

Prostate Cancer Clinical Trials - PHEN's Rally Update and Next Steps

13th Annual African-American Prostate Cancer Disparity Summit
PHEN: Prostate Health Education Network

Bernard W. Parker MD, FACP
CAPT, Commissioned Corps, USPHS
Medical Officer and Program Director,
COPTRG, NCORP

Agenda

- Describe the NCI Community Oncology Research Program (NCORP)
- Discuss disparities-related research within NCORP
- Identify prostate cancer research sponsored by the NCI

Overview of NCORP

- NCORP = NCI Community Oncology Research Program; launched 8/01/14
 - Previously the Community Clinical Oncology Program (1982-2014)
 - Housed within the Division of Cancer Prevention, National Cancer Institute
- A national NCI-supported network that brings cancer prevention, clinical trials and cancer-care delivery research (CCDR) to individuals into their communities.
- There are 3 components which comprise NCORP:
 - NCORP Research Bases (n = 7): Centers that design and spearhead multicenter clinical trials; provide overall management & regulatory compliance.
 - NCORP Community Sites (n = 46): Healthcare facilities which accrue patients into NCI-approved cancer clinical trials and research studies.
 - NCORP Minority/Underserved Community Sites (n = 12): Community sites with patient population $\geq 30\%$ racial/ethnic minorities or rural residents.

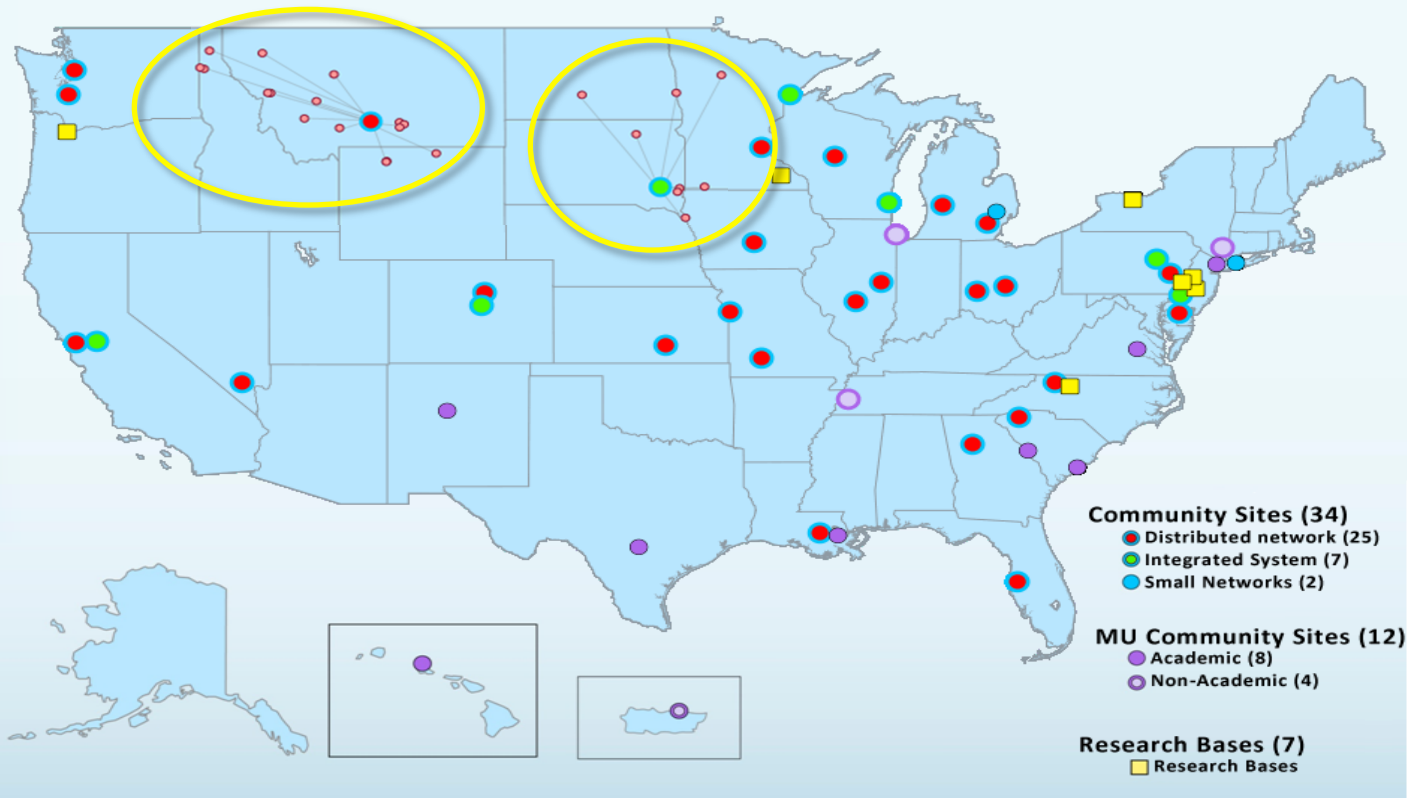
Overview of NCORP (continued)

