



NIA IMPACT
COLLABORATORY
TRANSFORMING DEMENTIA CARE

Overview of Health Equity Work in the Collaboratory

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Objectives

- Brief overall IMPACT progress
- **Integration of health equity across IMPACT**
 - **Health Equity Team**
 - **Cross Collaboratory**
 - **Individual Cores**
- Measure/evaluate metrics of health equity integration
- Organization

Health Equity Central to IMPACT Mission

- Minoritized populations
 - Higher rates of dementia
 - Worse outcomes
 - Under-represented in traditional RCTs
 - Opportunity for ePCTs

Mission

To build the nation's capacity to conduct ePCTs of interventions within health care systems (HCS) for people living with dementia (PLWD) and their care partners (CPs)

Health Equity: Pragmatic Trials

- To achieve mission, IMPACT must
 - Conduct health equity focused ePCTs
 - Integrate health equity into **all aspects of the scientific conduct** of ePCTs
 - Train investigators from all backgrounds and with health equity focus
 - Hold ourselves accountable
- Limited prior work on integrating health equity into pragmatic trials
- Starting from blank slate





Health Equity Team



Leader



Ana Quiñones,
PhD, MS

Executive Committee Members



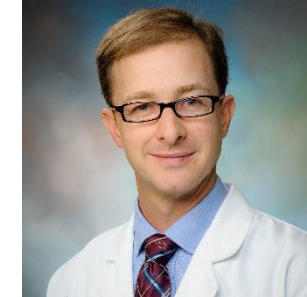
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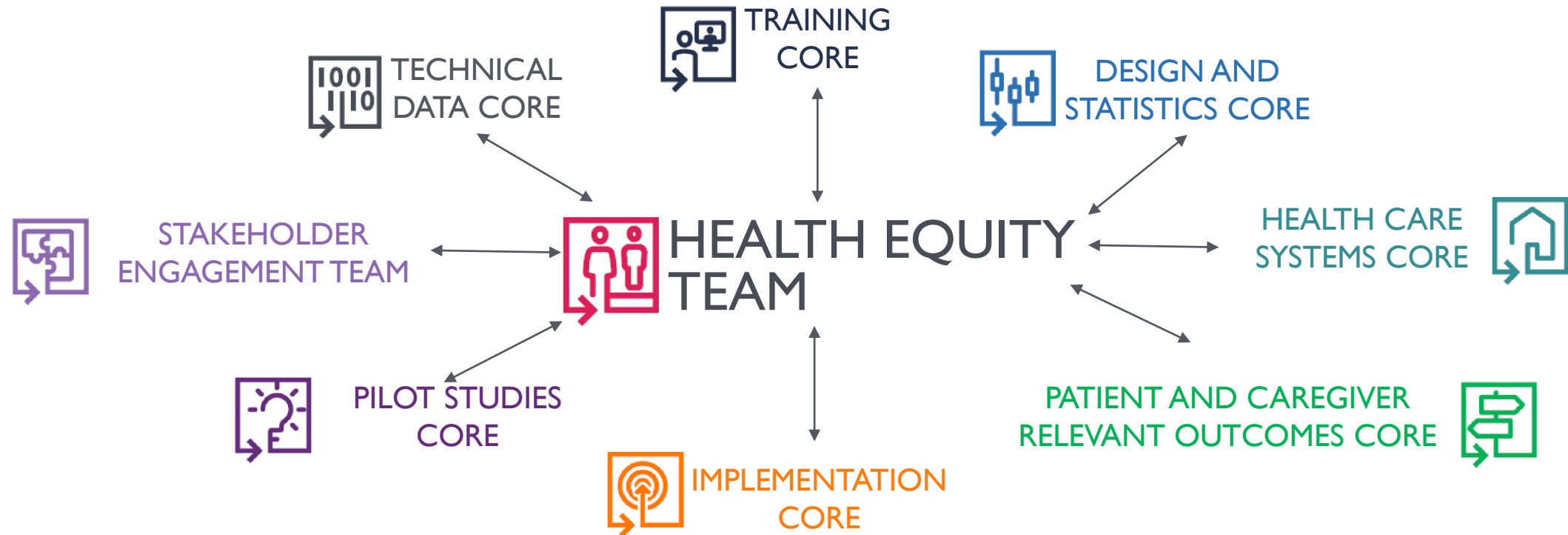


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Integrating Health Equity across IMPACT



