TRANSFORMING CANCER CARE & RESEARCH IN COMMUNITY HOSPITALS.

NCI Community Cancer Centers Program
Status Update

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National Cancer Advisory Board, Bethesda, Maryland, February 18, 2010
NCI Collaborative Effort

- **NCI OD**
  - Dr. Maureen Johnson
  - Ms. Jean Lynn

- **CRCHD**
  - Dr. Ken Chu
  - Dr. Sanya Springfield

- **DCCPS**
  - Dr. Steve Clauser
  - Dr. Julia Rowland
  - Dr. Irene Prabhu Das

- **DCLG**
  - Dr. Beverly Laird
  - Ms. Cheryl Jernigan

- **DCP**
  - Dr. Worta McCaskill-Stevens
  - Ms. Diane St. Germain

- **DCTD**
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- **NCICB**
  - Dr. Ken Buetow
  - Dr. Leslie Derr
  - Ms. Brenda Duggan

- **OBBR**
  - Dr. Carolyn Compton
  - Dr. James Robb

- **OCE**
  - Ms. Mary Anne Bright
  - Ms. Sabrina Islam-Rahman

- **SAIC-Frederick, Inc.**
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  - Mr. Shannon Jackson
  - Ms. Deb Hill
  - Mr. Frank Blanchard

- **Consultants**
  - Dr. Arnie Kaluzny
  - Dr. Mary Fennell
  - Ms. Donna O’Brien
NCCCP Status Report

- Where We Have Been
- Where We Are
- Where We Are Going
Defined the Need

- 85% of cancer patients receive their care in their local communities
- Practice patterns and quality, not optimal
- Disparities, a continued national challenge
- Limited research within community setting,
  3% of adults accrued to cancer trials
- Expanding science requires new approaches, infrastructure, connections
Set NCCCP Goals and Mechanisms

Enhance Access

Improve Quality of Care

Expand Research

Disparities  Clinical Trials  Advocacy  Biospecimens  Survivorship  Quality of Care  caBIG (IT)

Cancer Continuum

Prevention  Screening  Treatment  Palliative Care  Follow-up  Survivor Support  End-of-life Care
Awarded 10 Subcontracts with 16 sites in 2007
Emphasized Unique Program Attributes

- **Public-Private Partnership**
  - Local co-investment ($2.65 for every $1 NCI dollar)

- **Physician-Management Partnership**
  - Direct involvement of hospital leadership

- **Networking Among Sites**
  - Extensive subcommittee work and sharing of best practices

- **Leveraging of NCI scientific resources**
  - NCI-designated Cancer Centers
  - CCOPs, MB-CCOPS, CNPs, etc.

- **Rigorous program evaluation methods**
  - RTI International, independent evaluation contractor
Where we are – Progress and Challenges

- Healthcare Disparities
- Quality of Care
- Survivorship and Palliative Care
- Clinical Trials
- Biospecimens
- Information Technology
Healthcare Disparities

Challenge

• Sites’ knowledge and capacity to focus disparities efforts to drive measurable improvements

Accomplishments

• Developed NCCCP Disparities Vision, Workplan and Dashboard with metrics to focus effort
• Improved sites understanding of how to identify and address healthcare disparities
• Sites have built capacity and invested in staff and programs
• Improved race/ethnicity tracking – OMB Guidelines
Quality of Care

Challenge

• Data and care coordination issues related to working with private practice physicians

Accomplishments

• Created and implemented site-assessment tools for multi-disciplinary care, & genetics counseling and testing

• Participating in National Quality Initiatives
  – Commission on Cancer’s *Rapid Quality Reporting System*
  – ASCO Quality Oncology Practice Initiative® NCCCP data
Breast Cancer Measures

- **BCS**: Radiation therapy is administered within 1 year (365 days) of diagnosis for women under age 70 receiving breast conserving surgery for breast cancer.

- **MAC**: Combination chemotherapy is considered or administered within 4 months (120 days) of diagnosis for women under 70 with AJCC T1cN0M0, or Stage II or III hormone receptor negative breast cancer.

- **HT**: Tamoxifen or third generation aromatase inhibitor is considered or administered within 1 year (365 days) of diagnosis for women with AJCC T1cN0M0, or Stage II or III hormone receptor positive breast cancer.

Colon Cancer Measures

- **12RLN**: At least 12 regional lymph nodes are removed and pathologically examined for resected colon cancer.

- **ACT**: Adjuvant chemotherapy is considered or administered within 4 months (120 days) of diagnosis for patients under the age of 80 with AJCC Stage III (lymph node positive) colon cancer.

Rectal Measure

- **AdJRT**: Radiation therapy is considered or administered within 6 months (180 days) of diagnosis for patients under the age of 80 of with clinical or pathologic AJCC T4N0M0 or Stage III receiving surgical resection for rectal cancer.
ACT Measure Description:
Adjuvant chemotherapy is considered or administered within 4 months (120 days) of diagnosis for patients under the age of 80 with AJCC Stage III (lymph node positive) colon cancer.