- A national NCI-supported network that brings cancer prevention, clinical trials and cancer-care delivery research (CCDR) to individuals into their communities.
 - Cancer Prevention Studies: evaluate new methods of detecting cancer risk and preventing primary and secondary cancers.
 - Cancer Control Studies: evaluate symptom management, rehabilitation, and continuing care interventions designed to minimize the burden of cancer and improve quality of life.
 - Cancer Care Delivery Research: evaluates how complex, multi-level forces (e.g. social factors, financing systems, organizational structures and processes, health technologies, provider and patient behaviors) affects cancer outcomes, access to cancer care, the quality and cost of cancer care and health of cancer patients.

Overview of NCORP (continued)

- Interacts with the following NCI Programs:
 - National Clinical Trials Network (NCTN): oversee late-phase cancer treatment and advanced imaging trials.
 - NCI Cancer Trials Support Unit (CTSU): provides administrative support to NCTN's phase 3 (and selected phase 2) studies, as well as selected NCORP studies.
 - NCI Central Institutional Review Board (CIRB): provides a centralized approach to human subject protection through a process that streamlines local IRB review of adult and pediatric multi-center cancer treatment trials.

NCORP Community Site, MU Community Site and Research Bases Geographic and Organizational Diversity



Focused Population by NCORP Minority Underserved Sites

NCORP MU SITE	STATE	POPULATION
GaCares	GA	African Americans
Stroger (SHCC)	IL	African Americans
Gulf South	LA	African Americans
New Mexico	NM	Hispanics; Native Americans
Montefiore	NY	African Americans; Hispanics
Columbia University	NY	African Americans; Hispanics
San Juan	PR	Hispanics
Medical Univ of S Carolina	SC	African Americans
Baptist Health	TN	African Americans
Hawaii	HA	Asians, Native Hawaiians and other Pacific Islanders
Virginia Commonwealth Univ	VA	African Americans
South Texas Pediatric	Tx	Pediatric African Americans; Hispanics

Research Agenda for NCORP Cancer Prevention, Control & Screening Trials

- **Mechanisms of cancer-related symptoms**
- **Biomarkers of risk for treatment-related toxicities**
- **Molecularly targeted agents**
- **Post-treatment surveillance**
- **Management of precancerous lesions**
- **Enhance accrual of racial/ethnic and other under-represented populations**
- **Over-diagnosis and under-diagnosis**

NCORP is an Academic/Community Partnership

Clinical Trials for prevention, symptom science, comparative effectiveness, and screening

- 7,700 patients in Years 1, 2, & 3

Accrual to National Clinical Trials Network (NCTN) treatment and imaging trials

- 10,141 patients in Years 1, 2, & 3

Cancer Disparities Research in NCORP

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

Need for further research to reduce disparities and improve outcomes for underserved populations across the continuum of care

