

Dissemination and Implementation

Wynne E. Norton, PhD
Program Director, Implementation Science
National Cancer Institute

Preconference Workshop:
Essentials of Embedded Pragmatic Clinical Trials

Academy Health Annual Research Meeting
June 1, 2019

Disclosures

- I have no financial relationships to disclose.
- Opinions are mine, not official positions of the National Cancer Institute, the National Institutes of Health, or the U.S. federal government.

Learning Goals

- Learn methods for designing ePCTs so findings can be easily implemented.
- Build in sustainability from the beginning.
- Identify considerations for dissemination of study results.

Important Things to Know

- D&I science provides key insight into how best to disseminate and implement findings from research studies.
- Developing interventions with stakeholder input is critical for future dissemination and implementation of study findings.

What is D&I Science?

What can we learn from D&I science to inform
D&I practice of ePCT research?

Evidence-Based Interventions, Practices, Programs, Guidelines



www.thecommunityguide.org

WHAT WORKS

**Cancer Prevention and Control:
Cancer Screening**
Evidence-Based Interventions for Your Community



Research-Tested
Intervention Programs (RTIPs) <http://rtips.cancer.gov/rtips/>

■ RTIPs – Moving Science into Programs for People



EffectiveInterventions
HIV PREVENTION THAT WORKS



Negative results

Original research

“PUBLICATION PATHWAY”

18%

Dickersin, 1987

variable

Submission

It takes 17 years to turn 14% of original research to the benefit of patient care



Inconsistent indexing

Poynard, 1985

Reviews, guidelines, textbook

9.3 years

Implementation

Balas & Boren, 2000

Sometimes, the step from best evidence to best practice is simple; however, most of the time it is not, and we need various strategies targeting obstacles to change at different levels...

Grol & Grimshaw, 2003

Dissemination Research

- “Scientific study of targeted distribution of information and intervention materials to a specific public health or clinical practice audience. The intent is to understand how best to communicate and integrate knowledge and the associated evidence-based interventions.”
- How, when, by whom, and under what circumstances does evidence spread?
- How do we package and share evidence to increase adoption and use?

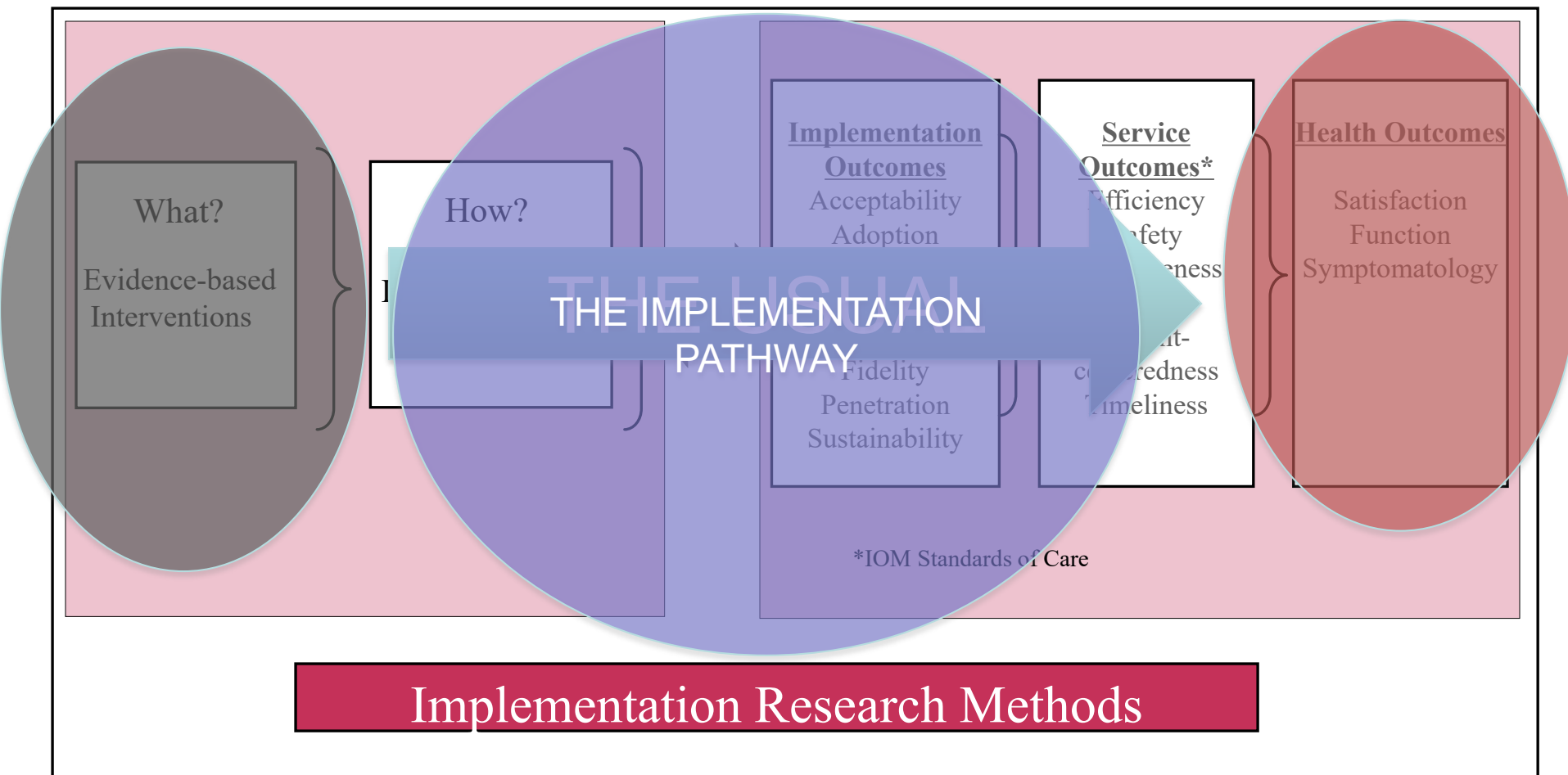
Dissemination and Implementation Research in Health PAR, NIH, 2019

