Cancer Care in Low-Resource Areas: Cancer Treatment, Palliative Care, and Survivorship Care

Session 3: Models and Strategies to Deliver cancer Care in Low-resource Settings

Improving Patient Access to Cancer Care: The Role of Clinical Trials and Implementation Science
Academic and Community Collaboration for Cancer Clinical Trials: One State’s Perspective

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The State of New Mexico

• Rich multiethnic diversity

• Population: 2,059,179
  – 47.3% Hispanic
  – 39.4% Non Hispanic white
  – 8.6% American Indian
  – 3.3% Other Minorities
  – 1.5% Multiple

• Tremendous Disparity:
  – Per Capita Income: ranked 48th
  – 20% below national level
  – Uninsured: 10.9% (19.6)*

• Distinct Cancer Patterns


*https://factfinder.census.gov/faces/tableservices/jsf/pages
Cancer Incidence, New Mexico (2004-2013)

Average Annual Age-Adjusted Incidence Rate per 100,000 (US 2000 Standard), 2004-2013

Courtesy of NM Tumor Registry, C. Wiggins (PI)
New Mexico Cancer Care Alliance

- Non-profit (501c3) public-private joint venture: UNMCCC, 5 health systems, virtually all NM community-based oncologists
- Governed by constitution and bylaws creating a single statewide cancer IRB and integrated infrastructure for the management and oversight of cancer clinical interventions and trials
- Based at UNM Comprehensive Cancer Center (UNMCCC); UNMCCC Director is the Board Chair with authority over all NMCCA trials
- Financial support: UNMCCC, NM Health Systems, and specific Participants.
Why was NMCCA created?

• Increase access to clinical trials in NM.
  ➔ Provides expanded access to clinical trials

• Improve the efficiency in how trials are conducted, and improve overall cancer care in the state.
  ➔ Provides research support for community practices & hospitals

  ➔ Provides education to patients & families
NMCCA: Background

- Established February 2002
- New Mexico not for profit 501c (3)
- Independent Board of Directors
- By-laws and Articles of Incorporation
- Application to the IRS for a not-for-profit determination
What does it mean to be a Participant?

• Participant Class/categories ➔ dictate board seats and voting for super majority items:
  – Class A are physicians
  – Class B, C and D are institutional ➔ Institutional Participants pay an annual participation fee:
    • B – Government entities, Founding Hospitals
    • C – Founding Community Based Hospitals
    • D – Community Based Hospitals
  – Affiliate Participants
What does it mean to be a Participant?

• Class A, B, C & D Participants: agree to provide the NMCCA the first right of refusal prior to opening a clinical trial at their practice/facilities

• Institutional Participants
  – B & C provided cash and/or in-kind contributions
  – D did not provide cash contribution
Agreements

• Research Services Agreement:
  – Appoints NMCCA as its representative for the purpose of entering into clinical trials with sponsors.
  – Identifies duties and responsibilities of NMCCA and each Participant

• IRB Authorization Agreements:
  – Authorize use of UNM IRB, NCI CIRB and WIRB for review of trials opened under the auspices of the NMCCA
Process for Activation of a New Site

- New Sites are approved by the NMCCA Board and contracts signed.
  - When new physicians join a site, the individual PI is approved but no additional contracts are executed
  - Paperwork submitted to NCI, including training investigators and staff
- NMCCA notified by NCI when components are added to each NCI Research Base (SWOG, NRG, etc)
- Update any FWA and IRB authorization
- Contacts for pharmacy, laboratory and imaging, ancillary depts, (like cardiology, ophthalmology), etc.
Process to identify, approve & open studies

- NMCCA executes Confidentiality Agreement
- Obtain protocol & send to disease specific Clinical Working Group
- If disease specific CWG approves, sent to PRMC for approval.
- PRMC approval, NMCCA regulatory Coordinators submit to IRB, obtain Medicare Coverage Analysis for industry sponsored trials and NMCCA executes contract & budget.
- NMCCA is responsible for ongoing continuing review, amendments and external adverse event reporting
UNMCCC/NMCCA Integrated Clinical Research Structure

