The Clinical Trial Accrual Challenges Facing Northern Michigan

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The MCC is a statewide, broad-based partnership that strives to include all interested public and private organizations and provides a forum for collaboration (communication, coordination, and the sharing of resources) to reduce the burden of cancer among the citizens of Michigan by achieving the Consortium's research-based and results-oriented cancer prevention and control priorities.
What are Clinical Trials?

- Research studies that explore whether a medical strategy, treatment, or device is safe and effective for humans. (NIH)
  - Prevention
  - Screening
  - Diagnostic
  - Treatment
  - Quality of Life
Phases of Treatment Trials

- **Phase 1:**
  - The first step in testing a new treatment in humans. These studies test the best way to give a new treatment and the best dose.

- **Phase 2:**
  - Studies that evaluate effectiveness on a certain condition. Treatments may be compared with similar participants receiving a different treatment, an inactive substance (placebo) or a different drug.

- **Phase 3:**
  - Compare the new treatment to the current standard by studying different populations, dosages, schedules or combinations.

- **Phase 4:**
  - After FDA approval for market use and continued monitoring.
What is your current role within your institution?

A. Administrator
B. Physician
C. PA/NP
D. Nursing Staff
E. Professional Staff
What type of institution do you represent?

A. Hospital/Health System
B. Public Health
C. Non-Profit Agency
D. Payor Organization
E. Private Clinical Practice
F. Other
Why we should all be engaged?

- A source of continuous quality improvement
- May be the best treatment option for a patient
- Advance best practices in efficacy and efficiency
- Clinical Trials result in lessened cancer burden
- Participation and accrual are required for American College of Surgeons Commission on Cancer accreditation
Accrual and Cancer Programs

- The Institute of Medicine’s Report in 1999 entitled “Ensuring Quality Cancer Care” made several recommendations, including “access to clinical trials”

- American College of Surgeons
  - Eligibility Standard: Clinical Trial Information
    - A policy or procedure is used to provide cancer-related clinical trial information to patients.
  - Standard 1.9: Clinical Trial Accrual

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<thead>
<tr>
<th>Category</th>
<th>Minimum Required Percentage*</th>
<th>Commendation Percentage*</th>
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<tbody>
<tr>
<td>Integrated Network Cancer Program</td>
<td>6</td>
<td>8</td>
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<tr>
<td>NCI-designated Comprehensive Cancer Center Program</td>
<td>10</td>
<td>30</td>
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<tr>
<td>Academic Comprehensive Cancer Program</td>
<td>6</td>
<td>8</td>
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<tr>
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<td>Comprehensive Community Cancer Program</td>
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<td>40</td>
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<tr>
<td>Freestanding Cancer Program</td>
<td>2</td>
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*Of the number of annual analytic cases.
Does your Institution participate in a cooperative group?

A. Yes
B. No
C. I Don’t Know

0% 0% 0%
Does your institution have a collaborative relationship with other clinical trial providers?

A. Yes
B. No
C. I Don’t Know

0% 0% 0%
What % of your patient population participate in Clinical Trials?

a. 25% or greater
b. 11-24%
c. 6-10%
d. 1-5%
e. None
f. I Don’t Know
Utilization Data

- **National**
  - Nearly 25% of all cancer patients are eligible for enrollment in clinical trials, yet only 2.5-3% of patients actually participate.
  - Reports have indicated that 40% or more of NCI sponsored trials have failed to meet their accrual goals.

- **State**
  - 2011 MiBRFS reports indicated a statewide accrual rate of 4.4% of patients participating in clinical trials as a part of their cancer treatment.

- **Local**
  - The American College of Surgeons reported 70 patients in the Michigan Northern Lower Peninsula accrued during 2011 and 2012.
Why Michigan Should be Better?

- Two Comprehensive Cancer Centers
- Growing number of academic medical centers
- Access to 6 Community Oncology research programs
- 42 Commission on Cancer Accredited Programs
  - 2 NCI designated Comprehensive Cancer Programs
General Barriers to Accrual

- Trial Design and Patient Eligibility Criteria
- Financial Coverage
- Information Sharing
- Patient Awareness
Design and eligibility

- Age
- Stage
- Diagnosis
- Previous treatments
- Performance score
- Combination of all above
What factors contribute to the enrollment challenges of your patients (ranked)?

