Improving Cancer Symptom Management in Scalable Pragmatic Trials: Overview of the IMPACT Consortium

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NCI CANCER MOONSHOT
A program of the National Cancer Institute of the National Institutes of Health

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Cancer Symptom Challenges

Cancer-related symptom burden is substantial

- 1/3 of cancer patients have 3 or more moderate to severe symptoms such as pain and fatigue
- Patients experience multiple symptoms concurrently
- Symptoms are often inadequately treated

Poorly controlled symptoms contribute to:

- Nonadherence, treatment delays and discontinuation
- Emergency room visits and unscheduled hospitalizations
- Impaired physical and social functioning
- Poor quality of life
- Lower rates of return to work and impaired ability to work

Major Barriers to Effective Symptom Control

- **Symptoms not systematically assessed and reported**
  - Patient-reported outcomes (PROs) not used in many practice settings
  - When used, PRO reports do not facilitate clinical decision-making
- **Symptoms not adequately managed**
  - Providers unfamiliar with existing clinical practice guidelines
  - Resources for symptom management not identified or used
- **Lack of systematic efforts to translate research into practice**
  - RCTs show benefits of integrated symptom assessment and reporting
  - Implementation science approach yet to be applied to addressing barriers and promoting adoption of integrated systems

Cancer Moonshot℠

2016 White House call to action lead to a national "Moonshot" initiative to eliminate cancer as we know it, with >$1 billion to jumpstart the work

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GOAL: Accelerate progress in preventing, diagnosing, and treating cancer to accomplish a decade's worth of work in 5 years

RECOMMENDATION F:

Minimize cancer treatment's debilitating side effects

Accelerate the clinical adoption of integrated systems to monitor patient-reported symptoms and provide decision support using implementation science approaches and evidence-based symptom management guidelines.

NCI Response:
National symptom management effort

GOAL: support the implementation, evaluation, and scalability of integrated electronic systems that systematically collect and manage symptoms through guideline-concordant clinical interventions tested in randomized pragmatic trials

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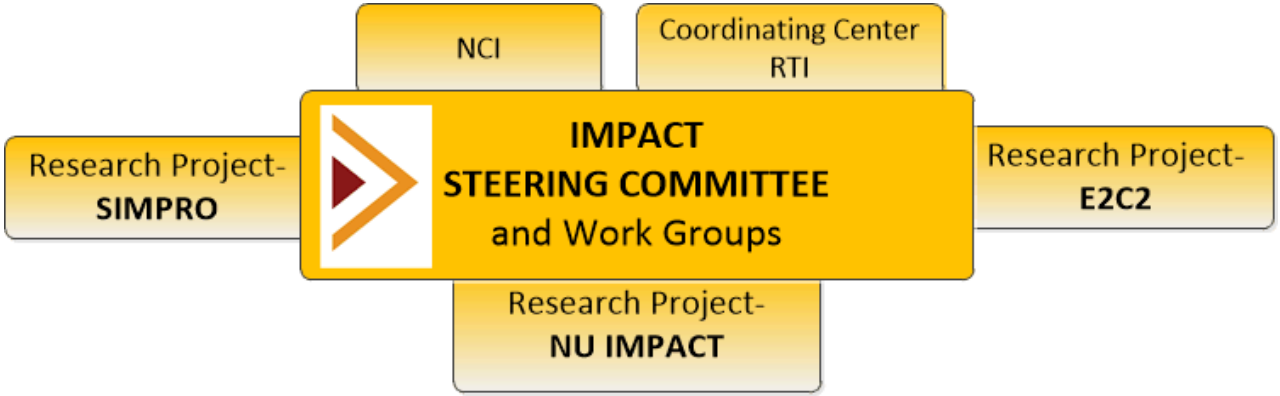
Consortium Overview

- **3 research centers and 1 coordinating center: Testing symptom management interventions integrated in electronic health records (EHR) systems**
  - Routinely monitor patient symptoms (e.g., pain, physical functioning)
  - Trigger guideline-concordant clinical responses for management in patients across the cancer continuum

- **Pooled consortium-wide data to evaluate**
  - Symptom control, treatment delivery, healthcare utilization
  - Patients across the cancer continuum and underserved, under-resourced populations

- **Implementation Science Approaches**
  - Feasibility, acceptability, scalability, sustainability
  - Employ stepped wedge cluster randomized trial designs

Consortium Organization



- Three distinct, but coordinated Research Centers allow for individual and consortium-wide projects, common data elements for pooled analyses
- Coordinating Center supports networked research to systematize implementation approaches and harmonize key variables
- NCI supports each Center and provides scientific advice to Consortium