Disparities Efforts within the Division of Cancer Prevention (DCP)

- **August 2011: Co-Morbidities in Cancer Clinical Trials**
- **October 2011: a Collaborative Approach to Reduce Cancer Disparities: Research Priorities**
- **February 2014: AACR/ACS/ASCO/NCI Disparities research Think Tank**
- **February 2016: Developed screening tool to collect expanded demographic data and barriers to enrollment (DCP-001)**
- **December 2016: Formation of the Disparities Integration Working Group**
- **DCP-002 Early Onset Malignancies Initiative (EOMI)**
- **Clinical Trials Targeting Minority/underserved Populations**

DCP's efforts /strategies to enhance minority accrual

- “Charting the Future of Cancer Health Disparities Research: A Position Statement From the American Association for Cancer Research, the American Cancer Society, the American Society of Clinical Oncology, and the National Cancer Institute”
- Journal of Clinical Oncology, Vol 35, No 26 (September 10), 2017: pp 3075-3082
- “NCI defines cancer health disparities as adverse differences in cancer incidence, cancer prevalence, cancer mortality, cancer survivorship, and burden of cancer or related health conditions that exist among specific population groups in the United States.”

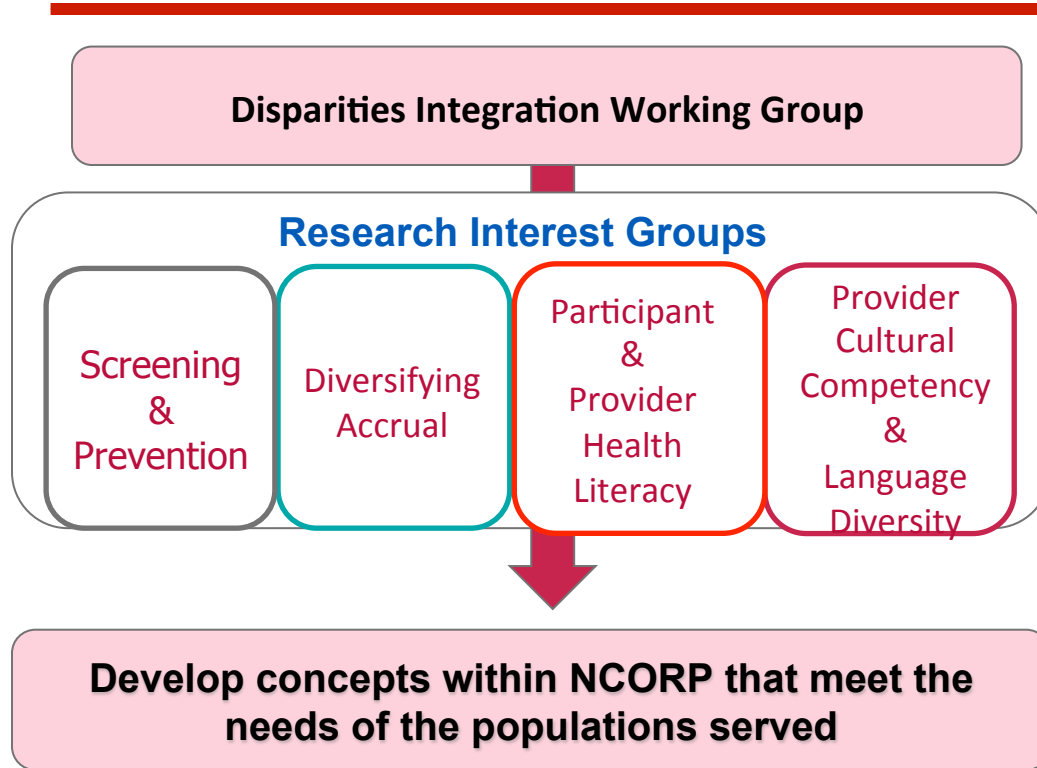
DCP-001 Objectives

- **Collect broader demographic and clinical data:**
 - generate hypotheses and research questions
 - characterize patients that are screened but not enrolled
 - understand how these factors may influence study outcomes
- **Understand site- and trial-specific accrual barriers to develop effective strategies to improve accrual particularly for under-represented populations**
- **Use the number of patients screened to better determine the effort toward patient enrollment in NCORP**
 - credit assignment and infrastructure support