Implementation Research

- “Scientific study of the use of strategies to adopt and integrate evidence-based health interventions into clinical and community settings in order to improve patient outcomes and benefit population health.”
- How do we best implement evidence-based interventions, practices, and programs in routine, real-world settings?
- What approaches are needed to facilitate integration, adaptation, and sustainability of evidence in delivery settings?

Dissemination and Implementation Research in Health PAR, NIH, 2019

Implementation Pathway



Proctor et al., 2009

Implementation Strategies

1. Evaluation and iterative strategies

- Assess readiness
- Identify barriers and facilitators

2. Interactive assistance

- Facilitation
- Technical assistance

3. Adapting and tailoring to context

- Tailor strategies
- Promote adaptability

4. Develop stakeholder relationships

- Identify local opinion leaders
- Build coalitions

5. Train/educate stakeholders

- Conduct training
- Develop educational materials

6. Supporting clinicians

- Audit and feedback
- Revise professional roles

7. Engage consumers

- Involve end-users
- Use mass media

8. Use financial strategies

- Alter incentive structures
- Develop disincentives

9. Change infrastructure

- Mandate change
- Change physical structures

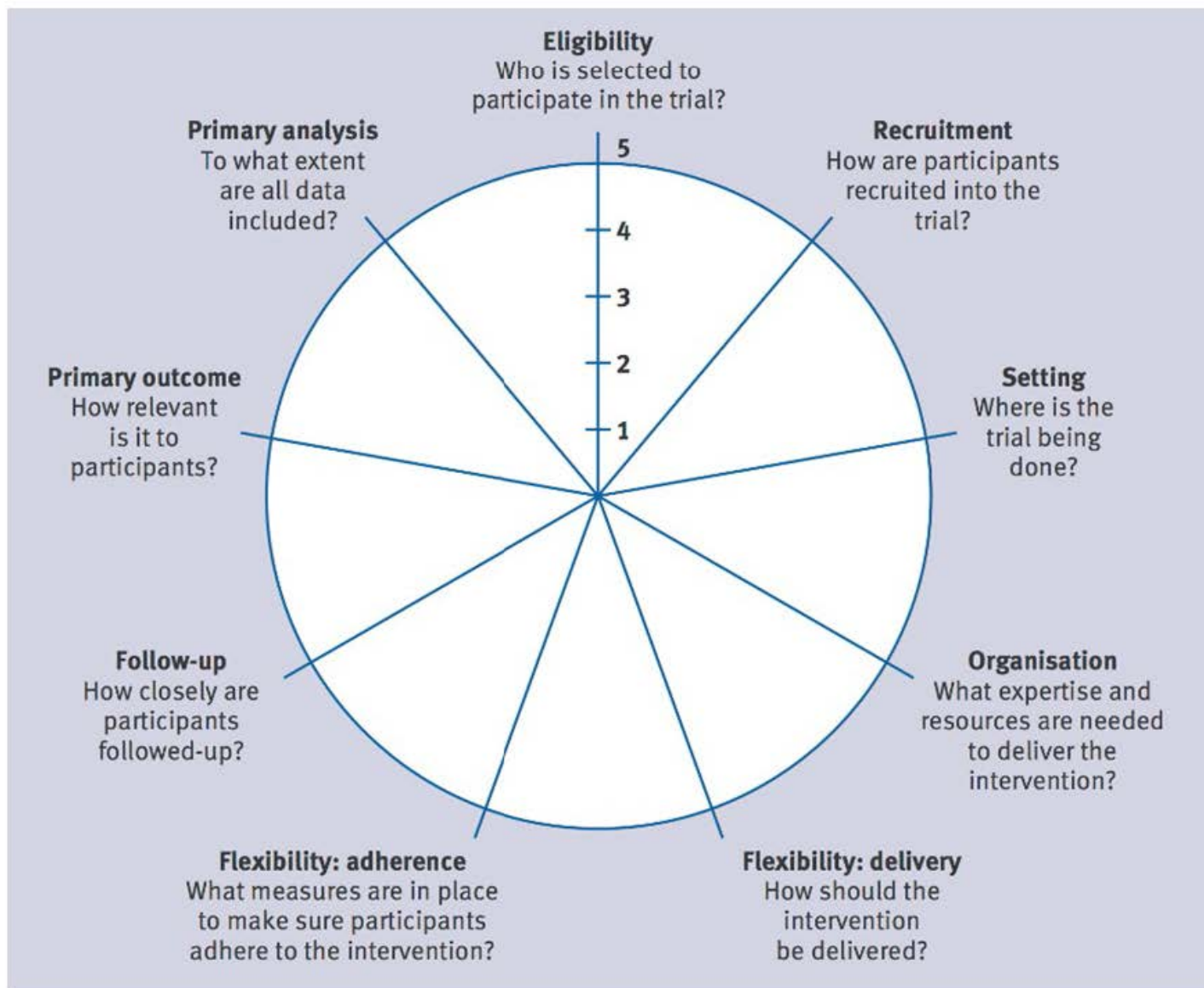
Powell et al., 2012; Waltz, et al., 2015

Implications of D&I Research for Practice

Designing with Dissemination in Mind

- Is this a priority question or issue among end-users?
- To whom would the results apply? Will there be a demand for the study results or intervention?
- Are stakeholders involved in identifying the research question, selecting the appropriate research design, collecting priority outcome data, and sharing results?
- Could this intervention be delivered within the existing structure of the delivery system? What would need to change? Is that type of change feasible, realistic, affordable?

