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ADULT AND CHILD CONSORTIUM FOR HEALTH OUTCOMES RESEARCH AND DELIVERY SCIENCE
UNIVERSITY OF COLORADO | CHILDREN'S HOSPITAL COLORADO

Evaluation and Outcomes in Dissemination and Implementation Science

(Overview/Teaser)

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Overview

- D&I vs. usual health services and effectiveness research outcomes
- Representativeness and equity
- Reporting and transparency (StaRI and Expanded CONSORT)
- Pragmatic measures
- Applying above to YOUR questions

Key Differences Between Traditional RCTs and Pragmatic D&I Trials (PCTs)

	A traditional RCT tests a hypothesis under ideal conditions	A PCT compares treatments under everyday clinical conditions
GOALS	To determine causes and effects of treatment	To improve practice and inform clinical and policy decisions
DESIGN	Tests the intervention against placebo using rigid study protocols and minimal variation	*Tests two or more real-world using flexible protocols & local customization*
PARTICIPANTS	Highly defined and carefully selected	More representative because eligibility criteria are less strict
MEASURES	Require data collection outside routine clinical care	Brief and designed so data can be easily collected in clinical settings
RESULTS	Rarely relevant to everyday practice	Useful in everyday practice, especially clinical decision-making

D&I vs. Usual HSR Outcome Measures

	‘Usual’ HSR	D&I
Primary Purpose	Effectiveness	Adoption, Implementation, Sustainability
Level	Primarily Individualized	Multi-level, especially setting
Scope and Cost	Narrow & High	Broad and Low
Emphasis	Fidelity	Adaptation
Key Focus	Mechanism	Context

Types of Outcomes in Implementation Research

Implementation Outcomes

- Acceptability
- **Adoption**
- Appropriateness
- **Costs**
- Feasibility
- Fidelity
- **Penetration**
- Sustainability

Service Outcomes

- Efficiency Safety
- Effectiveness
- **Equity**
- Patient centeredness
- Timeliness