NCORP Disparities Integration Working Group Objectives

- Develop disparities related concepts within NCORP that meets the needs of the populations served
- Cultivate disparities related research questions that could be embedded in existing NCORP trials
- Identify challenges and barriers to incorporating disparities research questions in NCORP trials
- Facilitate alignment and communication around MU site and Research Base interests

Research Interest Groups



DCP-002 Early Onset Malignancies Initiative (EOMI)

Collaboration between NIH Center for Cancer Genomics and NCORP

- Collects early onset cancer specimens and other matching biological samples from six cancer sites among racially and ethnically diverse population groups
- N=2400

Breast, Prostate, Colorectal, Liver, Kidney and Multiple Myeloma

Minority/Underserved NCORPs sites will collect the samples

- Non-Hispanic Blacks, American Indian/Alaska Natives, Non-Hispanic Whites
- Those of Hispanic ethnicity

CCOP/NCORP Disparities Research: 2010 to present

Research Base	Protocol #	Protocol Title	Status	Date	Target population
Wake Forest	WFU-01414	Improving Resection Rates Among African Americans with NSCLC ("Southern Lung Cancer Study")	Active	1/21/15	African Americans
ECOG-ACRIN	ECOG-E1Z11	A Cohort Study to Evaluate Genetic Predictors of Aromatase Inhibitor Musculoskeletal Symptoms (AIMSS)	Active	5/21/13	Asian; African Americans (subgroups accrued)
COG	COG-AALL03N1	Understanding the Ethnic and Racial Differences in Survival in Children with Acute Lymphoblastic Leukemia	Complete	10/9/13	Multiple race/ethnic groups

CCOP/NCORP Disparities Research: 2010 to present

Research Base	Protocol #	Protocol Title	Status	Date	Target population
DCP	DCP-001	Use of a Clinical Trial Screening Tool to Address Cancer Health Disparities in the NCI Community Oncology Research Program (NCORP)	Approved	02/06/16	Multiple race/ethnic groups
DCP	DCP-002	Early Onset Malignancies Initiative (EOMI): Molecular profiling of Breast, Prostate, Colorectal, Liver, Kidney, and Multiple Myeloma among Racially and Ethnically Diverse Populations	Approved	11/21/16	Multiple race/ethnic groups
Alliance	A191402CD	Testing Decision Aids to Improve Prostate Cancer Decisions for Minority Men	In Review	05/03/16	African Americans Native American

CCDR trial – Alliance: AA men educational tool kit

- Title: “Testing Decision Aids to Improve Prostate Cancer Decisions for Minority Men” (Alliance A191402CD)
- <https://clinicaltrials.gov/ct2/show/NCT03182998>
- This randomized phase III trial studies how well decision aids work in improving knowledge in patients with prostate cancer. Decision aids may improve patients' knowledge of their condition and options for treatment, and may also help when talking with their doctor
- **Study Chair:** Jon Tilburt, MD (tilburt.jon@mayo.edu)
- **Activated:** 07/14/17

CCDR trial – Alliance: AA men educational tool kit

- Design: Randomized, parallel-assignment, open-label supportive care study
 - Experimental Arm 1: “Knowing your Options” decision aid before consult
 - Experimental Arm 2: “Prostate Choice” decision aid during consultation
 - Comparator Arm 3: Usual Care
- Inclusion Criteria
 - Men 18 years and older
 - Recent (w/i 4 months) newly-diagnosed biopsy-confirmed prostate cancer
 - Stage T1-3N0M0; Gleason Score 6 to 10; PSA < 50 ng/mL
 - Scheduled consult to be the 1st after diagnosis (not 2nd opinion or previous consultation)

