ASCO's Quality Training Program

Project Title: Increasing New Patient Accrual to Clinical Trials in the GU Medical Oncology Clinic

Presenter's Name: Nancy B Davis, MD; Deborah E Wallace, MSN; Vicki Stephens, RN

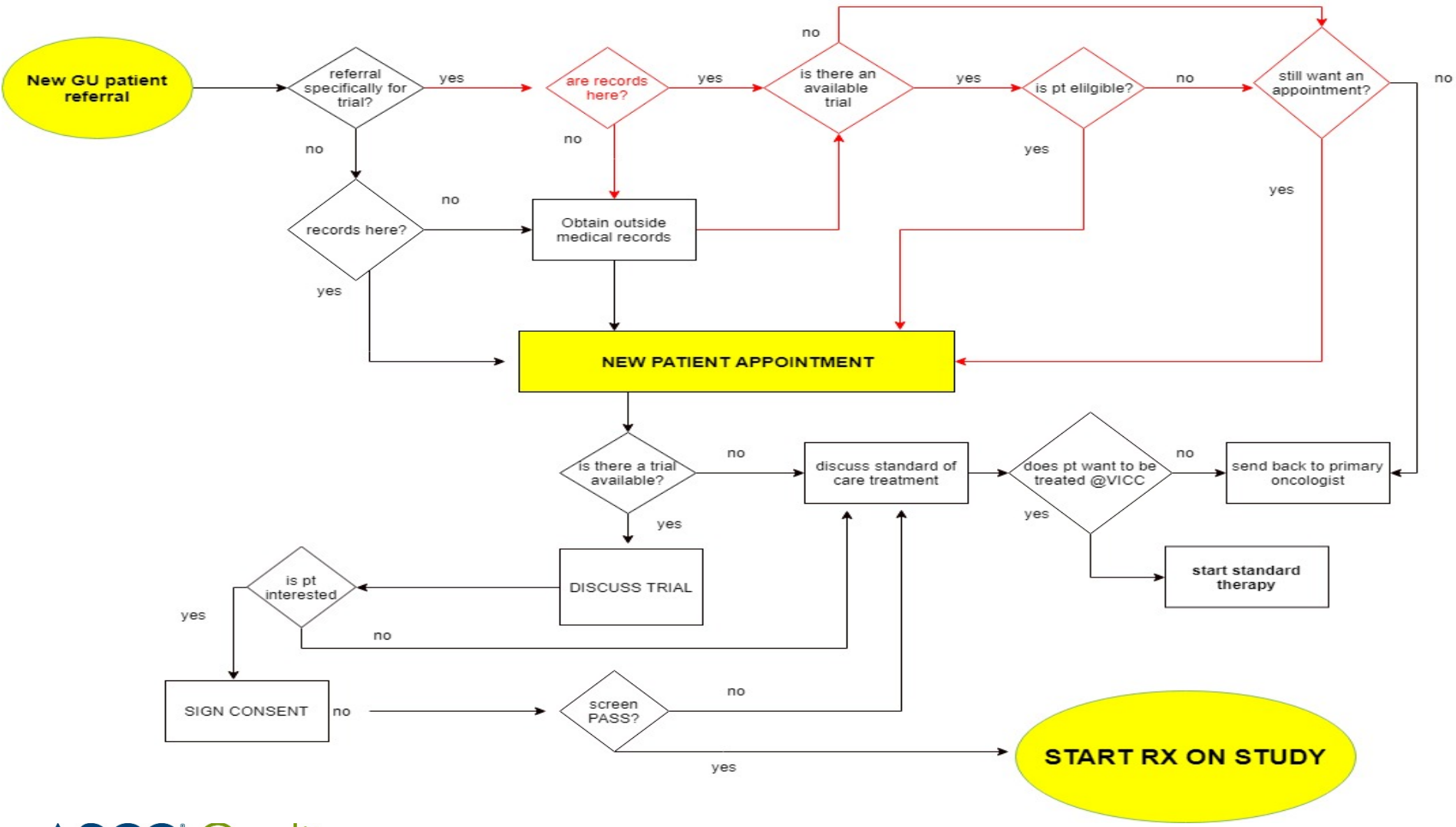
Institution: Vanderbilt University Medical Center / Vanderbilt Ingram Cancer Center

Date: 5 December 2018

Problem Statement

- The GU medical oncology clinic **enrolled 5% of new patients** seen between March 1 and May 31, 2018 to clinical trials.
- There is a **desire to increase** clinical trial accrual in order to provide our patients with access to new therapies and to fulfill our commitment as a NCI-designated cancer center.
- Note: While GU is only 1 of 9 solid tumor clinics at Vanderbilt, improved accrual within the GU group will **contribute significantly** to that commitment.
- **If effective, the process could improve cancer center accrual from all solid tumor clinic groups**.

Process Map



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Institutional Overview

The Vanderbilt Ingram Cancer Center (VICC) is a quaternary care academic cancer center located in Nashville, TN, which is the “buckle" of the "cancer belt" – seven contiguous states with the highest death rates from cancer. Our mission is to alleviate cancer death and suffering through pioneering research; innovative, patient-centered care; and evidence-based prevention, education and community activities. We strive to provide all of our patients with the best available treatment options, offering a multidisciplinary approach to cancer care and a large portfolio of all phases of clinical trials as well as standard treatment options. The GU oncology clinic is one of multiple subspecialty solid tumor oncology clinics at the VICC and currently has 3 medical oncologists who share 2.5 RNs, 2 Research Nurses and other resources with the Melanoma and Sarcoma subspecialties.

