Cancer Care Delivery Research

Site Example: Spartanburg Regional Medical Center
Upstate Carolina CCOP

Lucy Gansauer, RN, MSN, OCN
Objectives

• Describe steps to conduct CCDR
• Identify CCDR resources within your program
• Identify how to build CCDR capacity
• Share lessons learned
Gibbs Cancer Center

- 538 beds, tertiary Medical Center
- Multi-hospital system
- More than 500 physicians
- Serve 5 county region in North and South Carolina
- Magnet Hospital Certification
- Comprehensive Community Cancer Center Certification by the ACoS CoC
- Outstanding Achievement Award in 2006 & 2009.
- 1800 new analytic cases
- QOPI Certified
- CCOP since 1983
- MD Anderson Affiliation since 2005
- 7 medical oncologist employed
Initial Experience with CCDR

- Spartanburg was selected as a NCI Community Cancer Center Program (NCCCP) site in 2007

- Initially we were looking to expand our capability in disparities.
Collaborations

- Established collaborative relationships with:
  - Academic Institutions
  - NCI Designated Cancer Centers
  - NCI Community Network Program
Collaborations

- Reached out to partners letting them know of interest
- Educated partners on our site’s capabilities
- Networked with research staff
- Identify mutual research interests
- Developed MOUs around research
NCORP

- Development of capacity to conduct **cancer care delivery research** in the following areas:
  - Genetic Counseling
  - Multidisciplinary Care
  - Navigation/Care Coordination
  - Supportive/Palliative Care
  - Outreach Programs for minority/underserved populations

NCORP RFA
Past Experience with CCDR

*Developed Capacity*
Navigation Study

A Program to Increase Clinical Trial Participation (*Navigation to Increase Guidance and Awareness of Trials for Thoracic and Esophageal Cancers or NavIGATE*).

Examined the specific barriers to clinical trial (CT) participation for lung and esophageal cancer patients.

Attempted to increase participation and retention in CT through a lay-patient navigator pilot project that educates patients about clinical trials and provided social support.

Specific Aim 1: To describe the specific barriers to CT participation.
Specific Aim 2: To describe changes in knowledge and attitudes about CT.
Specific Aim 3: To assess the impact of adding a CTs’ navigator to the multidisciplinary cancer care team.

Collaborative study with MUSC, St. Joseph Candler, Sponsor: NCI
Promoting the Role of Cancer Research within an African American Community: A Focus on Prostate Cancer

- Study to assess, among dyads of older and younger AA men, changes in knowledge and attitudes about prostate cancer and research participation following a pilot education program for promoting positive health decision making and behaviors
- Activities: recruitment, consent, and focus groups.
- Accruals: 134 (129 AA, 15 white)
- Collaborative study with USC
- Funded by the NCI Community Networks Program Centers U54 CA153461-01
A Comprehensive Assessment of the Knowledge, Perceptions, and Communication Needs about Clinical Trials Among Adults in Rural SC.

- This research addressed the important question of how to promote awareness of and participation in CT among rural residents in SC.
- SRHS had the largest recruitment in SC, and sent the most education materials about clinical trials for the communications analysis.
- Collaborative study with USC.
- Accruals: 81 AAs among four focus groups.
- Sponsor: Health Sciences SC.
- PI: Sei-Hill Kim, PhD.
Effects of an Eight-Week Mind-Body Skills Group on Stress and Mood

- The research protocol aims to further understand how mind-body skills have short and long term influence on stress and mood profiles
- Interventions and pre- and post-evaluations with Profile of Mood States tool
- Accruals: 21
- Sponsor: SRHS Foundation
Patient-Reported Outcomes

Validation Study of the Patient-Reported Outcomes Version of the Common Terminology Criteria for Adverse Events (PRO-CTCAE).

- This study validated a set of questions about the PRO-CTCAE Version of the Common Terminology Criteria for Adverse Events
- Patients entered their symptoms using a touch screen laptop
  Accruals: 124 (56 AA 45%)
- Sponsor: NCI
Current CCDR Studies
Navigation Study

Improving Resection Rates Among AAs with NSCLC ("Southeastern Lung Cancer Study")

- Five-year R01 study to improve rates of lung-directed therapy with curative intent (LDTCI) among AAs with early stage, clinically suspicious or biopsy-proven NSCLC via a navigation intervention
- The hypothesis is that a navigation intervention aimed at reducing potential barriers to care will improve rates among AA patients

- MUSC multi-site study. Sponsor: NCI.
Qualitative Research Study

Factors that Promote Adherence to Endocrine Treatment for Female Breast Cancer Patients

