Targeting Impact: Identifying, Mitigating, and Reporting the Loss of Generalizable Impact in Health Outcomes Research

Participation, Representativeness, and Effectiveness

Ermyas Birru, PhD; Joshua D. Cockroft, MD; Russell E. Glasgow, PhD; Amy G. Huebschmann, MD, MSc

University of Colorado School of Medicine

Date: April 28, 2026

Agenda for Today's Presentation

Discussion Questions

- Have you seen similar tools or papers you would recommend for us to review?
- Have we missed any key steps or issues? Are some steps less clear?
- Ideas about making the PrePARE tool more user friendly?
- Thoughts about who/what groups might most benefit and should be targeted for more user testing?

Conflicts of Interest

Competing interests: No conflicts of interest. The views presented here are author's opinions and not that of National Institute of Health.

Funding statement: Support for this article provided in part by NCI grant R01CA282292 (RG and AH); HRSA training grant T32HP42016 (AH, JC, RG), and the Rapid and Rigorous Patient-centered Program (R2P2) funded and supported by the Anschutz Acceleration Initiative (AAI), a partnership between The Anschutz Foundation and the University of Colorado School of Medicine (RG, AH, and EB).

The support by the Health Resources and Services Administration (HRSA) of the U.S. Department of Health and Human Services (HHS) is part of an award totaling $2,243,839.00 with 0% percentage financed with non-governmental sources. The contents are those of the author(s) and do not necessarily represent the official views of, nor an endorsement, by HRSA, HHS, or the U.S. Government. For more information, please visit HRSA.gov.

Generalizable Impact

We consider **generalizable impact** in terms of a balance of external validity and internal validity: the potential for future generalization to the broader target population and replication of the research findings from a given project

Key factors that influence generalizable impact

Participation

The rate of **participation** of settings and participants

(*e.g., % patients reached, % of providers delivering*)

Representativeness

The **representativeness** of settings, implementation staff, and participants

(*e.g., geography, ethnicity, types of health systems*)

Effectiveness

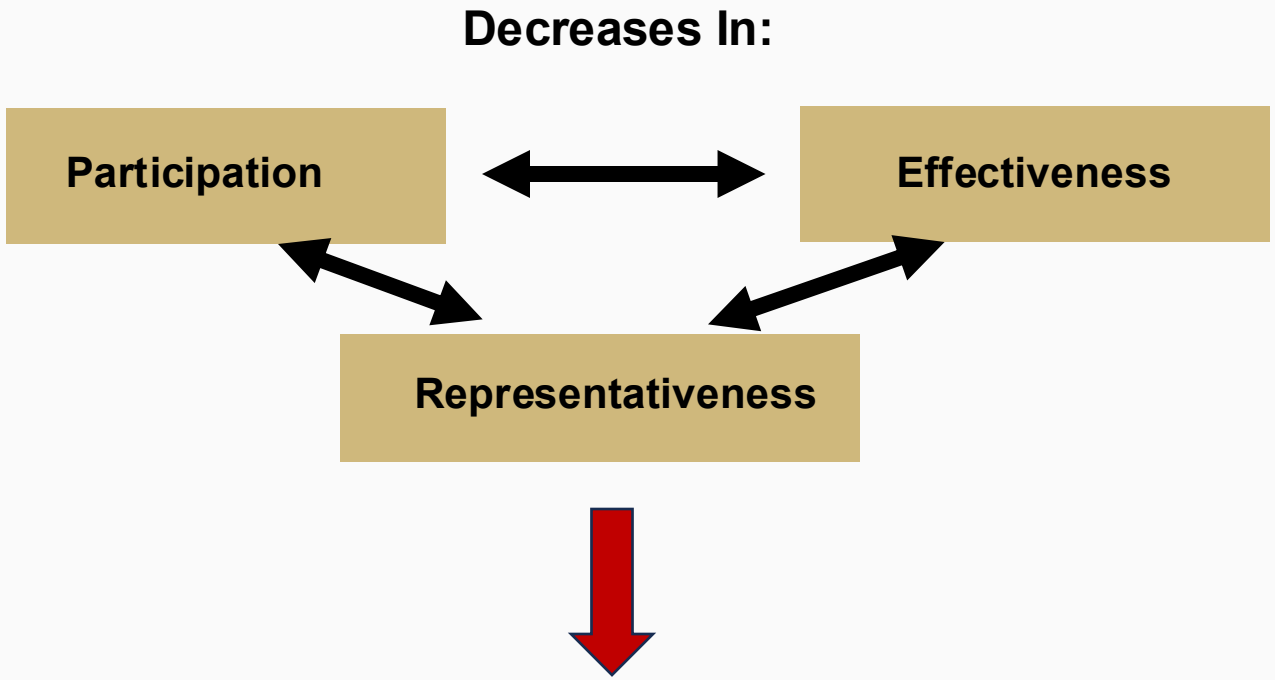
Issues that influence **Effectiveness**

(*e.g., intervention intensity, fidelity, tailoring, and engagement***)**

Jolles et al., *Int J Equity Health*, 2024; Huebschmann et al., *Annu Rev Public Health*, 2019; Murad et al., *BMJ Evid Based Med*, 2018.

