NIA IMPACT COLLABORATORY

TRANSFORMING DEMENTIA CARE

National Institute on Aging (NIA) IMbedded Pragmatic Alzheimer's Disease (AD) and AD-Related Dementias (AD/ADRD) Clinical Trials (IMPACT) Collaboratory (NIA U54AG063546)

ARE YOU READY FOR A PRAGMATIC TRIAL? THE RAPT MODEL & IMPLEMENTATION CONSIDERATIONS

IMPACT GRAND ROUNDS NOVEMBER 21, 2019

Agenda

- Introduction to the NIA IMPACT Collaboratory's Dissemination and Implementation (D&I) Core
  - Scientific premise and aims
- The Pragmatic-Explanatory Continuum Indicator Summary 2 (PRECIS-2) and Readiness Assessment for Pragmatic Trials (RAPT)
  - How they differ and complement each other
- D&I Core as a resource
- Questions

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INTRODUCTIONS

Introductions: Co-Leads of D&I Core

Laura N. Gitlin, PhD, FGSA, FAAN
Distinguished University Professor and Dean
College of Nursing and Health Professions
Drexel University

Joseph E. Gaugler, PhD
Robert L. Kane Endowed Chair in Long-Term Care & Aging, Professor
School of Public Health
University of Minnesota

Introductions: Key Members

Eric Jutkowitz, PhD
Assistant Professor
Department of Health Services, Policy & Practice
Brown University School of Public Health

Rosa Baier, MPH
Associate Director, Center for Long-Term Care Quality & Innovation
Associate Professor
Department of Health Services, Policy & Practice
Brown University School of Public Health

BROWN
School of Public Health

Core Members & Areas of Expertise

- Dr. Maria Boltz (Penn State)
  - Nursing homes
- Dr. Rick Fortinsky (Uconn)
  - Primary care
  - Medicaid Waiver
  - Medicare Advantage
- Dr. Nancy Hodgson (UPenn)
  - Home
  - Nursing home
  - Community based
- Dr. Kimberly Van Haitsma (Penn State)
  - Nursing homes

Areas of Expertise

- Identification of:
  - Theory to guide Implementation
  - Strategies for Implementation
  - Measures to understand stakeholder and environmental readiness
  - D & I Measures
- Development of Implementation Components
- Mixed Methods for Implementation
- Readiness Assessment for Pragmatic Trials (RAPT) Model
- Development of Team and Stakeholder Involvement
- Measuring Fidelity

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DISSEMINATION AND IMPLEMENTATION CORE: OVERVIEW AND PREMISE

Defining Dissemination & Implementation Research

Dissemination:

- Scientific study of targeted distribution of information and intervention materials to a specific public health or clinical practice audience.
- Understand how best to communicate and integrate knowledge and associated evidence-based interventions.
- Understand mechanisms and strategies to deliver and “package” evidence to local settings

Implementation:

- Scientific study of use of strategies to adopt and integrate evidence-based health interventions into clinical and community settings to improve individual outcomes and benefit population health.
- Seek to understand the behavior of providers of all types, organizations, caregivers, persons with dementia, and policy makers *in context* and how they influence adoption, implementation, and sustainability of dementia care interventions, guidelines, etc.
- Study of local contexts to guide effective implementation of evidence Unidirectional flow of information is insufficient to achieve practice change/implementation

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

D&I Core Scientific Premise & Aims

Fundamental scientific premise:

- D&I considerations critical to address throughout a dementia care project's life-cycle
- The persistent failure of widespread implementation of proven interventions in healthcare systems (HCS) for persons living with dementia (PLWD) and caregivers is due in large part to inattention to D&I science

D&I Core Aims

- Conduct, regularly update, and disseminate syntheses of the scientific literature regarding implementation of non-pharmacologic interventions
- Advance a framework for identifying stage of development of pilot studies and their readiness for conducting ePCT
- Provide ongoing technical assistance tailored to study needs from the outset of project development to enable advancement of implementation and dissemination plans

Our core seeks to develop a knowledge base about *how* dementia care interventions are implemented, integrated and sustained across diverse settings and populations, and how dynamic flows of information occur.

