



NRG Cancer Care Delivery Research

Mary Cooley, PhD, RN, FAAN, CCDR Chair
Matthew Hudson, PhD, MPH, CCDR Vice-Chair

NRG Oncology Semi-Annual Meeting
July 17, 2020

NRG NCORP Cancer Care Delivery Research Priorities



Concepts/protocols focused on:

- Integrating patient-reported outcomes into clinical practice (extends survival);
- Enhance access to proven survivorship and palliative care strategies optimizing survivor and family quality of life;
- Optimize screening strategies based on disease risk including patients in the post-treatment surveillance phase of care; and
- Implement evidence-based symptom management strategies addressing patients' needs during both active adjuvant and palliative treatment.

CCDR Committee Members

Karen Basen-Engquist
Maria Bell
Ronald Chen
Fumiko Chino
Heidi Donovan
Melissa Foust
Shefali Gajjar
Radikha Gogoi
Gregory Gressel
Natalya Greyz
Laurel Habel
Andrea Haggeman
Laura Holman
Julian Hong

Ismail Jatoi
Margaret Liang
Andrew McDonald
Nitin Ohri
Gilbert Padula
Laurel Pracht
Stephanie Pugh
Tonnica Sasanas
Kathryn Schmitz
Bernard Tawfik
Vivek Verman
Maira Visovatti
Joan Westendorp
William Wilson
Kaveh Zakeri

NCORP Liaisons

Disease Site	Liaison
Brain	Natosha Gatson (HDC)
Breast	Mylin Torres (CPC)
Cervix	Dana Chase (CPC)
GI colorectal/noncolorectal	Jordan Kharofa (CPC)
GU	Bridget Koontz (CPC)
H&N	Beth Beadle (CPC)
Lung	Nitin Ohri (CCDR)
Ovarian	Kathryn Pennington (CPC)
Uterine Corpus	Victoria Bae-Jump (HDC)

CCDR Fellow

Megan Mullins, PhD, MPH

Post-Doctoral Fellow, 2020-2022

University of Michigan

Megan is interested in understanding barriers to the receipt of quality cancer care. Her postdoctoral work will focus on generating evidence to identify gaps in the quality of cancer care among cognitively impaired older adults and understanding functional aging trajectories among cancer patients. Megan is passionate about care for gynecologic cancers and focusing on disparities among racial and sexual/gender minorities.



Pilot Project Awardees



Assessing the Impact of Financial Toxicity in Head and Neck Cancer Patients and Their Caregivers - Krupal B. Patel, MD, M.Sc, FRCS(C) and Maija Reblin, PhD, H. Lee Moffitt Cancer Center

Open NRG NCORP Trials

****accrual as of June 30, 2020**

Study No	Disease Site	Description	Date Activated	Target Accrual	Total Accrual	NCORP Accrual (%)	Expected Closure Date
NRG-CC007CD	Prostate	Survivorship care plan for prostate ca survivors on ADT to increase blood glucose and cholesterol checks in yr 2 after starting ADT & lower CVD risk	03/27/19	504	75	100%	December 2023

Developing CCDR concepts and protocols

Developing CCDR concepts and protocols	
A Randomized Phase II Study of Physical Activity Monitoring to Enhance the Delivery of Definitive Radiotherapy for Locally Advanced Non-small Cell Lung Cancer	N. Ohri, MD
Molecular classification-directed care in endometrial carcinoma: an observational prospective cohort study	S. Temkin, MD

NRG Foundation Trial

Received PA Cure Funding:

A Randomized Phase II Study of Physical Activity Monitoring to Enhance the Delivery of Definitive Radiotherapy for Locally Advanced Non-small Cell Lung Cancer



Nitin Ohri, MD, MS
Albert Einstein College of Medicine
Montefiore Medical Center
Department of Radiation Oncology

Study Design

- Study intervention (1:1 randomization)
 - Usual care versus
 - Usual care + wearable fitness tracker
 - Low/declining step counts → treating physicians alerted → increased supportive care utilization
 - Primary endpoint (binary): occurrence of any of the following during the study period (from radiotherapy initiation until 4 weeks after radiotherapy completion)
 - Hospital admission
 - Emergency room visit
 - Radiotherapy interruption (≥ 2 missed treatments, excluding machine issues or scheduled holidays)
- H0=40%, H1=20%, total sample size 144 subjects

NCORP Cancer Care Delivery Research Accomplishments and Updates

*Kate Castro, RN, MS, AOCN®
Nurse Consultant/CCDR Program Director
2020 NRG Summer Meeting
July 17, 2020*

CCDR Portfolio Summary (n=19)

- Current protocols
 - 8 open and accruing
 - 1 CIRB approved and awaiting activation (WF-1805CD)
 - 3 temporarily closed to accrual
 - 4 completed, data analysis underway
 - 3 closed to accrual
- Upcoming studies
 - 2 protocols in review at NCI (Alliance and SWOG)
- Accrual to CCDR studies (8/1/19 – 6/30/20)
 - 746 clinicians
 - 1795 patients

Cumulative incidence of financial hardship in metastatic colorectal cancer patients: Primary endpoint results for SWOG S1417CD.

ASCO[®]20 Virtual

Decision aids for localized prostate cancer: Initial outcomes from NCI Community Oncology Research Program Alliance Research Base Cancer Care Delivery Research (CCDR) Protocol - A191402CD - A Cluster-Randomized Trial.

Care Delivery Studies Seeking Additional Practices (as of 7/15/20)

Protocol Information	Contact
NRG-CC007CD Optimizing Survivorship Care Plans for Prostate Cancer Survivors Receiving Androgen Deprivation Therapy	Erica Field fielde@nrgoncology.org
WF-1804CD Assessing Effectiveness and Implementation of an EHR Tool to Assess Heart Health Among Survivors (AH-HA)	Wake Forest Study Team ncorp@wakehealth.edu
WF-1805CD Implementation and Effectiveness Trial of Head and Neck-STAR (HN-STAR)	Wake Forest Study Team ncorp@wakehealth.edu
URCC-18004CD Understanding the Impact of Drug Shortages on Oncology Care Delivery Open to URCC members	Jacque Lindke Jacque_Lindke@URMC.Rochester.edu
URCC-18110CD Implementing Palliative Care: Learning Collaborative vs. Technical Assistance Open to URCC members	Jacque Lindke Jacque_Lindke@URMC.Rochester.edu

Let's Chat!