- Patient Interview
- Treatment Staff Interviews

- Our team responsible for:
  - Revised Protocol from Tamoxifen to Endocrine therapy
  - Requested a Stipend for patients
  - Developed Schema
  - Recruitment Plan
  - Phone Scripting
  - Chart Reviews process
NCORP

Defines “participants” in CCDR as:

• Patients
• Practitioners
• Healthcare Organizations
ENABLE IV
*(Educate, Nurture, Advise, Before Life Ends)*

- Dissemination and Implementation Study
- Providing a coaching model for early palliative care
- Spartanburg is the research participant
### Table 2. Grant Project Year Timeline

<table>
<thead>
<tr>
<th>Quarter</th>
<th>Year 1 2013</th>
<th>Year 2 2014</th>
<th>Year 3 2015</th>
<th>Year 4 2016</th>
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<td>Aim 1a Establish Teams &amp; Prepare for Implementation</td>
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<td>Establish Site Teams, meeting schedule, consultant input, communication/feedback processes</td>
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<tr>
<td>Establish IRB Submission</td>
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<td>Establish data collection &amp; monitoring routines</td>
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<tr>
<td>Tailor ENABLE &amp; Nurse training</td>
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<tr>
<td>Collect Pre-implementation patient/caregiver data</td>
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<td>Aim 1b Implement</td>
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<tr>
<td>Prepare for site implementation</td>
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<td>Implement ENABLE</td>
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<td>Collect pre-post-implementation Adoption, Implementation, Reach, process &amp; outcome measures</td>
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<tr>
<td>Aim 2b Evaluate Effectiveness</td>
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<tr>
<td>Refine procedures/ create implementation manual</td>
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<tr>
<td>Collect post implementation patient, outcome data</td>
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<td>Establish maintenance and sustainability processes</td>
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<td>Disseminate at conferences</td>
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<td>Final reports and publications</td>
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### E.2.a Methods

**Aim 1**: Use CBPR in four NCCCP sites to create a rural, community-academic partnership to disseminate and implement the ENABLE model.

a) Create intra-and inter-institutional teams to examine and prepare for organizational/health system change.

**Task 1. Assembling the DH/NCCCP and Site Core Teams/Linking Agent Infrastructure.**

The Dartmouth-Hitchcock (DH)/NCCCP Core team (Dr. Bakitas (20%), Byock (5%), Tosteson (3%) and Ms. Bishop (20%) will serve as Linking Agents providing clinical and research expertise, implementation and
Aim 1:

- Use community-based participatory action research (CBPR) methods to establish a rural, community academic partnership infrastructure in four community cancer centers to identify necessary resources to disseminate and implement the ENABLE evidence-based, concurrent oncology palliative care model.
Aim 2:

- Use the RE-AIM evaluation framework, to assess institutional, clinicians and patients & caregivers outcomes prior to and following implementation of the ENABLE model.
Aim 2.b.

- Evaluate program effectiveness by comparing pre- and post-implementation quality of life, mood, and quality of care outcomes.
Outcome Measures

- Quality of Life (FACIT-Pal)
- Edmonton Symptom Assessment Scale (ESAS)
- Hospital Anxiety and Depression Scale (HADS)
- The Patient Assessment of Chronic Illness Care (PACIC)
- Quality of Life- Caregiver (QOL-C)
- Caregiver Burden Montgomery Borgatta Burden Scale (MBCB)
- Care Giver Depression/ Anxiety-HADS A&D
Site Benefits

- Engagement of the Palliative Care Team in research
- Review of our program components and outcome measures
- Development of a data base
- Advanced Care Planning Clinic
- Collaborative learning network with:
  - Maria Bakitas, DNSc
  - UAB Cancer Care Center
Definition

- Community-Based Participatory Research (CBPR) - “a partnership approach to research that equitably involves, for example, community members, organizational representatives, and researchers in all aspects of the research process” (Israel et al., 2003)
CBPR Core Values

- Participation, influence, and control of non-academics in the process of generating knowledge and change
- Sharing in decision making
- “Mutual ownership” of the processes and products of research
- Co-learning by researchers and community collaborators and “mutual transfer” of expertise and insights
Traditional Research and CBPR

Traditional Research
- Community is a passive subject of study
- Research Design – done by academic institution
- Needs Assessment, data collection, implementation, and evaluation – academic institution’s responsibility
- Usually sustainability plan is not included