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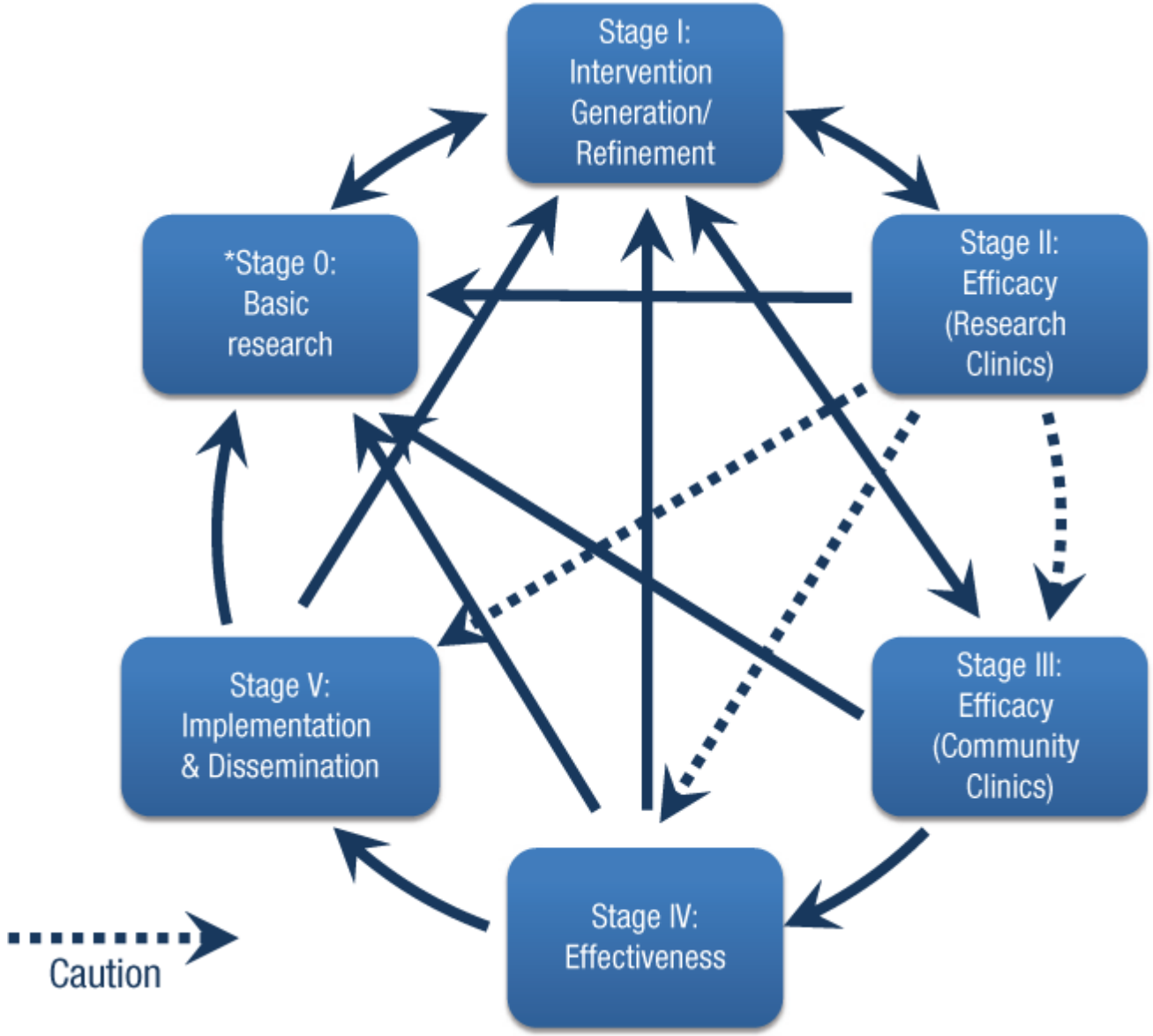
RAPT

Origins

- 2017 national research summit concluded that improving care for persons living with ADRD is a priority.
- Many non-pharmacologic interventions tested in stage II/III trials.
- Few replicated or tested in every day clinical care.