PRECIS-2: Pragmatic-Explanatory Continuum Indicator Summary

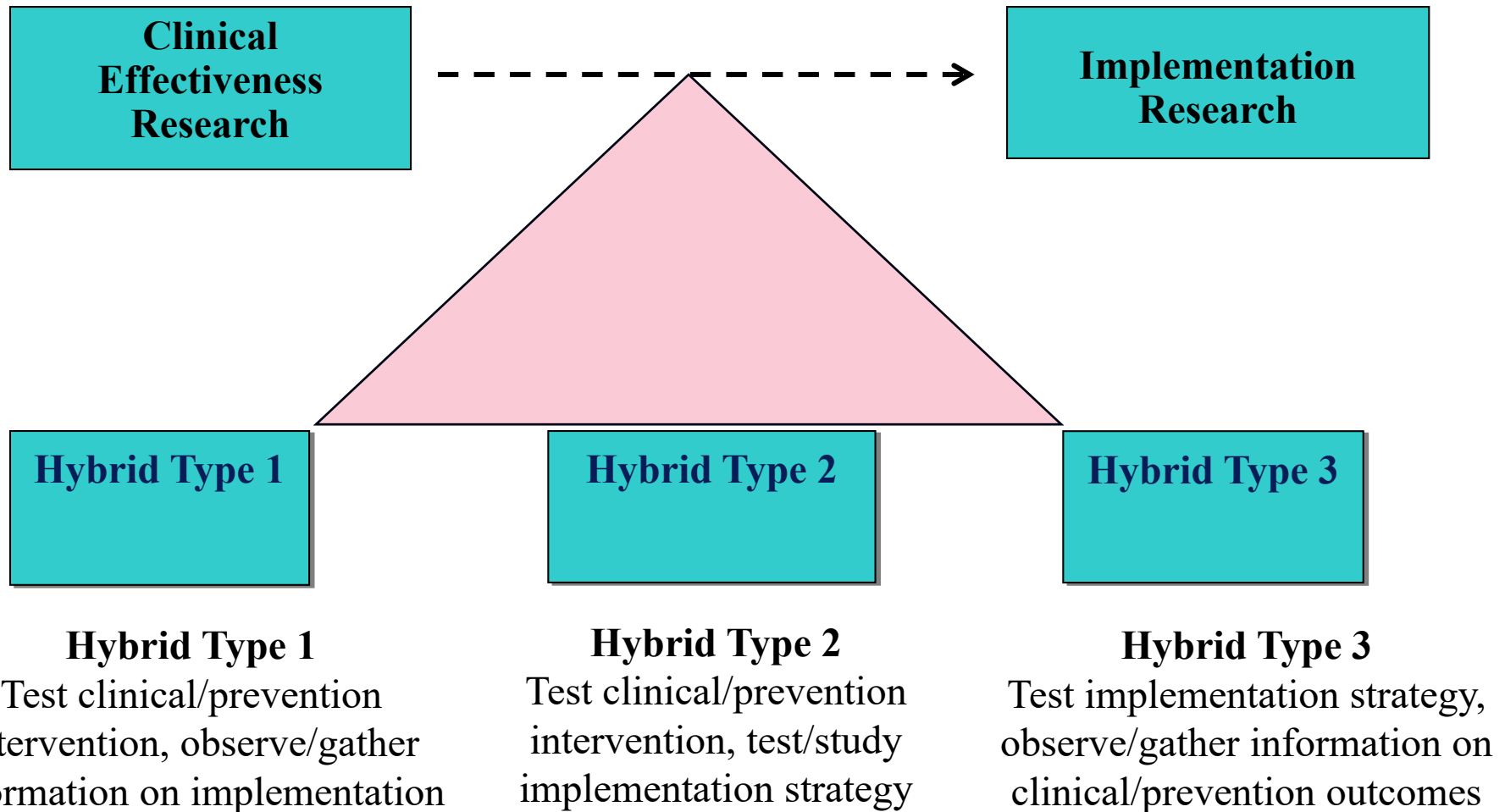


Loudon et al., 2015; 1 = Very explanatory, 5 = Very pragmatic

Planning with Implementation in Mind

- Hybrid effectiveness-implementation designs
- Opportunity to collect data on implementation barriers, facilitators, and processes during pragmatic RCTs to anticipate challenges and guide future efforts.
- Qualitative data (e.g., interviews, focus groups)
 - Assess barriers toward using practice during trial
- Quantitative data (e.g., surveys)
 - Measure providers' attitudes toward using practice

Hybrid Effectiveness-Implementation Designs



A Hybrid Effectiveness-Implementation Trial of an Evidence-Based Exercise Intervention for Breast Cancer Survivors

Rinad S. Beidas, Breah Paciotti, Fran Barg, Andrea R. Branas, Justin C. Brown, Karen Glanz, Angela DeMichele, Laura DiGiovanni, Domenick Salvatore, Kathryn H. Schmitz


The primary aims of this hybrid Type 1 effectiveness-implementation trial were to quantitatively assess whether an evidence-based exercise intervention for breast cancer survivors, Strength After Breast Cancer, was safe and effective in a new setting and to qualitatively assess barriers to implementation.

A cohort of 84 survivors completed measurements related to limb volume, muscle strength, and body image at baseline, 67 survivors completed measurements 12 months later. Qualitative methods were used to understand barriers to implementation experienced by referring oncology clinicians and physical therapists who delivered the program.

Beidas et al. (2014). *JNCI*.