Loss of Desired Generalizable Impact

Health outcomes researchers aspire for broad population-level impact of the interventions we develop, test and implement, but these efforts usually fall far short



What This Work Aims to Provide

1. Highlight issues of participation, representativeness and effectiveness that lead to generalizable impact
2. Provide guidance to identify and mitigate drop-offs in generalizable impact
3. Share tools and resources to estimate, record and report drop-offs in impact, in a standard, transparent way
4. Provide a brief demonstration of tools addressing these issues

Our Approach to Exploring and Addressing the Problem

Literature scan

Scanned studies, methods, and frameworks examining **P**articipation, **E**ffectiveness, **R**epresentativeness (**P/E/R)** factors across:

1. Planning
2. Implementation
3. Evaluation, and
4. Transparent reporting

Provide guidance and tools

1. Mapped RE-AIM to P/E/R factor across phases of research
2. Reviewed and revised existing tools
3. Conceptualized and conducted initial user testing of new tool

What Did We Learn from the Literature Scan?

- **Planning phase - eligibility**:
  - Restrictive study eligibility criteria;
  - Cultural and language barriers
- **Planning phase - recruitment**:
  - Individual barriers - distrust of research, competing priorities, logistical constraints
- **Implementation phase - retention**:
  - Structural barriers - transportation, physical proximity
- **Evaluation**: Trust, access, and power dynamics shape participation and retention
- **Transparent reporting is necessary but not sufficient**:
  - Participant losses are consistently documented (CONSORT diagram)
  - Limited emphasis on preventing these losses over time

Existing Tools and Frameworks to Capture P/R/E and Gaps

PRECIS-2 / PRECIS-2 PS / PRECIS-3

- Assessment of pragmatism
- Incorporate stakeholder input - alignment with usual care settings

NIH Stage model

- Anchors decision-making to trial purpose
- Clarify when and how to prioritize generalizable impact

RE-AIM Representativeness measures

- Moves beyond who is reached
- Where interventions occur, under what real-world conditions, and who ultimately benefited

Expanded CONSORT

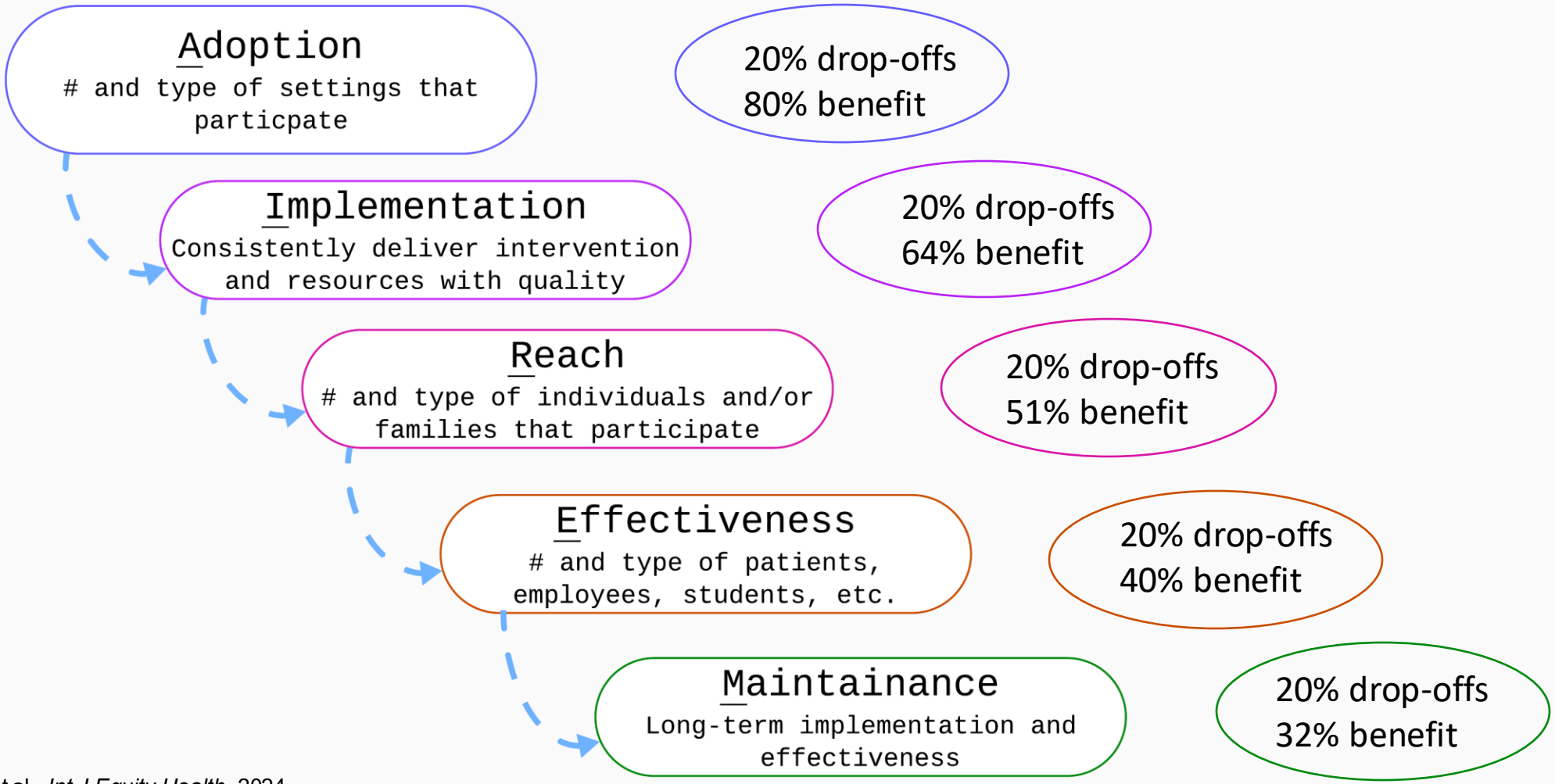
- Improve transparency - report drop-offs: participant & setting
- Extends impact tracking across participants and settings

