



**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)**

# HEALTH EQUITY AS FOUNDATIONAL TO THE DESIGN OF PRAGMATIC TRIALS

Ana Quiñones, PhD & Jonathan Jackson, PhD

April 16, 2020

# Housekeeping

- All participants will be muted
- Enter **all questions** in the Zoom **chat box** and send to everyone
- Moderator will review questions from chat box and ask them at the end
- Want to continue the discussion? Look for the associated podcast released about 2 weeks after Grand Rounds.
- Visit [impactcollaboratory.org](http://impactcollaboratory.org)
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# Health Equity Team (HET)

## Executive Committee

- Maria Aranda, PhD
- Peggye Dilworth-Anderson, PhD
- Ladson Hinton, MD
- Jonathan Jackson, PhD
- Ana Quiñones, PhD

## HET support

- Kate Peak, research assistant
- Sara Hooley, research associate
- Erin Luers, project director

## Administrative Core liaisons

- Susan Mitchell, MD (MPI)
- Ellen McCarthy, PhD

# Background

The Health Equity Team **contributes to the overall mission** of the IMPACT Collaboratory to build the nation's capacity to conduct pragmatic clinical trials of interventions embedded within health care systems for PLWD and their caregivers by:

***Developing and implementing strategies to address health equity in the conduct of pragmatic trials to ensure the IMPACT Collaboratory is a national resource for all Americans with dementia.***

# Background

- From Diversity & Inclusion Team to Health Equity Team
  - Better reflection of the charge and purpose of our Team
  - A more broad, generalizable approach informed by an equity conceptual lens
  - Inclusion is not enough, need to provide the necessary conditions for equitable access and participation

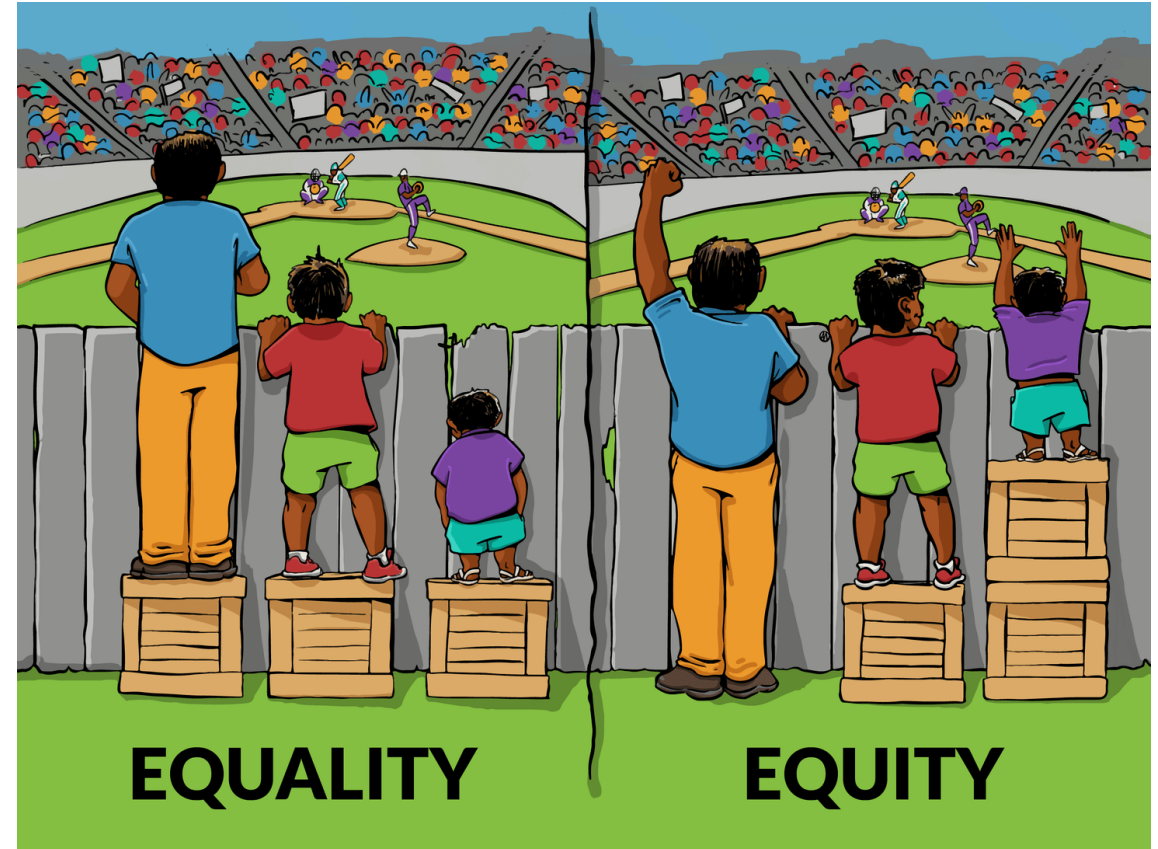


Image attribution: Interaction Institute for Social Change, by artist Angus Maguire  
<https://interactioninstitute.org/illustrating-equality-vs-equity/> & [www.madewithangus.com](http://www.madewithangus.com)

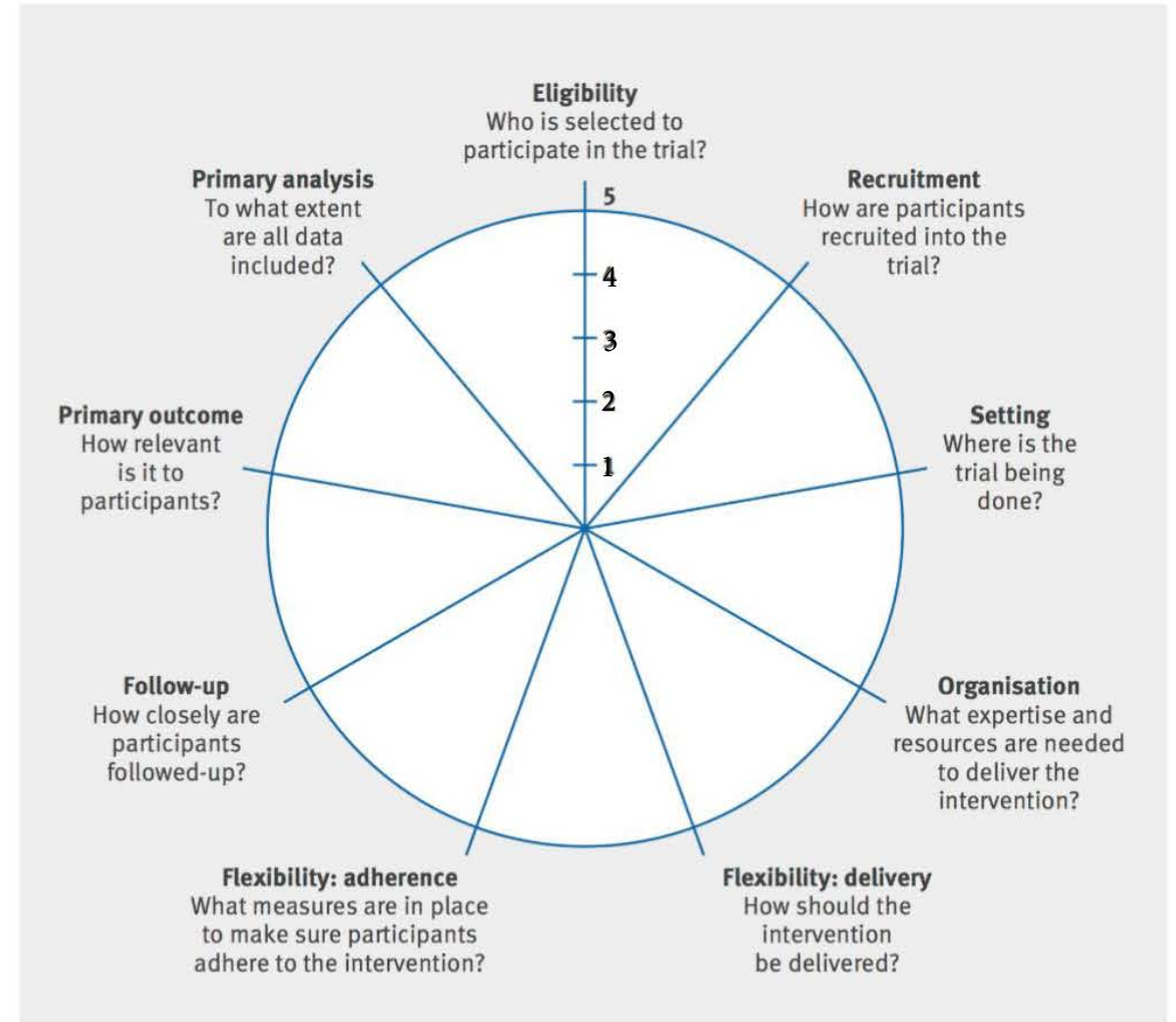
# HET Objectives

- **Develop and disseminate guidance and training materials** related to integrating health equity issues in the conduct of ePCTs among PLWD and their caregivers with health care systems.
  - **Generate and disseminate new knowledge**
- **Guide, support and monitor pilot studies** to ensure issues related to health equity are fully integrated into the scientific design and conduct of the research.
  - **Guide studies to be attentive; encourage monitoring and reporting**
- **Integrate with Core Working Groups** to ensure issues related to health equity are integrated into their specific research activities.
  - **Respond to what we learn in a cyclical and reciprocal way**

# Develop and disseminate guidance

- Pragmatic Explanatory Continuum Indicator Summary (PRECIS-2)