NIH Stage Model



Objective

- NIA funded an expert workshop to discuss criteria to determine non-drug ADRD interventions' readiness for PCTs

- Use expert input from workshop to develop a tool (RAPT) that interventionists can use to determine extent to which an intervention is ready for a PCT

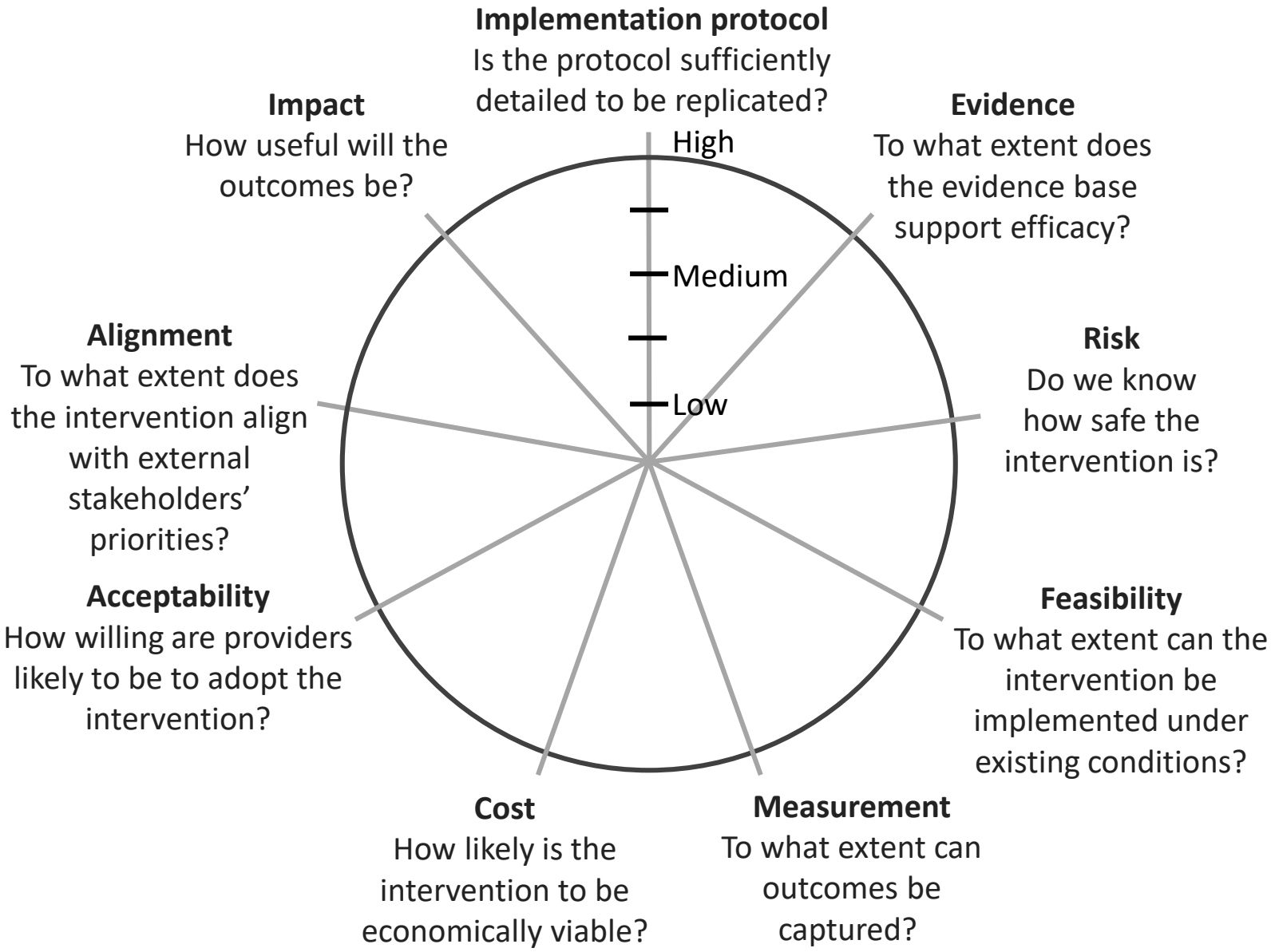
- *Baier RR, Mitchell SL, Jutkowitz E, McCreedy E, Mor V. Readiness assessment for pragmatic trials (RAPT): a model to assess the readiness of an intervention for testing in a pragmatic trial. BMC Med Res Methodol 2019 Jul 18;19(1):156.*