The VICC serves as a referral center for all of TN as well as the surrounding or nearby states of AL, KY, IL, IN, Western VA, Northeastern GA. Many of the patients seen and treated at the VICC come from underserved communities, where socioeconomic, racial and ethnic diversity abound.

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Team Members

Team Leader:

Nancy B Davis, MD

Project Sponsor:

Dr. Kim Rathmell

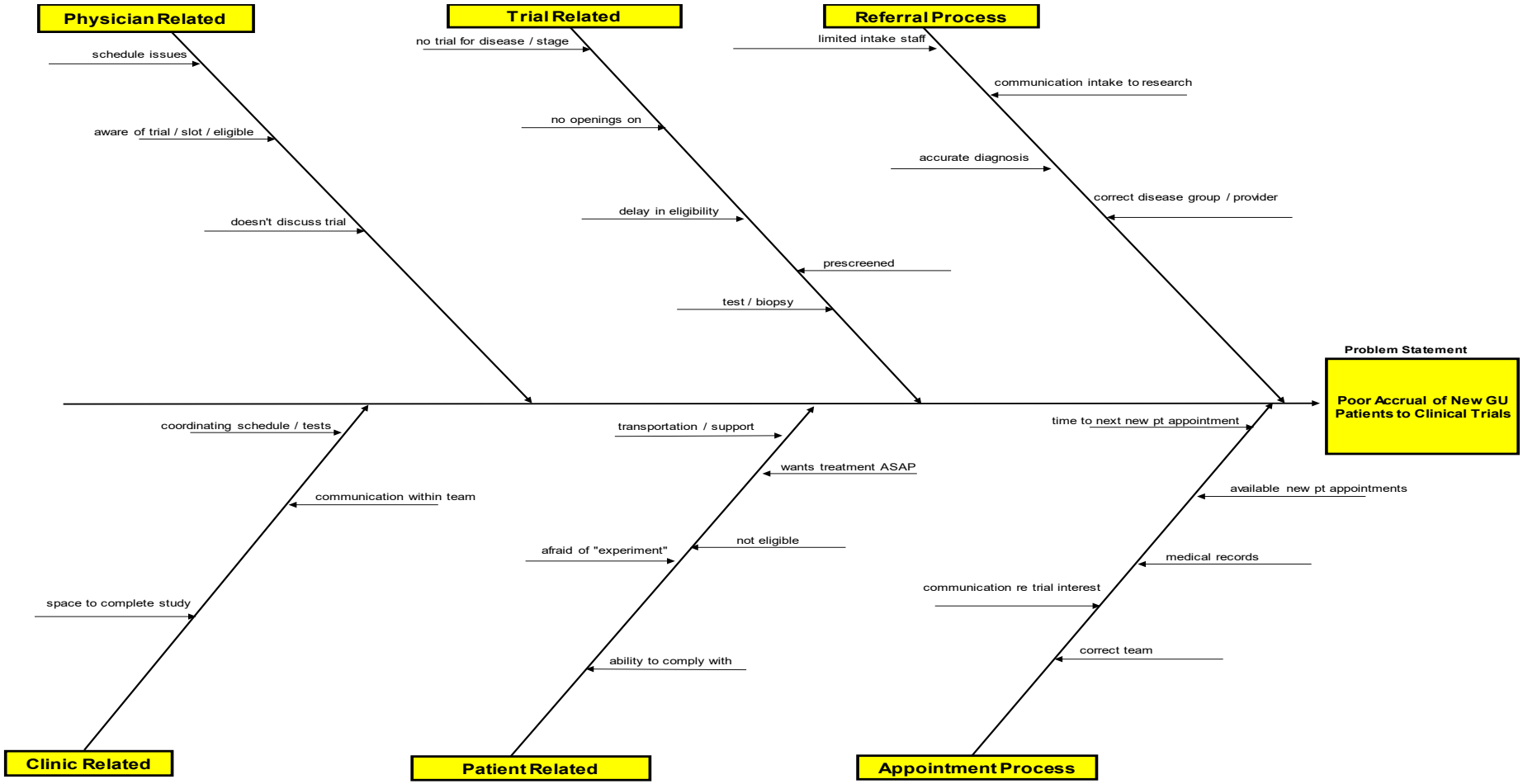
Core Team Members:

Debbie Wallace, MSN
Vicki Stephens, RN

Team Members:

Rhonda Hewett, RN
Julia Mitchell, RN Teresa Knoop, MSN Lynetha Verge, RN

Cause & Effect Diagram



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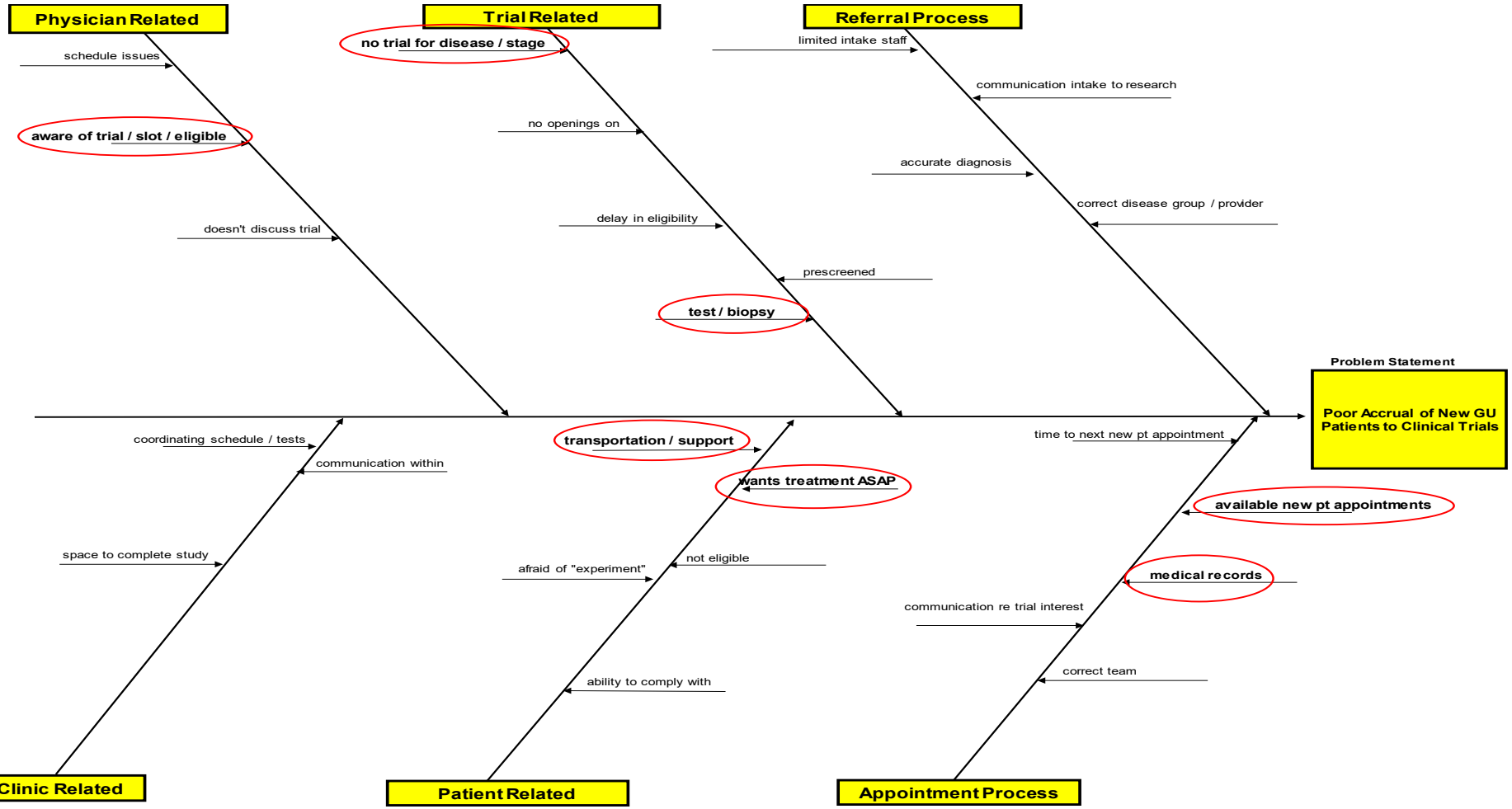
Cause & Effect Diagram



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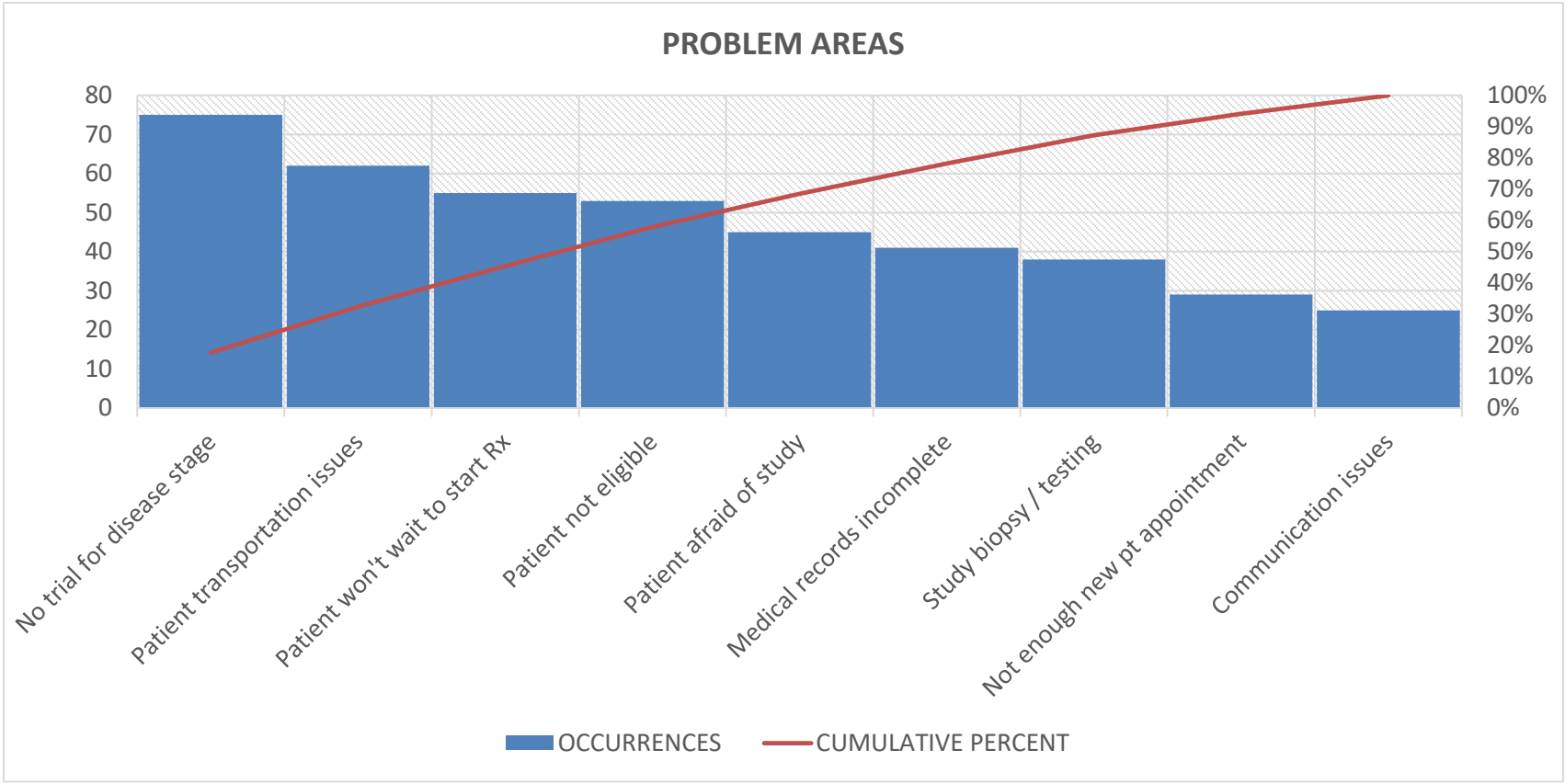
Diagnostic Data: Reasons for Low Trial Accrual