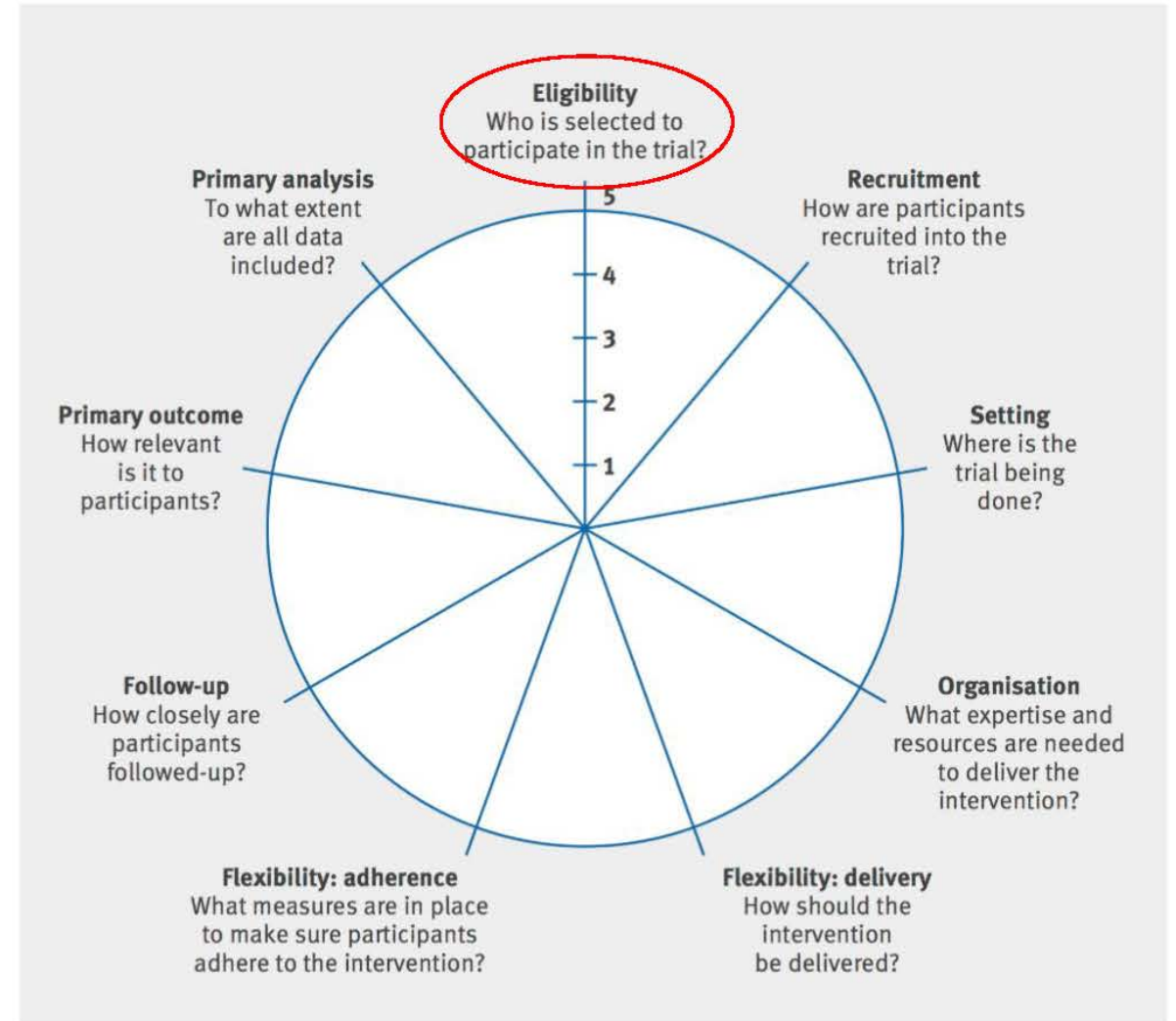
<http://www.precis-2.org/>



# Develop and disseminate guidance

- **Health equity considerations:**

- Minority group inclusion challenging due to eligibility occurring at HCS
- Accurate identification of demographic characteristics in electronic health record or administrative data is a major challenge

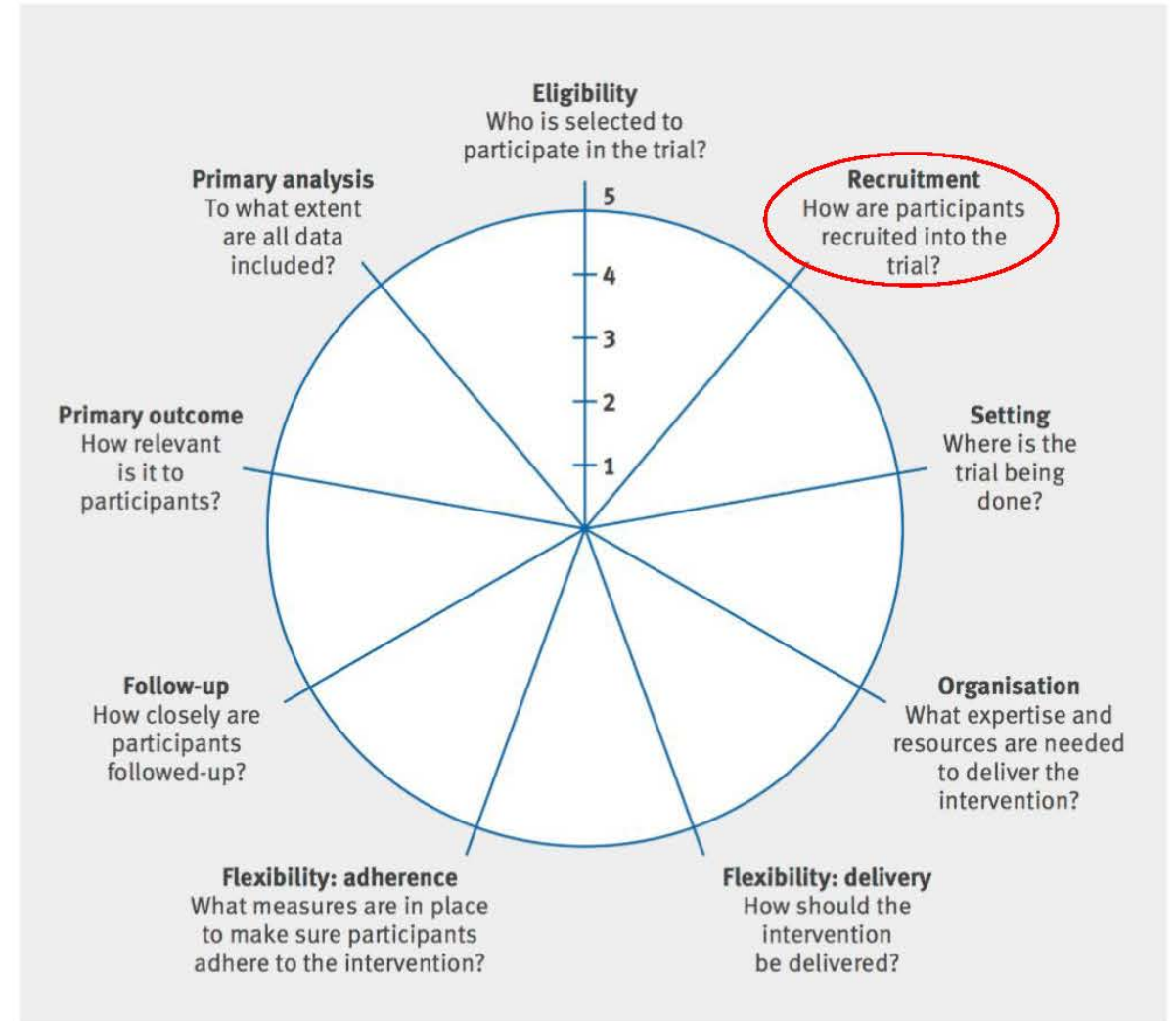




# Develop and disseminate guidance

- **Health equity considerations:**

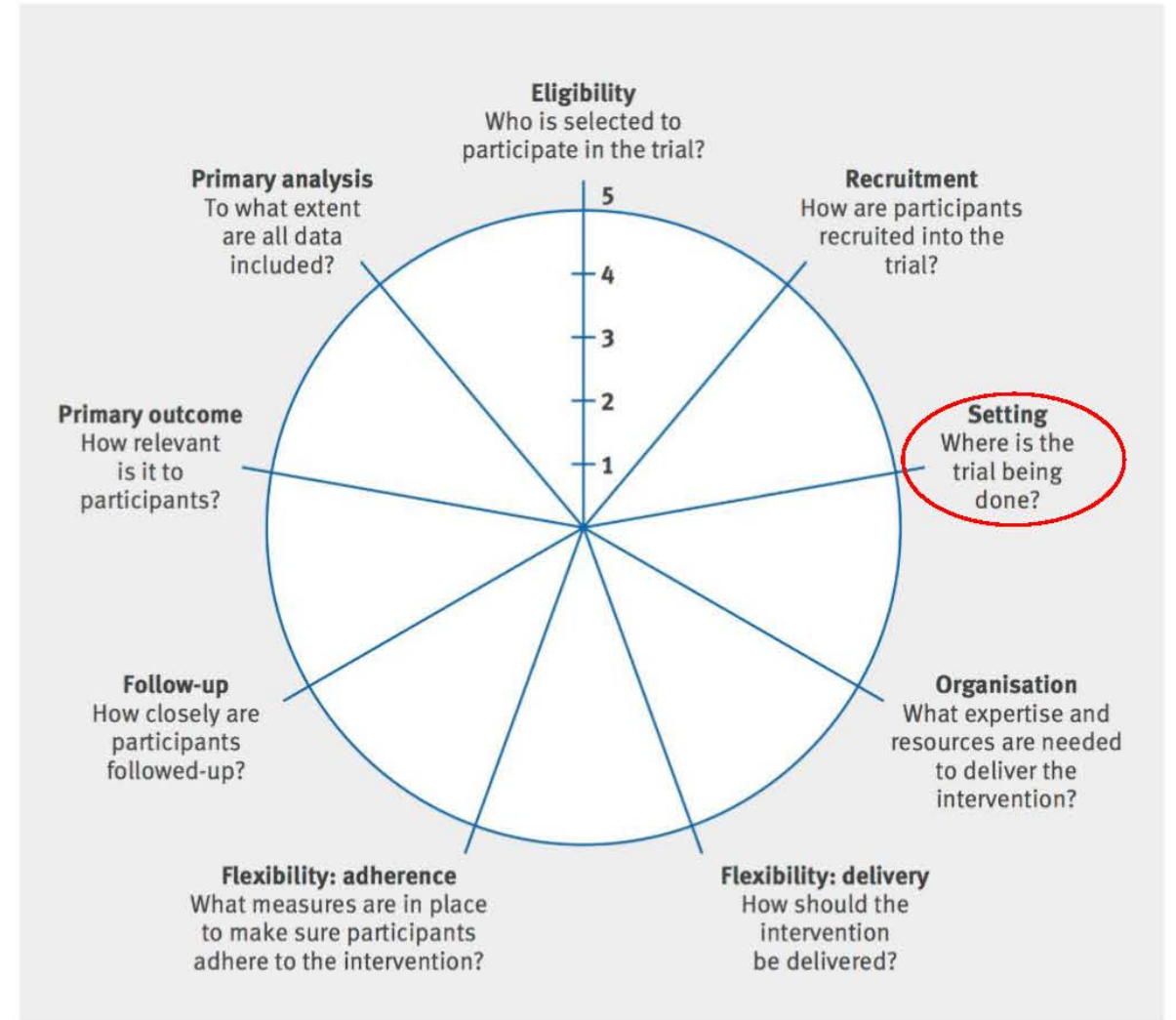
- Ensure HCS/sites serve minority populations willing to participate