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- **How has COVID-19 affected your participation in CCDR studies?**
- **What challenges do you foresee in the upcoming year for your CCDR study related work?**

NCI/AcademyHealth Visiting Scholar

- AcademyHealth
 - Pre-eminent professional society of health services researchers
 - Collaboration with Healthcare Delivery Program began 2017
- Visiting Scholar
 - Awarded every other year
 - 2019 - 2020 Recipient
 - Health Services Researcher and Implementation Scientist
 - Joined HDRP study factors associated with rural NCORP participation in care delivery studies



Shellie Ellis, M.A., Ph.D
University of Kansas

Rural NCORP Project

- Rural patients and providers are under represented in cancer research despite greater access-to-care burdens and poorer outcomes
- 46 NCORPs, 1000+ affiliates
- Lack data on rural representation in NCORP and degree to which rural affiliates participate in CCDR

Purpose:

- Obtain feedback on challenges encountered by rural NCORP affiliates in participating in cancer care delivery research (CCDR) studies
- Identify best practices and environmental context of those who are able to participate
- Inform research bases and affiliates on how to support rural practices



24 NCORP Affiliates/Sub-affiliates who
participated in structured interviews

Study results will be presented at NCORP
Annual Meeting - Part 2

October 6, 2020

NCORP Short Videos

- Previewed at the June NCORP Administrator Webinar
- NCORP PI's provide perspectives on the following topics:
 - Addressing fears about cancer clinical research
 - **Cancer care delivery research**
 - Cancer clinical trials bring options to patients
 - Getting access to cancer clinical trials in the community
 - Reaching underserved populations for cancer studies
 - Value of community-based cancer care
 - Why oncologists participate in research
- Available at <https://ncorp.cancer.gov/about/videos.htm> to download and use in social media, websites, and newsletters



2020 NCORP Virtual Annual Meeting

Save the Date

August 31, 2020 | 12-6pm

EST

&

October 6, 2020 | 2-5pm EST

Be on the lookout for registration and meeting agenda information in upcoming weeks.

Cancer Care Delivery Focused Sessions

- Results from completed CCD studies
- Pragmatic trials
- Organizational measures
- SENSE – Research Base
- NCI/AcademyHealth Visiting Scholar: NCORP rural-serving practices
- Panel Discussion



Let's Chat!

What CCDR topics would you like to discuss at the NCORP Annual Meeting?



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*Please don't hesitate to
reach out anytime*

CCDR Program Directors:

Brenda Adjei

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Kate Castro

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Improving Cancer Care and Outcomes: The Role of Healthcare Delivery Research

Paul Jacobsen, PhD

*Healthcare Delivery Research Program
Division of Cancer Control and Population Sciences
Bethesda, Maryland*

Disclosures

- No relevant financial relationship(s) exist
- Views expressed are my own and are not necessarily those of NCI, NIH, or HHS

Objectives

- Provide an overview of NCI's support for healthcare delivery research
- Describe current funding interests

Healthcare Delivery Research Program (HDRP)

Office of the Associate Director (OAD)



Paul Jacobsen
Associate Director



Janet de Moor
Deputy Associate Director

Nancy Miller
Senior Advisor to
Associate Director

Tonya Parker
Program Analyst

Annie Sampson
Public Health Advisor

FELLOWS:

Thomas Weaver
CRTA Fellow

CONTRACTORS:

Crystal Reed
Program Advisor

NCI Community Oncology Research Program

Brenda Adjei
Program Director

Kathleen Castro
Program Director

Ann Geiger
Scientific Director

CONTRACTORS:

Dusuba Sesay
Public Health Advisor

Healthcare Assessment Research Branch (HARB)



Paul Doria-Rose
Branch Chief

Health Systems and Interventions Research Branch (HSIRB)



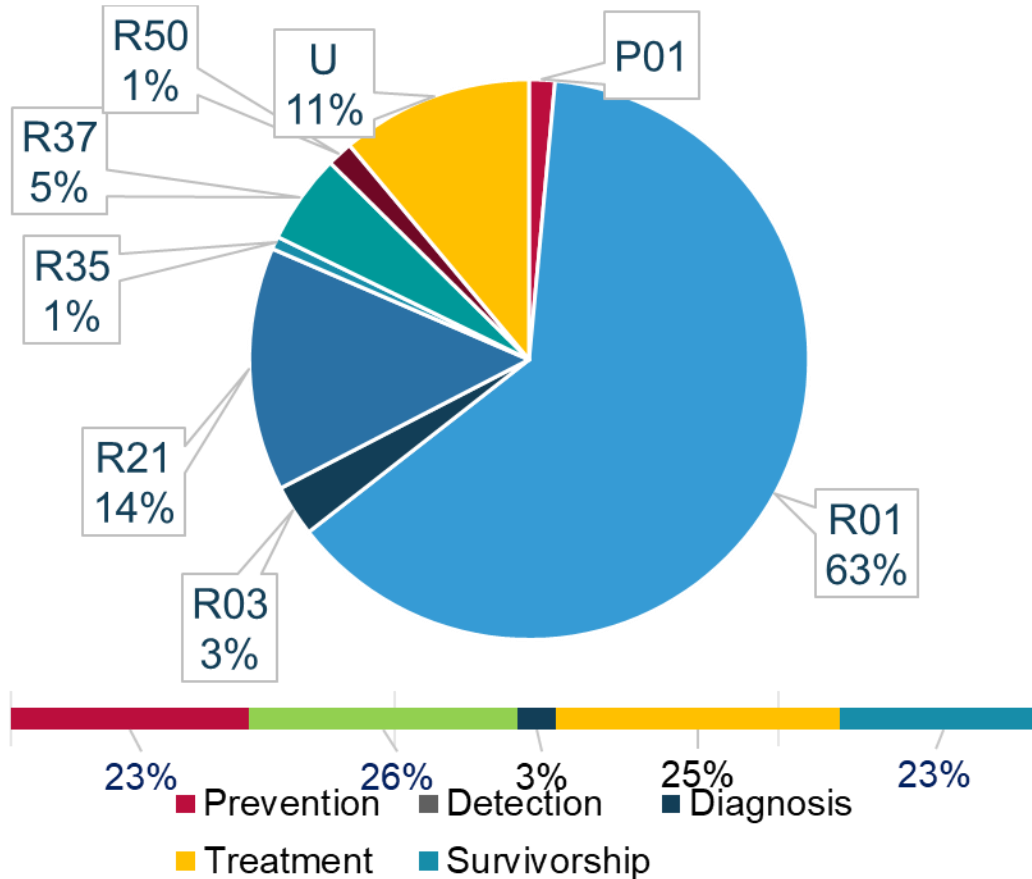
Sarah Kobrin
Branch Chief

Outcomes Research Branch (ORB)



Ashley Wilder Smith
Branch Chief

FY2019 Extramural Grant Portfolio (N=135)

