The National Cancer Institute
Community Oncology Research Program
(NCORP)
A “Local” Story

Connie Szczepanek RN, BSN
Director
Cancer Research Consortium of West Michigan
(CRCWM NCORP)
Grant Funded by the National Cancer Institute since 1983 and the following Members

1. Bronson Battle Creek
2. Lakeland HealthCare
3. Mercy Health Mercy Campus
4. Mercy Health Saint Mary’s
5. Munson Medical Center
6. Spectrum Health
7. Spectrum Health Reed City Hospital
8. West Michigan Cancer Center
9. Michigan State University College of Human Medicine
10. Van Andel Research Institute
Once Upon A Time.....

**NCI Clinical Trial History**

“In the early 1980s, two forces for the advancement of cancer care were in place: physicians trained at academic cancer centers were increasingly entering community practice to care for the majority of cancer patients in the country; but patients still had to travel to cancer centers to participate in cutting edge cancer clinical trials.”

“The identification of this problem was the impetus for the creation of the Community Clinical Oncology Program (CCOP). By introducing up-to-date cancer management into the community in the form of research clinical trials community physicians would also be more ready and able to apply the proven treatment regimens to all their patients. Diffusion of state-of-the art cancer treatment to the practices where people were being treated would be enhanced.”

(See: NCI CCOP History and NCI Strategic Plan)
Once Upon a Time ....

- Years of experience and participation in NCI funded research as
  - 4 CCOPs
  - 2 NCCCPs
- Hundreds of investigators
- Thousands of patients enrolled
- Across multiple MI counties
- At >28 hospitals/health care systems and >100 private practices
Changes in the National Oncology Research Arena

- NIH funding environment highly competitive
- Dollars increasingly limited
- Government ‘shut down’(s)
- An IOM Report
- Transformation of the NCI Research Enterprise
Changes in the National Oncology Research Arena

Cooperative Groups consolidated to become the National Clinical Trials Network - NCTN (3/1/2014); NCORP Research Bases selected (8/1/2014).

- CALGB, NCCTG and ACOSOG = The Alliance for Clinical Trials in Oncology
- NSABP and RTOG and GOG = NRG
- ECOG and ACRIN = ECOG-ACRIN
- SWOG remains
- COG remains as the Children’s Oncology Group
- Cancer Center Research Bases (URCC, WFCCC)
....And then there was a new day, a new way....

- A new program, a new grant, and an RFA
- New rules and structure
- 60 days to apply
- Over 3+ holidays
- On top of the usual challenges
  - Staff shortages
  - Audits
  - Life
  - Etc.
- Funding unknowns!!!
- And of course -- blizzard(s)

.......Enter NCORP!
NCI Community Oncology Research Program Overview (NCORP)
August 2014

A Collaboration of NCI's Divisions of Cancer Prevention, Cancer Control and Population Sciences, Cancer Treatment and Diagnosis, and Center to Reduce Cancer Health Disparities
What is NCORP?

- Pronounced with the P silent: “N-core”
- A community-based research program
- Builds upon the scope and activities of NCI’s previously supported community networks
  - NCI Community Clinical Oncology Program (Community Clinical Oncology Programs, Minority-Based Clinical Oncology Programs, Research Bases)
  - NCI Community Cancer Centers Program
- Integrates these prior networks into one new program to preserve and enhance cancer research in the community
- Receives support through UG1 grant awards
  - Funding of $93 million annually for 5 years
Why Support Cancer Research in the Community Setting?

• Majority of cancer care is provided in the community

• Increase the generalizability of study findings
  • Access to large diverse patient populations
  • Access to *real world* healthcare delivery settings
  • Testing feasibility of new interventions/processes

• Accelerates the uptake of evidence-based practice, new interventions, and processes into routine practice
Past Research Achievements in the Community Setting

• Contributed 40% of the overall treatment accrual to NCI’s clinical trials network

• Significant minority population accrual
  • MBCCOP: 63%
  • CCOP: 10%

• Incorporated cancer control, symptom management, risk reduction, and toxicity management

• Engaged primary care providers into the management of cancer/at-risk-of cancer patients

• Adopted new agents and technologies into clinical practice
NCORP Overall Goal

To bring cancer clinical trials and cancer care delivery research (CCDR) to people in their own communities, thereby generating a broadly applicable evidence base that contributes to improved patient outcomes and a reduction in cancer disparities.
NCORP Structure

NCORP consists of 3 components:

• Research Bases
• Community Sites
• Minority/Underserved Community Sites
NCORP Structure (Cont.)

