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
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

**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.
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
• 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

**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

**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
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.
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
## Consortium Members

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**Northwestern University IMPACT (NU IMPACT)**  
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