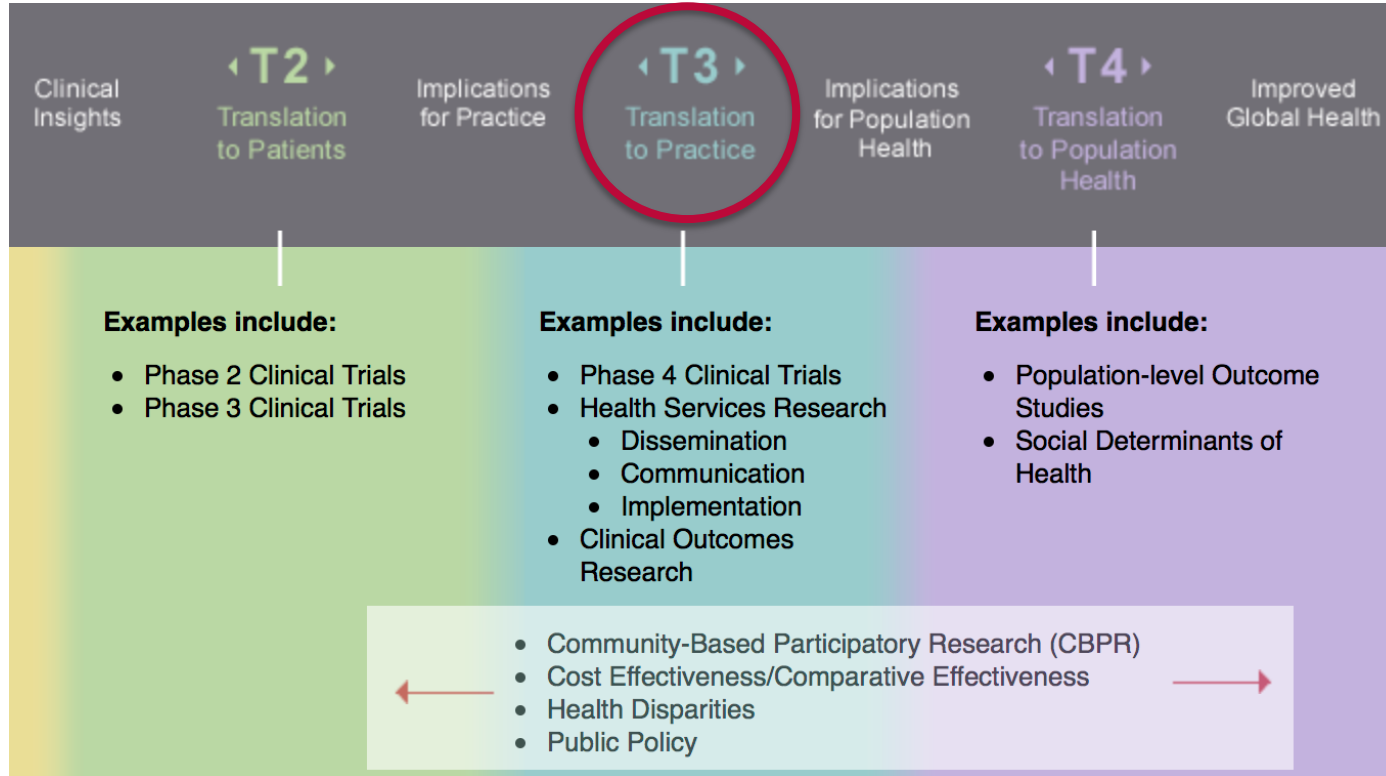


Translating Research Into Practice

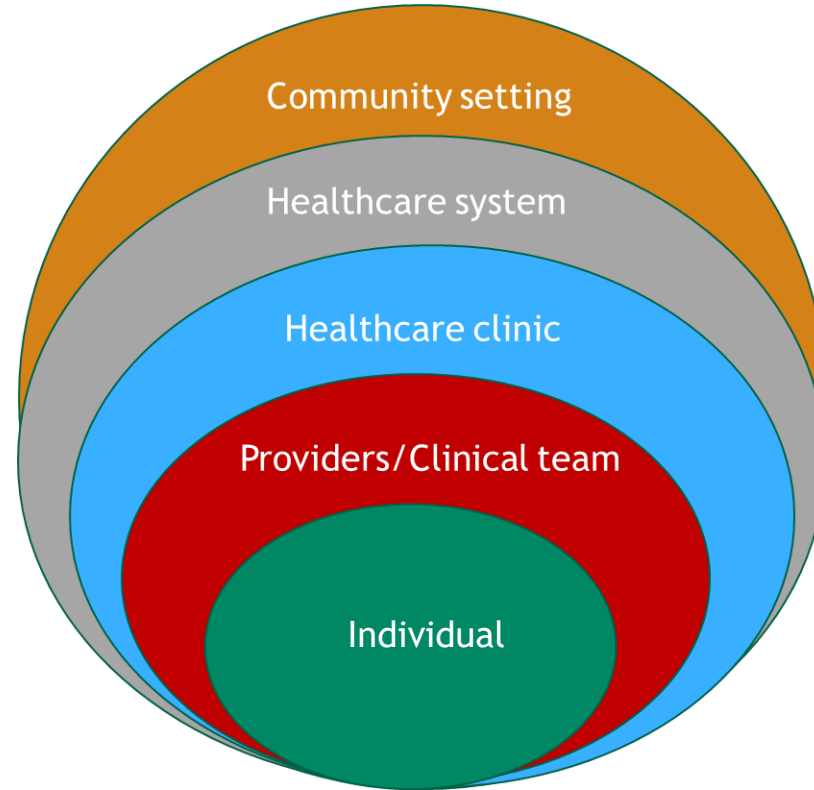


- Adoption of evidence-based practices and interventions in many aspects of cancer care has been limited
- Underscores importance of understanding and addressing factors influencing translation of research into clinical practice

Translating Research Into Practice



Multi-level Approach



Adapted from Taplin et al, JNCI Mono 2012;44:2-10

Types of Trials

- ***Explanatory Trials***

Estimate efficacy: benefit the intervention produces under controlled conditions

Comparator may be placebo or time/attention control

- ***Pragmatic Trials***

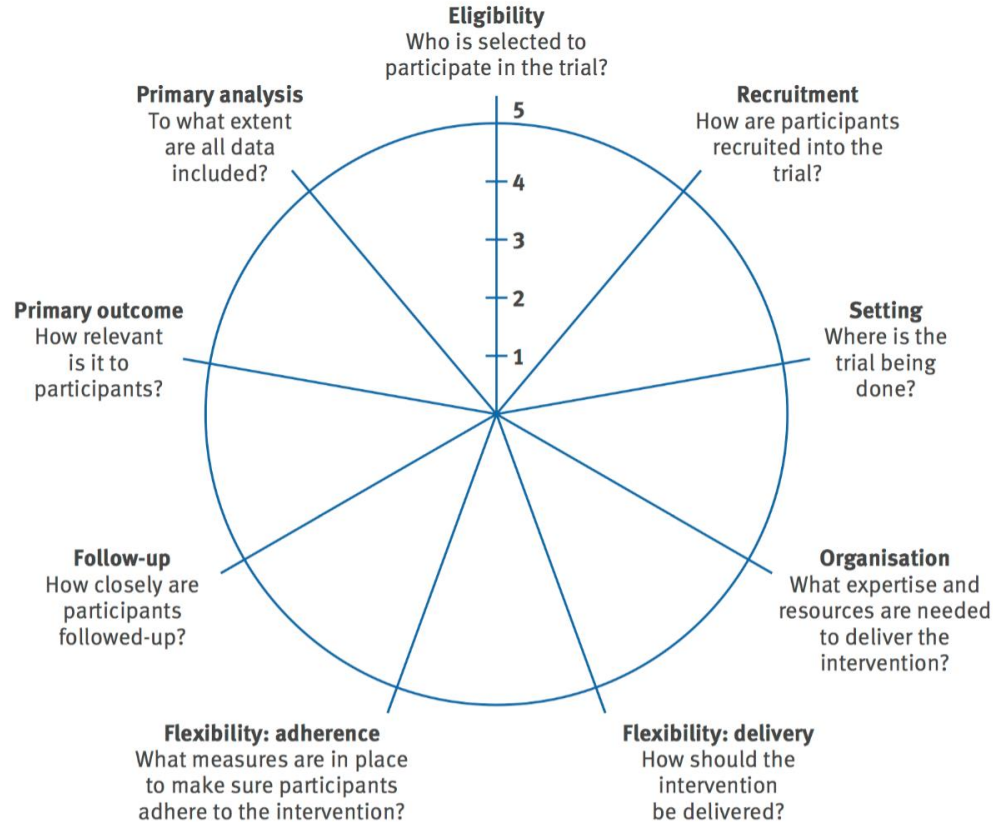
Estimate effectiveness: benefit the intervention produces in routine clinical practice

