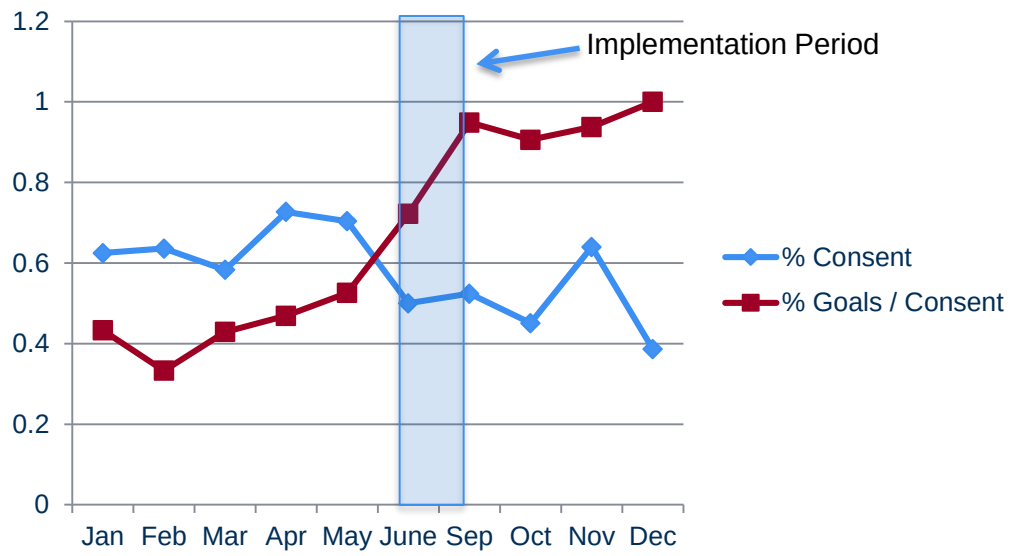
TEAM: WVU/MBRCC– Department of Hematology/Oncology

- **Team Leader-** Brendan Curley, DO, MPH
  Pharmacy- Michael Newton, PharmD, BCOP
- **Oncology-** Mohammed Almubarak, MD
  - Michael Craig, MD
  - Nilay Shah, MD

PROJECT SPONSOR:

- Scot Remick, MD Cancer Center Director

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)

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