Methods

- Following the workshop, summarized recommended criteria for assessing non-drug ADRD interventions ready for PCTs

- Emailed draft of RAPT to workshop participants and asked them to review for content and face validity

Readiness Assessment for Pragmatic Trials (RAPT)



1. Protocol

Is the protocol sufficiently detailed to be replicated?

Scoring Guidance		
Low	Medium	High
There is no protocol	The protocol provides some documentation, but may be difficult to replicate.	The protocol is well documented and is likely to be replicable.

2. Evidence

To what extent does the evidence base support the intervention's efficacy?

Scoring Guidance		
Low	Medium	High
There are no efficacy studies or the efficacy studies did not use rigorous methods (e.g., a RCT).	A single study using rigorous methods demonstrated efficacy.	Multiple studies using rigorous methods have demonstrated efficacy.

3. Risk

Is it known how safe the intervention is?

Scoring Guidance		
Low	Medium	High
The risks (harms and discomforts) are unknown or are known to be more than minimal (e.g., greater than ordinarily encountered in daily life).	The risks are unknown, but are likely minimal.	The risks are known to be minimal.

4. Feasibility

To what extent can the intervention be implemented under existing conditions?

Scoring Guidance		
Low	Medium	High
Resources necessary for implementation (e.g., staff, infrastructure, payment) are absent or insufficient.	Minor modifications to existing resources would enable implementation .	Implementation is possible with existing resources.

5. Measurement

To what extent can the intervention's outcomes be captured?

Scoring Guidance		
Low	Medium	High
Outcomes cannot be captured without major modifications to systems (e.g., clinical assessments, documentation, or electronic health records) or increases in staff time.	Outcomes can be captured with minor modifications to systems or increases in staff time.	Outcomes are already routinely captured.

6. Cost

How likely is the intervention to be economically viable?

Scoring Guidance		
Low	Medium	High
Cost-benefit/cost-effectiveness analysis has not been completed (formally or informally) and it is unknown whether benefits outweigh costs.	Cost-benefit/cost-effectiveness analysis has not been completed, but benefits are likely to outweigh costs.	Cost-benefit/cost-effectiveness analysis demonstrates benefits outweigh costs.

7. Acceptability

How willing are providers likely to be to adopt the intervention?

Scoring Guidance		
Low	Medium	High
Acceptability is unknown or staff are unlikely to believe the intervention is feasible or needed.	Acceptability is unknown, but staff are likely to believe the intervention is feasible or needed.	Acceptability is known and staff believe the intervention is feasible and needed.

8. Alignment

To what extent does the intervention align with external stakeholders' priorities?