IMPACT Accomplishments

Support Design & Conduct of ePCTs

National Competitions for ePCTs **11** Cycles

Pilot Grant Program
8 RFAs
6 Cycles complete
18 Grants awarded



Demonstration Projects Program

3 RFAs
2 Cycles complete
4 Grants awarded



Investigator Consultation

95 Applicant consultations



31 Funded investigator consultations

10 NIA-funded investigator consults
7 Ask an IMPACT Expert
~780 Expert-hours

Develop & Disseminate Knowledge

Knowledge Repository **330** Items
103 Peer reviewed articles
3 Best practice/guidance

3 Reports
34 Grand Rounds
32 Podcasts



JAGS Special Issue
11 Articles

6 Core iLibraries
PCRO iLibraries
55 Administrative sources
57 Other sources

Implementation iLibraries

42 Telehealth interventions records
6 Dementia care interventions records
31 Non-pharmacological care partner interventions records

TDC iLibrary 54 Identification of PLWD

11 Scientific Meetings & Workshops
5 Scientific Meeting Symposia
6 IMPACT Themed Workshops



Build Investigator Capacity

National Competitions for Investigator Training **7** Cycles



Career Development Award Program
4 RFAs
3 Cycles complete
9 Awardees



Health Care Systems Scholars Program
3 RFAs
2 Cycles complete
4 Awardees



IMPACT ePCT Video Learning Library **25** Modules
10 Topic areas
1 Certificate program

3 Training Workshops 2021-2023
174 Participants
64 Institutions



Catalyze Stakeholder Collaboration

Learning Health Network **36** Organizations
4 Communities
58 Members



Stakeholder Advisory Committee **13** Organizations
15 Participants

Lived Experience Panel

Alzheimer's Association collaboration

9 People living with dementia, care partners, and proxies



3 Topics 8 Meetings
Patient & Caregiver Relevant Outcomes
Ethics & Regulation
Health Equity



Goal

- Create set of practical guidance documents for investigators to integrate health equity into all aspects of ePCT design
- Mostly intended for design stage
- Broad, key considerations for each design element
 - Appreciate complexity
 - Framed as “first step” to users
 - Provide additional resources

Process

- Literature review (e.g., Progress-Plus, CONSORT Equity Extension)
- Solicitation from Cores/Teams of key priorities
- Task group
 - Collated & Cross-Checked
 - Created buckets
 - Prototypes
 - Introduction/Glossary/Resources
- Second round of edits by Cores/Team
- Task group finalized content
- Communications Team creates final product

Best Practices for Integrating Health Equity in ePCTs

6 Best Practices for Getting Started

Integrating Health Equity into ePCTs for Dementia Care



- 1 Consider health equity in all research questions. There are health equity considerations in all research questions. The key is to consider these issues early in the process.
- 2 Select a research question that addresses the needs of disadvantaged, underrepresented, and underserved populations.
- 3 Collaborate with community members in inclusive research. Engage representative stakeholders from diverse backgrounds. Their input is valuable across the trial.
- 4 Allocate sufficient resources to reach health disparity populations. Plan for the effort and budget needs for translation or interpretation, community partners, and project staff diversity.
- 5 Build a research team that includes health equity expertise. Your research team should include individuals with methodologic expertise, content knowledge, and health equity-relevant issues through community partnerships.
- 6 Design with health equity in mind. When you design an ePCT, keep in mind the needs of health equity populations. Report the Consortium Equity Extension.

NIA IMPACT Collaboratory | Best Practices for Health Care System and Participant Selection

6 Best Practices for Health Care System and Participant Selection

Integrating Health Equity into ePCTs for Dementia Care



- 1 Select health care systems (HCS) that are accessible and equitable for improved care.
- 2 HCS and participant selection should be met including pre-specified health equity considerations.

Consider health-equity-relevant features such as: state, rurality, organization, integrated delivery system, intervention implementation.

Consider health-equity-relevant characteristics such as: insurance status, sexual/gender identity, disabilities, diagnosis, education, socioeconomic status.

Consider the validity and bias of methods used to identify eligible participants. Methods should identify all eligible participants who may be "missing" (e.g., undiagnosed, record-based algorithm, validate if local data not include race, other system-related factors).

Consider threats to health equity for eligible participants. Once eligible participants are identified, such as mode of outreach (e.g., computer consent is needed, ensure an equitable approach).