A. Educational level
B. Knowledge/Awareness
C. Age
D. Transportation Issues
E. Finances
F. Snowbirds
Does your institution have an Electronic Medical Record?

A. Yes  
B. No  
C. Not Applicable  
D. I Don’t Know

0% 0% 0% 0%
Does your EMR “Flag” Potentially Eligible Clinical Trial Patients?

A. Yes
B. No
C. Not Applicable
D. I Don’t Know

0% 0% 0% 0%
The Good News on Patient Accrual Tracking

The AACI-NCI Clinical Trial Reporting Program report and timeline

- 1) **NCI-designated Cancer Centers** should develop processes and begin submitting accrual by September 2012.
- 2) **Other Grantee Institutions** conducting NCI-supported trials should develop processes and begin submitting accrual by January 2013.
Financial

- Coverage/Portability of Coverage
- Copay components for patient
- Internal payment processing
- Non-reimbursable expenses to the institution
Blues to cover routine services for approved cancer clinical trials

BCBSM and Blue Care Network will pay for routine professional and facility services provided as part of approved cancer clinical trials, effective for services provided on or after Feb. 1, 2002.

We've made this decision because we support the consensus agreement of the Michigan Working Group on Improving Cancer Outcomes—a statewide organization of health plans, oncologists and health care purchasers—that covering routine medical care services within the protocol of these approved clinical trials will improve patient participation in the trials.

Coverage

The routine services covered in an approved oncology clinical trial include such benefits as:

- Hospital admissions
- Physician visits
- Surgical procedures
- Laboratory tests
- X-rays
- Other ancillary testing and procedures

These services are subject to the copayments and deductibles in the patient's benefit plan.
Michigan Working Group to Improve Cancer Outcomes

Consensus Guidelines for Healthcare Coverage of Routine Patient Care Costs Associated with Oncology Clinical Trials

- Coverage provisions for Phase II and III cancer clinical trials that are sponsored or approved by any one of the following:
  - National Institutes of Health (NIH)
  - National Cancer Institute
  - U.S. Food and Drug Administration
  - U.S. Department of Defense
  - U.S. Department of Veterans Affairs
  - Centers for Medicare and Medicaid Services
  - Centers for Disease Control and Prevention

- Private insurance plans, HMOs and the Michigan Medicaid Program.
Does your institution provide financial navigation resources to patients?

A. Yes
B. No
C. I Don’t Know

Yes: 0%
No: 0%
I Don’t Know: 0%
Are your Financial Advisors familiar with Clinical Trials Coverage?

A. Yes
B. No
C. Not Applicable
D. I Don’t Know
In a collective group of 18 studies that reported barriers to awareness, lack of education regarding clinical trials was the most frequently reported barrier (n=13)

- Lack of culturally appropriate information (n=6)
- Lack of cancer knowledge (n=5)
- Lack of physician awareness of trials (n=4)

Do you have a patient education process that includes Clinical Trials?

A. Yes
B. No
C. I Don’t Know
What are your patients’ biggest concerns related to clinical trials? (ranked)

A. “Experimental”
B. Personal Expense
C. Coverage
D. Travel
E. Complexity of Information and Enrollment
F. Additional Testing and Time
Resources

- ACS materials
  - Brochures, posters, fliers, AV materials
- Clinical Trial Matching Service
  - A free, confidential program that helps patients, their families and health care workers find cancer clinical trials most appropriate to a patient's medical and personal situation
  - Cancer Clinical Trial specialists available via tollfree phone
  - Web access with electronic report returned
- NCI trial services
  - Clinical Trial Search Program
  - LiveHelp online chat
What are your institution’s major barriers to accrual? (ranked)

A. Physician and staff Buy-In
B. Lack of Staffing Resources
C. Minimal patient population/eligibility matching
D. Fear of losing patients
E. Expense
F. Time
G. Administration Support
What can you do to help?

- Get involved
- Provide information
- Encourage participation of others within your organization
What do you feel are most important targets for CT accrual improvement? (rank)

A. Improve communication between research providers
B. Electronic solutions
C. Coverage assistance
D. Patient awareness and engagement techniques
E. Institutional commitment
Would you be willing to commit to a workgroup to address this issue?

A. Yes
B. Not myself, but likely someone else
C. Unlikely
D. Unsure
THANK YOU!!!