Using implementation facilitation to implement primary care mental health integration via clinical video telehealth in rural clinics: protocol for a hybrid type 2 cluster randomized stepped-wedge design

Richard R. Owen^{1,2*} , Eva N. Woodward^{1,2,3}, Karen L. Drummond^{1,2}, Tisha L. Deen⁴, Karen Anderson Oliver⁵, Nancy J. Petersen^{6,7}, Scott S. Meit⁴, John C. Fortney^{8,9} and JoAnn E. Kirchner^{2,10}

Methods: This study is a hybrid type 2 pragmatic effectiveness-implementation trial of tele-PCMHI in six sites over 24 months. Tele-PCMHI, which will be delivered by clinical staff available in routine care settings, will be compared to usual care. Fidelity to the care model will be monitored but not controlled. We will use the Reach Effectiveness Adoption Implementation Maintenance (RE-AIM) framework to evaluate the patient-level clinical effectiveness of tele-PCMHI in rural VA clinics and also to evaluate the fidelity to and outcomes of the implementation strategy, implementation facilitation. The proposed study will employ a stepped-wedge design in

Owen et al. 2017. *Implementation Science*.

Implementing Alcohol Misuse SBIRT in a National Cohort of Pediatric Trauma Centers—a type III hybrid effectiveness-implementation trial

Michael J. Mello^{1,2,3*} , Sara J. Becker⁴, Julie Bromberg^{1,3}, Janette Baird^{1,3}, Mark R. Zonfrillo^{1,3,5} and Anthony Spirito⁶

Background: The American College of Surgeons mandates universal screening for alcohol misuse and delivery of an intervention for those screening positive as a requirement for certification as a level 1 trauma center. Though this requirement has been mandated for over a decade, its implementation has been challenging. Our research team completed an implementation study supporting seven pediatric trauma centers' compliance with the requirement by developing and implementing an institutional alcohol Screening, Brief Intervention and Referral to Treatment (SBIRT) policy for adolescent trauma patients. A mixed-methods approach indicated that SBIRT adoption rates increased at all sites; however, providers' fidelity to the SBIRT intervention was variable, and providers reported a number of barriers to SBIRT implementation. The goal of this study is to conduct a fully powered type III hybrid effectiveness-implementation trial to test the effectiveness of a comprehensive implementation strategy in increasing the implementation of SBIRT for alcohol and other drug use (AOD) in pediatric trauma centers.

Mello et al. 2018. *Implementation Science*.

Disseminating Study Findings

- **Go beyond traditional academic publication outlets**
 - Newsletters, listservs, webinars, press releases, policy briefs for relevant patient, consumer, practitioner, professional society groups
 - Tailor format and content to target audience
- **Presentations at non-traditional conferences**
 - Practice (vs. academic/research) meetings, community-based organizations, community health partners, health departments
- **Leverage social networks, social media, and online platforms**
 - Twitter, trusted peer-to-peer networks, online platforms (e.g., Sermo, Doximity, DailyRounds)

Implementing Study Findings

- **Implementation manuals**
 - Make manuals for interventions readily available and in user-friendly format to end-users

- **Partnerships, collaborations, C-suite executives**
 - Continue partnerships developed during trial
 - Share ‘best practices’ of implementing study findings
 - Collaborate with C-suite executives throughout trial, measure ROI, cost-effectiveness of intervention, cost-effectiveness of implementation
 - User-friendly version of CONSORT extension for pragmatic trials (Zwarenstein et al., 2008)

Select D&I Research Resources

Training Programs, Webinars



Advanced Topics in Implementation Science Webinars

Listen in as leaders in the field discuss
advanced dissemination and
implementation research topics and
answer questions from the community.