# Develop and disseminate guidance

- **Health equity considerations:**

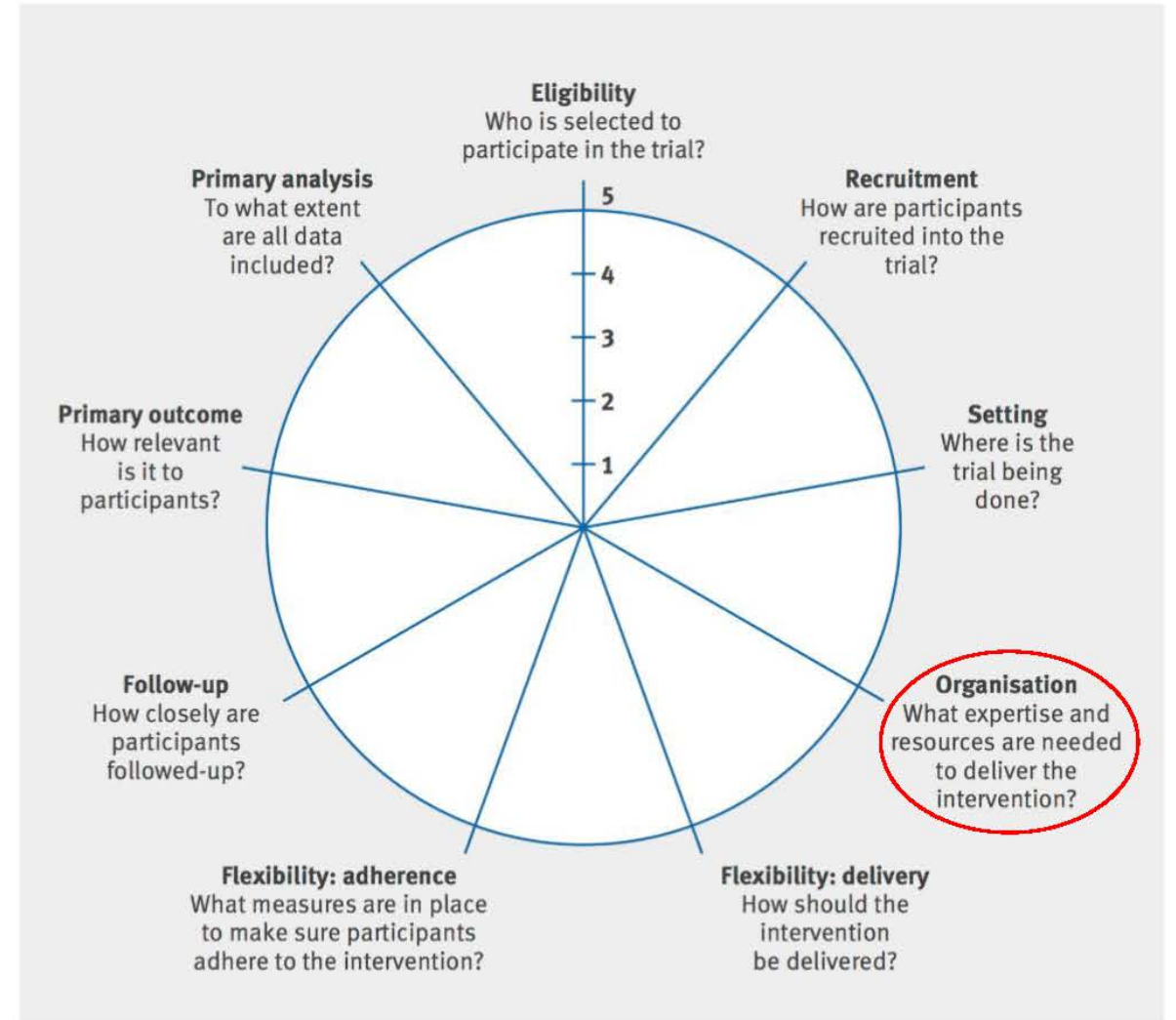
- Many HCS/sites of care are segregated; assess and ensure sufficient race/ethnic group population in HCS sites



# Develop and disseminate guidance

- **Health equity considerations:**

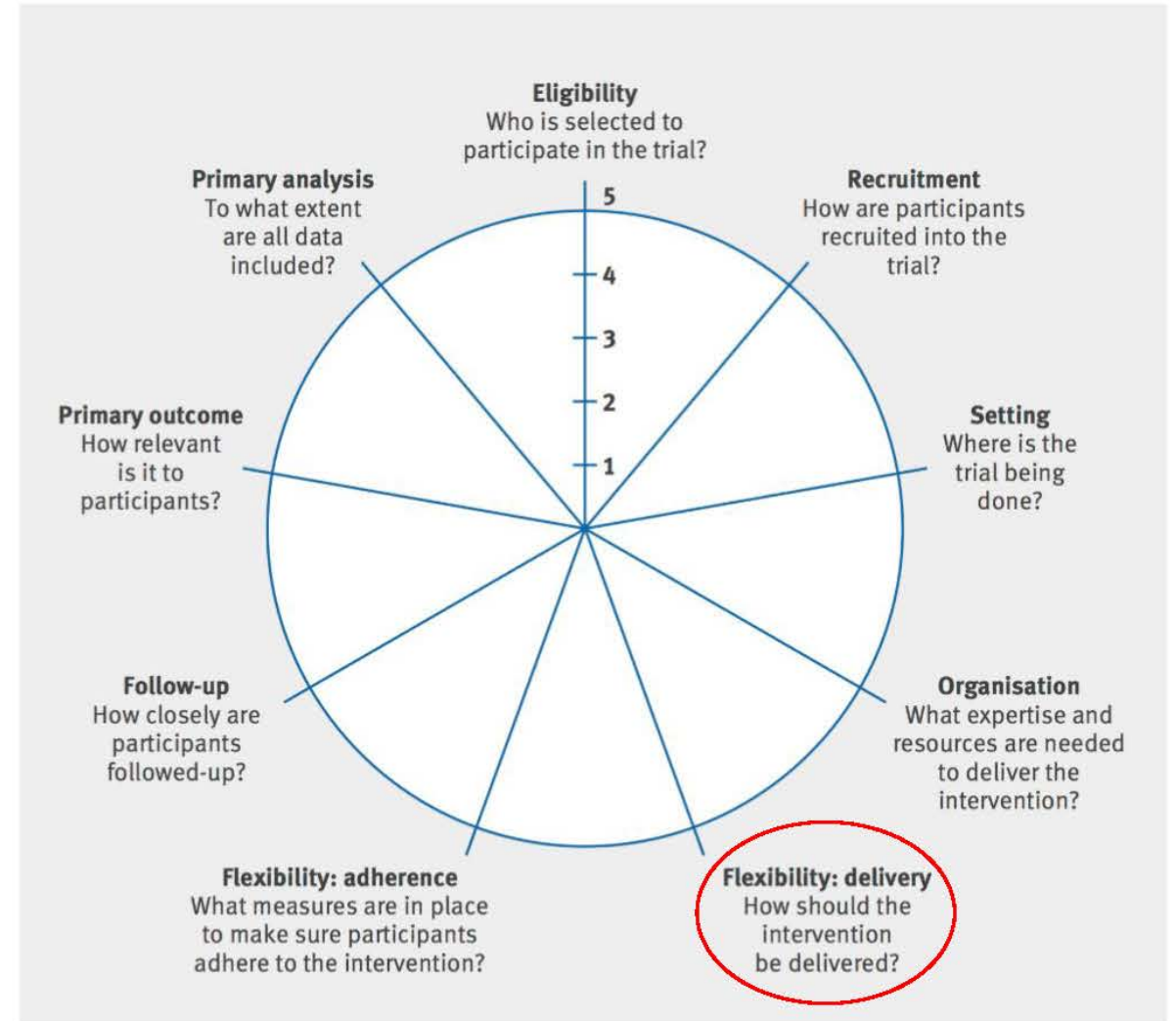
- Usual clinical workflow may result in a continuation of conditions that give rise to disparities, including potential provider bias



# Develop and disseminate guidance

- **Health equity considerations:**

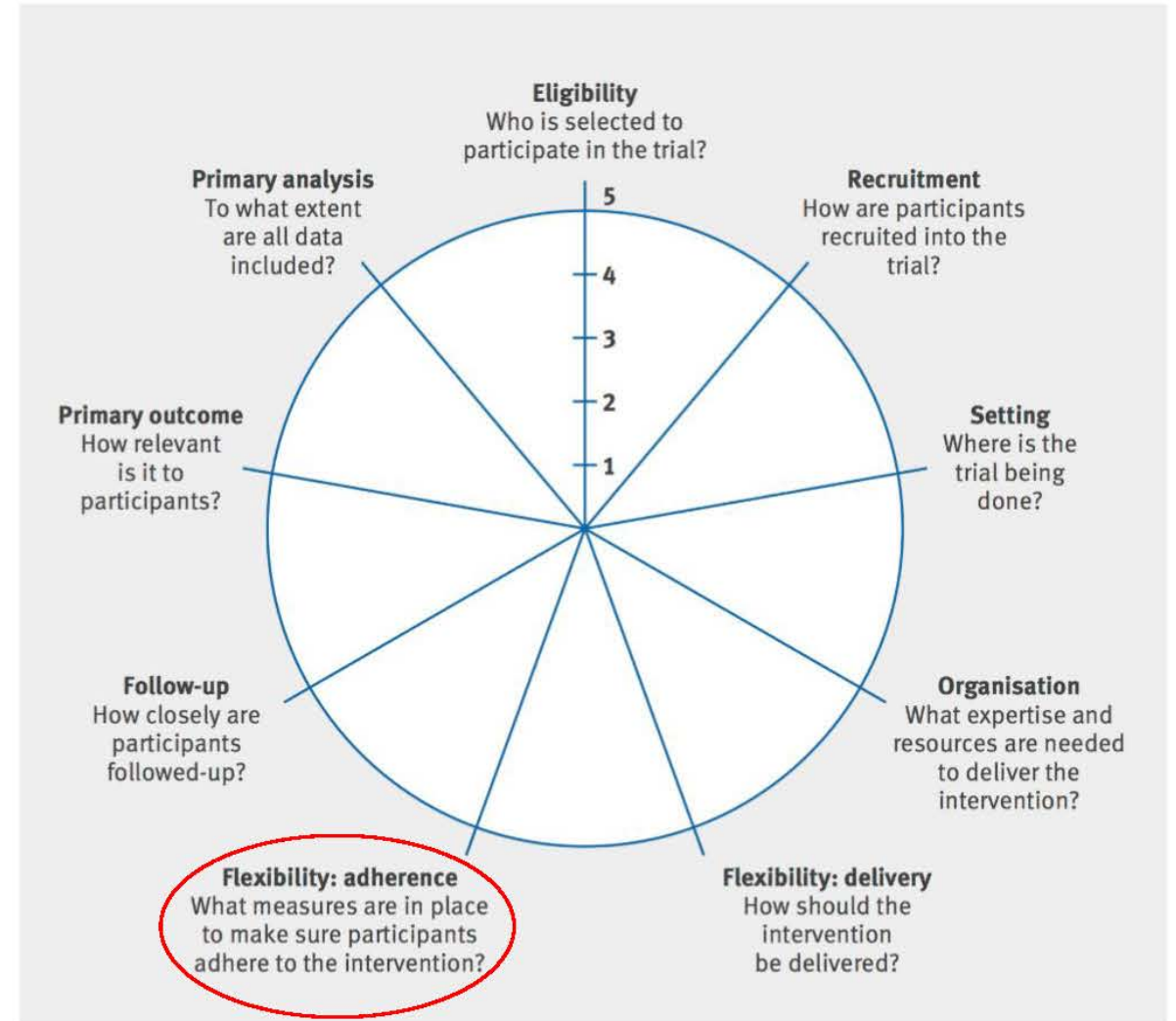
- Leaving intervention delivery up to providers may lead to replication of existing disparities in access or quality of care
- Background and training of providers may impact delivery