Based on reported cases diagnosed since: 03/03/2008

- Administered Therapy: 40% (n=2)
- Therapy Considered but not administered: 0% (n=0)
- Expected Therapy not reported: 40% (n=2)
- Non-Concordant: 20% (n=1)

Y-T-D Estimated:
66.7% (40 - 80)
NCCCP QOPI® Program

- NCCCP-affiliated oncology practices volunteer to participate
- ASCO provides practice profiles at the NCCCP site level
- NCCCP QOPI® physicians share improvement data, assess improvement opportunities, and QI targets

Siegel, RD., Clauser, SB., Lynn, JM. “A National Collaborative to Improve Oncology Practice: The NCI Community Cancer Centers Program QOPI Experience.” *Journal of Oncology Practice*, vol. 5(6) 2009.
Survivorship and Palliative Care

Challenges
• Lack of comprehensive approach and dedicated programs to address survivorship issues

Accomplishments
• Shared best practices on implementation of treatment summary and care plan documents
  – NCCCP QOPI® network identified best practices and strongest performers that other sites could learn from
• Developed program matrix assessment tools for:
  – comprehensive palliative care delivery
  – comprehensive psychosocial care delivery
• Showcased model educational/intervention programs for survivors and their families
Clinical Trials

Challenges

• Limited participation in clinical trials, including minority and other underrepresented populations

Accomplishments

• High accrual to Wake Forest CLL Trial (Cancer Control):
  – Entered 63 patients (22% of trial total of 293) and provided 42% of the CTSU accrual
  – CCOP Research Base trial on CTSU menu with narrow accrual window

• Clinical trial log workgroup created a permanent IT application that allows for:
  – Dynamic data entry… reliable data
  – Site directed management / accountability
  – Real-time queries/outcomes

• Collaborative Effort with CCOP Leadership
Welcome to the Patient Screening Log

Welcome to the NCCCP Clinical Trials Screening and Accrual Log, developed by the NCCCP Clinical Trials Subcommittee. The purpose of the log is to:

- capture the number of participants screened for trials and the subsequent screening methods used;
- document successful trial enrollments;
- collect barriers to trial participation, both from the patient and physician perspectives; and
- analyze the data to identify any trial specific issues and develop strategies to overcome barriers.

Select a User: All

Create New Record

Record ID: 3.1-1 | Edit Record | View Record
Record ID: 3.1-2 | Edit Record | View Record
Record ID: 3.1-3 | Edit Record | View Record
Record ID: 3.1-4 | Edit Record | View Record
Record ID: 3.1-5 | Edit Record | View Record
Record ID: 3.1-6 | Edit Record | View Record
Record ID: 3.1-7 | Edit Record | View Record
Record ID: 3.1-8 | Edit Record | View Record
Record ID: 3.1-9 | Edit Record | View Record
Record ID: 3.1-10 | Edit Record | View Record
Record ID: 3.1-11 | Edit Record | View Record
Record ID: 3.1-12 | Edit Record | View Record

General Information

Important points to understand regarding the use of the log include:

- this log is password protected due to the confidential nature of the data
- a system generated unique patient identification number is associated with each entry in order to problem solve data issues;
- sites will develop Standard Operating Procedures to capture the entries identification number and associate with patient demographic data at the site in a confidential manner.
Biospecimens

Challenges
• Lack of high quality biospecimens for research purposes

Accomplishments
• 100% of sites use best practice formalin-fixation protocol for breast cancer ER/PR/HER2 testing
• Developed a model protocol for non-routine biospecimen disposal with the Disparities Subcommittee
  – For example: special religious and cultural requests
• 3 sites participate in the NCI TCGA program
• 5 sites participate in the Moffitt Total Cancer Care (TCC) program
  – Hartford Hospital had highest tissue quality of all TCC tissue source sites
Information Technology – caBIG and EHRs

Challenges
• caBIG® Technology Deployment – Lack of connectivity with national research cancer data network
• Limited use of EHRs and few linkages with private physicians

Accomplishments
• 11 of 16 NCCCP sites are implementing caBIG® tools
  – 3 sites have caBIG® tools in use to date (caTissue and NBIA)
  – 8 sites to implement caBIG® tools by summer 2010
• 9 of 16 NCCCP sites have operational HER
  – 2 additional sites to deploy EHR by summer 2010
• ASCO/NCCCP Oncology EHR Whitepaper – Oct 2009
Where We Are Going – New Initiatives
NCCCP Network is Expanding

- $80 million ARRA Investment
  (2 years of funding)
  - $40 million to current NCCCP organizations
    - 18 specific projects
    - Many NCI program collaborations (EDDP, CNP, PRO-CTCAE)
  - $40 million to new organizations
    - ~14 community cancer centers to join network
    - Raising the bar on program requirements

- Procurement process ongoing, awards anticipated by Spring 2010
QUESTIONS for the NCAB

• What is the role of NCI in developing community-based research infrastructure to enhance its mission?
• How can public-private partnership models (with local investment) be best leveraged by NCI?
• What do we need to learn during the next NCCCP funding period to inform the future of the program?
• End of Formal Presentation
New NCCCP Sites—Raising the Bar