Client Outcomes

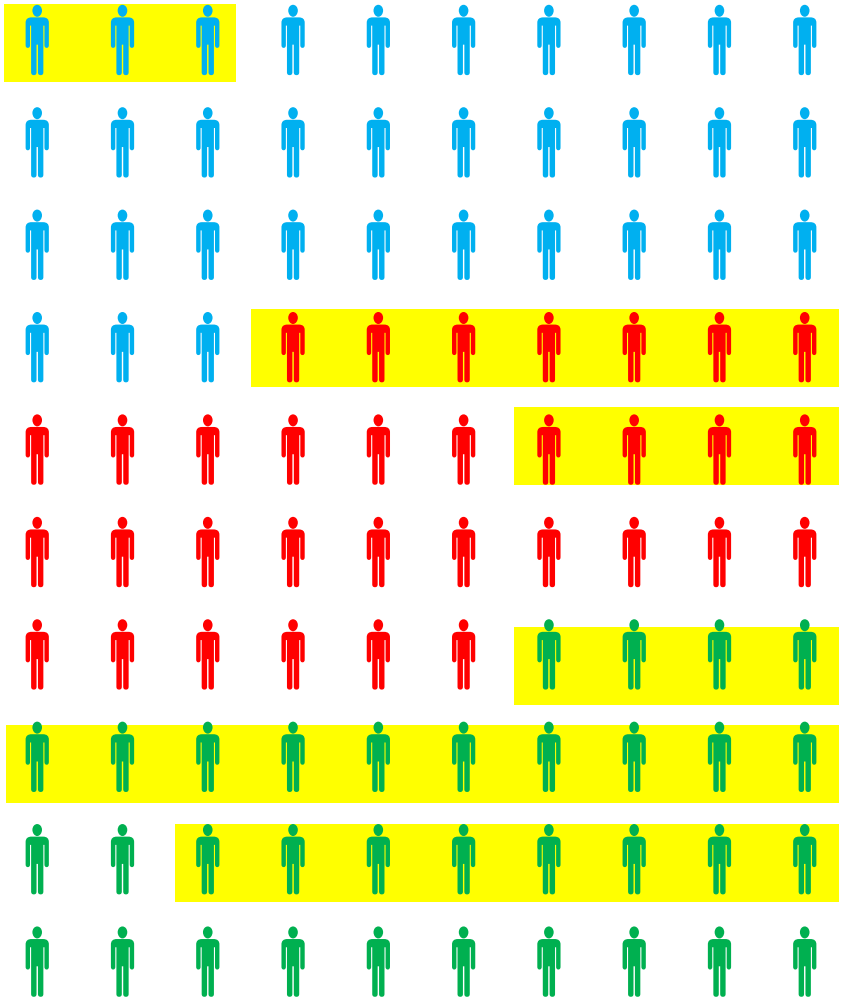
- Satisfaction
- Function
- Symptoms

Proctor E, Silmere H, Hensley M, et al. Outcomes for implementation research: *Administration And Policy In Mental Health* [serial online]. March 2011;38(2):65-76.

Key Outcomes Related to Health Equity

- Penetration (Reach)
- Representativeness- levels of community, setting, staff, patient
- Costs and Feasibility- for setting; staff; and patients/citizens/users
- Other

Population Health - Its about the denominator and health equity



Pragmatic Use of RE-AIM

RE-AIM Dimension	Key Pragmatic Priorities to Consider and Answer
Reach	**WHO** is (was) intended to benefit and who actually participates or is exposed to the intervention?
Effectiveness	**WHAT** is (was) the most important benefits you are trying to achieve and what is (was) the likelihood of negative outcomes?
Adoption	**WHERE** is (was) the program or policy applied and WHO applied it?
Implementation	**HOW** consistently is (was) the program or policy delivered, **HOW will (was) it be adapted, HOW much will (did) it cost, and WHY will (did) the results come about?**
Maintenance	**WHEN** will (was) the initiative become operational; how long will (was) it be sustained (Setting level); and how long are the results sustained (Individual level)?

Glasgow R and Estabrooks P, *Preventing Chronic Disease*, 2018 Jan 4;15:E02

Moral of this RE-AIM Story?

- All steps or phases in translation are important and provide opportunities to improve population health
- It is about the DENOMINATOR
- It is about REPRESENTATIVENESS and EQUITY

RE-AIM History & Directions Summary

- Purpose to balance reporting & focus on IV and EV
- Has evolved significantly and hopefully will continue
- Key issue is representativeness (& equity) at multiple levels- setting; staff; patient
- Recent additions/foci on: cost; adaptation; reasons for participating or not; & qualitative measures
- Not a theory; but can be used for planning, adjustment, evaluation (& D4D)
- Directions = context (PRISM) & pragmatic SH use

Evaluation Planning Tool Based on RE-AIM

Planning and Evaluation Questions for Initiatives Intended to Produce Public Health Impact*

Below you will find questions to help you in the planning, delivery, and evaluation of you program or policy initiative. Questionsin bold are recommended if you have limited time or resources to collect these data.

We do not expect you to be able to answer all of these questions, or that all of them to apply to our specific project. You need to decide which of the 'dimensions or issues' below are most important for your initiative (we use 'initiative' below to refer to both policies and programs). Thinking through these issues though will help you to increase the chances that your initiative will be successful, and sustained if successful.

Please see RE-AIM.org for tips (hyperlinked) andRE-AIM.org and http://cufamilymedicine.org/evaluationhub/ for other potentially useful information.