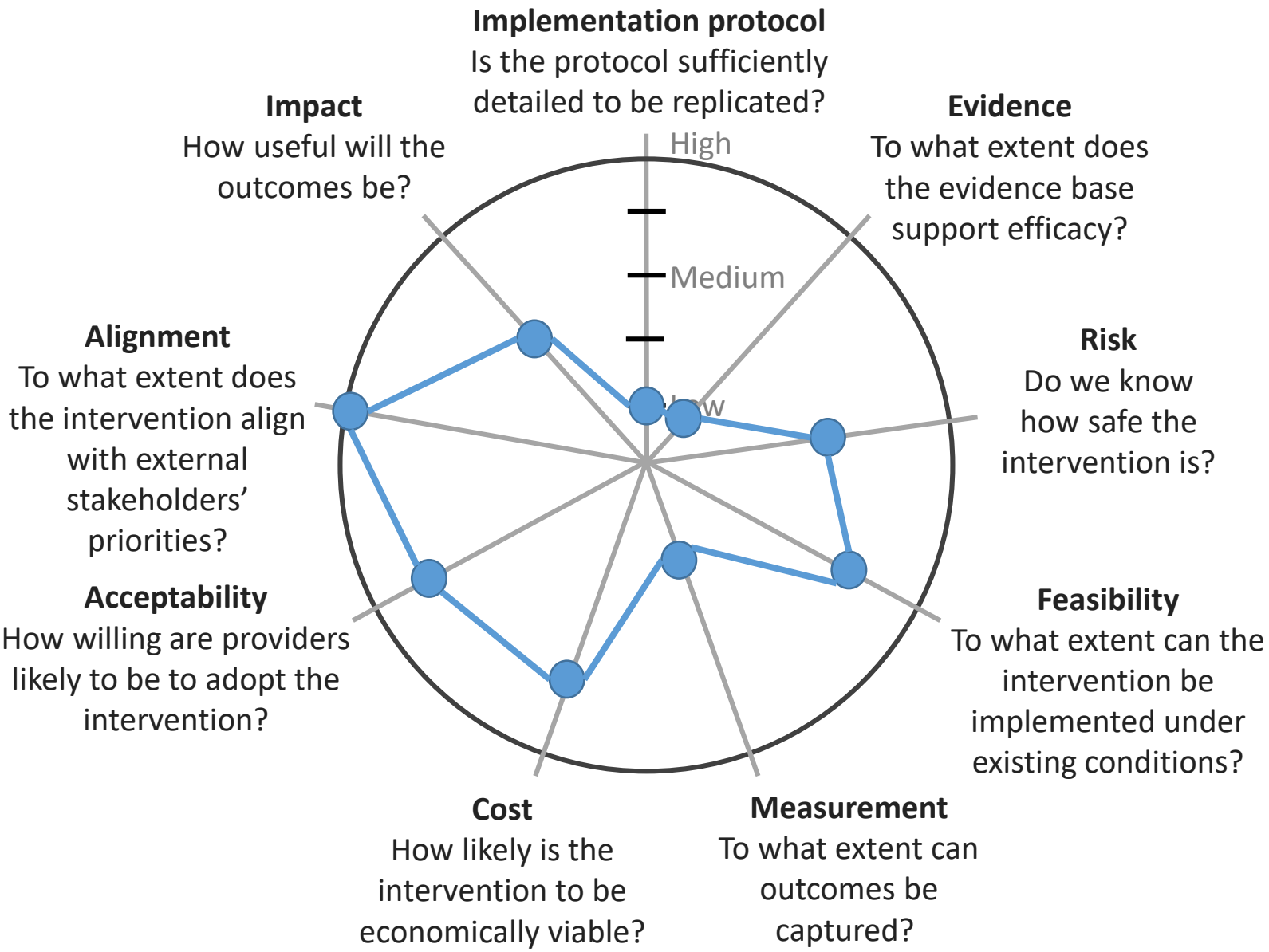
Scoring Guidance		
Low	Medium	High
Stakeholders (policymakers, payors, advocates, and others) do not believe the intervention addresses a current or anticipated priority.	Some stakeholders believe the intervention addresses a priority.	Most or all stakeholders believe the intervention addresses a priority.

9. Impact

How useful will the intervention's results be?

Scoring Guidance		
Low	Medium	High
Providers and stakeholders (policymakers, payors, advocates, and others) are unlikely to believe that the outcomes are useful (e.g., to inform clinical care or policy).	Some providers or stakeholders are likely to believe the outcomes are useful.	Most or all providers and stakeholders are likely to believe the outcomes are useful.