CBPR
- Involves the community being studied in the research
- Research Design – done with representatives from community & academic institution
- Needs Assessment, data collection, implementation, & evaluation – everyone’s responsibility
- Sustainability is a priority
CBPR: Issues to keep in mind

- Willingness to truly “listen” & participate
- Willingness to share power – budget issues
- Trust is earned and it takes time
- Early uncertainty with process and outcomes
- Slow process
CBPR Points

- View community members as advisers and experts
- Develop relationships with leaders in the community
- Sustain relationships beyond the research study itself
- Acknowledge and make use of existing community structures

(AHRQ, 2003)
Our Plan for CCDR

What’s the plan?
NCORP CCDR

- Component(s) should have a committed team involving:
  - oncologists, primary care and other providers
  - other professionals (e.g., administrators, care coordinators, genetic counselors),
  - staff responsible for managing databases (e.g., cancer registries, electronic medical records, claims databases) and a
  - senior administrator to facilitate implementation of studies that address organization and processes of care.
NCORP CCDR Plan

- Upstate Carolina CCOP
- Southeast Cancer Control Consortium CCOP
- Submitted a joint NCORP application

- Identified two sites for CCDR
  - Spartanburg Regional Medical Center
  - Novant Health Forsyth Medical Center
CCDR Principal Investigator

James D. Bearden, III, MD, FACP
- Spartanburg Regional Healthcare System

Judith O. Hopkins, MD, Co-PI
- Novant Health Forsyth Medical Center
CCDR Plan

- Development of a CCDR Plan
- Face-to-face meetings twice a year
- Quarterly Conference Calls of the CCDR Committee
- CCDR education twice a year at Business Meetings
- Develop community outreach strategies for minority accruals
- Present progress report at the Business Meetings
Cancer Care Delivery Research Plan:

- **Aim 1**: Further development of capacity, expertise, and experience in conducting CCDR
- **Aim 2**: Outline pilot projects over the duration of the award
- **Aim 3**: Mentoring additional *Consortium* components to participate in pilot projects
- **Aim 4**: Develop pilot research studies that will yield viable research questions for CCDR protocols and proposals with research base affiliations
Cancer Care Delivery Research Concepts

• **Concept 1:** Economic Study to examine adherence to guidelines in the utilization of follow-up imaging (CT, PET, and Bone Scans) in early stage cancer care outside of guidelines. Is there a difference in adherence to guidelines based on race or ethnicity? What is the economic burden of additional scans outside of guidelines?

• **Concept 2:** Navigation Pilot Study utilizing nurse navigators to increase enrollment into adjuvant chemotherapy protocols prior to surgery for breast tumors >2 cm with palpable axillary nodes. Are nurse navigators effective in increasing utilization of neo-adjuvant therapy with early education and intervention? Has navigator intervention increased utilization of neo-adjuvant chemotherapy for disparate and minority populations?
Cancer Care Delivery Research Concepts

- **Concept 3:** Impact of Navigation on CT Accruals; determine impact of patient navigation on minority CT accruals at a community cancer center. 
  - Aim 1: Increase awareness of CT in minority populations
  - Aim 2: Measure navigation interventions for CT education, referrals

- **Concept 4:** Head & Neck Navigation Pilot Study to demonstrate impact on Quality of Life (QOL) & quality of care for head and neck cancer patients utilization navigation services
  - Aim 1: Examine the impact of navigation on tx delays & interruptions
  - Aim 2: Explore effects of navigation on CT accruals
  - Aim 3: Examine the effects of navigation on head and neck patients’ QOL measures using NCCN distress scale tool
Cancer Care Delivery Research Concepts

- **Concept 5:** Tobacco Cessation Pilot Project Study to enroll head and neck cancer patients into a cancer center tobacco cessation program.
  Aim 1: Identify best practices for head and neck cancer patients in tobacco cessation program. Does study population have less missed appointments?
  Aim 2: Review the quality & economic benefits of tobacco cessation

- **Concept 6:** Oral Chemotherapy Adherence Pilot Project Study to examine an Automated Voice Response (AVR) system intervention to manage symptoms and adherence to oral agents utilized in a community cancer center setting among rural and medically underserved patients
Look for Capacity at Your Site
NCORP Data Capacity

- Descriptions of organizational structures
- In-depth information on specialists and specialized programs (e.g., palliative care)
- Service utilization data
- Billing/financial data
- Quality monitoring data
- Organizational policies such as personnel practices
- Clinical protocols
- Reimbursement arrangements
Data Capacity