• 7 Research Bases
  • Serve as NCORP research hubs
  • Design and conduct multi-center cancer prevention, control and screening/post-treatment surveillance clinical trials and Cancer Care Delivery Research (CCDR) studies
NCORP Structure (Cont.)

• **34 Community Sites**
  - Accrue participants to NCORP clinical trials and CCDR; NCTN treatment and imaging trials and quality of life studies

• **12 Minority/Underserved Community Sites**
  - Accrue participants to NCORP clinical trials and CCDR; NCTN treatment and imaging trials and quality of life studies
  - Have a patient population comprising at least 30% racial/ethnic minorities or rural residents
NCORP Sites

- Community Sites (34)
- Minority/Underserved Community Sites (12)
- Research Bases (7)
- State contains catchment areas for NCORP sites
NCORP Approach

- Design and conduct:
  - Cancer prevention, control, and screening/post-treatment surveillance clinical trials
  - Multi-level CCDR studies (e.g., patient, clinician, organization, system level)
- Enhance patient/provider access to treatment/imaging trials under the reorganized NCTN
NCORP Approach (Cont.)

- Facilitate minority/underserved participation in clinical research
- Increase integration of disparities research questions across all study types/settings
- Integrate the expertise of primary/specialty care providers, health services and behavioral researchers with oncologists
- Accelerate knowledge transfer into clinical practice and healthcare systems/organizations
NCORP Research Areas

CCDR is an area of research expansion.

Cancer Care Delivery Research

Minority/Underserved Accrual

Treatment and Imaging Clinical Trials

Cancer Prevention, Control and Screening/Post-Treatment Surveillance Clinical Trials and HRQOL Studies

Cancer disparities research
Cancer Care Delivery Research (CCDR)

• A multidisciplinary field of scientific investigation
• Examines how social factors, financing systems, organizational structures/processes, health technologies, and healthcare provider and individual behaviors affect:
  • Cancer outcomes
  • Access to and quality of care
  • Cancer care costs
  • Health and well-being of cancer patients and survivors

NCORP’s CCDR focus encompasses individuals, families, organizations, institutions, providers, communities, populations, and their interactions.
Why Include Cancer Care Delivery Research in NCORP?

• Precision medicine is adding to the complexity of care
• Rapidly changing health care system
  • Affordable Care Act
  • Accountable Care Organizations
  • Merging of practices
  • Diverse, often fragmented, provision of care
• Urgent need for evidence about how these changes influence:
  • Patient outcomes
  • Disparities in care

*The dynamic healthcare environment demands a better understanding of routine oncology care delivery.*
NCORP Disparities Research

- Persistent disparities exist
  - Cancer incidence, mortality, and quality of life
  - Access to and quality of care
- Increase in the number of minority/underserved populations
- Determinants of disparities (social factors, health care systems, co-morbidities) disproportionately affect outcomes for underserved populations
- Challenge to fully and equitably implement new technologies and targeted therapies for the underserved

Further research is needed to reduce disparities and improve outcomes for underserved populations across the continuum of care
Disparities Research Crosses All NCORP Areas

Addresses clinical trial and CCDR questions related to the more serious, prevalent cancers and cancer-related problems which disproportionately affect racial/ethnic minorities and other underserved populations

- Studies to enhance racial/ethnic minority and underserved participation in clinical trials
- Studies addressing determinants of disparities (e.g. social and health care system factors, co-morbidities, and genomics)
- Studies that evaluate differential outcomes in minority/underserved populations
## NCORP Clinical Trials Research Agenda

<table>
<thead>
<tr>
<th>Type</th>
<th>Focus</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cancer Prevention</td>
<td>Identify/evaluate interventions to reduce cancer risk and incidence</td>
</tr>
<tr>
<td>Cancer Control</td>
<td>Reduce incidence/co-morbidity of cancer and its treatment, enhance quality of life</td>
</tr>
<tr>
<td>Cancer Screening</td>
<td>Evaluate early diagnosis interventions and cancer recurrence</td>
</tr>
<tr>
<td>NCTN Treatment Trials</td>
<td>Identify secondary endpoints of health-related quality of life or patient-reported outcomes</td>
</tr>
</tbody>
</table>
Examples of Topics of Interest