Comparator is typically usual care

Pragmatic Trials

Element	Explanatory trial	Pragmatic trial
Eligibility	Numerous exclusions; use of study-specific selection tests	Few exclusions; participants resemble usual care patients
Recruitment	Use of targeted invitations, advertising, or incentives	Through scheduled appointments or clinical systems
Setting	Single center or specialized trial/academic centers	Multiple centers, characteristic care settings
Organization	Added staff, additional training, more than usual experience	Use of organizational resources typical of usual care
Flexibility: delivery	Strict protocol, monitoring of and measures to improve compliance	Flexibility similar to usual care; few, if any restrictions on co-interventions
Flexibility: adherence	Exclusion for nonadherence; efforts to improve adherence	No more than usual encouragement to adhere to intervention
Follow-up	More frequent or longer visits; more extensive data collection	No more than usual follow-up
Primary outcome	Surrogate or physiologic outcome; assessment expertise required	Outcome of obvious importance to participants
Primary analysis	May include only completers or those following treatment protocol	Intent to treat with all available data

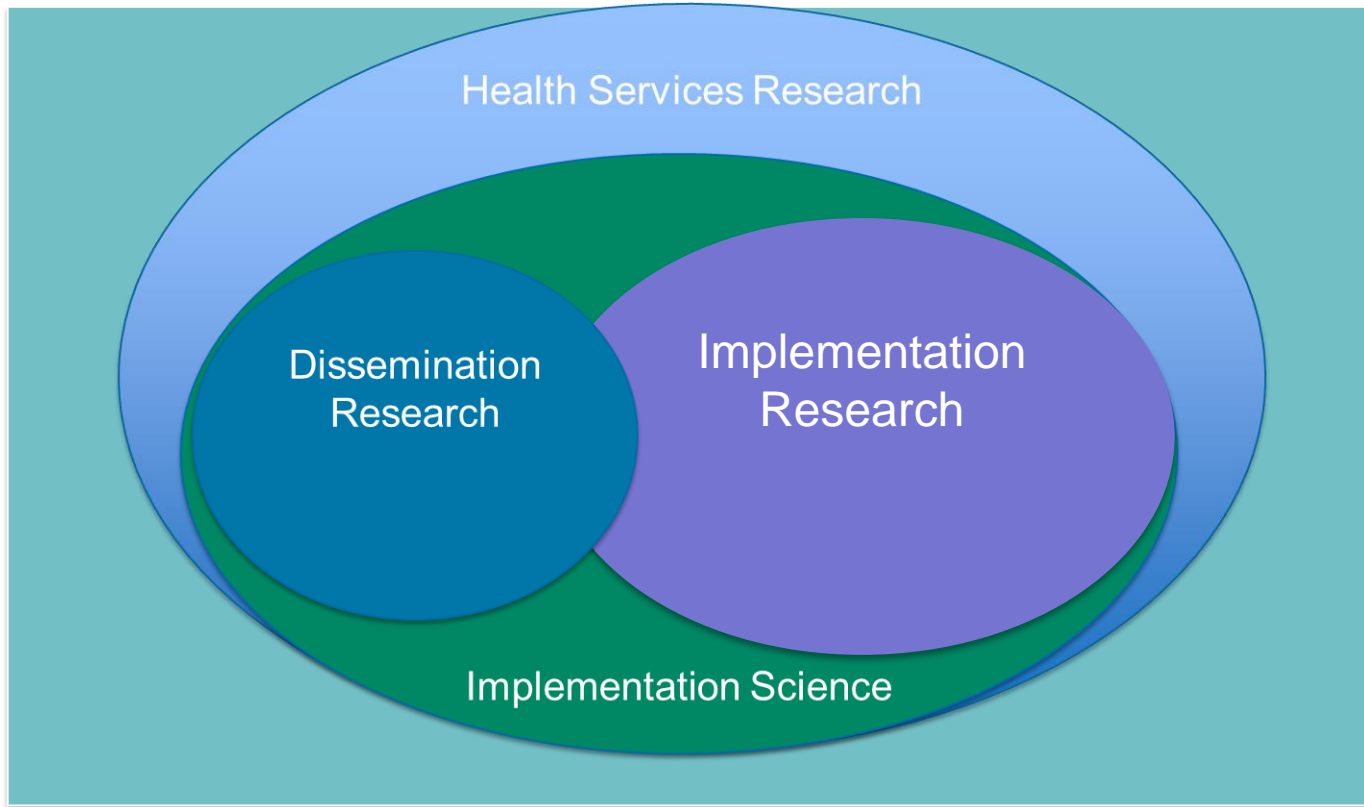
Pragmatic Trials



The PRagmatic-Explanatory Continuum Indicator Summary 2 (PRECIS-2) wheel.

Adapted from [BMJ 2015;350:h2147](#)