NIA IMPACT Collaboratory | Best Practices for Health Care System and Participant Selection

6 Best Practices for Community Stakeholder Engagement

Integrating Health Equity into ePCTs for Dementia Care



- 1 Apply a health equity approach to stakeholder engagement throughout the study. Engage stakeholders through methods that matter, tailoring interventions to the needs of the community when designing enrollment strategies.
- 2 Engage stakeholders from diverse backgrounds. Consider the racial, social, and cultural backgrounds of the community members you are engaging.
- 3 Engage the community early and often. Include a period of "pre-engagement" to understand preferences, and needs, and throughout is progress. Support rather than scientific leadership.
- 4 Use a mix of strategies to reach diverse populations. Partner with community leaders, businesses, recreation or social media, and local radio, social media, and other community-based organizations.
- 5 Evaluate the impact of stakeholder contributions. Assess the experiences of stakeholders and the impact of their contributions throughout the study.
- 6 Disseminate results to the community. Plan to deliver presentations and reports to the community at the completion of the study.

NIA IMPACT Collaboratory | Best Practices for Health Care System and Participant Selection

6 Best Practices for Design and Analysis

Integrating Health Equity into ePCTs for Dementia Care



- 1 Clearly state health-equity-relevant aims & hypotheses. All ePCT designs should employ health equity principles, but not all will formally investigate hypotheses relevant to health equity. If an ePCT has explicit objectives related to health equity they should be clearly stated in the aims and hypotheses.
- 2 Pre-specify analyses related to health equity. Analyses related to health equity should be specified during the design phase (e.g., to estimate heterogeneity of treatment effects across participant subgroups).
- 3 Be explicit in sample size justifications with regard to health equity objectives. Sample size justification should support health equity aims and hypotheses. Comparisons between subgroups may not be powered to demonstrate differences with high probability, but may still be important for reporting results, and should be justified on that basis.
- 4 Consider stratified randomization on health-equity-relevant parameter. Stratified randomization may help ensure a balance of health-equity important parameters across clusters and trial arms, and can be especially useful if such parameters may directly influence clinical outcomes of the ePCT.
- 5 Collect data to allow description and reporting of health-equity-relevant participant characteristics. Design data collection to enable construction of tables and/or flow diagrams to describe participants across equity-relevant groups that were included in the trial, received the intervention, and lost to follow-up.
- 6 Be aware of, monitor, and report differential risk-benefit across health-equity-relevant groups. Adequately protecting the interests of diverse populations requires knowing if/how their risk-benefit balance may differ from that of the general population.

NIA IMPACT Collaboratory | Best Practices for Health Care System and Participant Selection

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6 Best Practices for Intervention Design and Implementation

Integrating Health Equity into ePCTs for Dementia Care



- 1 Determine who is meant to benefit from the intervention. Consider the racial, social, socioeconomic, linguistic and cultural backgrounds of the people who will receive the intervention (providers, people living with dementia, people in the healthcare system).
- 2 Involve key stakeholders in intervention design. Stakeholders who represent the backgrounds of the people who will receive the intervention should be involved in its design, content, delivery and adaptation.
- 3 Adapt interventions for different settings and populations. Most existing interventions of PLWD and their CPs need to be adapted for use in different settings. Take a systematic approach to adaptation. Document and report adaptations.
- 4 Ensure intervention materials are accessible to health-equity-relevant groups. Ensure intervention materials are acceptable and accessible to health equity-relevant groups (e.g., languages spoken, settings, and cultural practices).
- 5 Identify and address barriers to equitable participation. Barriers to equitable participation may include:

PLWD and CPs	Providers
Computer access, transportation, time and cost, acceptability of intervention	Inequitable training, limited time, discriminatory attitudes, intervention acceptability, incongruence of background with PLWD & CP

- 6 Monitor implementation across health-equity-relevant groups. Plan to monitor implementation (reach, coverage, intensity) and adapt if inequities occur. Document and report adaptations.