What remains to be done

- Lack of interactive tools to anticipate, justify, and guide design decisions that affect external validity
- Limited attention to cumulative "drop-off" across socio-ecological levels and implementation phases
- Shift from primary focus on reporting losses to proactive loss mitigation and prevention

Loudon et al., *BMJ*, 2015; Norton et al., *Implement Sci*, 2021; NIH Stage Model for Behavioral Intervention Development, National Institute of Health; Jolles et al., *Int J Equity Health*, 2024, Glasgow et al., *Am J Prev Med*, 2018

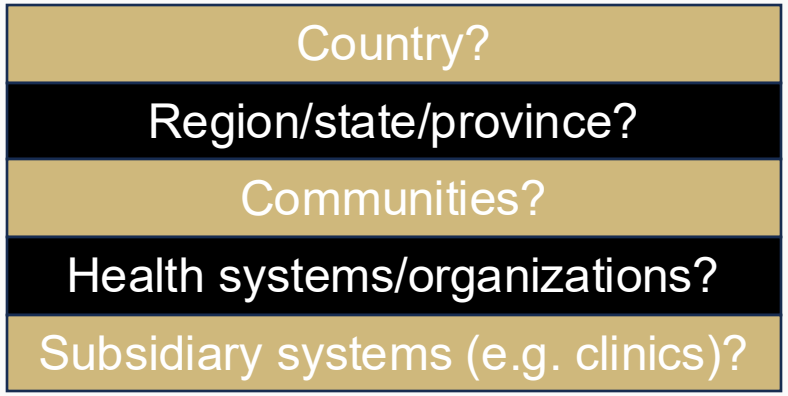
Mapping RE-AIM (or AIREM) to Impact (Drop-offs)



Jolles et al., *Int J Equity Health*, 2024,

Adoption

What:



Choice of setting(s)

Engagement of settings

- Why are we choosing and inviting specific settings?
- How representative and diverse are our chosen study settings?
- Are there reasons why invited settings are not participating?
- How should we engage different settings to facilitate participation?

Considerations:

- Engage potential partners early within scope and resources
- Build consensus on participation requirements
- Allow site flexibility
- Integrate into existing workflows

Implementation

How **complex** or **burdensome** is our intervention and study to participants and sites?

How much can our intervention or study procedures be **adapted/tailored** to better fit the context of our study setting?

How **consistently** can our intervention be delivered with **fidelity** to core functions?

How can we address barriers to **participant engagement** with the intervention and study procedures?

Considerations:

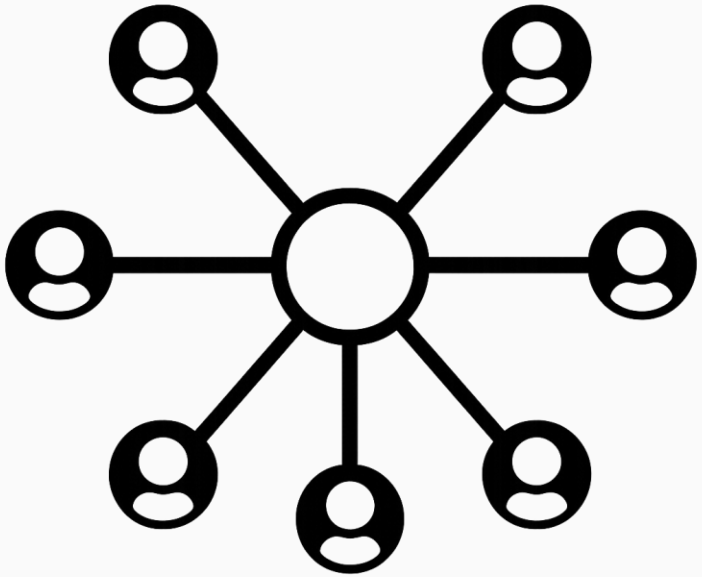
- Define functions/forms a priori
- Align with workflows
- Track and document modifications -> impact
- Balance intensity with ease of engagement

Reach

What recruitment strategies can we use to address barriers to participation?

What is our rationale for our inclusion criteria? Is it too restrictive?