Dimension or Issue	Key questions (ones in bold most important to consider)	Probes and follow-up questions
Wherewill initiative be conducted? **(Adoption)**	**What settings or organizational types are you targeting** (e.g., schools, workplaces, clinics, community setings or organizations)?	What are key characteristics of the settings you want to participate? Who might be interested in thisinitiative and why? What is needed to encourage them to get engaged? How will settings hear about this? What were characteristics of settings that did not participate (e.g., location, facilities, finances, personnel)
	*** How many of these settings and organizations do you estimate will use the program or particpate in your policy?**	What supports (for example, policies or similar programs) or threats are there? How will you know if organizations used the initiative? Who can help gather information about this? What is needed to train volunteers and who will do this?

www.RE-AIM.org

http://cufamilymedicine.org/evaluation_hub/

Questions? "I am all ears!"

Reporting in D&I Research

- Context and Representativeness (Expanded CONSORT)
- Implementation- including fidelity, adaptation, and variability
- Costs- stakeholder perspective, replication costs, feasibility
- Standards for Reporting Implementation Studies (StaRI)

Reporting for D&I vs. Usual HSR

	HSR	D&I
Focus	Internal validity (some EV)	External validity (some IV)
Priority	Fidelity	Adaptation
Format	CONSORT	Expanded CONSORT; StaRI

Evidence-Based…on what?

External Validity/ Pragmatic Criteria, Often Ignored

- Participant **Representativeness**
- **Setting and Staff** Representativeness
- **Context**
- Community/Setting Engagement
- **Adaptation**/Change
- **Costs/Feasibility** of Treatment
- Sustainability
- Comparison Conditions