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Aim Statement

Increase clinical trial accrual of new patients referred to the GU Medical Oncology clinic to 8% (2x baseline) between September 1 and November 30, 2018

Measures

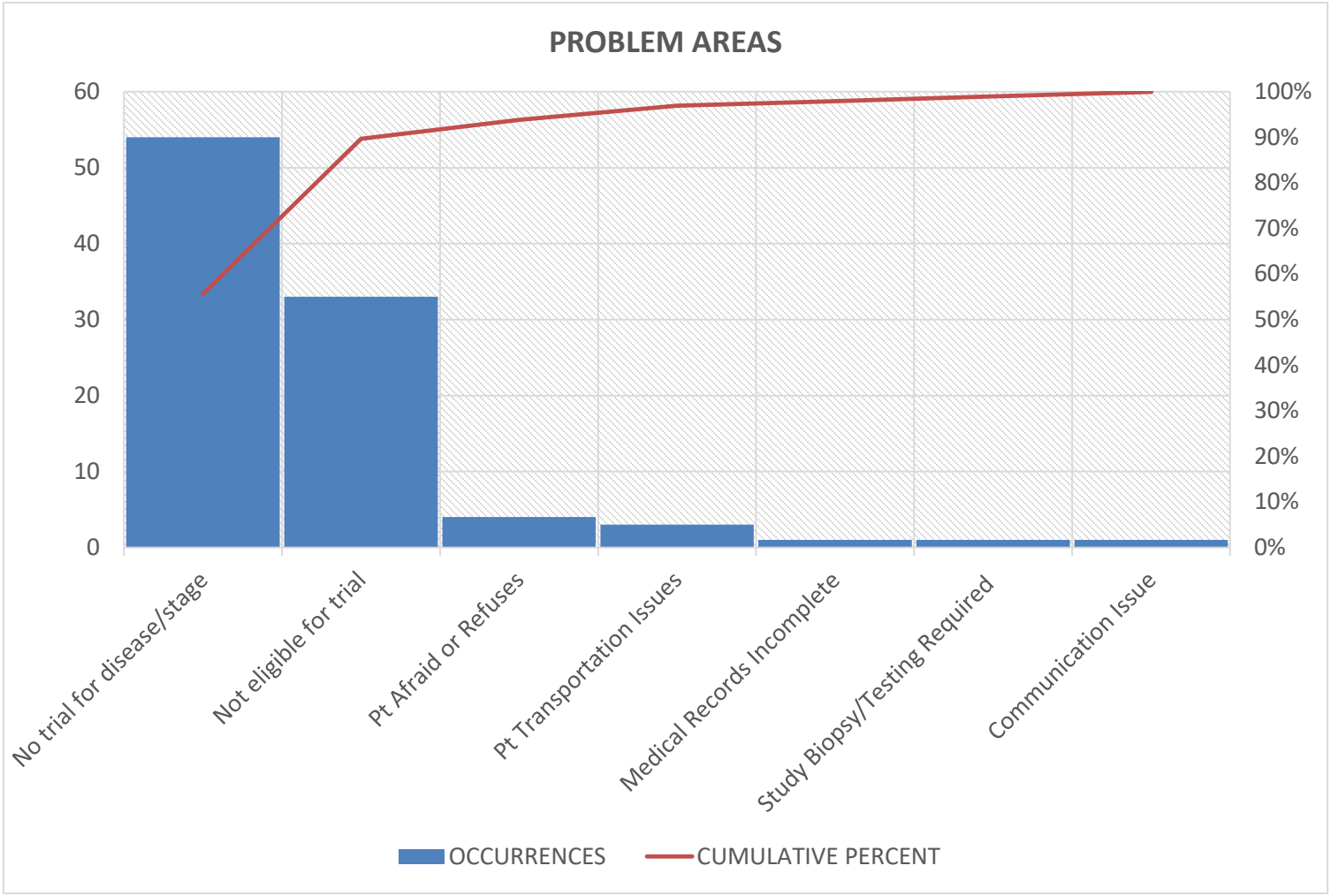
- **Measure:** Percentage of new patients seen enrolled on clinical trials; Percentage of new patients seen had clinical trial discussion on 1st visit
- **Patient population:** All new patients seen in the VICC GU Medical Oncology clinic regardless of primary cancer site
  - Considered excluding diseases for which no trials available to open: testicular & penile
- **Calculation methodology:**