# Develop and disseminate guidance

- **Health equity considerations:**

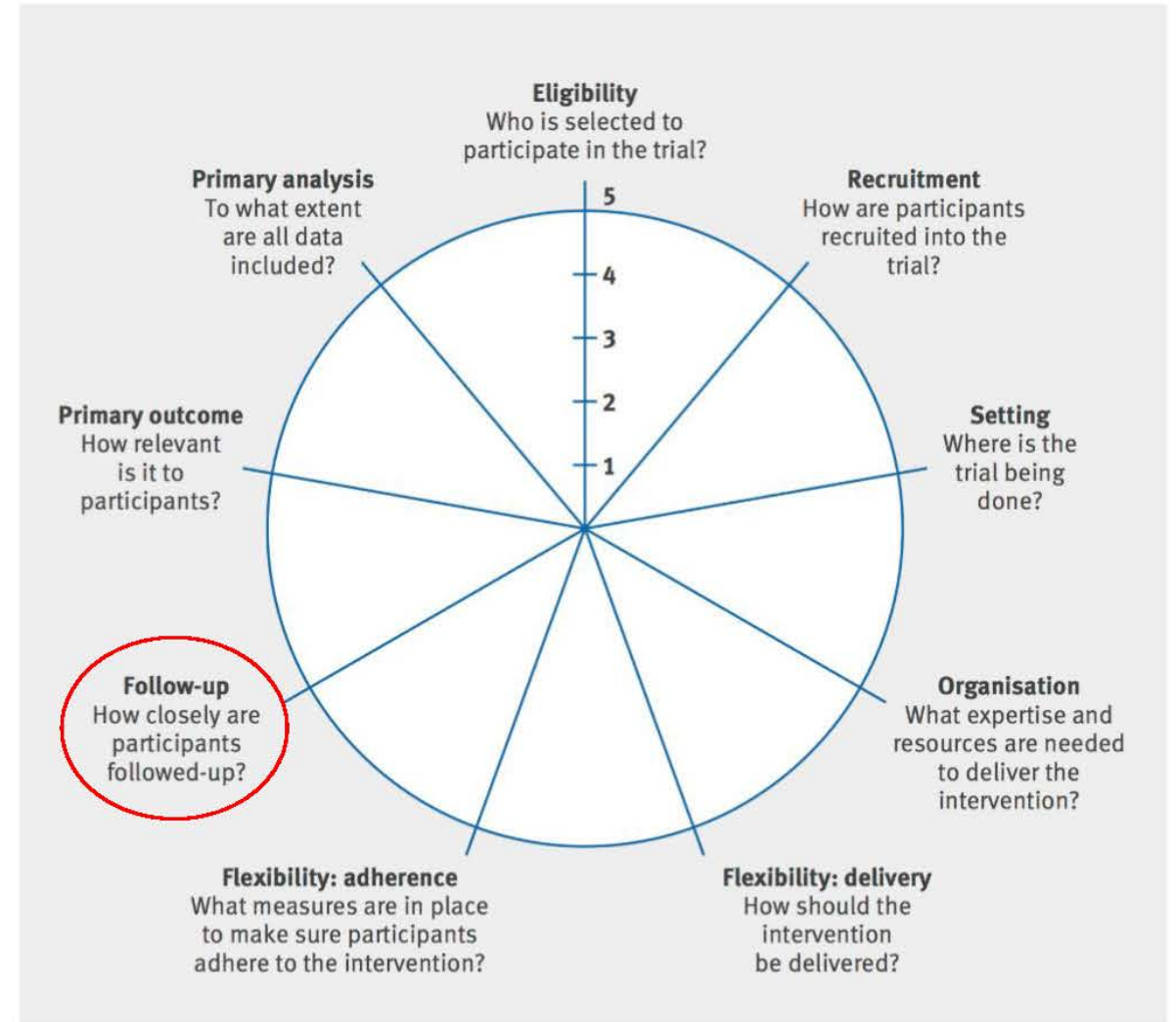
- Tailoring or adaptation of evidence-based interventions to diverse populations may be ad hoc or may not occur at all
- Adherence to intervention may be uneven as a result



# Develop and disseminate guidance

- **Health equity considerations:**

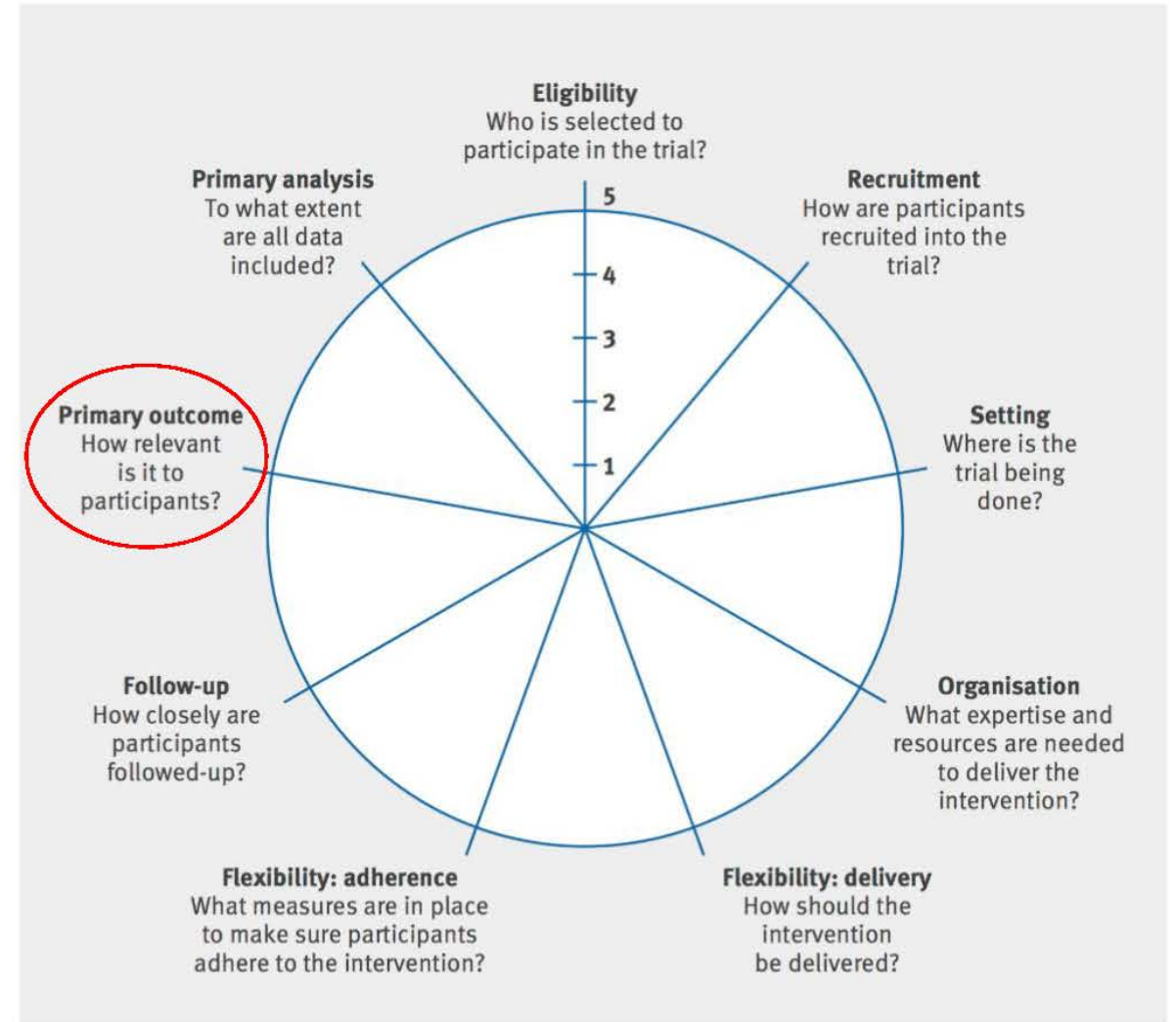
- Unclear if monitoring of minority groups will occur in order to assess sustained outcome effects or differential rates of attrition/retention in standard/usual follow-up care