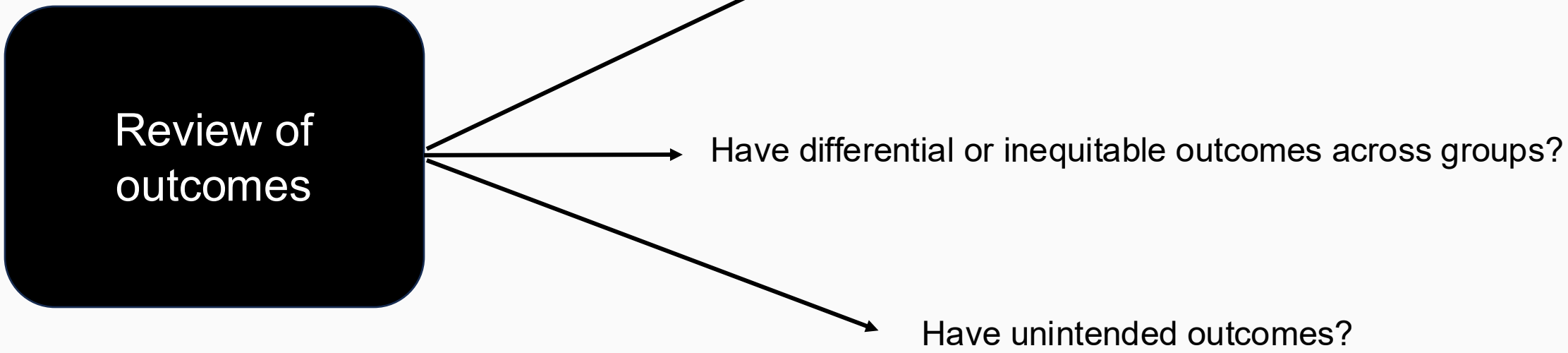
Are our consent methods burdensome or insensitive?



Considerations:

- Pilot and refine recruitment strategies
- Document inclusion/exclusion effects
- Pilot and revise consent procedures
- Use culturally responsive language

Effectiveness



Considerations:

- Monitor outcomes over time
- Examine subgroup differences
- Evaluate acceptability, feasibility, cost, other outcomes

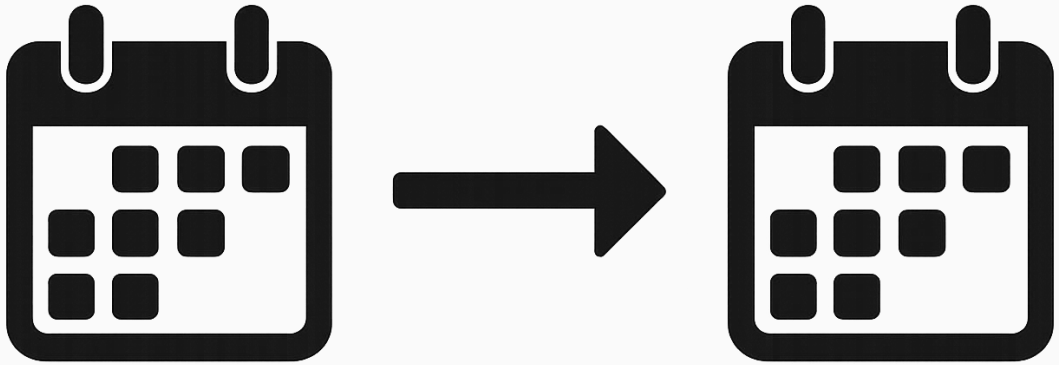
- Offer flexible participation
- Co-design engagement strategies
- Allow re-entry to study
- Tailoring of intervention

Maintenance

How do we:

Sustain benefit of the intervention at the individual or group level?

Sustain delivery of the intervention by study settings?



Considerations

- Co-design sustainability strategies
- Report sustainability intent and capacity
- Use "boosters" or low-intensity virtual supports

Tools to plan for or report P/E/R factors and generalizable impact

Key: These tools apply not just during the study, but take into consideration the setting where we are sampling our sites and the population from which we are drawing participants.

01

RE-AIM Cascade Tracking Worksheet

Emphasis: Planning + Monitoring

Timing: Before and during study implementation

Research / Project Stage	Challenge	Actions Taken During Planning	Later Actions Taken	Notes
Adoption (multi-level)	Diversity of sites participating			
Implementation	Consistent delivery of intervention (fidelity)			
	Level of adaptation to address emerging issues			
	Time, cost, and burden requirements			
Reach	Recruitment methods that appeal to key groups			
	Breadth of eligibility criteria			
	Opt-in informed consent			
Effectiveness	Level of participant engagement			
	Tailoring to different subgroups			
Maintenance	Setting resources to continue the program			
	Level of follow-up support			