Translating Research Into Practice



Adapted from Mitchell & Chambers, J Oncol Pract 2017;13:523-

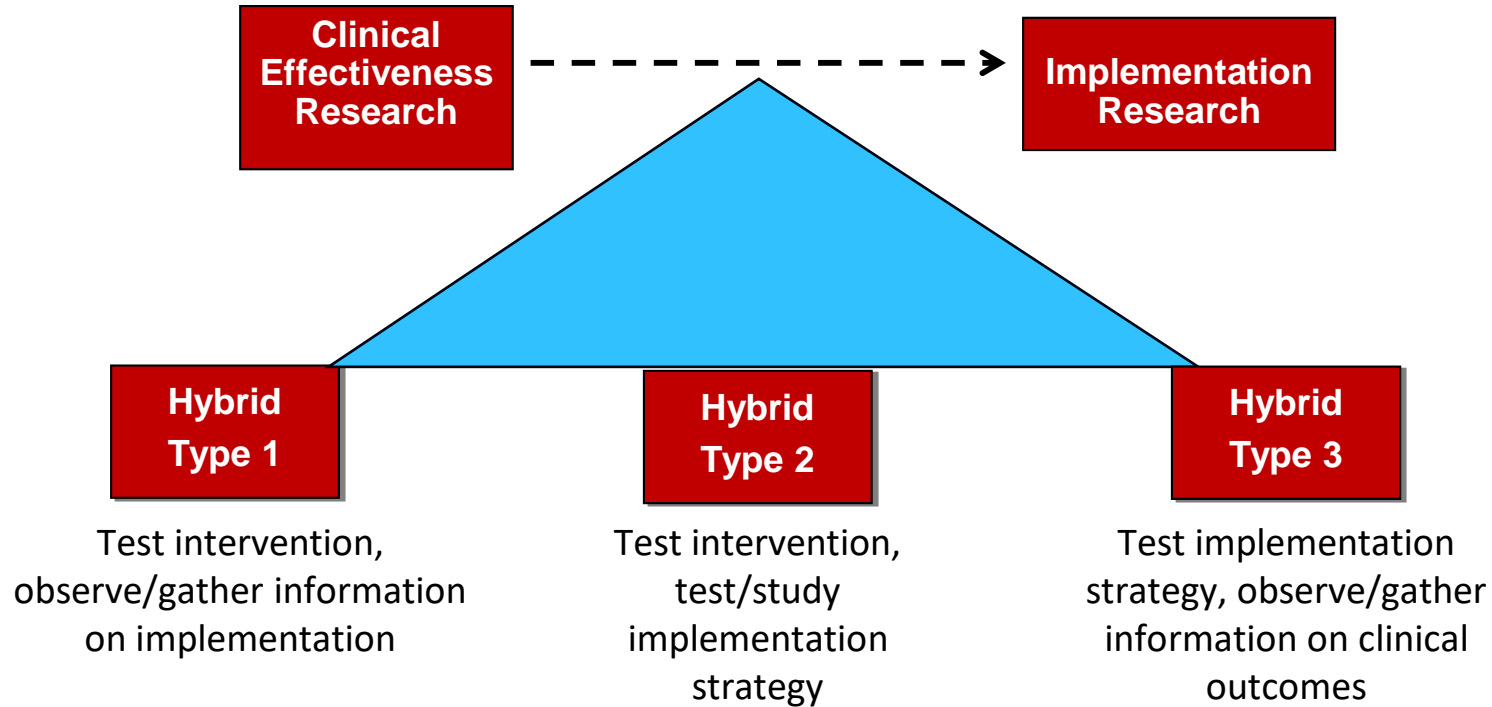
Translating Research Into Practice

Dissemination research: scientific study of targeted distribution of information and intervention materials to a specific public health or clinical practice audience; intent is to understand how best to spread knowledge and associated evidence-based interventions

Implementation research: scientific study of use of strategies to promote adoption and integration of evidence-based health interventions into clinical and community settings; intent is to improve patient outcomes and benefit population health

<https://grants.nih.gov/grants/guide/pa-files/PAR-19-274.html>

Effectiveness-Implementation Hybrid Designs



Adapted from Curran et al, Med Care 2012;50:217-226

Selected Funding Opportunity Announcements

Prevention

- *Linking Provider Recommendations to Adolescent HPV Vaccine Uptake* (R21, R01, R03, PAR-19-358/359/360, exp. 9/8/22)

Screening/Early Detection

- *Multilevel Interventions in Cancer Care Delivery: Follow-up to Abnormal Screening Tests* (R01, PA-17-495, exp. 1/8/21)

Diagnosis/Treatment

- *Using Information Technology to Support Systematic Screening and Treatment of Depression in Oncology* (R21, R01, PA-18-492/493, exp. 5/8/21)
- *Intervening with Cancer Caregivers to Improve Health Outcome and Optimize Healthcare Utilization* (R21, R01, PAR-19-352/355, exp. 9/8/22)
- *Surgical Disparities Research* (R01, PAR-20-079, exp. 7/6/22)
- *Improving Interprofessional Teamwork and Coordination During Cancer Diagnosis and Treatment* (R01, P01, NOT-CA-059, exp. 1/8/22)
- *Oral Anticancer Agents: Utilization, Adherence, and Health Care Delivery* (R01, P01, R21, NOT-CA-20-026, exp. 1/8/23)

<https://healthcaredelivery.cancer.gov/funding/opportunities.html>

Current Priorities – Funding Opportunity Announcements

Multiple Points

- *De-implementation of Ineffective or Low-value Clinical Practices along the Cancer Care Continuum* (R01, NOT-CA-20-021, exp. 5/10/22)
- *Identifying Innovative Mechanisms or Interventions that Target Multimorbidity and Its Consequences* (R01, PAR-20-180, exp. 9/8/23)
- *Dissemination and Implementation Research in Health* (R01, R21, R03, PAR-19-274/275/276, exp. 5/8/22)

Resources and Training

The National Cancer Institute (NCI) Division of Cancer Control and Population Sciences (DCCPS) hosts this training institute to provide participants with a thorough grounding in conducting multilevel intervention (MLI) research with a specific focus on cancer, across the cancer control continuum. The institute utilizes a combination of a one-day in-person and distance learning sessions (4 months) that cover relevant theory and its use in multilevel intervention research; study approaches and methods (quantitative, qualitative, and mixed methods); and additional topics central to the design, successful funding, and conduct of research on multilevel healthcare delivery interventions. Faculty and guest lecturers are leading experts in multilevel research.



<https://healthcaredelivery.cancer.gov/mlti/>

Resources and Training



One of the most critical issues impeding improvement in the health of people across the cancer continuum today is the enormous gap between what we know can optimize health and cancer care and what gets implemented in everyday practice. Research on dissemination and implementation (D&I) seeks to address this gap by understanding how best to ensure that evidence-based strategies to improve health and prevent disease are effectively delivered in clinical and public health practice. D&I research draws from a variety of behavioral and social science disciplines and employs approaches and methods that in the past have not been taught comprehensively in most graduate degree programs.

Implementation Science Consortium in Cancer (ISCC)

[Home](#) / [Initiatives](#) / Implementation Science Consortium in Cancer



The objectives of ISCC are to:

- Foster communication among investigators engaged in implementation science projects across the cancer continuum;
- Promote collaborative research projects to fill implementation science gaps that would extend beyond a single study; and
- Identify and develop solutions to common theoretical, methodological or empirical challenges in implementation science in cancer.

<https://cancercontrol.cancer.gov/IS/>

Thank You

Paul.Jacobsen@nih.gov



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www.healthcaredelivery.cancer.gov



[@NCICareDelivRes](https://twitter.com/NCICareDelivRes)

www.cancer.gov

www.cancer.gov/espanol

Questions?

NRG-CC007CD

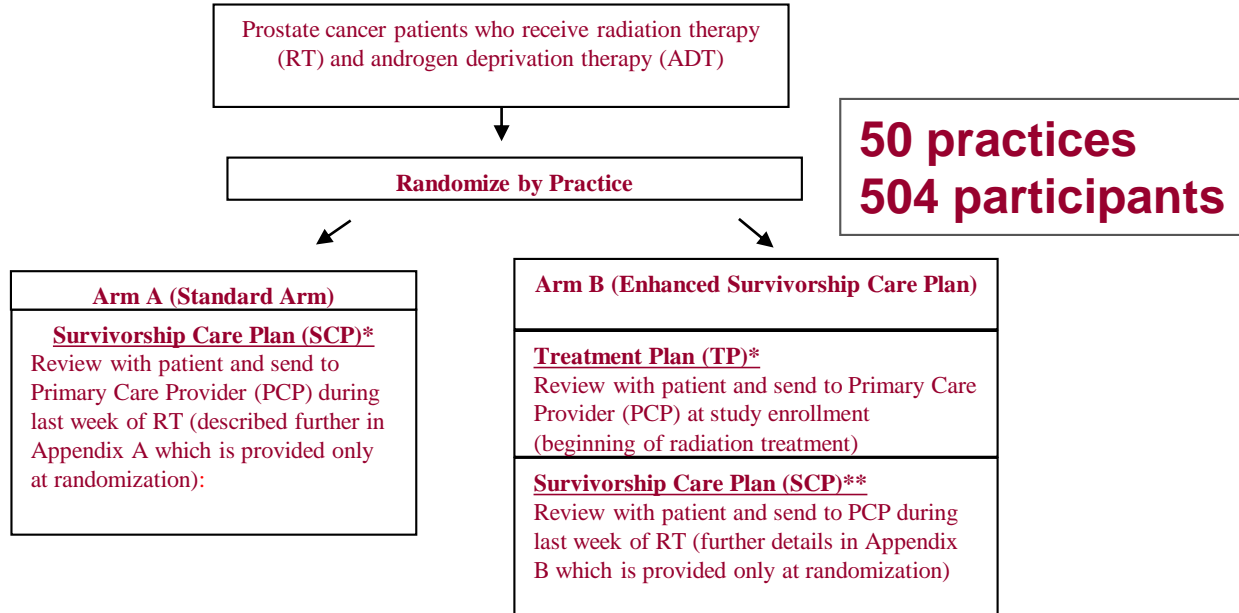
Increasing the dose of survivorship care planning in prostate cancer survivors who receive androgen deprivation therapy