Annual D&I Conference

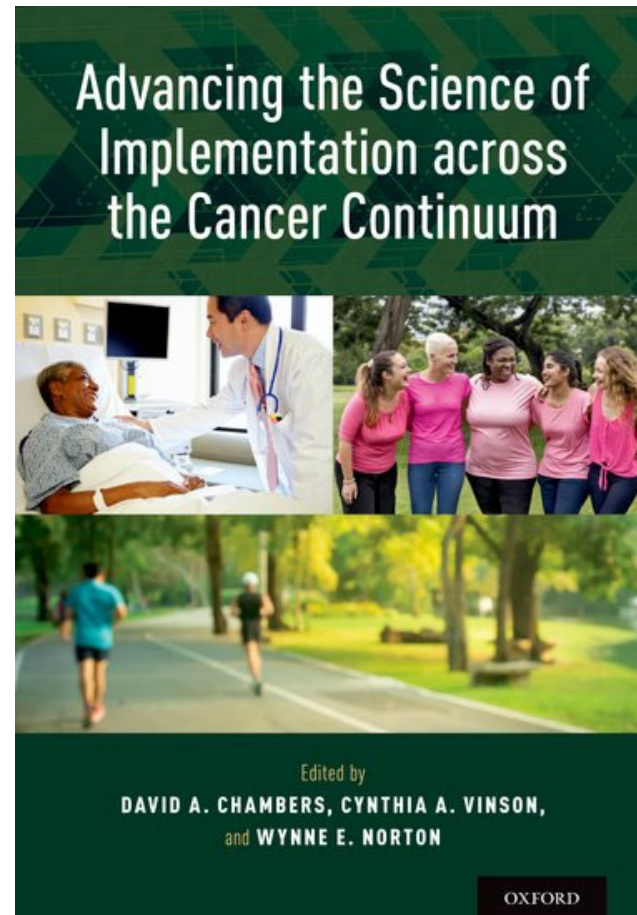
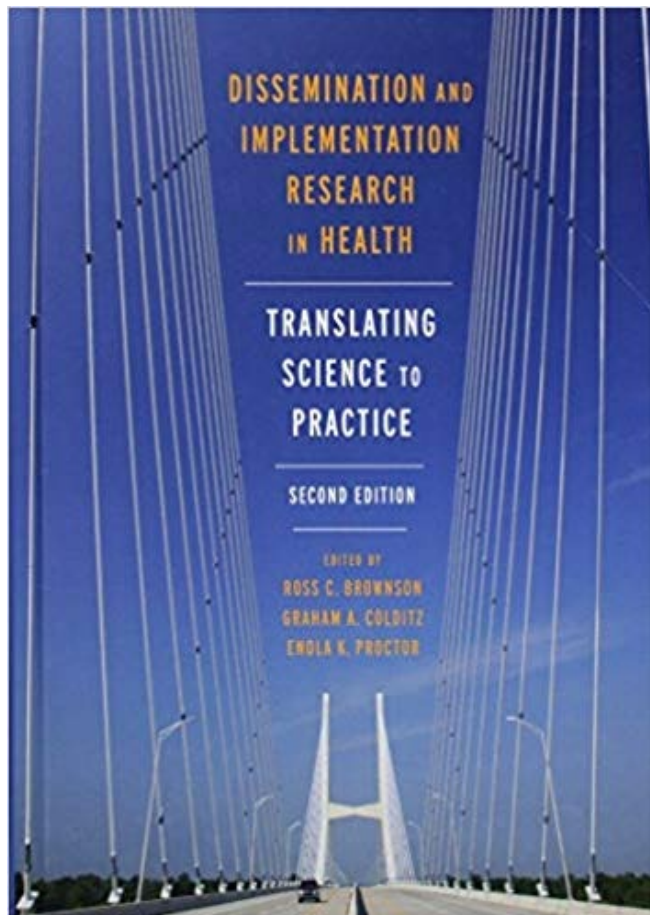
12th Annual Conference on the Science of Dissemination and Implementation in Health

Learn about the latest innovations in the science of D&I;
Explore new research findings and contribute to the next set of research priorities;
Identify and understand challenges facing D&I research; and
Network and collaborate with leading experts in the field.

DATE & TIME December 4-6, 2019 **LOCATION** Crystal Gateway Marriott, Arlington, VA

Supported by NIH, AcademyHealth, AHRQ, PCORI, RWJF, VA

Textbooks, Journal



Implementation Science

Important Things To Do

- Think about designing your study in ways that can facilitate broader dissemination and implementation.
- Involve patients, providers, organizational leaders, and other key stakeholders in the design and conduct of the trial to increase applicability and relevance to other potential end-users.
- Create materials (e.g., manuals, resources, training documents) that can be distributed after the study to help disseminate findings.
- Use a variety of outlets to share study findings with practitioner communities.

Questions? Comments?

Thank You!

Wynne E. Norton, PhD
Program Director, Implementation Science
Division of Cancer Control and Population Sciences
National Cancer Institute

wynne.norton@nih.gov



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