Tools to plan for or report P/E/R factors and generalizable impact

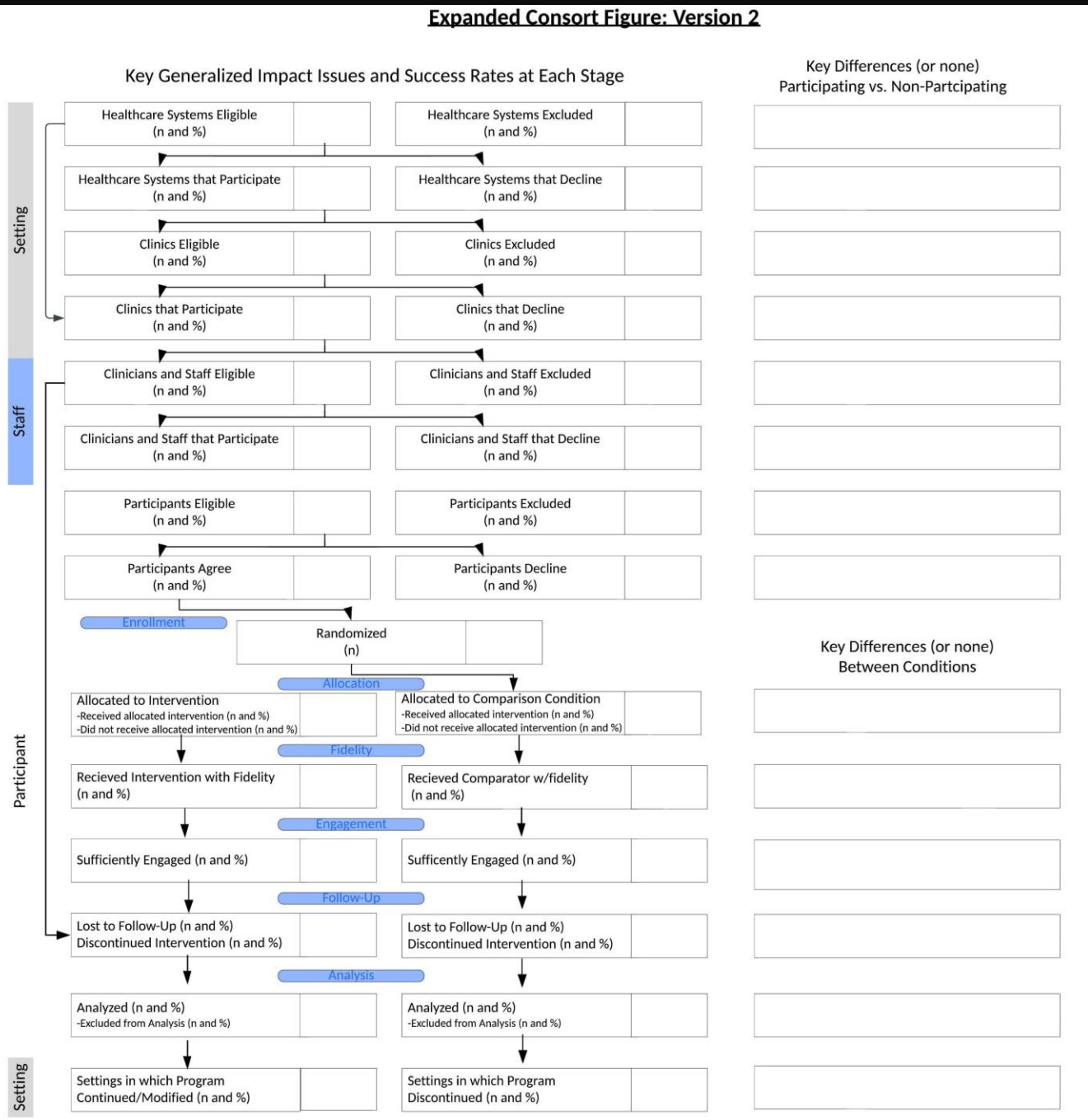
02 Expanded CONSORT Diagram V2.0

Emphasis: Reporting

Timing: After study completion

Key: These tools apply not just during the study, but take into consideration the setting where we are sampling our sites and the population from which we are drawing participants.