# Develop and disseminate guidance

- **Health equity considerations:**

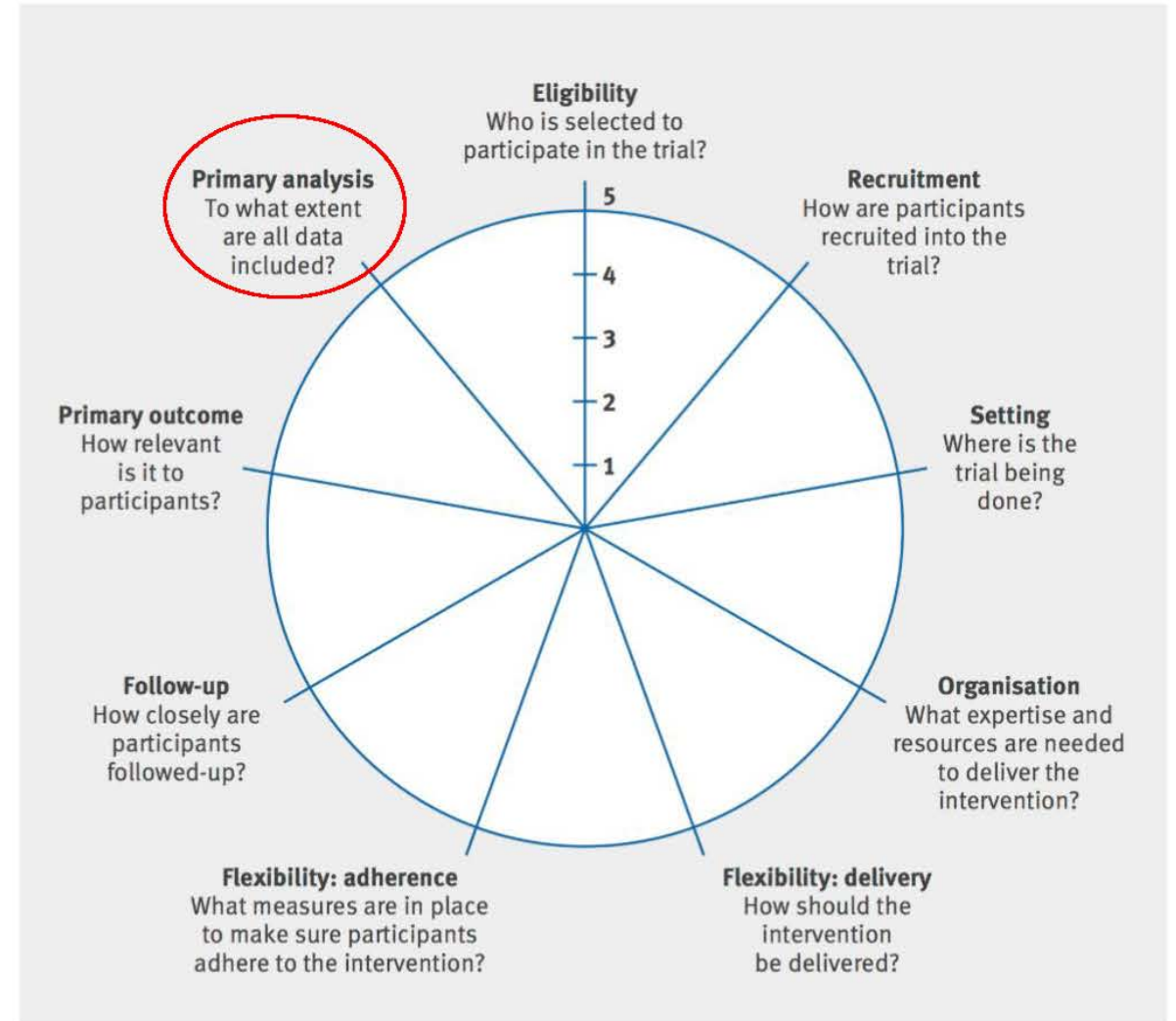
- Outcomes must be relevant and important to minority populations
- Instruments to assess outcomes must be translated and validated for linguistically and culturally diverse groups



# Develop and disseminate guidance

- **Health equity considerations:**

- Subgroup analyses require sufficient minority participants to enable comparisons
- Subgroup analyses may also falsely suggest lower effectiveness for minorities if there is differential delivery or implementation
- Up-front work with stakeholders to identify important measures for data collection

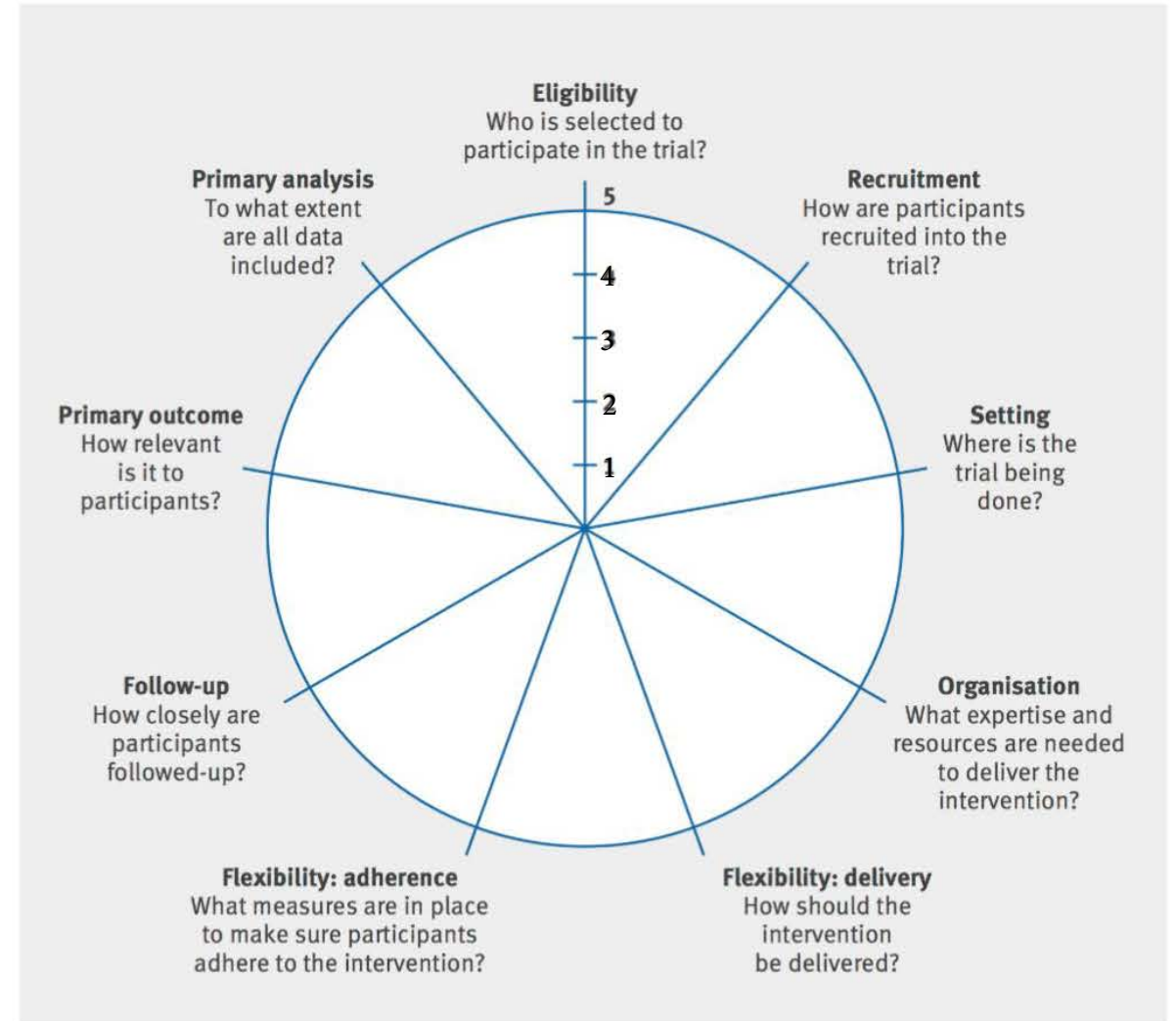




# Integrate with Core Working Groups

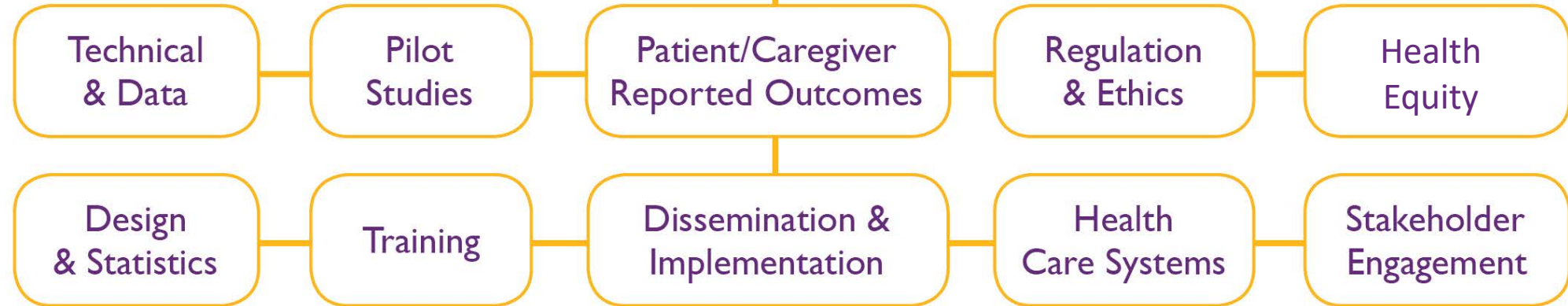
- **Health equity considerations:**

- Need to harmonize needs between / among CWGs
- Develop standard measures that translate between CWGs
- PRECIS-2 framework may be limited for this use
  - *Health Equity* lens suggests PRECIS-2 may benefit from additional dimensions



# Integrate with Core Working Groups

## WORKING GROUP CORES & TEAMS



# Integrate with Core Working Groups

## HEALTH CARE SYSTEMS

Nursing Homes  
Assisted Living  
Home Health  
Rehab  
Hospice  
Hospital

## DATA SOURCES

Medicare  
MDS  
EHRs  
  
Identifying PLWD

## ETHICS/ REG

Vulnerable Population  
  
Consent Capacity  
  
Federal Wide Assurance

## OUTCOMES

Relevant to AD/ADRD  
Caregivers  
HCS  
  
Ascertain from Particular Datasets

## DESIGN/ STATS

Cluster RCT  
Dyadic  
Loss to F/U

## IMPLEMENT

Complex Interventions  
  
Challenging Settings  
  
Adherence

# Equity Contributions to Core Working Groups

## CARE SYSTEMS

Demography  
(within /  
among HCS)

Representa-  
tiveness (wrt  
HCS census,  
disease  
burden,  
community)

## DATA SOURCES

Missing-  
ness &  
gaps in  
data  
sources

Stakeholder  
outcomes

Data burden

## ETHICS/ REG

Engage-  
ment  
metrics for  
vulnerable  
populations

Consent  
language &  
format

## OUTCOMES

Triangulation  
and  
alignment of  
outcomes  
across all  
stakeholder  
groups

## DESIGN/ STATS

DAGs  
Quantitative  
bias  
analyses  
(modified E-  
value)

