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
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.
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.
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
**Poor Accrual of New GU Patients to Clinical Trials**

**Problem Statement**

1. **Physician Related**
   - Schedule issues
   - Aware of trial / slot / eligible
   - Doesn't discuss trial
   - Coordinating schedule / tests
   - Communication within team
   - Space to complete study

2. **Trial Related**
   - No trial for disease / stage
   - No openings on
   - Delay in eligibility
   - Test / biopsy
   - Placement
   - Transportation / support
   - Wants treatment ASAP
   - Communication re: trial interest
   - Medical records
   - Correct team

3. **Referral Process**
   - Limited intake staff
   - Communication intake to research
   - Accurate diagnosis
   - Correct disease group / provider
   - Available new pt appointments
   - Time to next new pt appointment

4. **Appointment Process**
   - Correct disease group / provider
   - Communication re: trial interest
   - Medical records
   - Correct team

**Patient Related**

- Afraid of "experiment"
- Not eligible
- Ability to comply with

**Clinic Related**

- Limited intake staff
- Communication intake to research
- Accurate diagnosis
- Correct disease group / provider
- Available new pt appointments
- Time to next new pt appointment

**ASCO Quality Training Program**
Poor Accrual of New GU Patients to Clinical Trials

**Physician Related**
- schedule issues
- aware of trial / slot / eligible
- doesn't discuss trial

**Trial Related**
- no trial for disease / stage
- no openings on
- delay in eligibility
- test / biopsy
- prescreened
- wants treatment ASAP
- afraid of "experiment"
- not eligible
- ability to comply with

**Referral Process**
- limited intake staff
- communication intake to research
- accurate diagnosis
- correct disease group / provider
- correct team
- communication re trial interest
- space to complete study
- coordinating schedule / tests
- transportation / support
- time to next new pt appointment

**Clinic Related**

**Patient Related**

**Appointment Process**

- available new pt appointments
- medical records
Diagnostic Data: Reasons for Low Trial Accrual

PROBLEM AREAS

- No trial for disease stage
- Patient transportation issues
- Patient won’t wait to start Rx
- Patient not eligible
- Medical records incomplete
- Study biopsy / testing
- Not enough new pt appointment
- Communication issues

OCCURRENCES | CUMULATIVE PERCENT
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:**
  \[
  \frac{\text{# new patients enrolled}}{\text{# new patients seen}} \times 100\%
  \]

- **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

<table>
<thead>
<tr>
<th>MONTH</th>
<th># NEW PTS SEEN</th>
<th># DISCUSSED</th>
<th># ENROLLED</th>
</tr>
</thead>
<tbody>
<tr>
<td>MARCH 1-31</td>
<td>42</td>
<td>9</td>
<td>3</td>
</tr>
<tr>
<td>APRIL 1-30</td>
<td>29</td>
<td>8</td>
<td>2</td>
</tr>
<tr>
<td>MAY 1-31</td>
<td>31</td>
<td>3</td>
<td>0</td>
</tr>
<tr>
<td><strong>TOTAL</strong></td>
<td><strong>102</strong></td>
<td><strong>20 (19%)</strong></td>
<td><strong>5 (5%)</strong></td>
</tr>
</tbody>
</table>
True Baseline Causes for Low Accrual

The chart illustrates the problem areas contributing to low accrual, with the x-axis representing different causes and the y-axis showing the cumulative percent. The causes include:

- No trial for disease/stage
- Not eligible for trial
- Pt. Afraid or Refuses
- Pt. Transportation Issues
- Medical Records Incomplete
- Study Biopsy/Testing Required
- Communication Issue

The chart shows that 'No trial for disease/stage' is the most significant cause, followed by 'Not eligible for trial'. The cumulative percent indicates the proportion of occurrences leading to low accrual, with the graph reaching 100% at the end.
## Interim Data

<table>
<thead>
<tr>
<th>MONTH</th>
<th># NEW PTS SEEN</th>
<th># DISCUSSED</th>
<th># ENROLLED</th>
</tr>
</thead>
<tbody>
<tr>
<td>JUNE</td>
<td>22</td>
<td>4</td>
<td>3</td>
</tr>
<tr>
<td>JULY</td>
<td>39</td>
<td>12</td>
<td>6</td>
</tr>
<tr>
<td>AUG</td>
<td>35*</td>
<td>5</td>
<td>2</td>
</tr>
<tr>
<td>TOTAL</td>
<td>96</td>
<td>21 (22%)</td>
<td>11 (11%)</td>
</tr>
</tbody>
</table>

* = 1 patient censored
Prioritized List of Changes (Priority/Pay–Off Matrix)

Ease of Implementation

High

Impact

Communication

Low

Prescreen eligibility

Patient travel assistance

Open new trials

Patient education
Prioritized List of Changes (Priority/Pay-Off Matrix)

<table>
<thead>
<tr>
<th>Impact</th>
<th>Ease</th>
<th>Difficult</th>
</tr>
</thead>
<tbody>
<tr>
<td>High</td>
<td>Communication</td>
<td>Open new trials</td>
</tr>
<tr>
<td>Low</td>
<td>Prescreen eligibility</td>
<td>Patient education</td>
</tr>
<tr>
<td>Date of PDSA Cycle</td>
<td>Description of Intervention</td>
<td>Results</td>
</tr>
<tr>
<td>-------------------</td>
<td>-----------------------------</td>
<td>---------</td>
</tr>
<tr>
<td>8/1/18</td>
<td>Initiated prescreening of all new patients</td>
<td>Increased accrual of new GU patients to clinical trials</td>
</tr>
<tr>
<td>[10/1/18]</td>
<td>Open clinical trials for more stages</td>
<td>TBD</td>
</tr>
<tr>
<td>[10/1/18]</td>
<td>Ask trial sponsor to include patient travel stipend in budget</td>
<td>Reimbursement for travel &gt; 100 miles allowed</td>
</tr>
<tr>
<td>11/1/18</td>
<td>Formalize clinical trial list and distribute</td>
<td>Increased awareness, Increased referrals from Urology</td>
</tr>
</tbody>
</table>
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

<table>
<thead>
<tr>
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<th># NEW PTS SEEN</th>
<th># DISCUSSED</th>
<th># ENROLLED</th>
</tr>
</thead>
<tbody>
<tr>
<td>SEPT</td>
<td>26</td>
<td>4</td>
<td>1</td>
</tr>
<tr>
<td>OCT</td>
<td>33*</td>
<td>6</td>
<td>2</td>
</tr>
<tr>
<td>NOV**</td>
<td>28</td>
<td>4</td>
<td>0</td>
</tr>
<tr>
<td>TOTAL</td>
<td>87</td>
<td>14 (16%)</td>
<td>3 (3%)</td>
</tr>
</tbody>
</table>

* = 1 patient censored
** = through 11/21/18
GU Medical Oncology Clinic
New Pts, Trial Discussed, Pts Enrolled

Month Seen as New Pt

Number of Ind Patient

March April May June July August Sept Oct Nov

Total New Pts
Discussed Trial
Enrolled
Percentage of New Pts Enrolled on Trials

MAR - NOV

Percentage

MAR  APR  MAY  JUN  JUL  AUG  SEP  OCT  NOV

UCL  14.060

6.444
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
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

**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

**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

**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