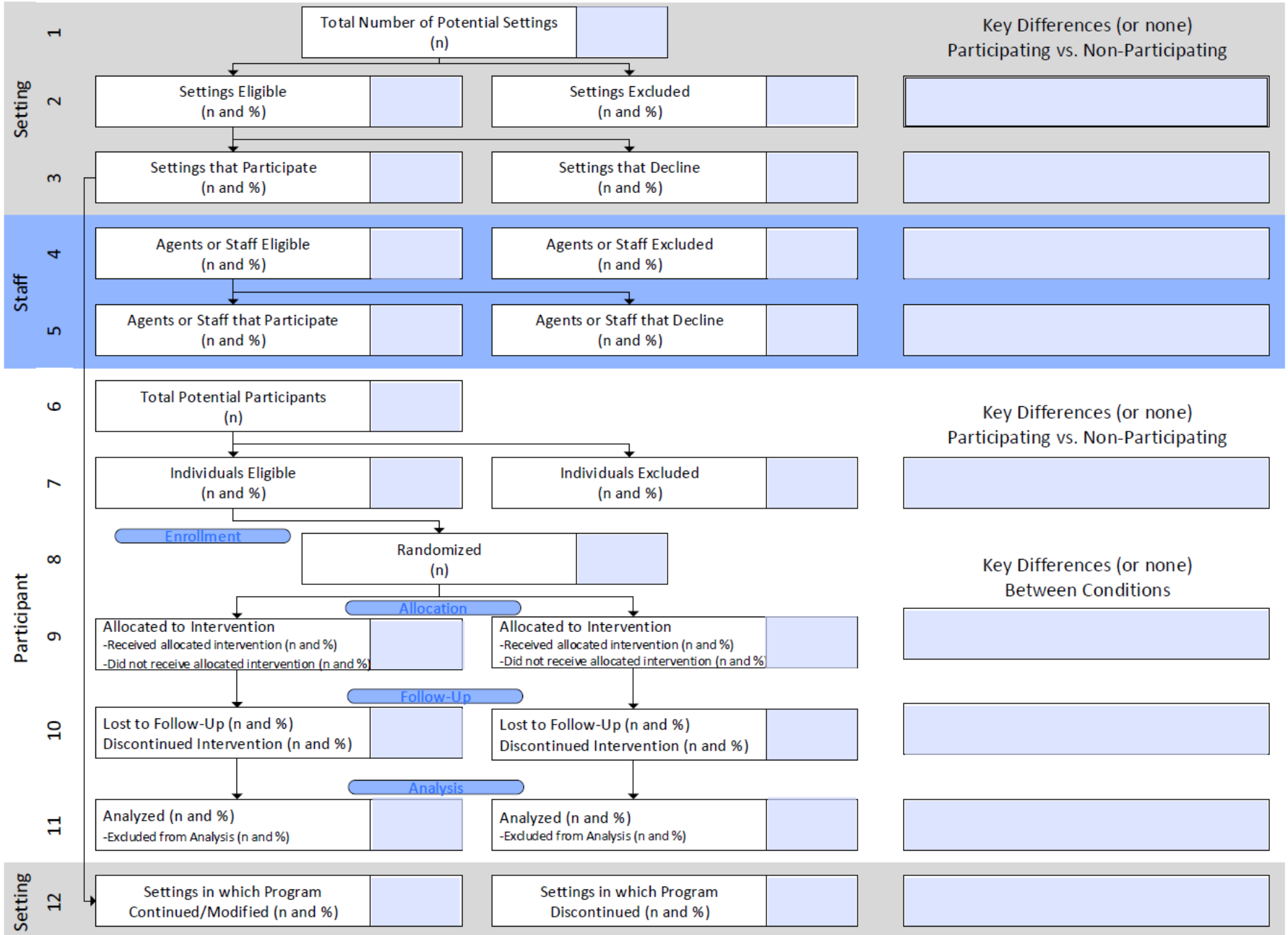
Expanded CONSORT Figure

- Existing CONSORT Figures for RCTs focus almost exclusively on internal validity
- Use of CONSORT- required by most medical journals, has improved quality and reporting on internal validity
- Until now, no comparable resource has addressed external validity. **URL: https://goo.gl/8X2gzL**