**NMCCA Staffing:**
- Executive Director
- Clinical Research Manager, PRMC Coordinator and 4 Research Coordinators
- Finance Manager

**NMCCA sites employ & fund their research staff**
Clinical Research Operations: Study Management

• Regulatory Coordinators – NMCCA staff assigned to submit study to the IRB for all NMCCA sites.
  – They manage each study assigned for all sites participating in the trial.
  – Assigned by disease CWG.

• NMCCA staff manage Site, PI and Staff records centrally
  – Training, NCI #s, CVs, CLIAs, Normal Values, etc
Clinical Research Operations: Contracting/Budgeting

• One contract and budget/study with NMCCA and sponsor. NMCCA,
  – invoices sponsor
  – distributes funds to site for patient enrollments
  – reimburses third party vendors

• NMCCA develops the Medicare Coverage Analysis for the network
Time to Activate Clinical Trials: 14 weeks

Key process contributions to reduced time to clinical trial activation

- IRB submission to IRB approval
- PRMC approval to IRB submission
- CWG decision to PRMC approval
- Receipt of protocol to CWG decision
Clinical Research Operations: Quality Assurance & Auditing

• All sites within the NMCCA fall under the UNMCCC DSMP
  – Staffed and led by UNMCCC

• Research Nurses, Research Coordinators, Data Coordinators and Lab techs.
  – Employed by each site to manage the site workload with a dotted line to NMCCA CRM.
  – NMCCA employs Research Coordinators for sites with limited resources and accruals.
Goals, Metrics & Performance Indicators

• We measure the network, sites, investigators, staff, sponsor, IRB, etc...
• Important to involve all stakeholders in the identification and measurement of metrics
• Communicate the findings
New Mexico Model Governance & Communication

• Board of Directors – Quarterly
• Executive Committee – Quarterly
• Finance Committee – Annually
• CWG- Monthly
• PRMC – twice/month
• Staff Meetings – Quarterly
• Scientific Retreats of PIs – 3x/year
• Staff Training - annually

• Quality Assurance Committee (Staff) – Quarterly → Identifies expectations and requirements of key stakeholders (ex. Impact budget)
  – Accrual requirements, external: NCORP grant, NCI CCSG, Community Hospitals CoC, & individual site accrual goals.
  – Accrual requirements, internal: investigator, research coordinator, CWG, site & overall accrual/ research FTE (NMCCA network)
NMCCA Audit Report

Operating margin

- 2012: 2.9%
- 2013: 6.1%
- 2014: 6.4%
- 2015: 10.3%
- 2016: 9.6%

Program efficiency

- 2012: 91.8%
- 2013: 93.1%
- 2014: 94.1%
- 2015: 90.7%
- 2016: 92.2%

Altman Z ratio

- 2012: 3.4
- 2013: 3.2
- 2014: 3.3
- 2015: 3.4
- 2016: 3.0
- Healthy: 2.9

Courtesy of Ricci & Co, LLC
Legislative Wins

- SB requiring insurance companies to cover the routine procedures associated with cancer clinical trials (2003)
- Funding from state via NMDOH to NMCCA for patient and healthcare provider education and training
- Other state funding: NMDOH to support the online resources for cancer patients through the Albuquerque Cancer Coalition (also on the NMCCA website)
Lessons Learned

• **FLEXIBILITY**
  - One size does not fit all.

• **AUTOMATION/IT solutions**
  - Consider e-Regulatory Binders, use WebEx for meetings and interactions, etc.
  - The sooner you implement automation/IT solutions, the sooner your staff gets efficient.

• **COMMUNICATION**
  - Do not overlook this important task.
  - Relationship management & establishment of shared expectations provides clarity when complexity of trials increase & problems occur.
Thank you

Questions?