- Mechanisms of symptoms and treatment-related toxicities
- Observational and longitudinal studies to understand natural history of symptoms and toxicities
- Post-treatment surveillance (e.g., tumor markers of recurrence, optimal screening modalities)
- Under and over-diagnosis
- Management of pre-cancerous lesions
NCORP Organizational Structure

NCI

Clinical Trials and Translational Research Advisory Committee (CTAC)

Coordinating Center for Clinical Trials

Division of Cancer Control and Population Sciences (DCCPS)
- NCORP Associate Director

NCORP

Research Bases:
- NCTN Groups
- Cancer Centers
  - Cancer Prevention and Control Trials
  - Cancer Care Delivery

Community Sites:
- NCORP
- NCORP-Minority/Underserved
  - Cancer Prevention and Control Trials
  - Treatment Trials
  - Cancer Care Delivery

Division of Cancer Prevention (DCP)
- NCORP Director

Evaluation and Prioritization of Research Concepts
Steering Committee:
- Disease specific
- Symptom mgt./QoL
- Cancer Care Delivery

Extramural Investigators
- NCI-designated Cancer Centers
- Other Academic Centers
  - Health Care Organizations
  - Nonprofit Research Organizations

Center to Reduce Cancer Health Disparities (CRCHD)

Division of Cancer Treatment and Diagnosis (DCTD)

CIRB Central Institution Review Board

CTSU Cancer Trials Support Unit

National Clinical Trials Network (NCTN)
- Treatment Trials
NCTN and NCORP Relationship

NCTN Focus (CTEP):
- Late-Phase Treatment Trials
- Advanced Imaging Trials

NCORP Focus (DCP):
- Cancer Prevention and Control Trials
- CCDR
- Comparative Effectiveness Research

These slides are the property of the presenter. Do not reproduce without express written consent.
Additional Resources for NCORP

NCORP Web Site
http://ncorp.cancer.gov

NCI Division of Cancer Prevention
http://prevention.cancer.gov/NCORP

NIH Grants and Funding
http://grants.nih.gov/grants/
NCORP Leadership

• **NCORP Director:**
  Worta McCaskill-Stevens, MD, MS
  Division of Cancer Prevention (DCP)

• **NCORP Associate Director:**
  Rachel Ballard-Barbash, MD, MPH
  Division of Cancer Control and Population Sciences (DCCPS)
NCORP Sites

- Community Sites (34)
- Minority/Underserved Community Sites (12)
- Research Bases (7)
- State contains catchment areas for NCORP sites
NCORP in Michigan

- The only state with 3 of the 34 NCORP Community Sites
- An NCI/NIH Investment of $23+ million over 5 years
- NCORP Sites
  - Cancer Research Consortium of West Michigan (2014)
    - Formerly Grand Rapids Clinical Oncology Program (CCOP) and Kalamazoo CCOP (Since 1975/1983)
  - Michigan Cancer Research Consortium (Since 1994)
  - Beaumont NCORP (Since 2002)
NCORP in Michigan

- **Lives touched** (est.)
  - #Newly diagnosed cancer patients/yr = 28,000
    - >50% of the patients newly diagnosed in MI/year
  - #Patients registered to studies = 20,000
  - #Patients on study and in follow-up = 4,500
Possible Opportunities for MCC?

- Increase awareness and visibility re: the importance of federally funded clinical trials
- Highlight ongoing research work and findings
  - Website
  - Articles
  - Annual Meetings
- Identify potential areas for further research
  - Cancer Care Delivery questions
  - Across member systems and networks
Possible Opportunities for MCC?

- Review priority MCC objectives and further call out synergies with NCORP research
  - Ex. Health disparities
  - Ex. Access to care
  - Ex. Serving rural and underserved populations
- Reconvene a clinical trials workgroup to help facilitate dialogue, education, problem-solving
  - Ex. Funding and coverage of Clinical Trials
  - Ex. Clinical Trials billing compliance challenges
- Provide a forum for sharing best practices
Possible Opportunities for MCC?

- Consider links, partnerships, and projects
  - Ex. NCI, NCTNs
  - Ex. ASCO
- Look for opportunities for Young Investigators
  - Ex. Link to existing research
  - Ex. Develop concepts and research partnerships
Cancer Clinical Trials...

WE HAVE
Real Answers, Real Options, Real Miracles
Right here in our community!

...Hope for the Future