From the Field: Music & Memory



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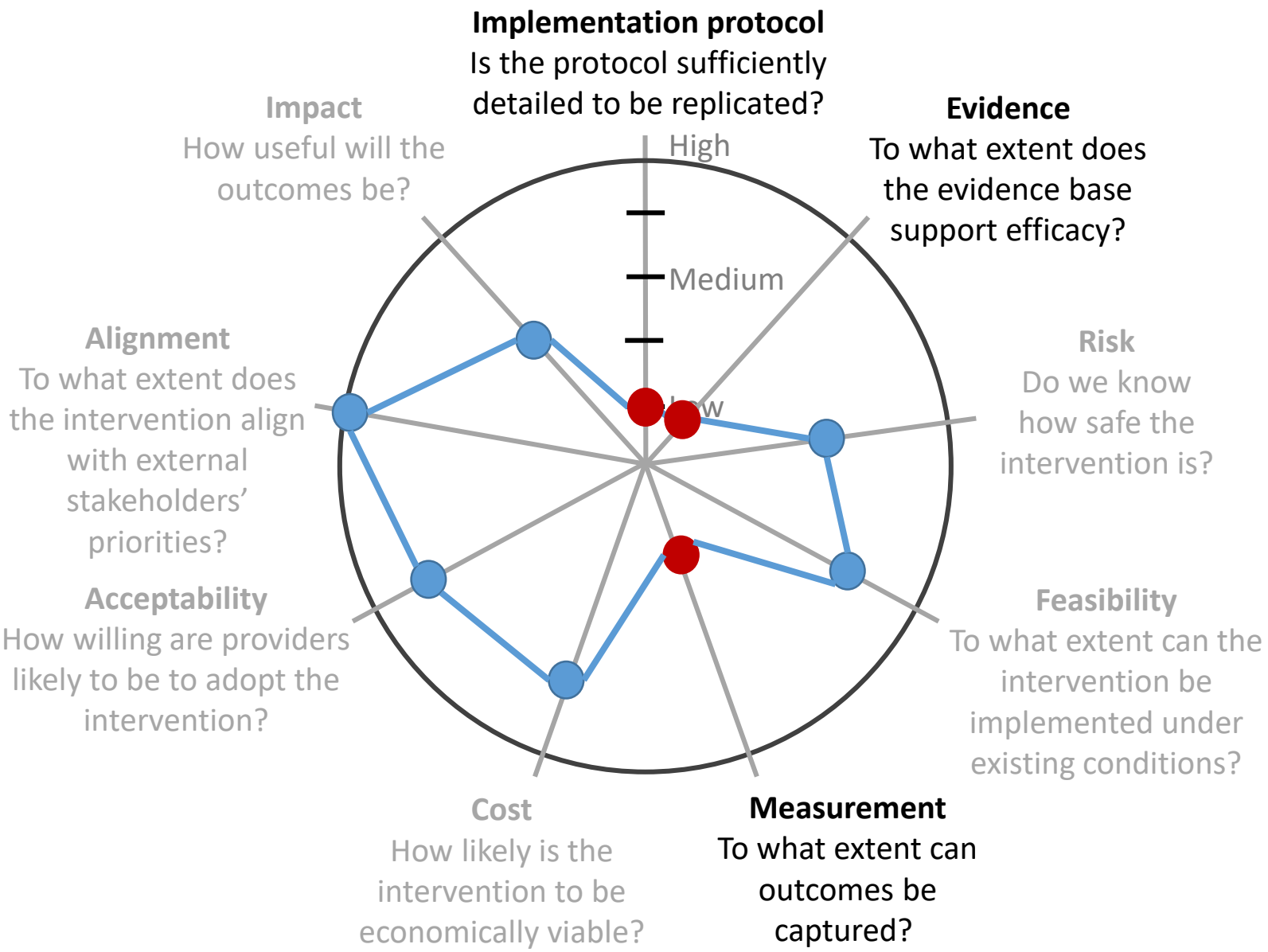