  # new patients enrolled / # new patients seen x 100%
- **Data sources:**
  - EPIC schedule to assess # new patients seen;
  - clinical trial enrollment stats;
  - GU business meeting / accrual stats (included # consented, # in screening and # on trial)
- **Data collection frequency: Bi-weekly**
- **Data quality (any limitations):**
  - There are 4 FTE GU MDs and 2 generalists who see some GU patients
  - The possibility of missing some of the GU new patients seen by the generalists exists

Baseline Data

MONTH	# NEW PTS SEEN	# DISCUSSED	# ENROLLED
MARCH 1-31	42	9	3
APRIL 1-30	29	8	2
MAY 1-31	31	3	0
TOTAL	**102**	**20 (19%)**	**5 (5%)**

True Baseline Causes for Low Accrual



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Interim Data

MONTH	# NEW PTS SEEN	# DISCUSSED	# ENROLLED
JUNE	22	4	3
JULY	39	12	6
AUG	35*	5	2
TOTAL	**96**	**21 (22%)**	**11 (11%)**

*= 1 patient censored

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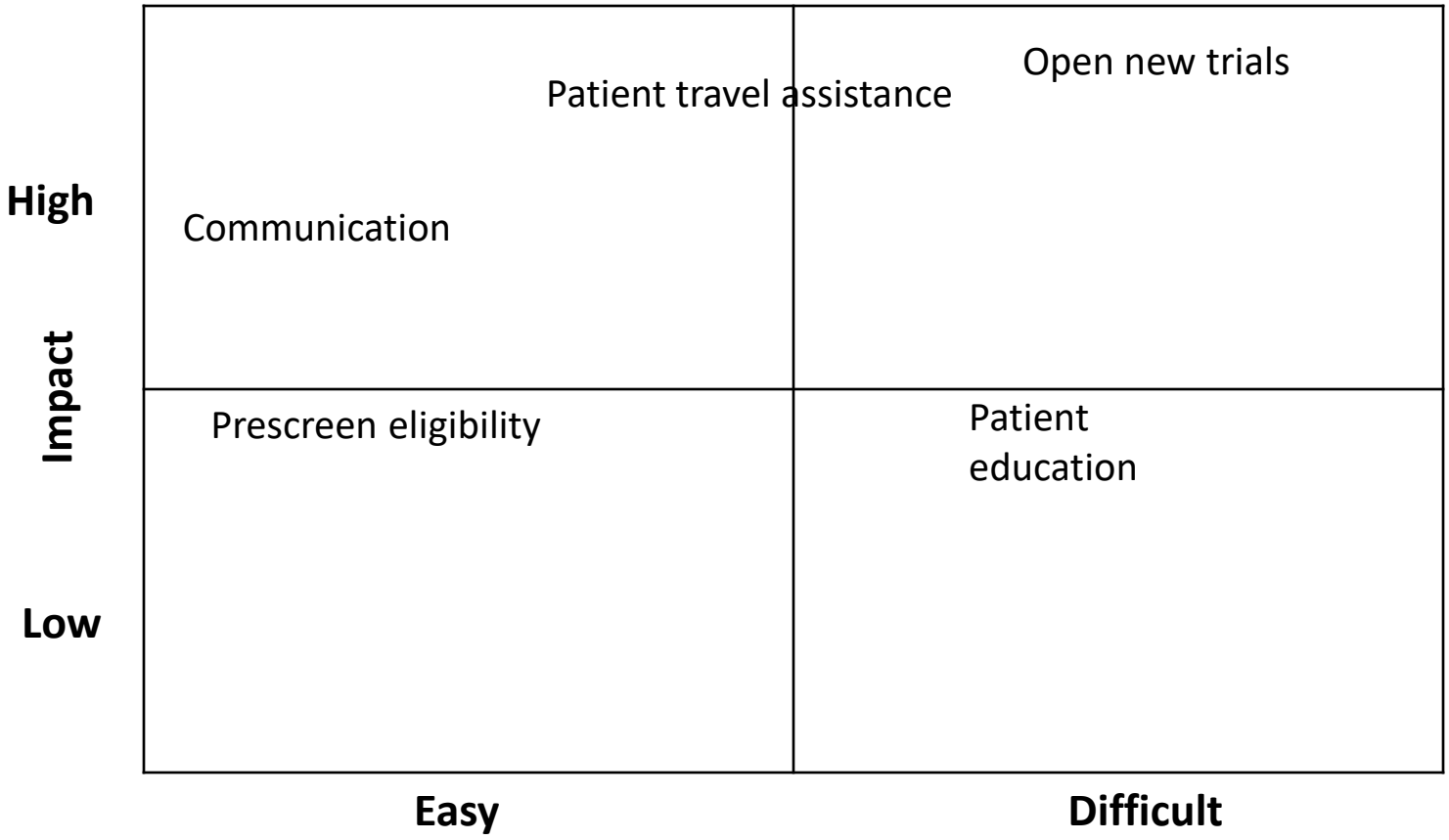
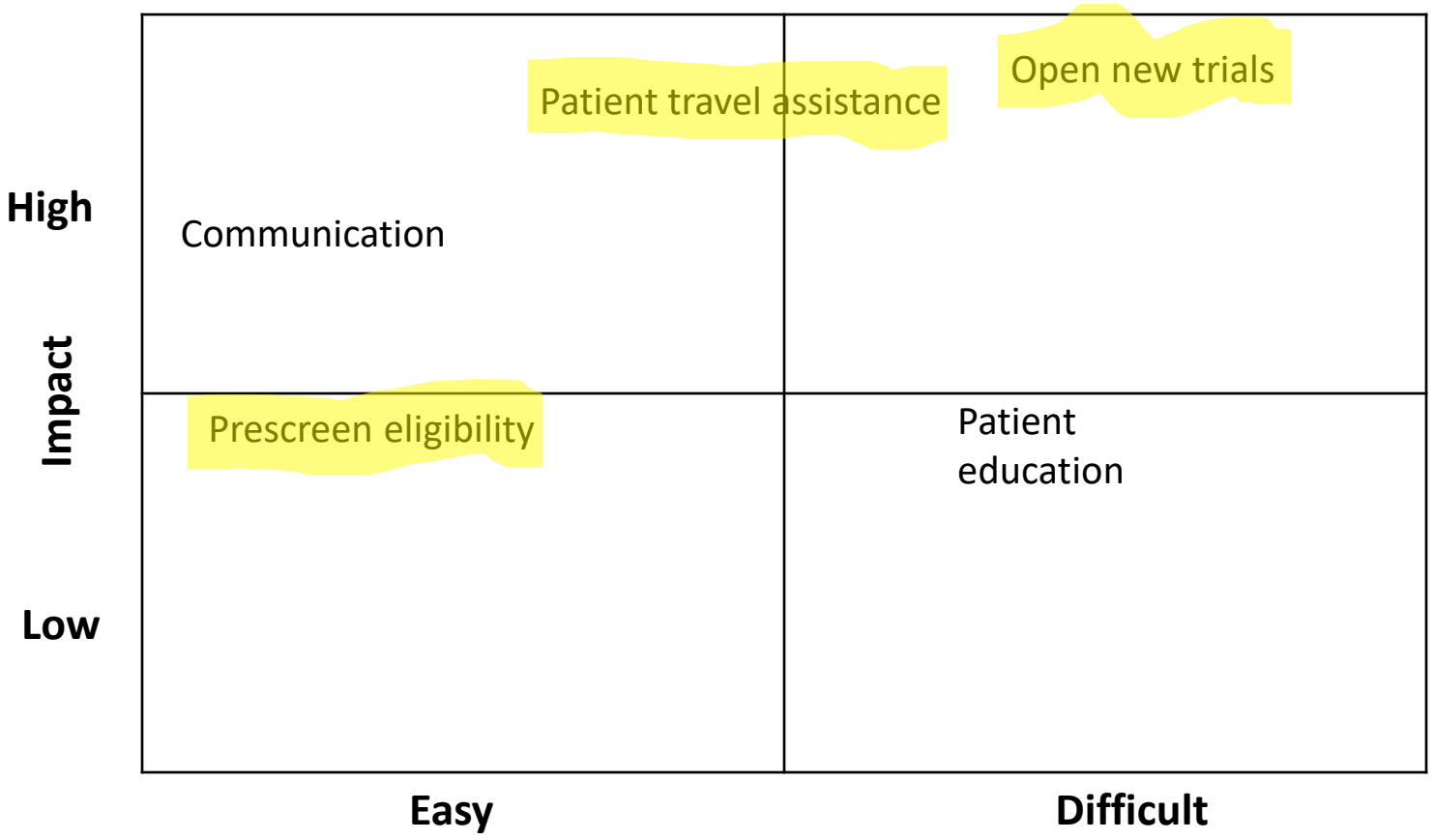
Prioritized List of Changes (Priority/Pay –Off Matrix)