Floating  
catchment  
area metrics

## IMPLEMENT

GOI Score

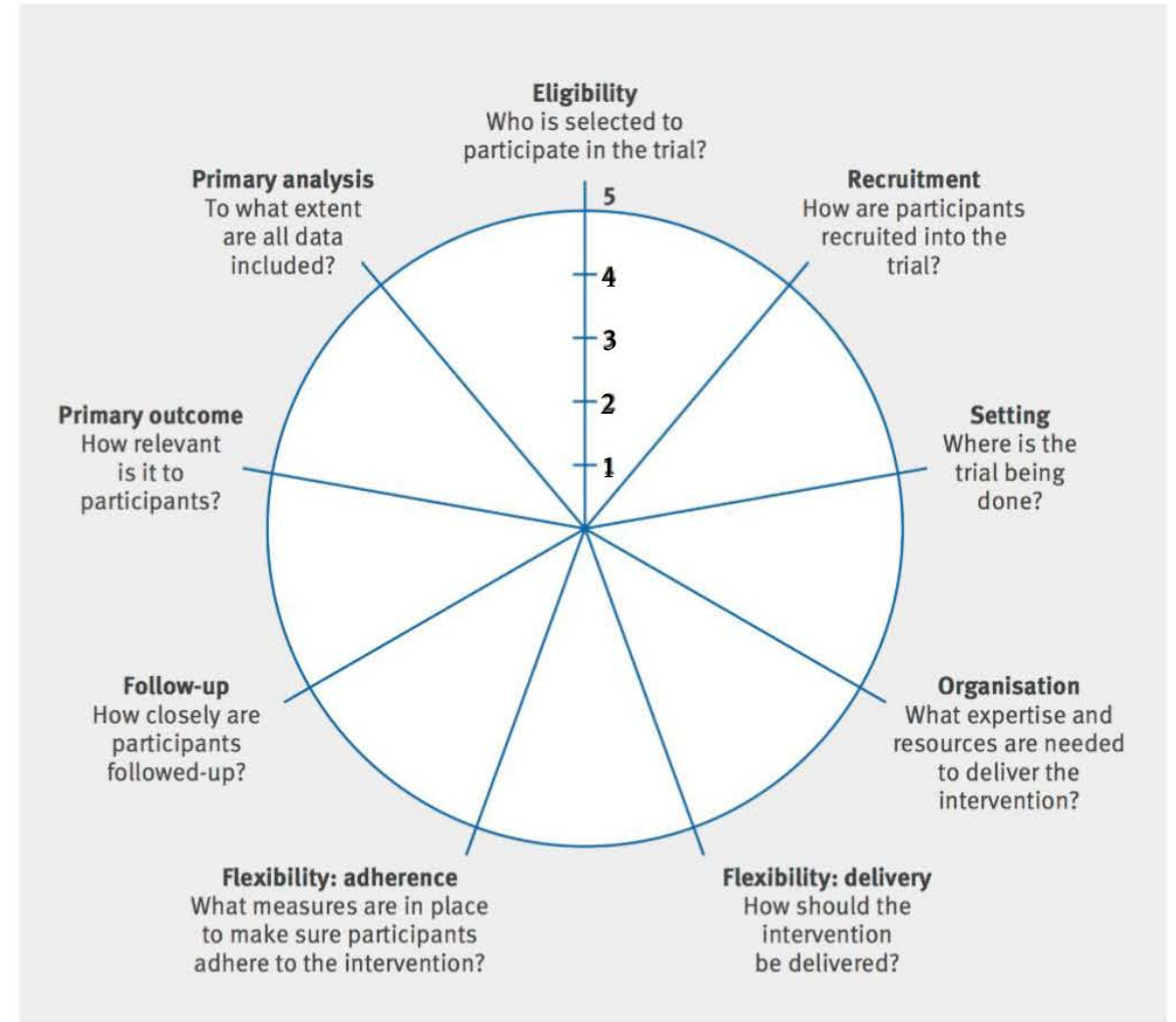
CFIR  
analyses

Positive /  
negative  
adaptation

# Defining HET, beyond Core Working Groups

- **Health equity considerations:**

- Recognize / operationalize bias in ePCT design
  - Bias arises orthogonally for 3 levels within each domain: **HCS / trial team / patient (and home environment)**
  - In practice, PRECIS-2 domains appear to emphasize only 1-2 levels of consideration in design
- Overlaps with HCS, Implementation, Stakeholder, Bioethics, Stats CWGs but no common tools



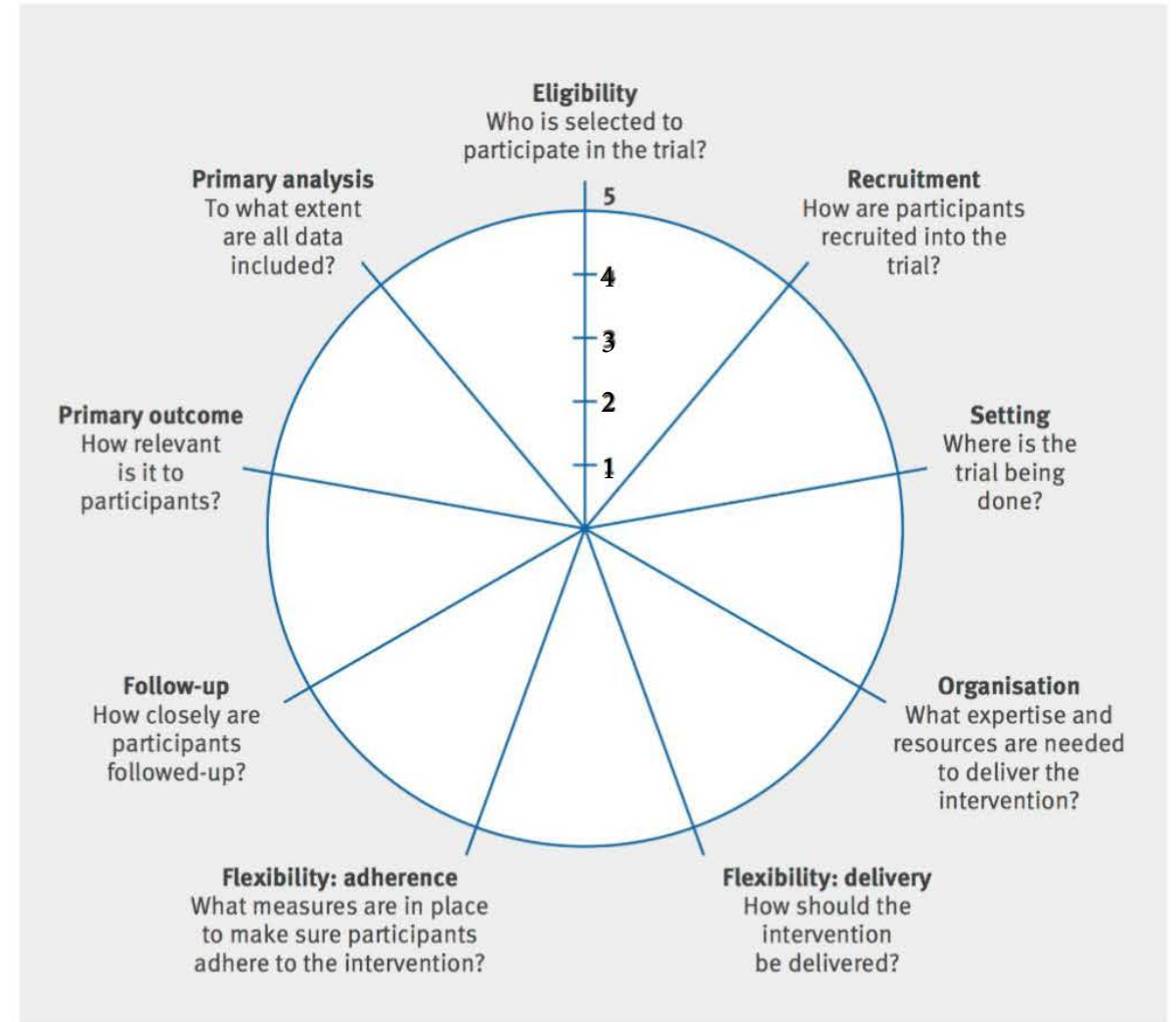
# Defining HET, beyond Core Working Groups

- **Health equity considerations:**

- Recast and integration of known challenges

- E.g., defining relative vs. absolute risk, alternative consent (Nicholls et al 2019, *Trials*), implementation concordance (Newhouse et al 2013, *Medical Care*),

- Need for common tools suggests HE may inform better use of PRECIS-2 or novel considerations



# Defining HET, beyond Core Working Groups

- **Health equity considerations:**

- Potential PRECIS-2 modifications

- Multidimensional domain considerations

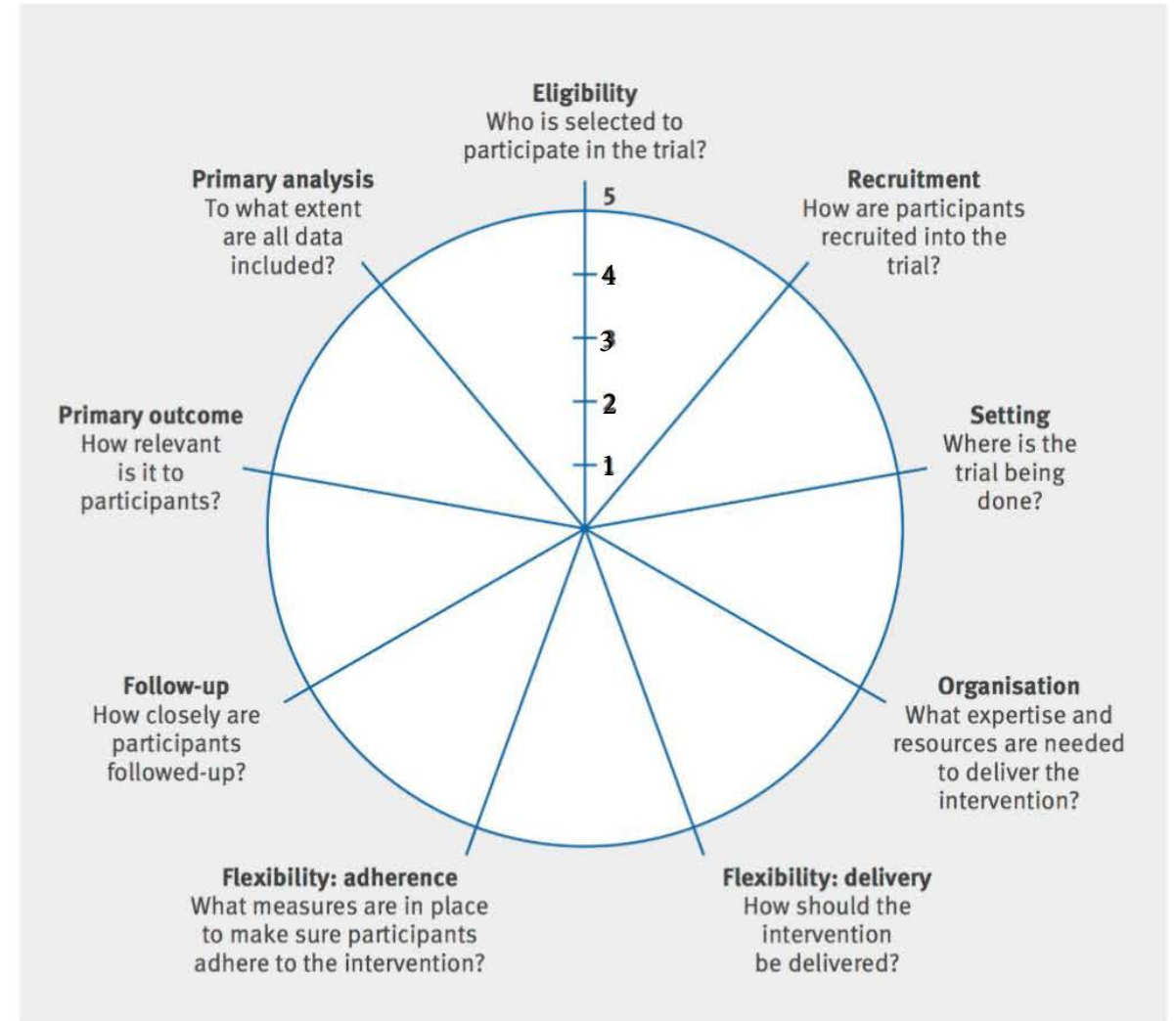
- Intraindividual / Interindividual / Systemic