NRG Oncology Semiannual
Meeting
July 17, 2020

Study Chairs

Ronald Chen, MD, MPH, University of North Carolina at Chapel Hill	Principal Investigator
Gilbert Padula, MD, Summa Health System	Study Co-Chair
Patricia Ganz, MD, Jonsson Comprehensive Cancer Center, UCLA	Study Co-Chair
Bridget Koontz, MD, Duke Cancer Institute	Study Co-Chair
Kate Yeager, PhD, RN, Emory University Hospital/Winship Cancer Institute	Study Co-Chair, Health Disparities
Stephanie Pugh, PhD, NRG Oncology	Statistician

Practice Randomization



*Treatment Plan (TP): Will be provided at beginning of radiation treatment. The TP will be provided to each practice randomized to Arm B. The TP will be provided to sites randomized to Arm B only.

**Survivorship care plan (SCP): Provided during the last week of radiation therapy. Includes all information in Treatment Plan (TP), and summarizes treatment received/is receiving.

Primary Objective

To determine if the experimental arm (increased doses of SCP) improves cardiovascular monitoring:

- Primary care provider visit
- Blood glucose
- Cholesterol

Time point: 2 years

Secondary and Exploratory Objectives

Secondary

- Cardiovascular risk score
- Patient-reported outcomes: coordination of care, satisfaction with care

Exploratory

- Whether health literacy modifies the effect of SCP

Logistics for Practice

- Each practice will be required to complete and submit a letter of intent (LOI) to NRG prior to participation. The LOI is required to set up each practice in the database.
- Submit NRG-CC007CD study specific training certificate to the CTSU Regulatory Office – required for PI and RA

Practice Randomization

- Randomization will occur once all practice eligibility criteria have been met.
- Practice notified of randomization assignment and provided arm specific appendices via an email to the lead PI and RA within the practice as designated on the LOI.
- Participation limited to 50 practices
 - Each practice can enroll up to 15 patients

Key Eligibility Criteria for Practices

- All institutions participating in a practice must
 - Be NCORP components or sub-components.
 - Have a mechanism for delivering SCPs to prostate cancer patients. Practices that currently provide SCPs are eligible, but will need to use the study-provided SCP template
 - See at least 10 patients meeting eligibility criteria per year
 - Complete and submit NRG-CC007CD Letter of Intent (LOI)
 - Obtain IRB approval
- Each PI and RA at a NCORP practice must complete NRG-CC007CD SCP training.

Key Eligibility Requirements for Participants

- Be able to complete questionnaires in English
- Diagnosis of prostate adenocarcinoma treated with RT plus ADT with curative intent
- Must have primary care provider and/or cardiologist or plan to obtain one within 14 days of starting RT

Rave

- Collection Time Points/Folders in Rave:
 - Baseline (collected at time of registration in OPEN)
 - RT Treatment
 - End of RT
 - 12 months post-RT
 - 24 months post-RT

Current Update

- Number of practices randomized: 27
- Number of patients enrolled: 84
- Enrolling sites: 16

Questions?

Molecular classification-directed care in endometrial carcinoma: an observational prospective cohort study

- Study Co-Chairs: Sarah M. Temkin, MD and Kathy Han, MD, MSc
- Co-investigators: Jessica McAlpine, MD, Kemi Doll, MD Anthony Fyles MD, Stephen Welch, MD, Helen MacKay, MD

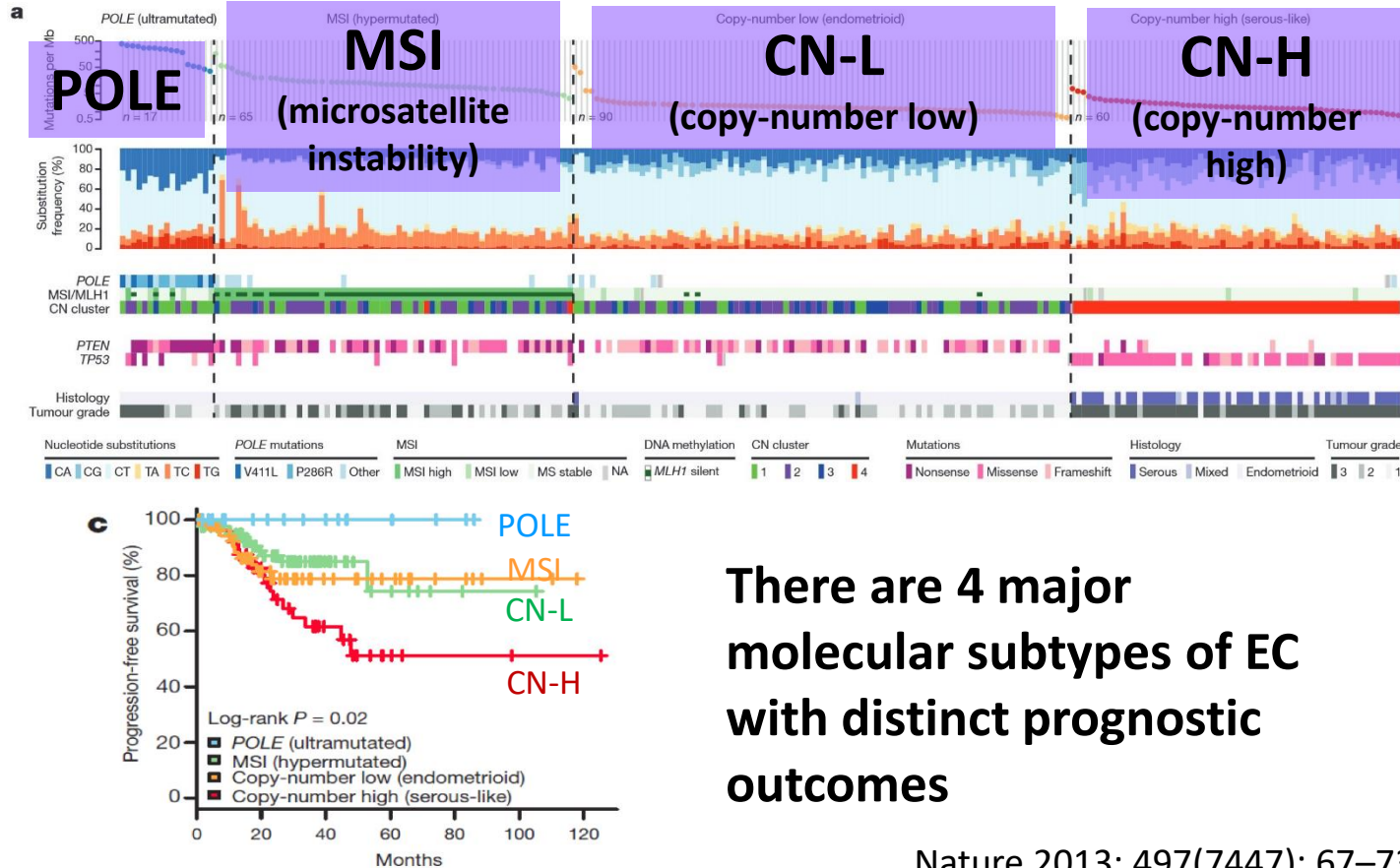
Defining the primary problem

- Cancers of the uterine corpus affect over 68,000 women per year in the US
- Most patients (80%) have local disease and a good prognosis
- Traditional risk stratification systems include histologic subtype, stage and grade but are not reliable at predicting prognosis
 - Inter-observer agreement for FIGO between pathologists is moderate (kappa 0.41-0.68)
 - Lack of consensus of histologic assignment in one-third or higher of high-grade endometrial cancers
 - NO algorithm for postoperative management leading to great variability in treatment between and within cancer centers
- Despite multiple prospective studies, an overall survival benefit of postoperative pelvic radiation has not been demonstrated