Prioritized List of Changes (Priority/Pay –Off Matrix)



PDSA Plan (Test of Change)

Date of PDSA Cycle	Description of Intervention	Results	Action Steps
8/1/18	Initiated prescreening of all new patients	Increased accrual of new GU patients to clinical trials	Formalize process
[10/1/18]	Open clinical trials for more stages	TBD	Continue to fill in portfolio; monitor accrual
[10/1/18]	Ask trial sponsor to include patient travel stipend in budget	Reimbursement for travel > 100 miles allowed	Continue process
11/1/18	Formalize clinical trial list and distribute	Increased awareness, Increased referrals from Urology	Update list monthly and prn

Materials Developed & Utilized

- Updated Clinical trials spreadsheet
  - Allows visualization of studies arranged by diagnosis and stage
  - Allows quick evaluation of “holes” in portfolio
  - Easy identification of open or pending trials

- Weekly EPIC reports of new patients
  - Inclusive of all GU med onc provider schedules
  - New patients “10k”-foot view of eligibility
  - Provider notified of possible trial options prior to date of service

Change Data

MONTH	# NEW PTS SEEN	# DISCUSSED	# ENROLLED
SEPT	26	4	1
OCT	33*	6	2
NOV**	28	4	0
TOTAL	**87**	**14 (16%)**	**3 (3%)**

*= 1 patient censored
**= through 11/21/18

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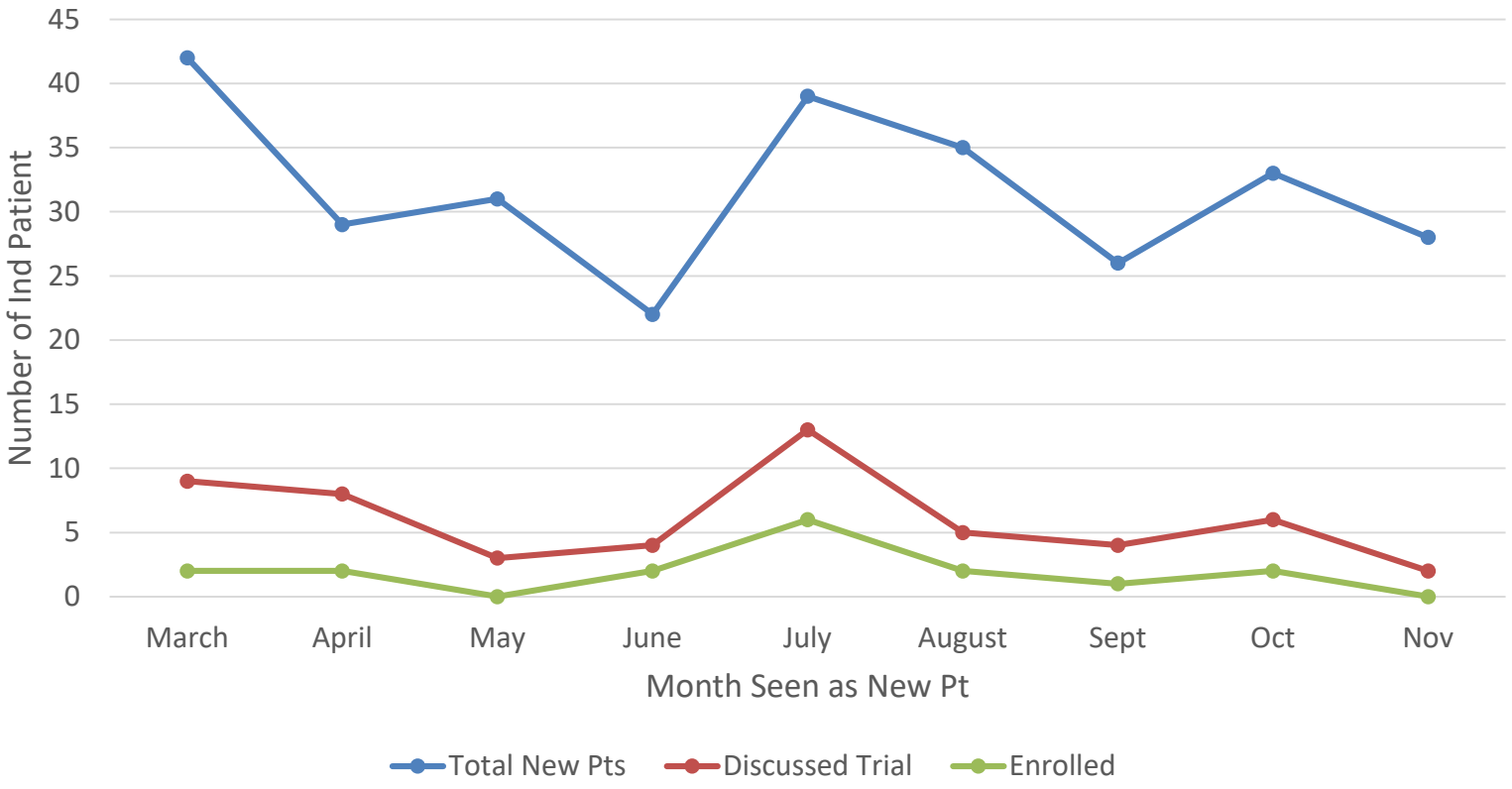
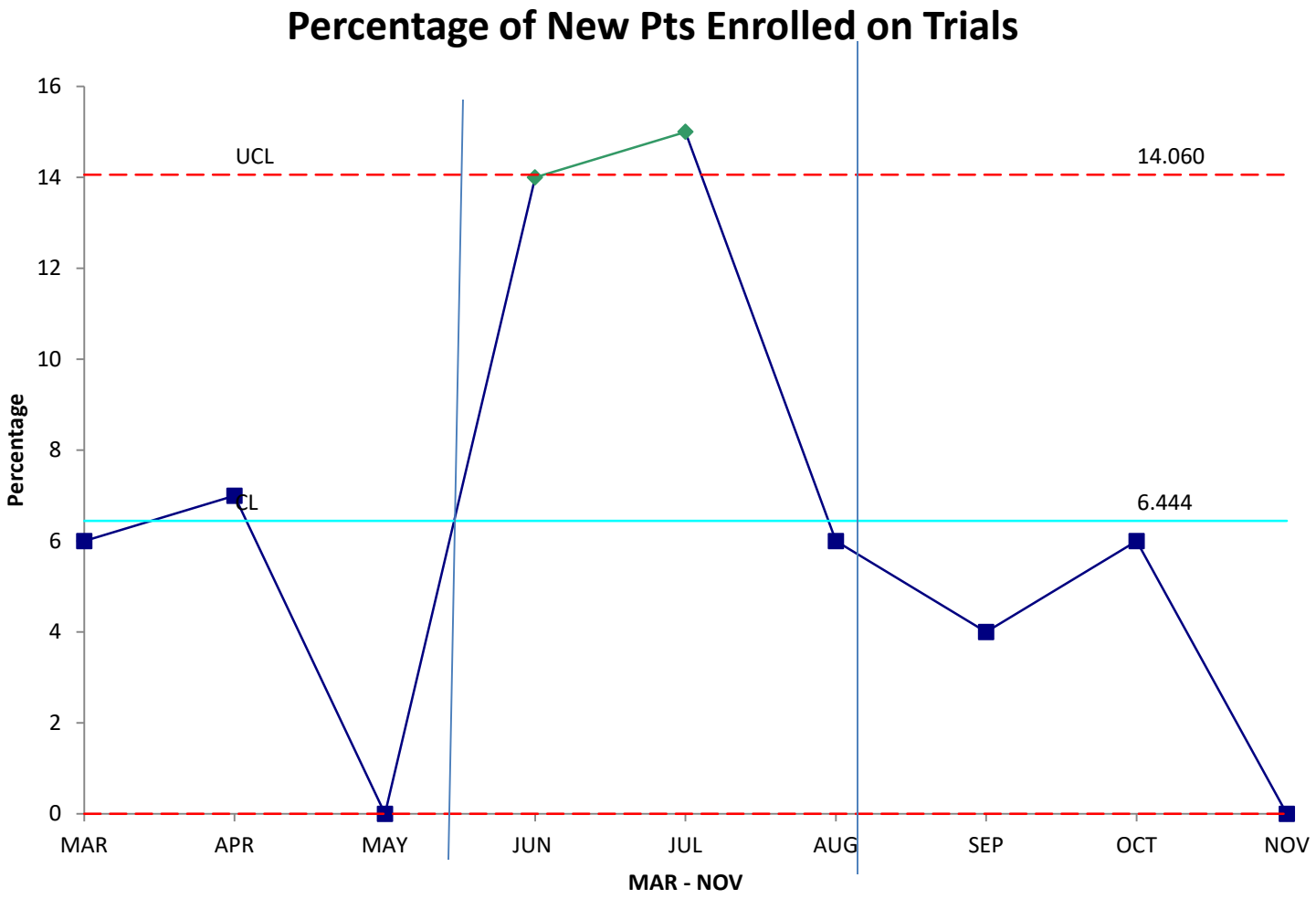
GU Medical Oncology Clinic
New Pts, Trial Discussed, Pts Enrolled