Glasgow, Huebshmann, and Brownson , *Am J Prev Med*, 2018



Tools to Plan For or Report P/E/R Factors and Generalizable Impact

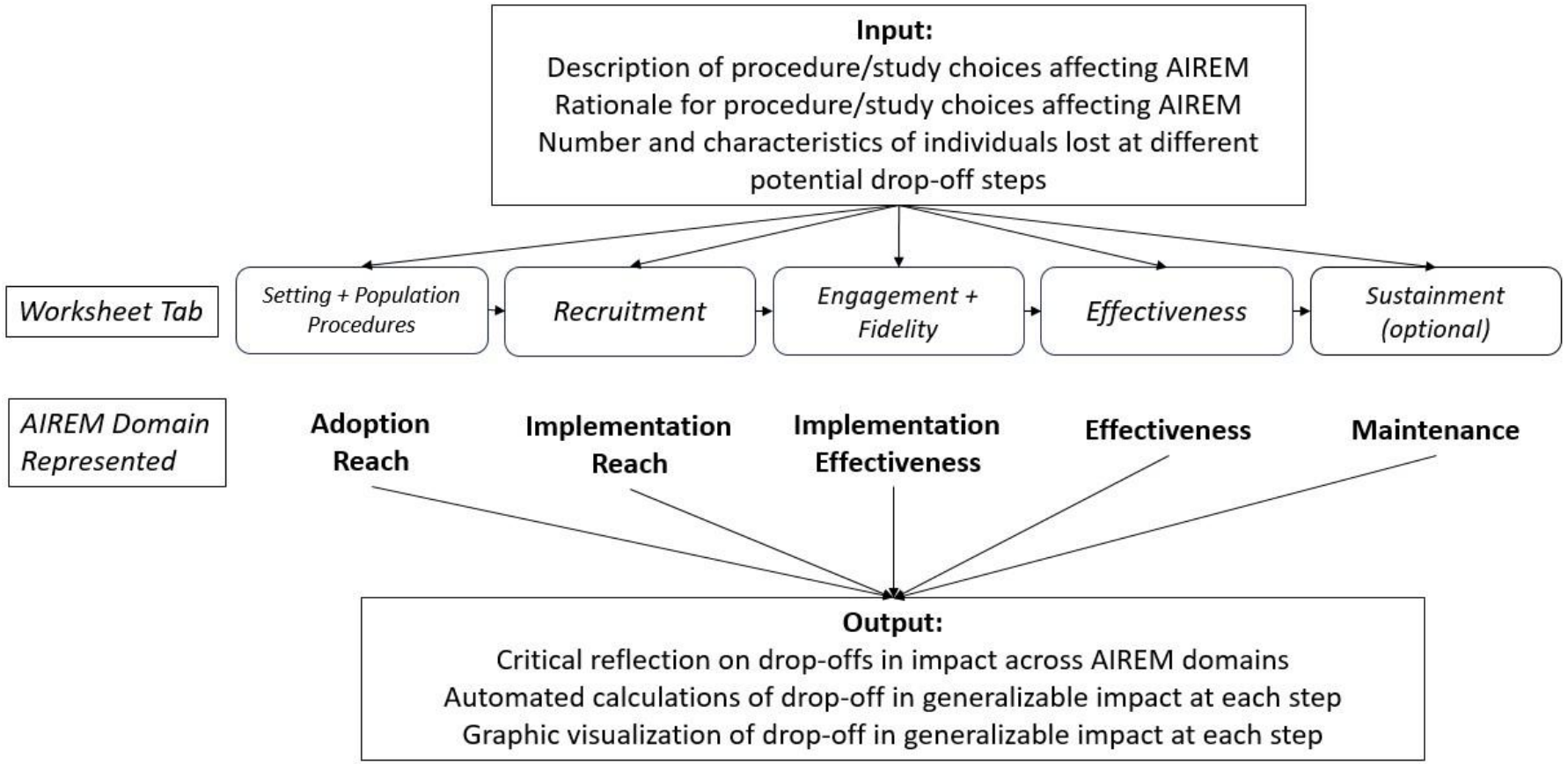
Key: These tools apply not just during the study, but take into consideration the setting where we are sampling our sites and the population from which we are drawing participants.

03

LOGIC-PRePaRE Calculator

Emphasis: Planning, Evaluation, Reporting

Timing: Before and after study implementation



At the link below you can:

Request copies of the Expanded CONSORT 2.0 and RE-AIM Cascade Worksheets with option to participate in a user feedback survey

Indicate willingness to participate in upcoming Think Aloud sessions May and June 2026 for the LOGIC-PRePaRE calculator or later survey-based user testing

Acknowledgements

- Bryan Ford, MPH
- Members of the Adult & Child Center for Outcomes Research & Delivery Science (ACCORDS) Primary Care Research Fellowship
- National Working Group on RE-AIM Planning and Evaluation Framework
- Abstract accepted to present at *The Colorado Pragmatic Research in Health Conference*
- Manuscript currently *under review* in the Journal of Clinical and Translational Science

Anschutz | Children's Hospital Colorado

ADULT AND CHILD CENTER FOR OUTCOMES RESEARCH AND DELIVERY SCIENCE (ACCORDS)

What's In It For You?

How might you use these tools?

- Proactively address issues that may affect the impact of your intervention
- Provide insights into reasons why an intervention may not have had desired or predicted impact

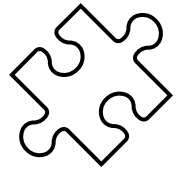
Why might you use these tools?

- Transparency on factors that may decrease impact or replicability of studied interventions
- Improve the translation of interventions to real-world practice
- Prompt transparent reporting of issues likely impacting replication

Discussion: Q&A

- Have you seen similar tools or papers you would recommend for us to review?
- Have we missed any key steps or issues? Are some steps less clear?
- Ideas about making the PrePARE tool more user friendly?
- Thoughts about who/what groups might most benefit and should be targeted for more user testing?

Key Messages & Future Directions

	Key Messages	Future Directions
1	Be proactive, anticipatory, and transparent - not automatic	Further development & testing 
2	Consider participation, representativeness, AND effectiveness at every step	Strategies to prevent drop-off 
3	Align with NIH Gold Standard: transparency, replication, accepting negative results	Systems issues & unintended consequences 
4	Adapt tools to your project - not all steps may be relevant or matter equally	Health equity applications 