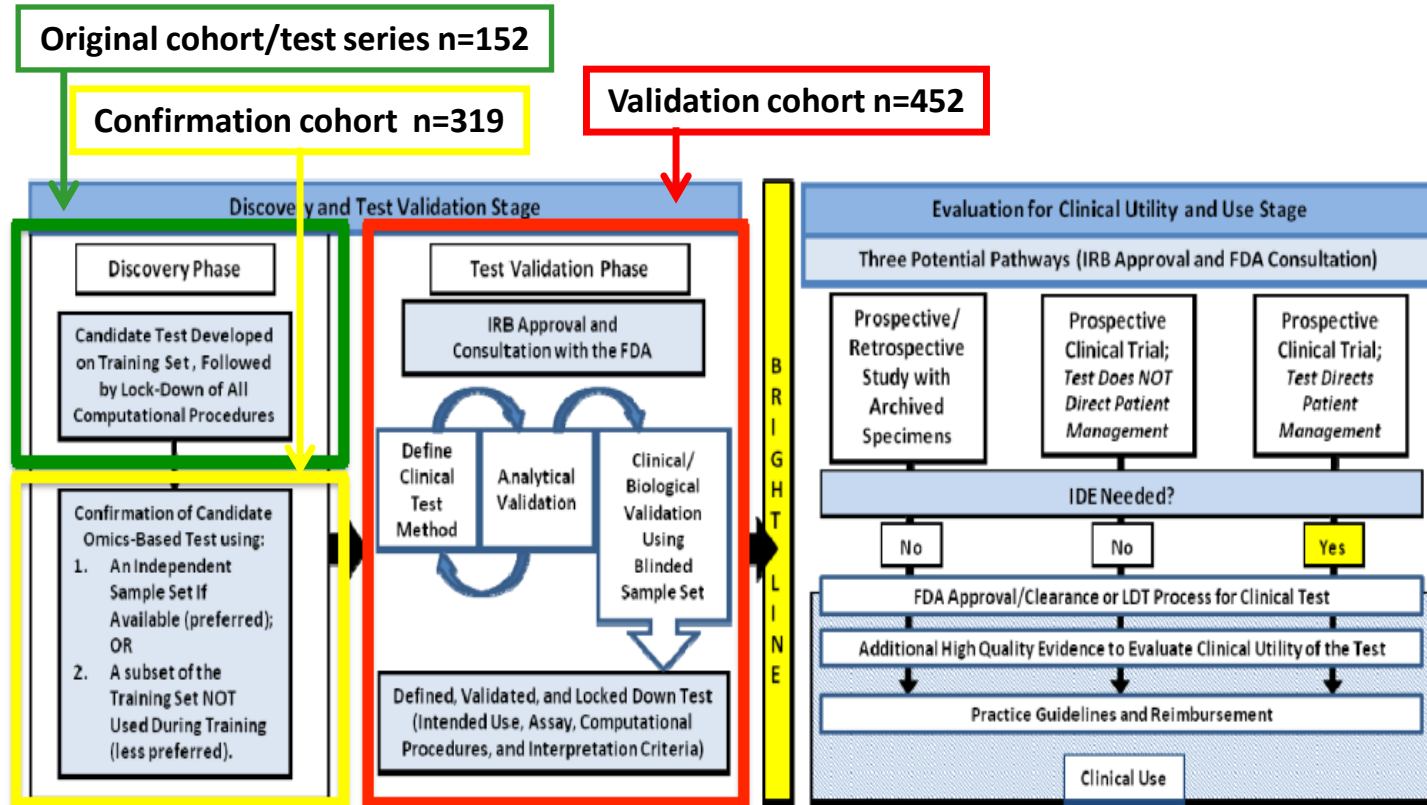
OVER
TREATMENT

The Cancer Genome Atlas (TCGA) Endometrial Cancer



There are 4 major
molecular subtypes of EC
with distinct prognostic
outcomes

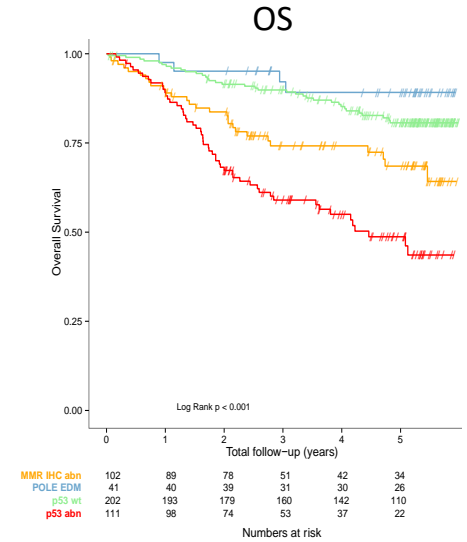
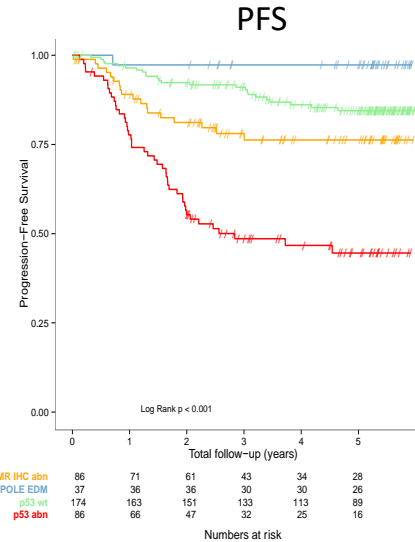
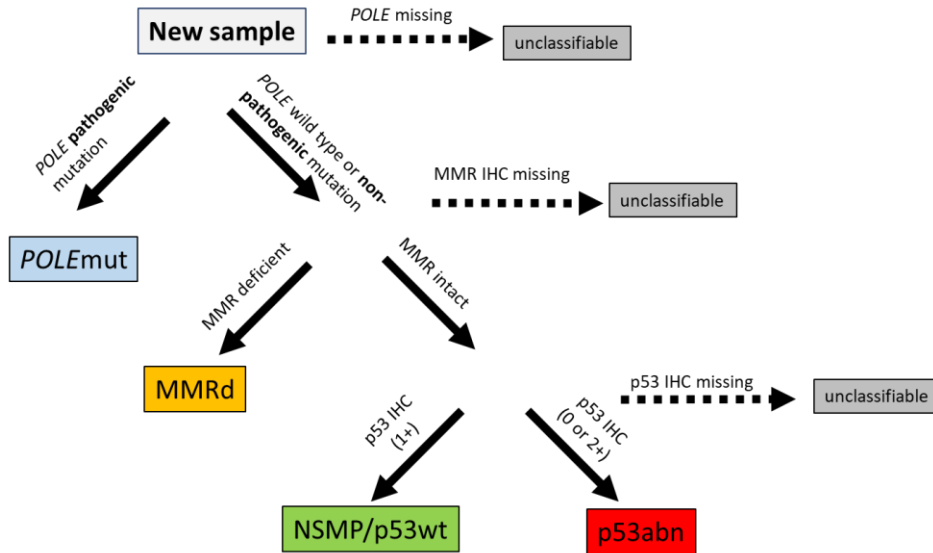
Development of a pragmatic molecular classifier in ECs: strict adherence to IOM guidelines