- Implement caBIG®
- Collect biospecimens according to *NCI Best Practices for Biospecimen Resources*
- Electronic health records in place
- Increased baseline clinical trials accrual requirement and must be active in NCI-sponsored trials
- Race and ethnicity tracking by OMB guidelines across all areas
18 ARRA Projects for Current Sites

- Projects span all NCCCP Components
  - Disparities, Clinical Trials, Quality of Care, Survivorship & Palliative Care, Biospecimens, Communications, and IT

- Includes New Partnership Opportunities
  - CTEP’s Early Drug Development Program
  - CRCHD’s Community Networks Program
  - DCCPS, CTEP and DCP’s PRO-CTCAE
    - MSKCC partnership to pilot electronic patient-reported outcomes for adverse events (PRO-CTCAE) in a community setting
### Program Expectations are Increasing (some examples)

<table>
<thead>
<tr>
<th>Current Expectations (deliverables)</th>
<th>Current Success (exceeding deliverables)</th>
<th>Next Generation Program (new baseline)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Assess caBIG® implementation</td>
<td>9 sites implementing a component of caBIG® by June 2010</td>
<td>Required implementation of caBIG® with data sharing capability</td>
</tr>
<tr>
<td>Assess NCI Best Practices for Biospecimens</td>
<td>8 sites submitting tissue to TCGA or Moffitt TCC 16 sites → new formalin fixation guidelines</td>
<td>Progress in implementing NCI Best Practices required</td>
</tr>
<tr>
<td>No requirement to track OMB race and ethnicity</td>
<td>9 sites tracking OMB race and ethnicity <em>(Note: CHI to all 70 hospitals)</em></td>
<td>OMB race and ethnicity tracking required</td>
</tr>
<tr>
<td>Increase evidence based cancer care</td>
<td>16 sites participating in CoC RQRS</td>
<td>NCCCP Quality initiative (e.g. RQRS) required</td>
</tr>
<tr>
<td>25 Clinical Trial accruals/yr</td>
<td>NCCCP Electronic accrual log project</td>
<td>At least 8 NCI active trial accruals required + 25</td>
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</tbody>
</table>
## Methods and Data Sources Timetable

<table>
<thead>
<tr>
<th>Evaluation Methods and Data Sources</th>
<th>Y1</th>
<th>Y2</th>
<th>Y3</th>
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</thead>
<tbody>
<tr>
<td><strong>Programmatic Data</strong></td>
<td></td>
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<tr>
<td>Site surveys</td>
<td>Baseline</td>
<td>Interim</td>
<td>Final</td>
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<tr>
<td>Quarterly progress reports</td>
<td>Quarterly</td>
<td>Quarterly</td>
<td>Quarterly</td>
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<tr>
<td>Network meeting minutes &amp; projects</td>
<td>Monthly</td>
<td>Monthly</td>
<td>Monthly</td>
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<tr>
<td>Subcontract deliverables</td>
<td>Monthly</td>
<td>Monthly</td>
<td>Monthly</td>
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<tr>
<td><strong>Evaluation Data</strong></td>
<td></td>
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<tr>
<td>Site visits (i.e., interviews with program staff, key stakeholders)</td>
<td>●</td>
<td>●</td>
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<td>Patient focus groups</td>
<td>●</td>
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<tr>
<td>Patient survey</td>
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<td>Micro-cost study</td>
<td>●</td>
<td>●</td>
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<tr>
<td>Strategic case interviews</td>
<td>●</td>
<td>●</td>
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<tr>
<td>Comparative data analysis (i.e., with NCDB via RQRS)</td>
<td>●</td>
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<td>●</td>
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<tr>
<td>Assessment of secondary data (e.g., American Hospital Association)</td>
<td>●</td>
<td>●</td>
<td>●</td>
</tr>
</tbody>
</table>

● = one data collection point
# Upcoming Evaluation Reports

<table>
<thead>
<tr>
<th>Evaluation Deliverables</th>
<th>Date Due</th>
</tr>
</thead>
<tbody>
<tr>
<td>Patient Survey Findings – Site Summaries</td>
<td>October 2009</td>
</tr>
<tr>
<td><strong>Micro-Cost Study Report (Year 1 Findings)</strong></td>
<td>November 2009</td>
</tr>
<tr>
<td>Cross-site Case Study Report (Year 1-2 Findings)</td>
<td>February 2010</td>
</tr>
<tr>
<td><strong>Overall Wave 1 Patient Survey Report</strong></td>
<td>February 2010</td>
</tr>
<tr>
<td><strong>Year 3 Annual Evaluation Report</strong></td>
<td>September 2010</td>
</tr>
<tr>
<td><strong>Final Evaluation Report</strong></td>
<td>July 2011</td>
</tr>
</tbody>
</table>
NCCCP CT Screening & Accrual Log:
Top reasons cited for barriers to accrual

- Did not meet trial criteria
  - Co-morbidities
  - Insufficient / Unavailable pathology samples
  - Time requirement from surgery or therapy
- Patient declined participation
  - Preference for standard treatment
  - No desire to participate in research
  - Perceived side effects too great
- MD declined to offer participation
  - Medical concerns re: age/frailty
  - Medical Concerns re: tolerating tx/performance status
  - Study on hold