NIA IMPACT Collaboratory | Best Practices for Health Care System and Participant Selection

6 Best Practices for Selecting Outcomes

Integrating Health Equity into ePCTs for Dementia Care



- 1 Select outcomes relevant to health disparity populations. Select outcomes with evidence of broad value in health disparity populations.
- 2 Assess the validity of outcomes for equity-relevant groups to ensure applicability in specific populations. Assess existing evidence of outcome validation regarding race, ethnicity, educational attainment and other health equity-relevant characteristics.
- 3 Explore how outcomes may be interpreted with respect to norms and expectations of equity-relevant groups. Review qualitative and comparative research on cultural differences in the lived experience of people living with dementia (PLWD), and the meaning of potential outcome domains.
- 4 Consider pilot work to evaluate acceptability and psychometrics of outcomes for health disparity populations. In the absence of evidence of psychometric properties in specific populations, pilot work may be needed to assess an outcome measure's validity, reliability, and cross-cultural differences in these groups.
- 5 Require linguistic and health literacy accessibility in outcome ascertainment. For clinically embedded patient/care partner relevant outcomes, ensure forward and back-translation required for linguistic and health literacy accessibility.
- 6 Ensure health equity of outcome data capture. For PLWD and care partners, assess and adapt for limited computer, internet or smart phone access. For healthcare systems, assess the need for enhanced technical assistance for outcome data in populations at risk for health disparities.

NIA IMPACT Collaboratory | Best Practices for Health Care System and Participant Selection

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6 Best Practices for Getting Started

Integrating Health Equity into ePCTs for Dementia Care



1

Consider health equity in all domains of ePCT design

There are health equity considerations in all ePCT design domains, as guided by the PRECIS-2 framework. The key is to consider these issues early in the design phase and throughout the trial's conduct.

2

Select a research question that matters to health disparity populations

All trials are ethically required to maximize their social value. One way to achieve this is to prioritize questions that address the needs of health disparity population including those that are historically disadvantaged, underrepresented, or otherwise underserved.

3

Collaborate with community members to ensure relevant, respectful, and inclusive research

Engage representative stakeholders who are knowledgeable about the community. Keep in mind there are many aspects of diversity (e.g., race/ethnicity, geography, education). Consultation with community members is valuable across the trial lifespan.

4

Allocate sufficient resources to ensure appropriate and inclusive engagement of health disparity populations

Plan for the effort and budget needed to support inclusive participant engagement. Examples include budgeting for: translation or interpretation services, remuneration of research activities for community partners, and project staff diversity training.

5

Build a research team that is diverse and knowledgeable about health equity issues

Your research team should include investigators, consultants, and project staff with the diversity, methodologic expertise, content knowledge, and training to enable rigorous integration of health-equity-relevant issues throughout the ePCT design.

6

Design with health equity monitoring & reporting in mind

When you design an ePCT, keep in mind the health-equity-relevant aspects that need to be monitored and reported. The Consort Equity Extension and Progress-Plus frameworks are useful guidelines.

6 Best Practices for Community Stakeholder Engagement

Integrating Health Equity into ePCTs for Dementia Care



1

Apply a health equity approach to stakeholder engagement throughout the study

Engage stakeholders throughout the study lifespan, including: choosing research questions and outcomes that matter, tailoring interventions and protocols, developing appropriate and accessible materials, designing enrollment strategies, interpreting data, and planning for dissemination and implementation.

2

Engage stakeholders who are representative of the ePCT participants

Each Best Practice has main statement and a couple sentences of explanation

3

Include a period of "pre-engagement" to get to know the community, understand their priorities, preferences, and needs, and build relationships and trust. Keep the community informed about the ePCT throughout its progress. Support the community through information, education, and other efforts. Use plain rather than scientific language.

4

Use a mix of strategies to identify stakeholders from health disparity populations

Partner with community leaders and groups. Go to places that community members frequent such as local businesses, recreation or senior centers, and places of worship. Use culturally-relevant media such as flyers, local radio, social media, and television.

5

Evaluate the impact of stakeholder engagement

Assess the experiences of stakeholders related to their involvement with the research. Describe how stakeholder contributions had an impact on study design and conduct.

6

Disseminate results to community stakeholders

Plan to deliver presentations (i.e., at community gatherings and settings) of results during and/or upon completion of the study.

Introduction

- Rationale
- How to Use
- Table of Contents
- Resources

Best Practices for Health Care System and Participant Selection

Integrating Health Equity into ePCTs for Dementia Care



Rationale

The NIH Revitalization Act of 1993 was enacted to compel scientists to design for, and report on, the effectiveness of our interventions by gender and racial/ethnic groups, yet the evidence base for underrepresented people living with dementia (PLWD) is sparse. Higher rates of dementia and worse health outcomes have been documented for many minoritized populations relative to PLWD who are non-Hispanic White, yet these populations that experience health disparities are vastly underrepresented in dementia efficacy trials. A concerted effort to integrate health equity into study designs is necessary to ensure we are conducting quality science and avoiding harm where evidence gaps exist. However, the efficacy, safety, and tolerability of treatments have not been sufficiently assessed for many groups that experience Alzheimer's disease (AD) and AD Related Dementias (AD/ADRD), creating critical knowledge gaps at a time when our aging population is becoming increasingly diverse.