The Institute of Medicine guidelines for development of 'omics-based tests. Micheel et al., IOM 2012

Talhoun, McAlpine Br J Can 2015
Talhoun, McAlpine, Cancer 2017
Kommoss et al, Annals Onc, 2018

Proactive Molecular Risk Classifier for Endometrial Cancer (ProMisE)



McConehy, McAlpine CCR 2016
 Talhouk, McAlpine Br J Can 2015
 Talhouk, McAlpine, Cancer 2017
 Kommoss et al, Ann Oncol, 2018

Primary Objective: Stepped Wedge Study Design

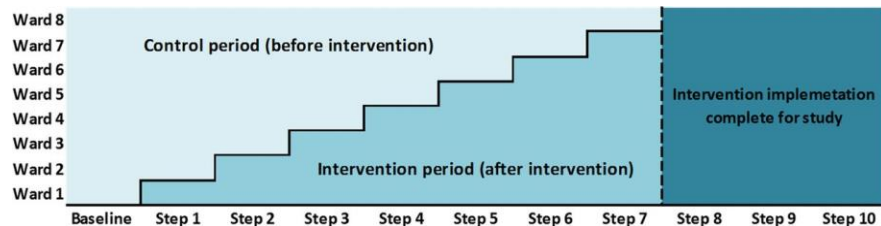
Research Methods & Reporting

The stepped wedge cluster randomised trial: rationale, design, analysis, and reporting

BMJ 2015 ; 350 doi: <https://doi.org/10.1136/bmj.h391> (Published 06 February 2015)

Cite this as: BMJ 2015;350:h391

Schematic of stepped-wedge cluster randomised controlled trial study design.



J I Westbrook et al. BMJ Open 2016;6:e011811

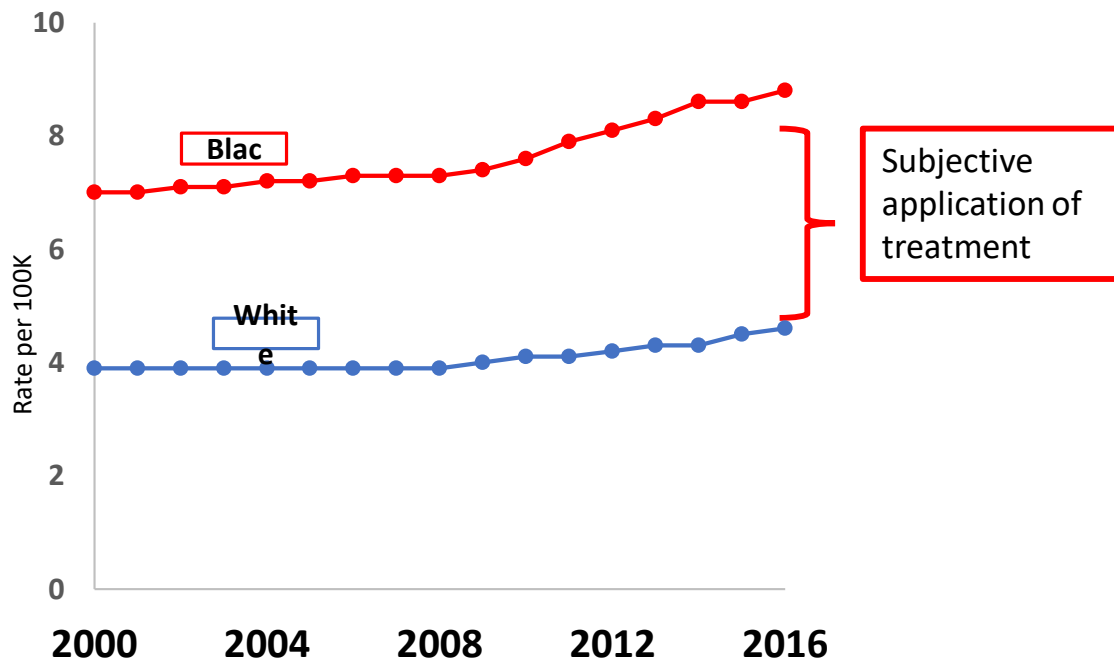
Patients at selected sites will be enrolled postoperatively onto this single arm prospective trial

- INTERVENTION 1:
 - **Institutional** incorporation of universal molecular testing
 - **Provider** education regarding molecular testing
- INTERVENTION 2:
 - **Patient** education regarding their molecular profile results.



- PRIMARY OUTCOME MEASURED:
 - **Decreased** rate of postoperative whole pelvic radiation in women diagnosed with early-stage EC (*reduces overtreatment*).

Endometrial cancer remains a malignancy with one of the highest racial inequities in survival



Major Secondary objectives:

- To measure differences in receipt of postoperative therapy between patients who self-identify as Black compared to White prior to and after instituting molecular classification.
- To measure progression-free and overall survival at 2 years compared to historical control (the majority of recurrences in this disease occur within 2 years of diagnosis)
- To evaluate concordance between local and central molecular classification



Thank you
and
questions

NRG CCDR Financial Toxicity Working Group

Presenter: Margaret Liang, MD, MS
University of Alabama at Birmingham

Disclosures

- I have no disclosures

Working Group Members

- Fumiko Chino, MD
- Melissa Foust, MSN, RN
- Radikha Gogoi, MD
- Gregory Gressel, MD, MSc
- Natalya Greyz, MD
- Laura Holman, MD, MS
- Ismail Jatoi, MD, PhD
- Margaret Liang, MD, MSHS
- Gilbert Padula, MD
- Tonnica Sasanias, RN, BSN
- Bernard Tawfik, MD
- Vivek Verma, MD
- Alex Wilson, MD, DABR
- Heidi Donovan, PhD, RN
- Laurel Pracht, patient advocate

Working Group Goals

- Develop concepts and submit protocols through NRG related to financial toxicity
- Foster clinical and research collaborations between subgroup members and across institutions
- Provide expertise on incorporation of financial toxicity into other NRG trials if needed by other NRG committees

Next Steps (from meeting 6/23/2020)

- Brainstorm original concepts
 - Focus on intervention (rather than descriptive) trials that meet CCCR goals
 - Assess availability of pilot data from working group members
 - Utilization of validated instruments (COST, QOL)
- Integrate financial toxicity into other protocols under development
- Other ideas
 - Impact of telehealth on financial toxicity
 - Increased costs for patients who are diagnosed with cancer through ED

Questions

thank you!