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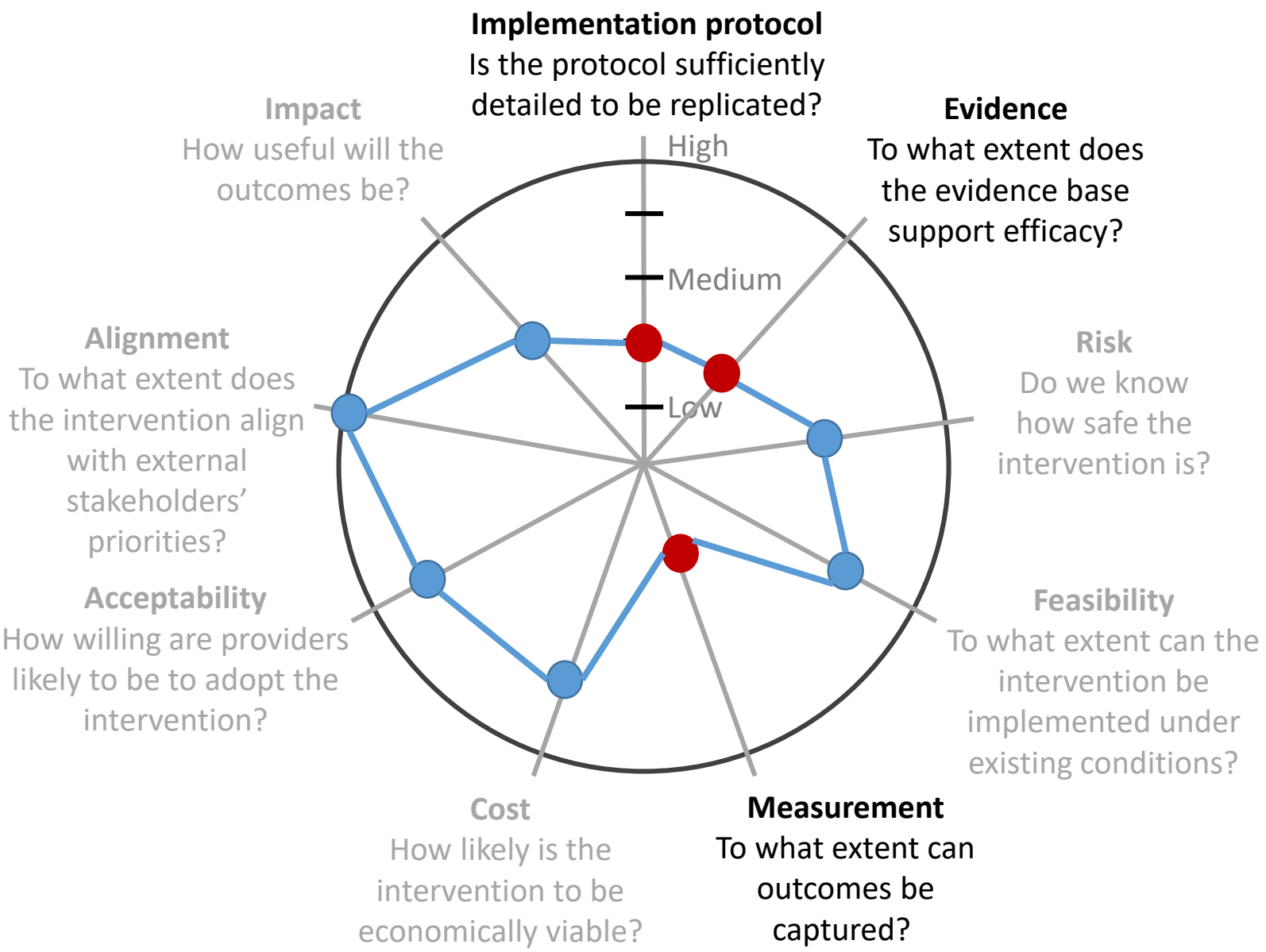