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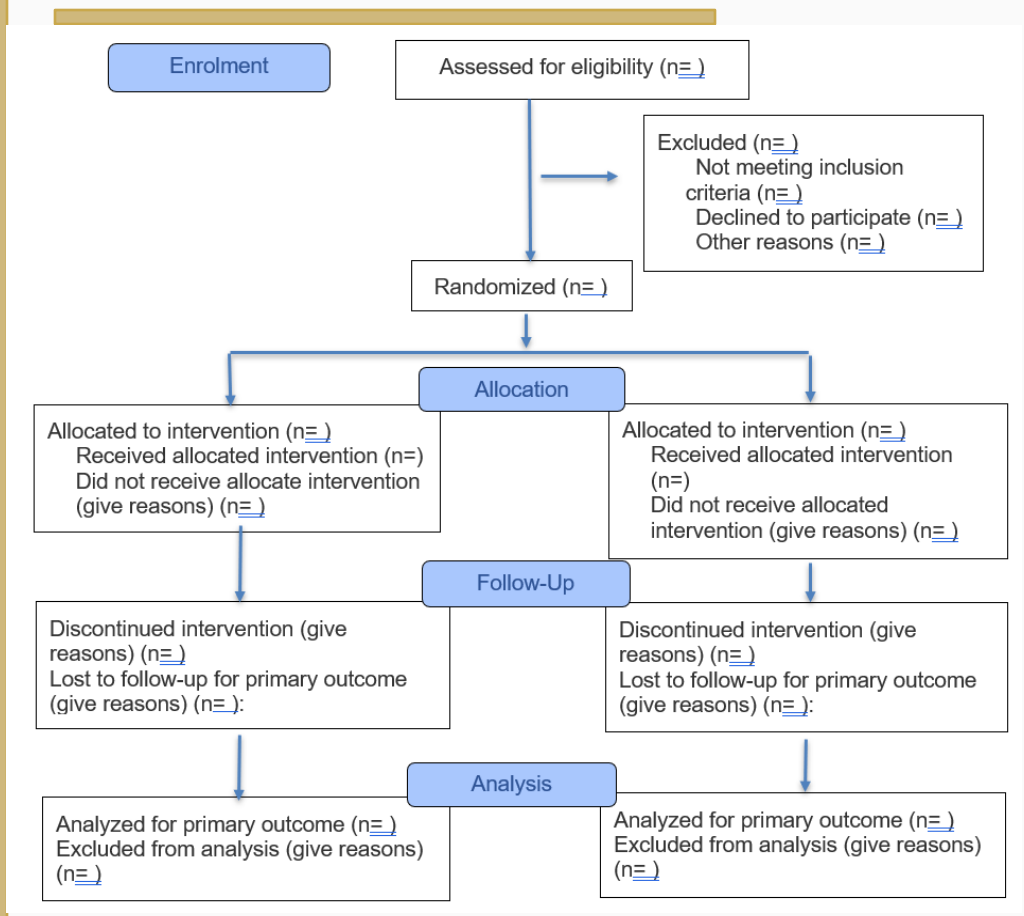
Demo Screenshots (Evolution to Expanded CONSORT 2.0)



CONSORT Diagram
(Hopewell et al., 2025)