CCDR trial – Alliance: AA men educational tool kit

- Primary Outcome: Knowledge assessed by Prostate CA Treatment Questionnaire, derived from ...
 - during-consultation “Prostate Choice”, and ...
 - pre-consultation “Knowing Your Options” decision aids
- Secondary Outcomes:
 - Decision Quality, measured by “Decisional Conflict Scale Decisional Regret”;
 - Quality of life assessed by questionnaire; and ...
 - Utilization as determined by chart review.

Current open NCI trials enrolling AA men with Prostate CA

Protocol Number	Title	Current Status	Black or African American Accrual	Total Accrual
9622	A Pilot Study of 18F-DCFBC PET/CT in Prostate Cancer (NCI Protocol 14-C-0140)	Active	13	116
NRG-GU002	Phase II-III Trial of Adjuvant Radiotherapy and Androgen Deprivation Following Radical Prostatectomy with or Without Adjuvant Docetaxel	Active	2	7
RTOG-0924	Androgen Deprivation Therapy and High Dose Radiotherapy with or Without Whole-Pelvic Radiotherapy in Unfavorable Intermediate or Favorable High Risk Prostate Cancer: A Phase III Randomized Trial	Active	329	1760

Current open NCI trials enrolling men with prostate cancer

Protocol Number	Phase	Document Title	Lead Organization Name
9984	II	A Randomized Phase 2 Study of Cediranib in Combination with Olaparib Versus Olaparib Alone in Men with Metastatic Castration Resistant Prostate Cancer	Yale University Cancer Center LAO (LAO-CT018)
A151221	Other	Serum Androgens as Prognostic of Survival in Metastatic Castration Resistant Prostate Cancer	Alliance for Clinical Trials in Oncology (ALLIANCE)
A191402CD	III	Testing Decision Aids to Improve Prostate Cancer Decisions for Minority Men	Alliance for Clinical Trials in Oncology (ALLIANCE)
CALGB-150201	Other	Laboratory Studies in Hormone Refractory Prostate Cancer	Alliance for Clinical Trials in Oncology (ALLIANCE)
CALGB-151003	Other	Evaluating the Effect of Tobacco on Prostate Cancer Outcomes	Alliance for Clinical Trials in Oncology (ALLIANCE)
E9802T1	Other	Evaluation of PSA Antibody on E9802: Confirmation and Concordance	ECOG-ACRIN Cancer Research Group (ECOG-ACRIN)
NCIC-PR.3A	Other	Evaluating Tissue Biomarkers of Outcome: Secondary Analyses of MRC RT01 and PR07	The Royal Marsden NHS Foundation Trust - Sutton (25163)
NRG-GU002	II/III	Phase II-III Trial of Adjuvant Radiotherapy and Androgen Deprivation Following Radical Prostatectomy with or Without Adjuvant Docetaxel	NRG Oncology (NRG)
NRG-GU003	III	A Randomized Phase III Trial of Hypofractionated Post-Prostatectomy Radiation Therapy (HYPORT) Versus Conventional Post-Prostatectomy Radiation Therapy (COPORT)	NRG Oncology (NRG)
RTOG-0924	III	Androgen Deprivation Therapy and High Dose Radiotherapy with or Without Whole-Pelvic Radiotherapy in Unfavorable Intermediate or Favorable High Risk Prostate Cancer: A Phase III Randomized Trial	NRG Oncology (NRG)
DCP-002	Other	Early Onset Malignancies Initiative (EOMI): Molecular profiling of Breast, Prostate, Colorectal, Liver, Kidney, and Multiple Myeloma among Racially and Ethnically Diverse Populations	NCI Division of Cancer Prevention (DCP)



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