- Value, or Return of Value as new domain

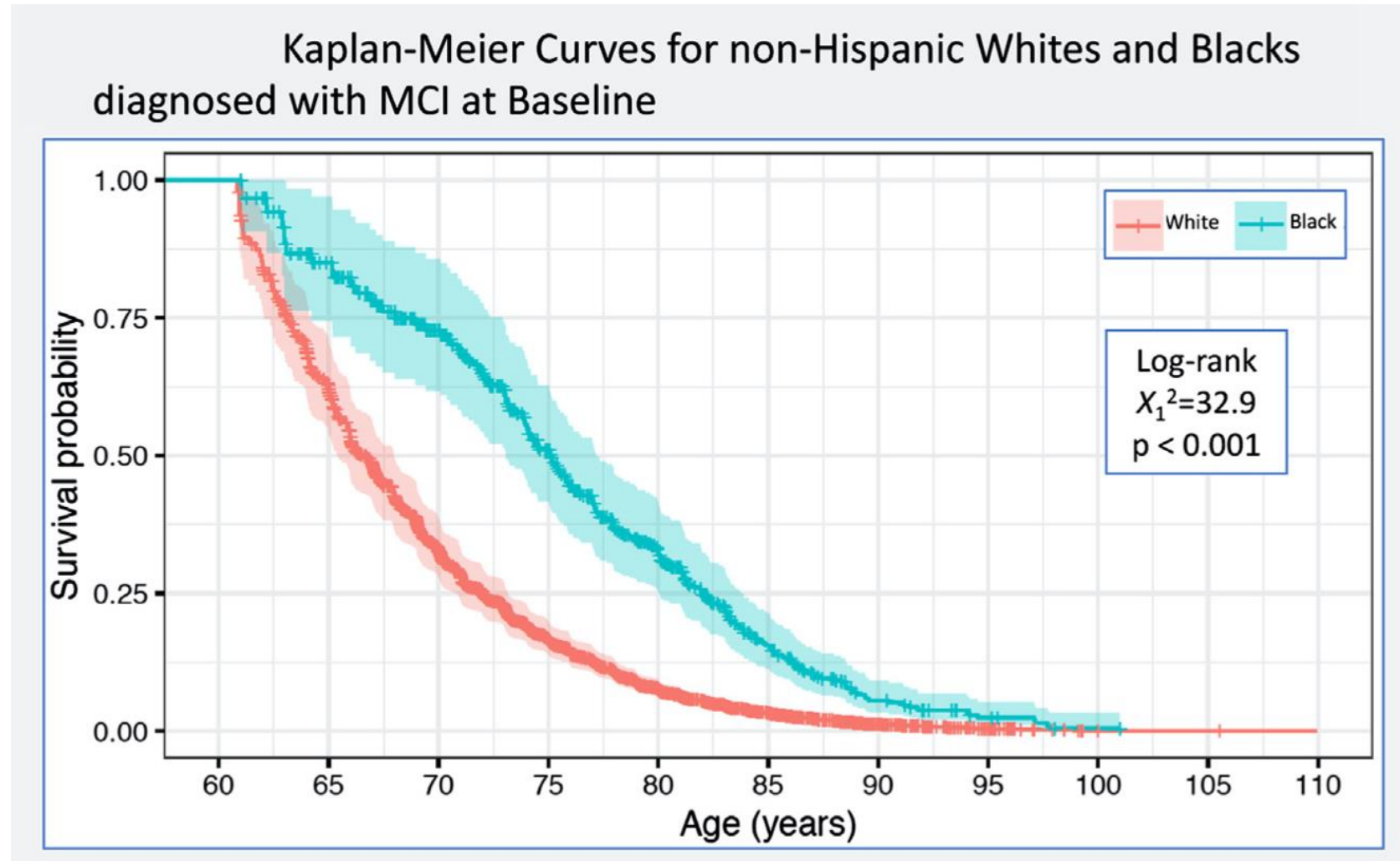
- Example from biostats

- Selection bias at level of individual

- Selection bias at level of *randomization*



# Defining HET, beyond Core Working Groups

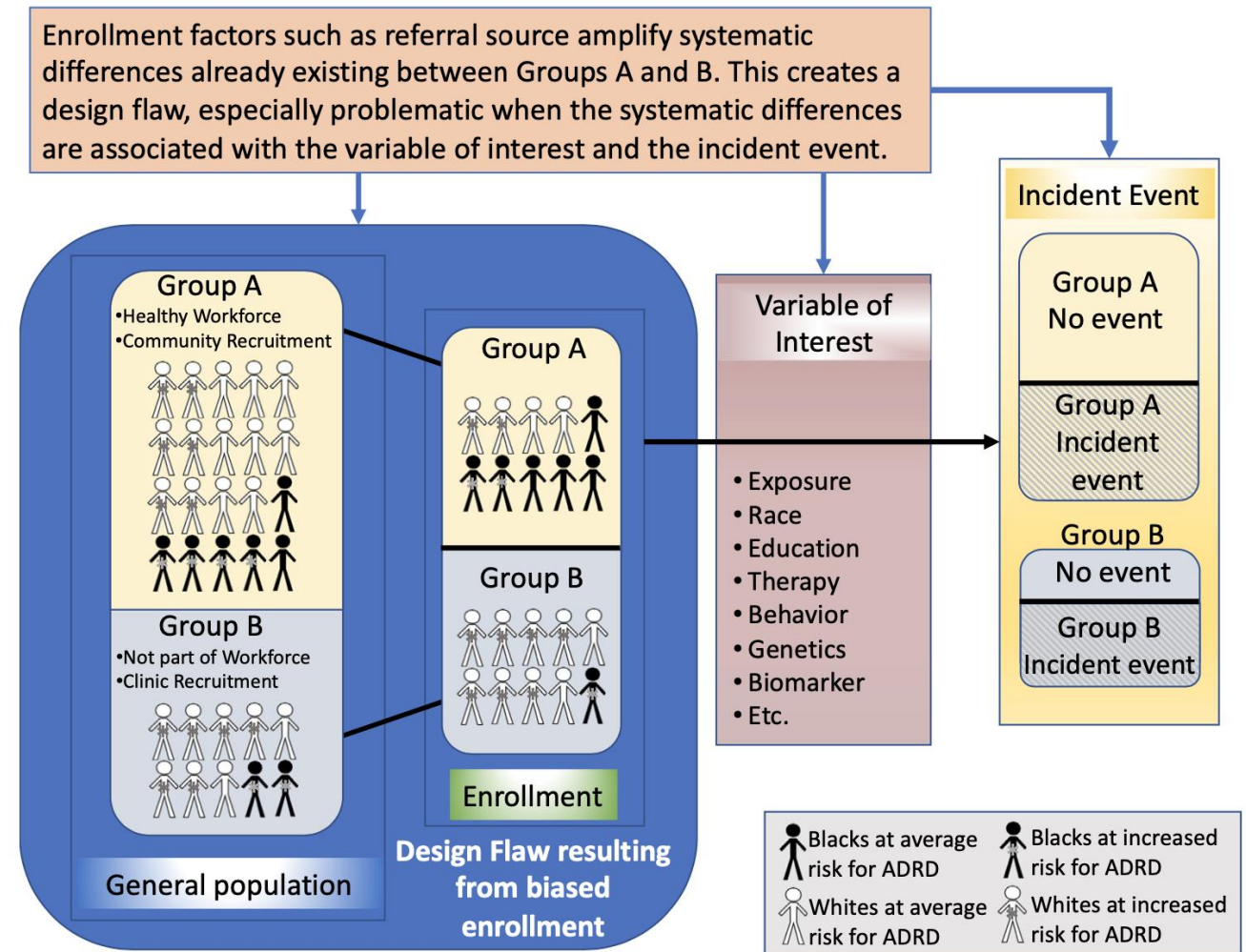




# Defining HET, beyond Core Working Groups

- **Health equity considerations:**

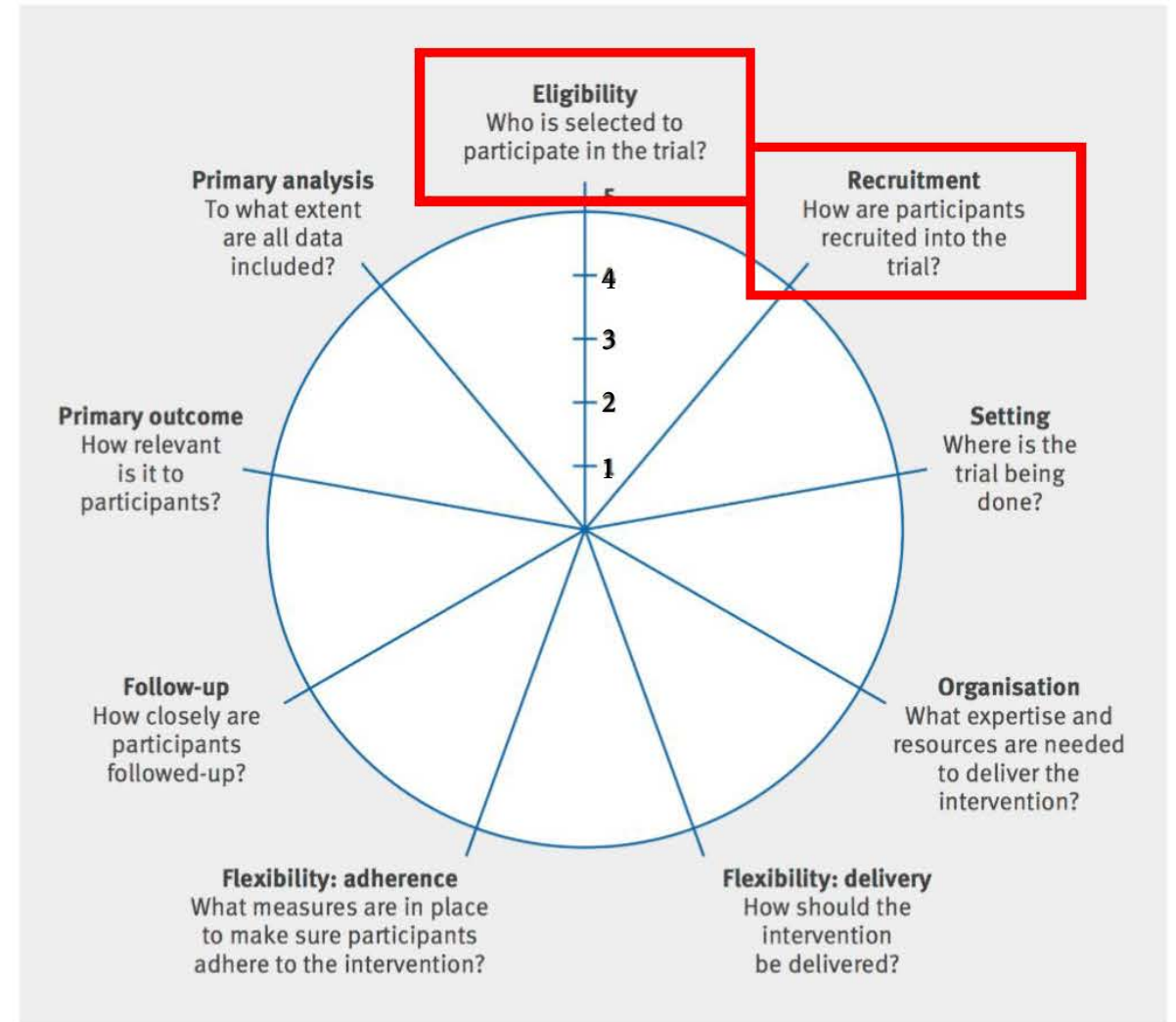
- Selection bias occurs at level of randomization
  - Not inherently subject-level
  - “Healthy worker bias” can occur at the level of the HCS too
  - ePCT does not sidestep this issue