- Tumor Registries
- Claims databases
- Electronic Health Record
- Integrated Data Bases
  - MIDAS
  - Epic
  - Cerner
  - Premier
Data Warehouse

- **Financial Sources** (e.g. CP3i, Peoplesoft, Lawson)
- **Departmental Sources** (e.g. Apollo)
- **Administrative Sources** (e.g. API Time Tracking)
- **EMR Source Marts** (e.g. Cerner)
- **Human Resources** (e.g. PeopleSoft)

Central topics:
- **Cancer**
- **Sepsis**
- **Readmissions**

Common, Linkable Vocabulary

Research Questions
Health Information Exchanges
Tumor Registry
National Cancer Data Base

- Cancer registries collect cancer information to produce statistics on cancer incidence and survival rates
Cancer Registry Data

- Demographics
- Race & Ethnicity
- Zip Codes
- Providers
- Health Care Coverage
- User defined fields
- CT Participation
Cancer-related Information

- Medical History
- Diagnosis
- Stage
- Prognostic indicators
- Treatments
- Cancer Recurrence
- Survival Data
CDC has established national standards to ensure the completeness, timeliness, and quality of Cancer Registry data.
### PATIENT INFORMATION

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### CANCER INFORMATION & DIAGNOSIS

- **Histology Text:** Intraductal Duct Carcinoma
- **Tumor Size:** 9
- **Path:** T1N0M0

### TREATMENT

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### PHYSICAL EXAM

- Papable mass in right breast and suspicious axillary lymph node on exam. Patient scheduled for biopsy.
- Pathology:
  - Approx. 1.5 cm mass that is mostly intraductal carcinoma with an area 9mm of invasive infiltrating duct carcinoma. Two sentinel nodes and four axillary nodes are negative for carcinoma.

### LAB TESTS

- ERA/PRA positive

### PATHOLOGY

- Path 9mm invasion, no positive nodes, localized

### X-RAYS/SCANS

- Papable mass in right breast and suspicious axillary lymph node on exam.

### TREATMENT

- Hormone/Steroid: Tamoxifen
- Immunotherapy: none recommended
- Transplant/Endocrine: none recommended
- Other Therapy: none recommended
Preparation for CCDR
Assessment

- Identify past CCDR research
- Assess areas of expertise and strengths
  - Staff
  - Partnerships
  - Information Systems
  - Integrated Data Bases
  - Data Warehouse
  - Tumor Registry
  - Quality Program-QOPI
Set Expectation

- Senior Leadership and PI as champions
- Provide CCDR Education
- Meet with effected staff
- Identify their concerns
Prepare your Clinical Research Department

- Most CCDR research has taken place outside of the clinical research department
- Understanding responsibilities
- Protocol selection
- Accruals
- Study Coordinator

Leading cancer research. Together.
Preparing Your staff

Human Subject Training
CITI Collaborative IRB Training Initiative

Training Modules:
- Modules focused on biomedical research
- Modules focused on Social and Behavioral research
- Continuing Education (CE) modules
CITI Training

• Meet with IRB to determine appropriate courses for CCDR
• Identify staff who will be involved in CCDR
• Complete required modules by effected staff
Lesson Learned

- Not everyone will embrace research
- Additional work for non-research staff
- Takes more time than anticipated
- Requires staff to work outside of their “comfort zone”
- It can be initially difficult working with outside investigators
Recommendation

- Prepare your organization
- Prepared your staff
- Select a CCDR Coordinator
- Reach out to Academic and NCI Designated Cancer Centers to partners with for CCDR
**Cancer Care Continuum.**

### TYPES of CARE

<table>
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<tr>
<th>Prevention</th>
<th>Detection</th>
<th>Diagnosis</th>
<th>Treatment</th>
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<td>Detection</td>
<td>Diagnosis</td>
<td>Cancer or Precursor Treatment</td>
<td>Recurrence Surveillance</td>
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### POTENTIAL FAILURES DURING the PROCESSES of CARE

- Failure to Identify Need to Screen or Counsel
- Failure in Access to Care
- Primary Prevention Failure
- Failure in Detection
- Failure During Follow-up of Abnormal Result
- Failure During Diagnostic Evaluation
- Failure of Treatment
- Failure in Surveillance
- Failure in Care

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Leading cancer research. **Together.**
SWOG

- Outcomes and Comparative Effectiveness Committee

- Committee will be re-touled as a Cancer Care Delivery Research Committee
THANK YOU

- Arigato
- Mahalo
- Grazie
- Spasiba
- Merci
- Gracias
- Danke
- Thoinks Moite
- Shukran