NCI Community Oncology Research Program - NCORP

Augusto Ochoa MD
Gulf South – Minority Underserved - NCORP
LSU Cancer Center
New Orleans
• Health disparities
• Minority Underserved
• Increased co-morbidities
• “Real world” oncology
Sites of the NCI Designated Cancer Centers
Realities for the Oncology Patient in the Community

• >90% Adult Cancer patients do not participate in a clinical trial.

• Most community oncologists are not located within 100 miles of comprehensive cancer centers.

• Many patients, even insured by Medicare/Medicaid cannot afford to travel for extended periods of time.

• Minority-underserved have even fewer options for prevention, early detection and follow-up.
Choices from the Community Oncologist Perspective

• Use standard of care
• Enroll patient on a pharmaceutical trial provided by the local drug representative
• Refer patient to the closest academic center and “lose” the patient
• If given the right opportunity the community oncologist will participate in structured clinical trials.
Hurricane Katrina 8/29/2005
Challenge for the Clinical Trials Program

MCLNO/Charity Patients

Pre-Katrina (Aug 2005) Post-Katrina (Sept 2007)

80% MB - CCOP patients tracked by mid 2007

Xiao & Harris, LSU SPH
Butler & Kaiser, LSU HCSD
Meetings with Community Oncologists

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<tr>
<th>Assess</th>
<th>C. Oncologist Opinions</th>
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<td>• What was their level of interest in Clinical Trials</td>
<td>• Very interested to participate in CT as a group, not individually.</td>
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<td>• What were the barriers for their participation</td>
<td>• Barriers:</td>
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<td>• What would be the incentives to participate</td>
<td>– Too many cooperative groups: complex regulatory, audits, data monitoring etc.</td>
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<td>– Should not detract from their financial bottom line.</td>
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Rules of the Community Clinical Trials Program

Academic Center

• Compete for and manage the grant (NCORP)
• Provide regulatory and data management support
• Provide EMR for clinical trials
• Support participation of C. Oncologists to cooperative group meetings

Community Oncologist

• Accept the academic IRB as the IRB of record (facilitated by C-IRB)
• Provide research nursing support and maintain records for audits
• Use EMR provided by academic center
• Agree to minimum number of enrollments
• Participate in monthly clinical trials meeting
National Clinical Trials Network

• Fewer cooperative groups = fewer contracts and fewer audits

• Streamlines Regulatory Affairs (C-IRB) and Data management

• Access to biology and genomics driven trials

• Access to multi-drug trials
NCORP

- Stimulus to consolidate smaller CCOPs, NCCCP into more effective NCORPs
- C-IRB – Streamlined regulatory
- Cancer Care Delivery Research – Health Disparities Research
  - Cancer care is more than just clinical trials
  - Understand cancer in your region: Tumor Registries
  - Know your patients in their environment: CCDR-HD
  - Develop participation of the communities: CBPR
  - Develop partnerships – Tumor registry – HIE programs
Gulf South – Minority Underserved - NCORP

- Two (2) MB-CCOPs + NCCCP
- Louisiana and southern Mississippi: 26 sites
- Increasing interest from community oncologists
  - Access to biology/genomics trials
  - Referral of patients without “losing” the patient
  - Joint management of complex cases
- Integrate State Tumor Registry and LA HIE in trial selection
New Initiatives

• Research initiatives
  – Collaborations with PCORI projects – smoking cessation and pre-enrollment
  – State-wide Health Disparities research programs

• Training
  – Minority research nurses (CRAs) and navigators: P20 with Dillard University
  – State-wide training course on new billing practices for clinical trials
Outcomes

• Too early to quantify
  – Shortened time for protocol approval
  – Increased referrals from community oncologists
  – Increased self-referrals for 2nd opinions
  – New requests from community practices to participate in NCORP
Challenges for the NCORP Sites

- Funding the infrastructure

- Staying engaged – Early stage clinical trials, biology/genomics trials, academic credit for clinical trials.

- Incentivizing the community oncologist – access to cutting edge clinical trials, adjunct faculty position.

- Incentivizing the community to participate – CBPR, stay closer to home.

- Keep the community (clinicians and patients) informed
Challenges for the Cooperative Groups

• Funding – Decreasing numbers of trials and patients. Fewer trials = fewer patients enrolled in the community (testing treatments in the “real world”)

• Prioritizing trials based on scientific rationale

• Pharmaceutical trials – If cooperative trials are not available, pharma trials will take their place.
Age-Adjusted Death Rates for United States, 2006 - 2010
All Cancer Sites
All Races (includes Hispanic), Both Sexes

Quantile Interval

- 193.3 to 209.5
- 184.5 to 193.3
- 177.9 to 184.5
- 174.3 to 177.9
- 166.3 to 174.3
- 131.3 to 166.3

United States Rate (95% C.I.)
176.4 (176.2 - 176.6)

Healthy People 2020 Goal C-1
160.6

Source: Death data provided by the National Vital Statistics System public use data file. Death rates calculated by the National Cancer Institute using SEER*Stat. Death rates (deaths per 100,000 population per year) are age-adjusted to the 2000 US standard population (19 age groups: <1, 1-4, 5-9, ..., 80-84, 85+). The Healthy People 2020 goals are based on rates adjusted using different methods but the differences should be minimal. Population counts for denominators are based on the Census 1969-2011 US Population Data File as modified by NCI. Healthy People 2020 Goal C-1: Reduce the overall cancer death rate to 160.6.

State Cancer Profiles may provide more current or more local data. Data presented on the State Cancer Profiles Web Site may differ from statistics reported by the State Cancer Registries (for more information).

Healthy People 2020 Objectives provided by the Centers for Disease Control and Prevention.