Percentage of New Pts Enrolled on Trials
16
14
12
10
8
6
4
2
0
Percentage
UCL
14.060
CL
6.444
MAR
APR
MAY
JUN
JUL
AUG
SEP
OCT
NOV
MAR - NOV

Conclusions

- Not everything is what it seems to be…
  - Our original premise is only a minor contributor to the problem
- The “process” works!
  - Identified the primary causative factor in poor trial accrual
- More than 1 solution for every problem
  - Processes were already initiated to modify the primary and other causes before their impact on accrual realized
  - A “fix” put into place for the perceived primary cause was effective
- Communication, communication, communication

Next Steps/Plan for Sustainability

- Continue efforts to “mind the gap”
- Revise, formalize method of prescreening new patients
- Increase communication within the GU medical oncology team and between different GU oncology teams
- Continue to “ask for what we want”
- Efforts to improve pre appointment methods

Nancy B Davis, MD
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Vicki Stephens, RN

Increasing New Patient Accrual to Clinical Trials in the GU Medical Oncology Clinic

AIM: Increase clinical trial accrual of new patients referred to the GU Medical Oncology clinic to 8% (2x baseline) between October 1 and November 30, 2018

INTERVENTION:

- Initiated weekly prescreening of the MD new patient schedules by research RN to identify possible clinical trials for which new patient would be eligible
- Made standard a request to pharmaceutical sponsored clinical trials for travel reimbursement for patients traveling > 100 miles
- Identified "holes" in GU clinical trial portfolio and began process to open trials for those stages

TEAM:

GU Med Onc Clinical Research:

- Rhonda Hewett, RN
- Julia Mitchell, RN
- Teresa Knoop, MSN

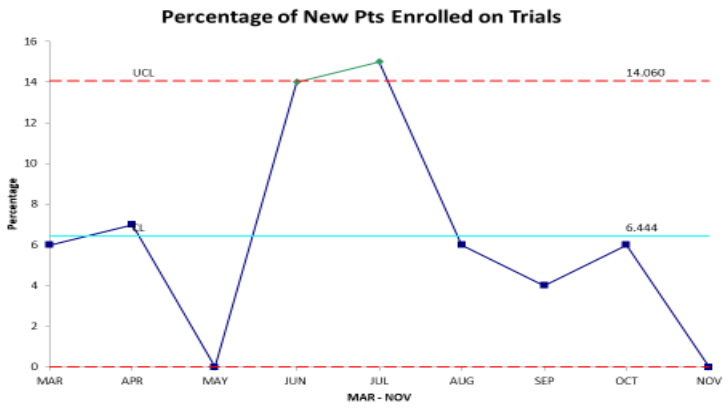
GU Med Onc Clinic:

- Lynetha Verge, RN

PROJECT SPONSORS:

- W. Kimryn Rathmell, MD/PhD

RESULTS: Interim increase in clinical trial enrollment seen; however, return to baseline percentage of patients enrolled.



CONCLUSIONS:

- Aim not met in intervention period
  - More time required
  - Time for trials to open
- More than 1 underlying cause requires more than 1 solution

NEXT STEPS:

- Continue to increase clinical trial options for underserved disease / stage / population
- Standardize request for travel support with pharmaceutical company sponsored trials
- Formalize methods (who, when, how) of prescreening scheduled new patients

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