# Defining HET, beyond Core Working Groups

- **Health equity considerations:**

- Selection bias occurs at level of randomization
- Solution
  - Eligibility / Recruitment domains of PRECIS-2 consider trial team and patient levels, but not the HCS level
  - Using a DAG illustrates this confound
  - More detailed demographics needed
  - Potentially consider contribution of Value domains

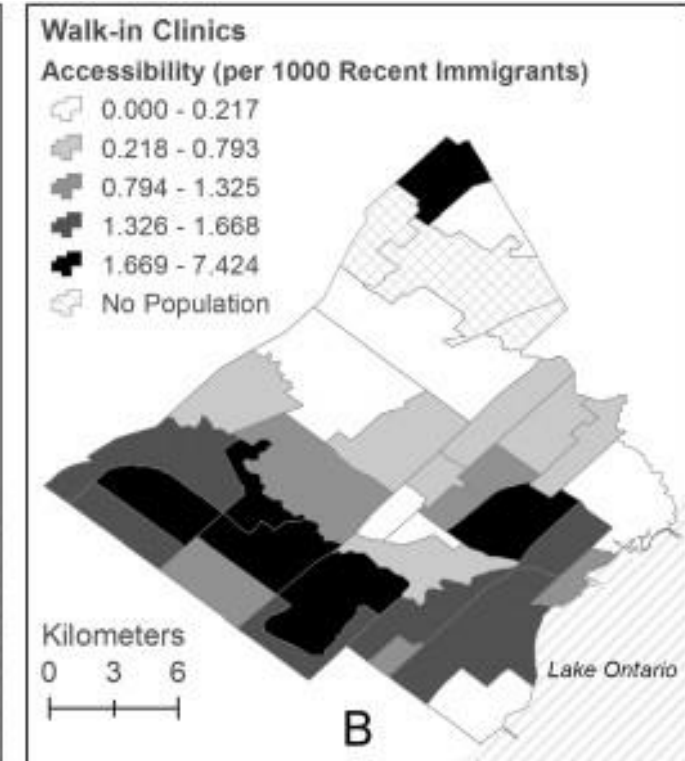
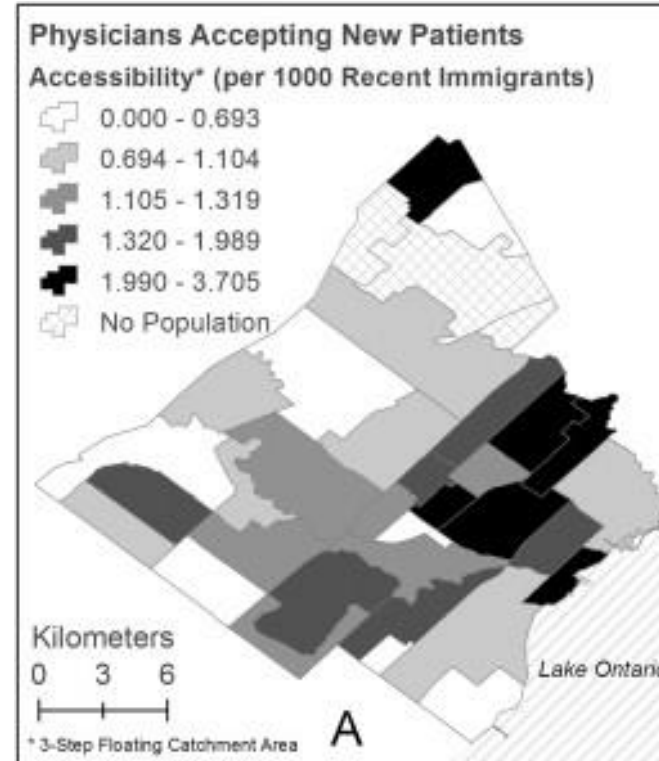


# Theoretical example

- **Health equity considerations:**

- FCA helps clarify access to HCSes

- Models supply, demand, and distance functions to better characterize catchment areas
- Predicts actual utilization within and across HCSes
- May compare with ePCT accrual and retention to determine differential enrollment, attrition, survival



# Theoretical example

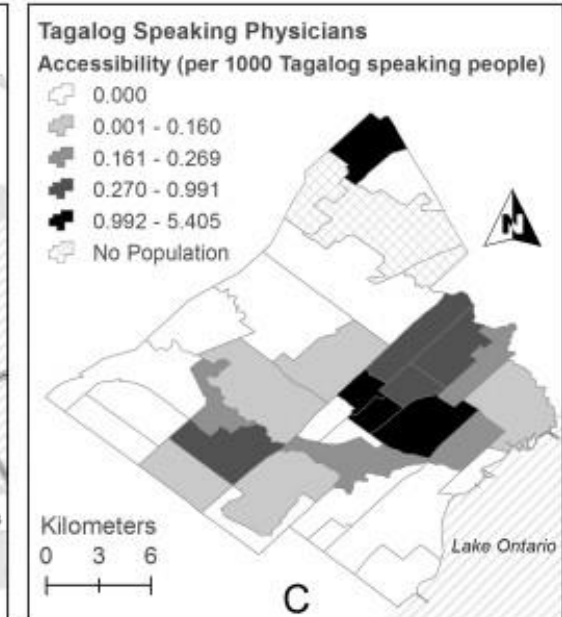
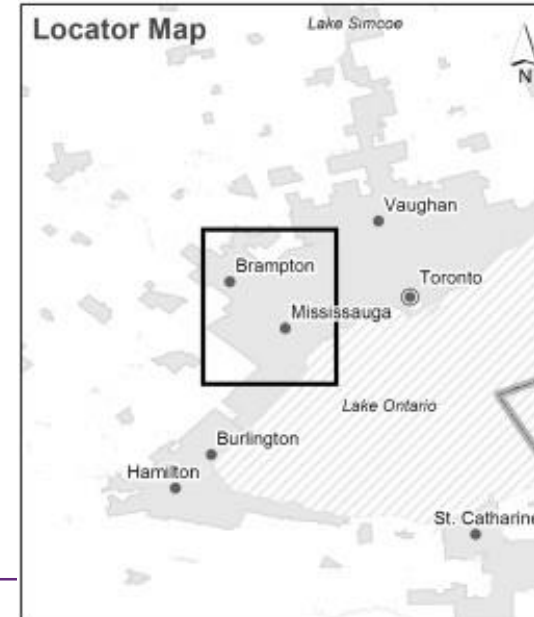
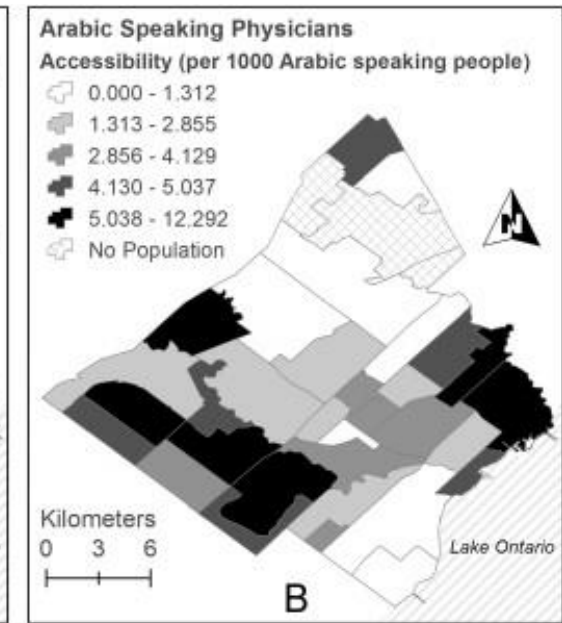
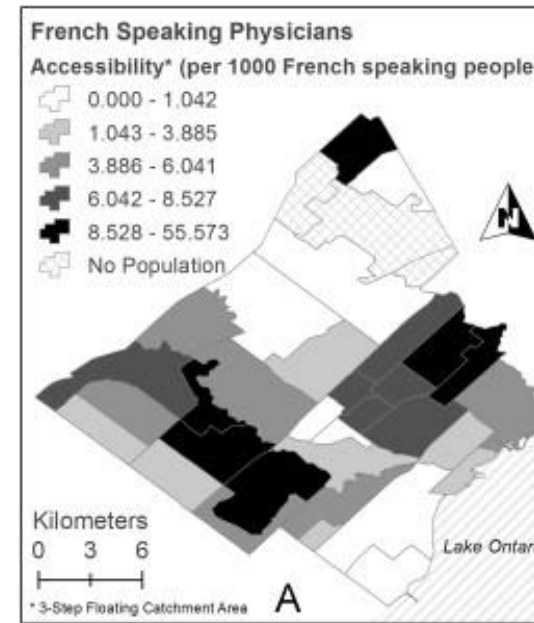
- **Health equity considerations:**

- FCA helps clarify access to HCSes

- Models supply, demand, and distance functions to better characterize catchment areas

- Predicts actual utilization within and across HCSes

- Can be modified and stratified to determine bias in theoretical access based on social factors (Bissonnette et al., 2012)



# Summary

- **Health equity is a crucial and unique aspect of ePCTs.** It is vital to reexamine PRECIS-2 domains with this lens to design for equity.
- **A health equity perspective promotes common ontologies between IMPACT CWGs.** Many working groups have the same goal but are measuring success differently; inequity happens when we prioritize one CWG's outcomes over another
- **The HET suggests additional ePCT measures to advance a science of equity.** The PRECIS-2 domain helps us understand how *pragmatic* a trial design is but doesn't inherently inform us about its *biases*. Robust reports about implementation, return of value, and selection / exchangeability, all framed via equity, may help clarify this dimension.

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Questions?