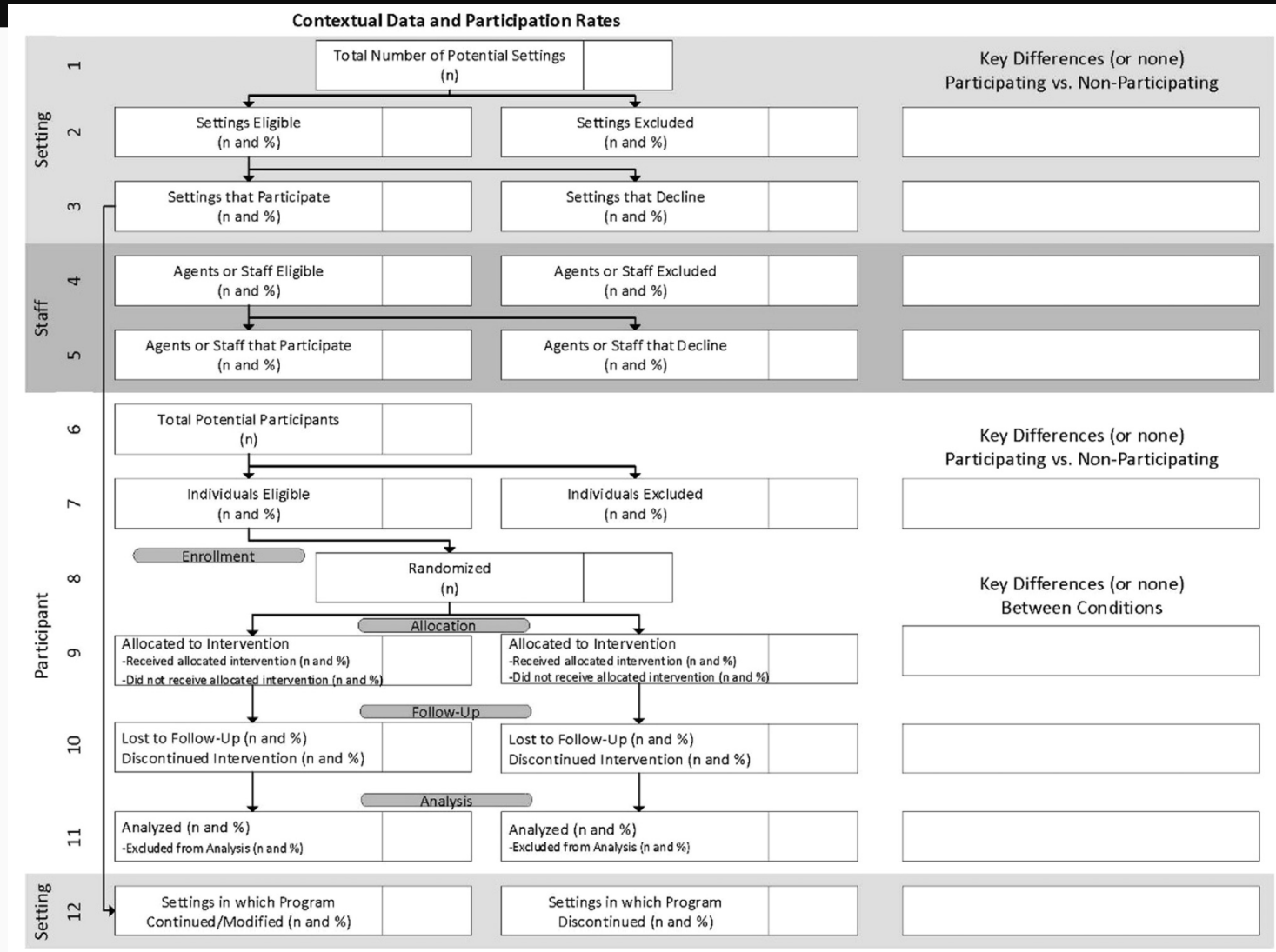


Figure 1. Expanded CONSORT figure.

(Glasgow et al, 2018)

Demo Screenshots (Filled LOGIC-PRePaRE)

Enter Text In Gold Colored Boxes

Enter Numbers in Aqua Colored Boxes

START BY COMPLETING THIS COLUMN AND THEN COMPLETE COLUMNS FROM LEFT TO RIGHT
↓

Setting and Population Procedures (Adoption and Reach)

Stage	Guidance on what to input	Setting or Population Procedure in Your Study	Rationale for choice of setting or population procedure	Who might be lost or ommitted?	Why might people be lost?
Setting		For each cell below, write out a brief description of the level/stage for your study	For each row describe the setting or population procedure and describe a rationale for the choice of setting or population protocol procedures	For each row, describe who might be lost or omitted due to the choice of setting or population protocol procedure	For each row, describe why people may be lost with that choice of setting or population protocol procedure
National:	Country where study will take place, e.g. USA →	*USA*			
State, Province or Region(s):	State Province or Region(s) targeted, e.g. Colorado →	Colorado, rural and urban counties			
Target Systems:	Systems that will participate in study, e.g. University of Colorado Health System →	Rural PBRN and UCHealth	Existing relationships with PBRN and with community providers in academic health system, hoping to capture both rural and urban experience as part of trial	Systems/clinics that do not have existing academic ties/relationships; practices with less buy-in or infrastructure to conduct to academic research	Limited access to academic health system, lack of existing infrastructure to conduct PBR
Participating Clinical / Study Sites:	Description of sites participating in the study who will deliver the intervention, comparison (or both), e.g. all Denver-based primary care clinics in University of Colorado Health System →	Rural: 6 practices, small to medium size provider pool serving adult populations in linguistically diverse counties Urban: 6 academic primary care practices	6 rural practices have already signed on and have participated in early engagement work through PBRN, 6 academic primary care practices with prior trial experience	See above	Existing infrastructure to deliver report tool, perceived benefit of report tool, percevid benefit of participating in research
Participating Providers:	Description of the types of providers who would recruit individual participants and/or deliver the intervention, comparison, or both, e.g. all primary care providers →	*All primary care providers in practices will be guided on use of report tool who choose to adopt the intervention tool*	Trying to have	Providers with limited buy in or experience with research	Limited buy in or experience, poor engagement strategies to equip providers on use of tool, some providers may choose not to adopt
Sampling, Recruitment, Population Procedures		For each cell below, write out a brief description of the population procedure for your study			
Source Population:	Describe the population that is served by providers who would recruit individual participants and/or deliver the intervention, comparison, or both, e.g. adult primary care patients from the Denver metro area →	Primary care patients served by 12 participating clinics across PBRN and UCHealth	Primary care setting that will ultimately deliver this tool		
Eligible Participants:	Describe the population eligible for your study based on your study's inclusion & exclusion criteria →	Adults > 18 years old with at least one cancer-related risk; exclusion: non English or Spanish speaking	Focus of study on adults with cancer-related risks; report tool available in English and Spanish	Non-English or Spanish speaking patients, adults without identified cancer-related risk, pediatric populations; patients with limited tech literacy or perceived benefit	Lack of ability to deliver intervention not in English or Spanish; perceived lack of benefit, limited tech literacy
Enrolled Participants:	Describe your goal sample size. Describe power analysis to determine sample size if applicable. Describe anticipated recruitment plan. Describe anticipated consent process. →	Goal 650 per intervention vs comparison arm to achieve adequate power	Goal 650 per arm	Patients with barriers to participation in the study,patients with limited perceived benefit of study	

Generalizable Impact | Conclusion

Demo Screenshots (Filled LOGIC-PRePaRE)

Guidance on what to input	**Population** *(Type in numbers in column H - as guided by Column G)*	
	For each row, estimate the number of people or participants at each level - NOTE - a graph will build from these numbers in lower left of this tab.	
Population of country where study is taking place →	*348,100,000*	
Population of state/region(s) where study is taking place →	6,000,000	
Total estimated number of people served in target system →	710,000	
Total estimated number of people served by the sites that will be involved in the study →	30,000	
Total number of people served by participating service delivery providers →	28,000	
Total number of people that are served by participating service delivery providers (this will be copied automatically from above) →	28,000	
Total number of people that could potentially be recruited from your study setting that would be eligible for your study →	20,000	
Total number of people you plan to enroll in your study in your intervention arm (left) and comparison arm (right) →	650	650
	Intervention arm above	Comparison arm above