The sparse evidence applicable to health disparity populations derived from AD/ADRD efficacy trials extends to pragmatic clinical trial designs embedded in health care systems (ePCTs, HCS). ePCTs aim to evaluate interventions in real-world settings. ePCTs have unique design features that introduce additional novel challenges with respect to health equity, yet to date there is very little guidance on how to integrate health-equity-relevant considerations into the design of impact ePCTs, including those targeting PLWD and their care partners.

How to Use this Packet

Health-equity-relevant considerations are necessary in all aspects of ePCTs. The key is to consider these issues early in the planning process, as well as systematically and throughout the conduct of the trial. Health-equity-relevant concepts can be nuanced and complex, and the degree to which researchers can incorporate health equity into each ePCT design component depends on the scope and objectives of the trial. These best practices are meant as a starting place for investigators to systematically explore how to integrate health equity into their ePCT design and identify potential pitfalls in their current research processes.

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Additional Resources

This best practices package includes a glossary of terms and well as key references for additional resources and publications. The community-based participatory research, implementation science, and cultural adaptation literature offer some additional guidance. We encourage investigators to seek more in depth guidance incorporating health-equity-relevant features into the ePCT from these resources as well as from methodological and content experts and key stakeholders.

- Glossary
- Resources

Glossary

This glossary is not intended to serve as a comprehensive set of definitions but instead as a starting point to those interested in reading more.



Community	Social grouping based on individual characteristics and/or geographic location.
Community Engagement	Community engagement is a process of and involving members of a community (defined by geography or by individual characteristics and membership to a group such as PWLD).
Community Health	<p>Community health refers to the wellbeing of a defined group of people and the context, actions, and conditions available to promote, protect, and preserve the community's health.</p> <p>The process of improving community health involves multisectoral and multidisciplinary collaborative efforts in evidence-based science, public health, to engage and work with communities, in a culturally appropriate manner, to optimize the health and quality of life of all persons who live, work, or are otherwise active in a defined community or communities."</p> <p>Goodman RA, Bunnell R, Posner SF. What is "community health"? Examining the meaning of an evolving field in public health. <i>Prev Med.</i> 2014;67 Suppl 1(Suppl 1):S58-S61. doi:10.1016/j.ypmed.2014.07.028</p>
Community Leader	Persons who is very knowledgeable about the community and takes responsibility for the growth, development and improvement of their community in a formal or informal way.
Community Members	People who live and interact in any personal or professional way in a specific community. https://www.countyhealthrankings.org/take-action-to-improve-health/partner-center/community-members
Community Partner	Any local organization (non-profit, for profit, governmental), groups or persons working together with another team to implement a project.
Community-Based Participatory Research (CBPR)	<p>Community-based participatory research is a collaborative research approach that is designed to ensure and establish structures for participation by communities affected by the issue being studied, representatives of organizations, and researchers in all aspects of the research process to improve health and well-being through taking action, including social change.</p> <p>AHRQ. https://www.ahrq.gov/research/findings/factsheets/minority/cbprbrief/index.html</p>
Cultural Adaptation Cultural Tailoring	<p>Cultural adaptation and cultural tailoring is a systematic process of modifying an evidence-based intervention to address language and cultural contexts to make it compatible with practices, meanings, and values of those involved. Cultural adaptations are a key aspect of implementation considerations necessary in ePCTs.</p> <p>Barrera M Jr, Castro FG, Strycker LA, Toobert DJ. Cultural adaptations of behavioral health interventions: a progress report. <i>J Consult Clin Psychol.</i> 2013 Apr;81(2):196-205.</p> <p>Stirman SW, Miller CJ, Toder K, Calloway A. Development of a framework and coding system for modifications and adaptations of evidence-based interventions. <i>Implement Sci</i> 2013</p> <p>National Standards for Culturally and Linguistically Appropriate Services (CLAS). https://thinkculturalhealth.hhs.gov/clas</p>

Best Practice Guidance On-line Video Program



Best Practices for Integrating Health Equity into Embedded Pragmatic Clinical Trials for Dementia Care

Best Practices for Integrating Health Equity into ePCTs for Dementia Care



Health Care System and Participant Selection

Part 1

Which populations are marginalized or underrepresented by your health care system ?