Glasgow, Huebschmann, Brownson. *Amer J Prev Med*, 2018, in press

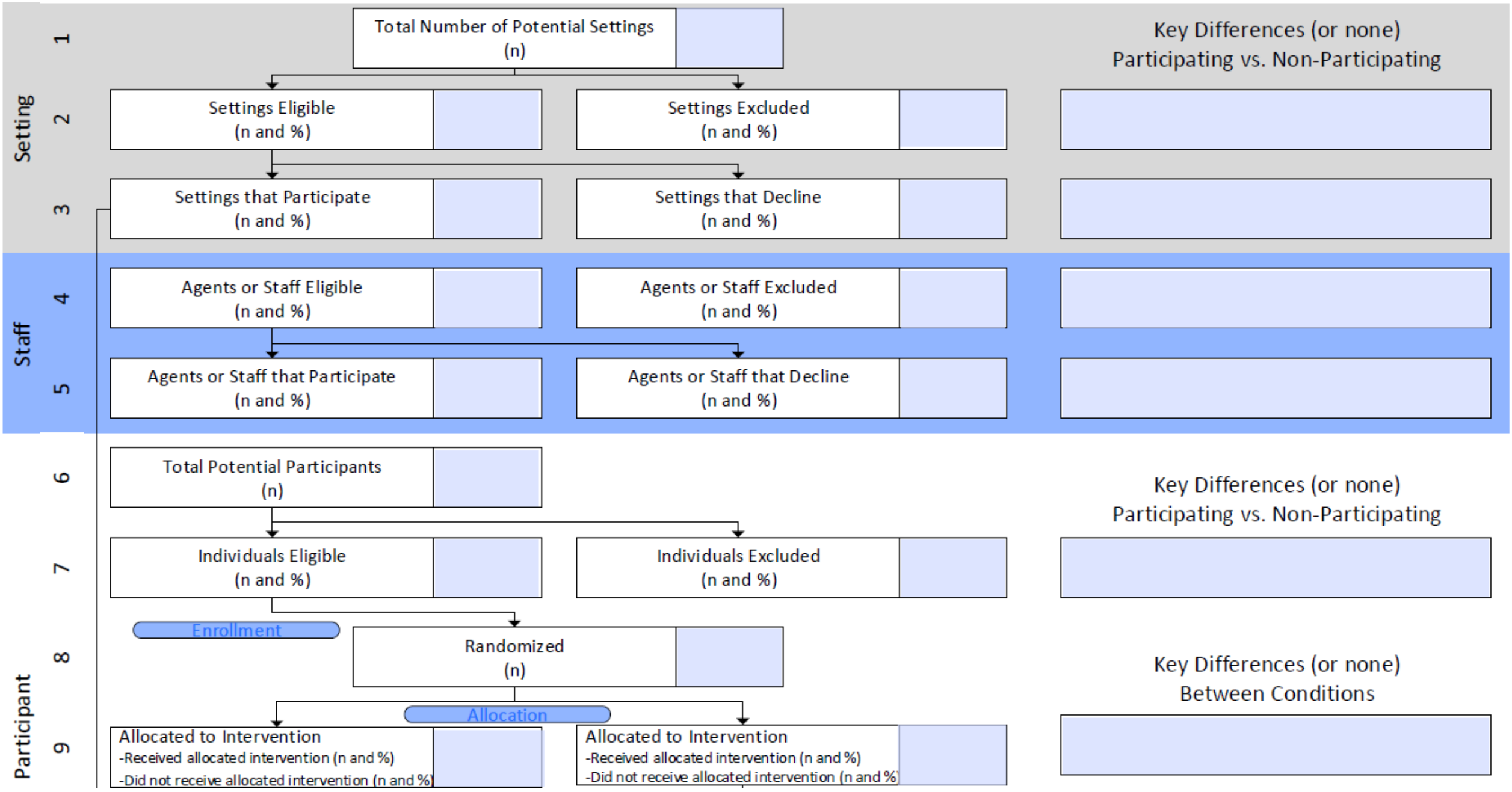
Expanded Consort Figure

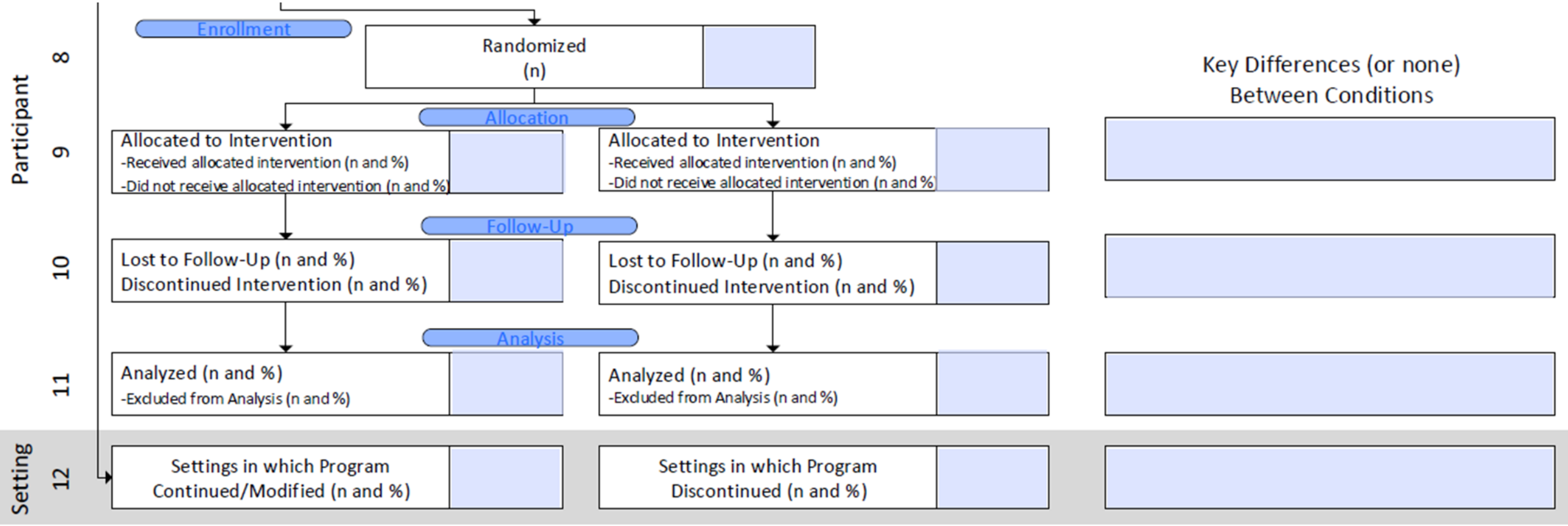
Contextual Data and Participation Rates



Expanded Consort Figure

Contextual Data and Participation Rates





URL: https://goo.gl/8X2gzL

Assessing Implementation

- Consistency of delivery (fidelity)
- Adaptation- what is modified by whom, when and how, with what impact (multi-method assessment)
- Variation- across patients, staff, settings
- Costs- next slide

Reporting Resources Required

- Reporting on cost and other resources in a standardized manner is useful in:
  - ✓ Demonstrating *value*
  - ✓ Promoting rigor, transparency and relevance to stakeholders
- Present *from perspective of stakeholders* and decision makers
- Simple is fine – sophisticated economic analyses are not needed
  - ✓ Report costs of conducting or replicating interventions
  - ✓ Beyond money, costs can include clinician and staff time, training, infrastructure, startup costs, opportunity costs

Ritzwoller, D P, et al. (2009). Costing behavioral interventions: A practical guide to enhance translation. *Annals of Behavioral Medicine*, *37*(2), 218-27.

Table 1 | Standards for Reporting Implementation Studies: the StaRI Checklist of items to be reported

Checklist item		Implementation strategy	Intervention†
Title	1	Identification as an implementation study, and description of the methodology in the title and/or keywords	
Abstract	2	Identification as an implementation study, including a description of the implementation strategy to be tested, the evidence-based intervention being implemented, and defining the key implementation and health outcomes	
Introduction	3	Description of the problem, challenge, or deficiency in healthcare or public health that the intervention being implemented aims to address	
	4	The scientific background and rationale for the implementation strategy (including any underpinning theory, framework, or model, how it is expected to achieve its effects, and any pilot work)	The scientific background and rationale for the intervention being implemented (including evidence about its effectiveness and how it is expected to achieve its effects)