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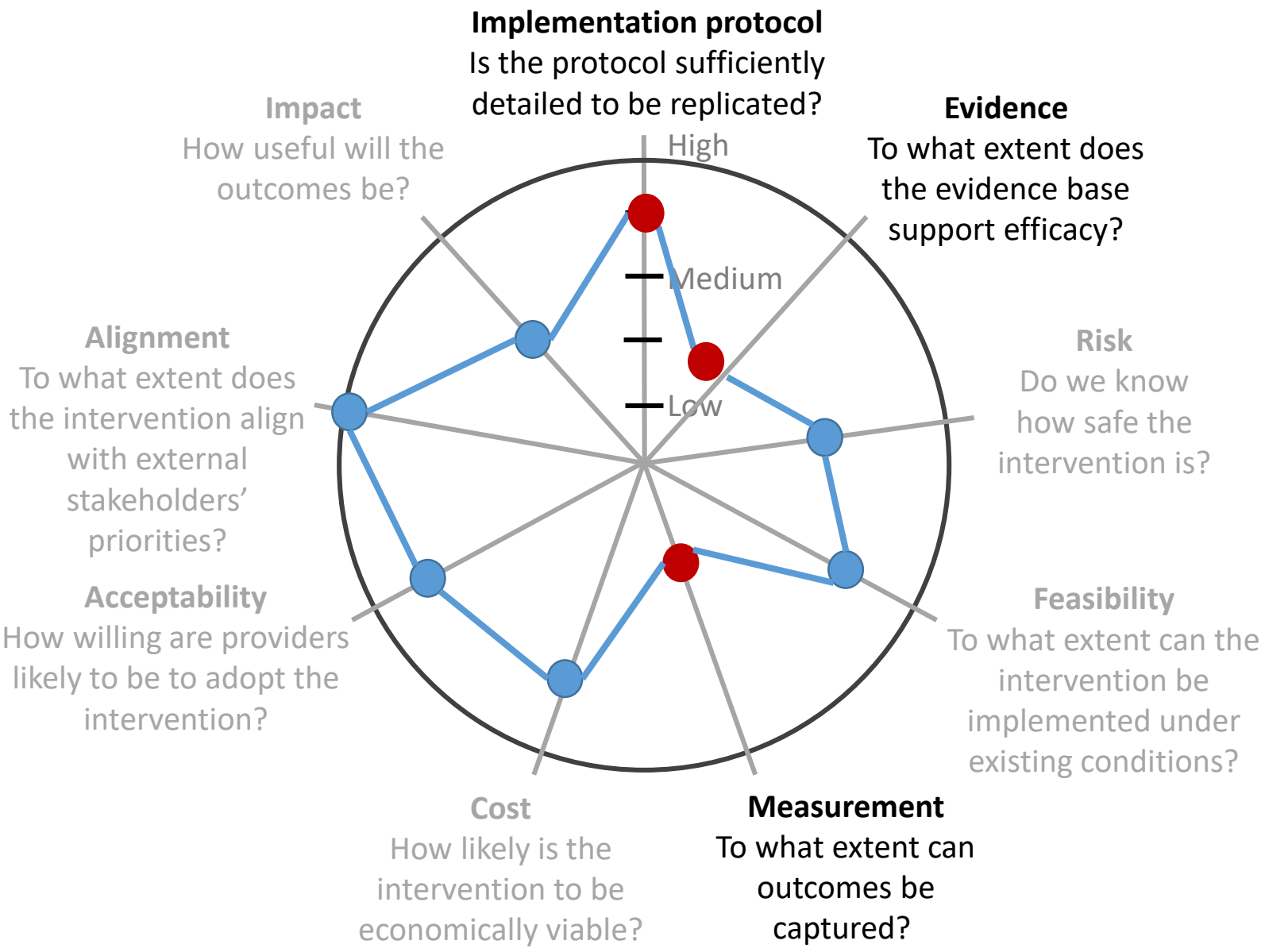

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THE D&I CORE AS RESOURCE

The D&I Core as a Resource

- Production of:
  - Living systematic reviews of pragmatic trials in dementia
  - Systematic reviews of dissemination and implementation of dementia care interventions
  - NASEM Decanal papers
  - Ongoing webinars and educational presentations at national conferences
- Technical assistance to D&I and other investigators
  - Creating an effective dissemination strategy at the outset of intervention design (i.e., from Stage 0 and up)
  - Consideration and refinement of resources for dissemination and implementation of dementia care interventions
- We will assist investigators in considering and utilizing various implementation frameworks to guide their dissemination plans

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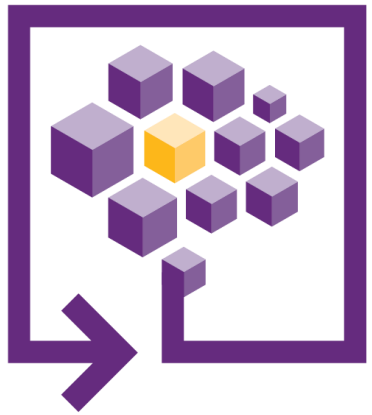
Questions?

Please add your question to the Zoom chatbox and "**send to everyone**" to ensure all speakers and moderators see your question.

Contact Us: IMPACTcollaboratory@hsl.harvard.edu



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