Research Centers

Northwestern University IMPACT **(NU IMPACT)**

- 13K patients, 1 health system
- 6 clinical practices
- English and Spanish-speaking patients receiving treatment with curative or non-curative intent or disease-free survivors
- Recruit from ethnically and racially diverse populations in **metropolitan Chicago**

Northwestern Medicine®

Symptom Management Implementation of PROs in Oncology **(SIMPRO)**

- 6K patients, 6 health systems
- GI, GYN, lung cancer pts receiving surgery or chemotherapy for advanced disease
- Recruit from diverse populations in community and rural settings in **ME, WV, NH, VT, TN, MS, and MA**

DANA-FARBER CANCER INSTITUTE
BAPTIST
Maine Medical Center MaineHealth
WVU Cancer Institute
Dartmouth-Hitchcock NORRIS COTTON CANCER CENTER
Lifespan Cancer Institute
Rhode Island Hospital · The Miriam Hospital Newport Hospital
Delivering health with care®

Enhanced, EHR-facilitated Cancer Symptom Control **(E2C2)**

- 15K patients, 1 health system
- 21 care teams
- Patients on treatment, monitored, or survivorship care for solid tumors
- Recruit from rural populations in **MN, IA, and WI**

MAYO CLINIC

Pragmatic trials using Implementation Science

- **Implementation science research** is defined as the **scientific study** of the use of **strategies** to adopt and **integrate** evidence-based health **interventions into clinical and community settings** in order to improve individual outcomes and benefit population health
- **Implementation Science** is **not** the same as deployment or other types of practice change efforts
- **Implementation Science** provides an approach to understand factors influencing implementation processes and outcomes (e.g., acceptability, adoption, adaptation, fidelity, sustainability)
- **Implementation Science** also allows for the ability to identify, develop, test, evaluate and/or refine implementation strategies

Dissemination and Implementation Research in Health PAR, NIH, 2019

Pragmatic Elements of IMPACT Research

Patient eligibility

- Where consenting is involved, studies feature minimal exclusion criteria

Settings

- Conducted mostly in community oncology settings where bulk of cancer care is delivered

Organization

- Studies are designed to be integrated into existing clinical workflow

Flexibility

- Studies allow flexibility in how symptom management interventions are delivered

Follow-up

- Limited follow-up assessing relying primarily on data collected as part of routine care

Sustainability

- Measure extent of adoption and contributors to success

Metrics for the Success of IMPACT

Formation of coordinated research network (short-term)

- Standardization and harmonization of key methodology
- Adoption of common framework to classify implementation activities

Timely completion of major milestones (intermediate)

- Implementation of integrated systems across practices
- Real-time monitoring of data submitted to coordinating center

Dissemination of high-impact findings (long-term)

- Publications showing effects of implementation across diverse settings
- Creation and distribution of “how to” methods and materials
- Availability of compelling “real world evidence” to inform national policies and standards for cancer symptom assessment and management

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Consortium Members

Research Triangle Institute (RTI) **Coordinating Center** **Principal Investigator:** Barbara Kroner	Northwestern University IMPACT (NU IMPACT) **Research Center** **Principal Investigator:** David Cella	Symptom Management Implementation of Patient Reported Outcomes in Oncology (SIMPRO) **Research Center** **Principal Investigators:** Deborah Schrag, Raymond Osarogiagbon, Sandra Wong	Enhanced, Electronic Health Record-Facilitated Cancer Symptom Control (E2C2) **Research Center** **Principal Investigator:** Andrea Cheville	**National Cancer Institute** **Science Officers:** Ashley Wilder Smith Roxanne Jensen Sandra Mitchell **Program Director:** Priyanga Tuovinen
Lisa DiMartino Jen Popovic Josh Richardson Bryan Weiner Mary-Anne Ardini Austin Booth Taylor Swankie Hudson Bilbrey	Sofia Garcia Denise Scholtens J.D. Smith Betina Yanez Michael Bass Nikki Lancki Frank Penedo September Cahue	Michael Hassett Ethan Basch Don Dizon Nadine McCleary Luann Berkshire Jessica Bian Ann Bishop Christine Cronin Nick Faris Haley Farrar Abigail Abbot Chris Gibbons Dan Gundersen Hannah Hazard Karen Hess Beverly Jordan Renae Keeley Christopher Lancaster Loretta Pearson Andrea Pusic James Reich Scot Remick Peter Solberg Hajime Uno Naneen Chace-Ortiz	Katie Ruddy Parvez Rahman Joan Griffin Aaron Leppin Charles Given Jeph Herrin Kurt Kroenke Minji Lee Lila Rutten Curt Storlie Nathan Tesch	Paul Jacobsen Wynne Norton Brianna Taffe Christine Hodgdon (patient representative)

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Questions?

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https://impactconsortium.org

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