What strategies could you take to engage them ?



How can you make the trial more flexible and reduce study burden ?



05:26 | 08:04

Part 5





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USERNAME

PASSWORD

Remember username



Moodle Platform

- Online learning management platform
- Houses all IMPACT training videos
- Provides options for users to take single course or participate in multi-course/module certificate program



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Certificate Program Organization

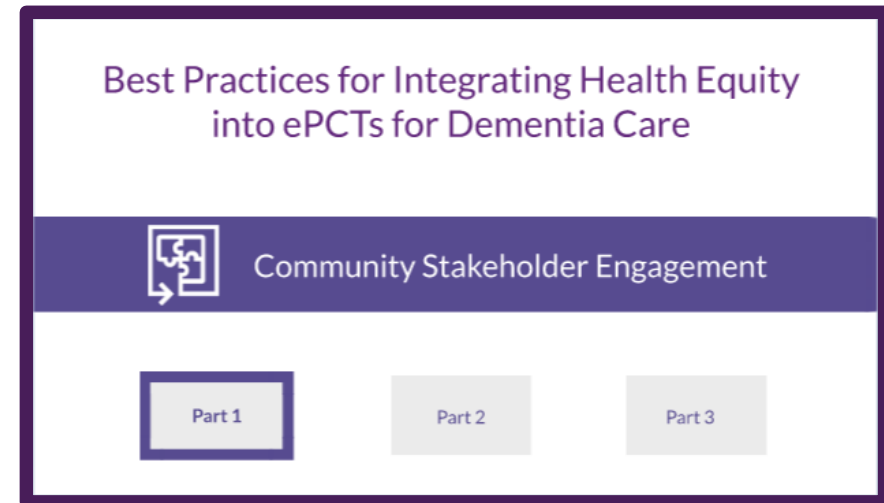
- Program Introduction
- Background and Rationale
- 6 courses
- Glossary and additional resources
- Evaluation



Sheets → Courses

- 6 Sheets → 6 Courses
- 2-5 Parts / course

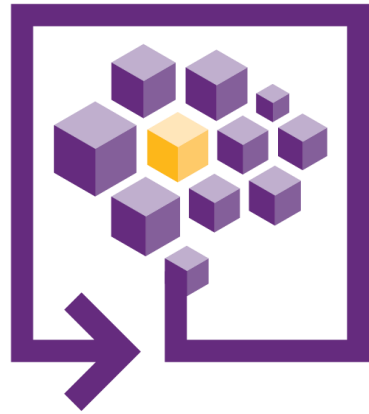
18 videos



- Part 1**
- 1 Apply a health equity approach to stakeholder engagement throughout the study
Engage stakeholders throughout the study lifespan, including: choosing research questions and outcomes that matter, tailoring interventions and protocols, developing appropriate and accessible materials, designing enrollment strategies, interpreting data, and planning for dissemination and implementation.
 - 2 Engage stakeholders who are representative of the ePCT participants
Consider the racial, social, and cultural backgrounds of potential study participants who will receive and deliver the intervention, including (PLWD), care partners (CP) clinicians, non-clinician medical staff, and community members.
- Part 2**
- 3 Engage the community before and during the ePCT
Include a period of "pre-engagement" to get to know the community, understand their priorities, preferences, and needs, and build relationships and trust. Keep the community informed about the ePCT throughout its progress. Support the community through information, education, and other efforts. Use plain rather than scientific language.
 - 4 Use a mix of strategies to identify stakeholders from health disparity populations
Partner with community leaders and groups. Go to places that community members frequent such as local businesses, recreation or senior centers, and places of worship. Use culturally-relevant media such as flyers, local radio, social media, and television.
- Part 3**
- 5 Evaluate the impact of stakeholder engagement
Assess the experiences of stakeholders related to their involvement with the research. Describe how stakeholder contributions had an impact on study design and conduct.
 - 6 Disseminate results to community stakeholders
Plan to deliver presentations (i.e., at community gatherings and settings) of results during and/or upon completion of the study.

Timeline

- Best Practice Sheets published - March 2022
- Program Planning – Summer 2022
- Development process piloted for 2 videos - Sept 2022
- Where we are now
 - 6 Completed or near completion
 - 7 in imaging and narration phase
 - 5 in storyboard production phase
- Anticipated launch
 - Goal is to complete storyboard and video development by end of June 2023



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