Aims and objectives	5	The aims of the study, differentiating between implementation objectives and any intervention objectives	
Methods: description	6	The design and key features of the evaluation (cross referencing to any appropriate methodology reporting standards) and any changes to study protocol, with reasons	
	7	The context in which the intervention was implemented (consider social, economic, policy, healthcare, organisational barriers and facilitators that might influence implementation elsewhere)	
	8	The characteristics of the targeted "site(s)" (locations, personnel, resources, etc) for implementation and any eligibility criteria	The population targeted by the intervention and any eligibility criteria
	9	A description of the implementation strategy	A description of the intervention
	10	Any subgroups recruited for additional research tasks, and/or nested studies are described	
Methods: evaluation	11	Defined pre-specified primary and other outcome(s) of the implementation strategy, and how they were assessed. Document any pre-determined targets	Defined pre-specified primary and other outcome(s) of the intervention (if assessed), and how they were assessed. Document any pre-determined targets
	12	Process evaluation objectives and outcomes related to the mechanism(s) through which the strategy is expected to work	
	13	Methods for resource use, costs, economic outcomes, and analysis for the implementation strategy	Methods for resource use, costs, economic outcomes, and analysis for the intervention
	14	Rationale for sample sizes (including sample size calculations, budgetary constraints, practical considerations, data saturation, as appropriate)	
	15	Methods of analysis (with reasons for that choice)	
	16	Any a priori subgroup analyses (such as between different sites in a multicentre study, different clinical or demographic populations) and subgroups recruited to specific nested research tasks	

Methods: evaluation	**11**	Defined pre-specified primary and other outcome(s) of the implementation strategy, and how they were assessed. Document any pre-determined targets	Defined pre-specified primary and other outcome(s) of the intervention (if assessed), and how they were assessed. Document any pre-determined targets
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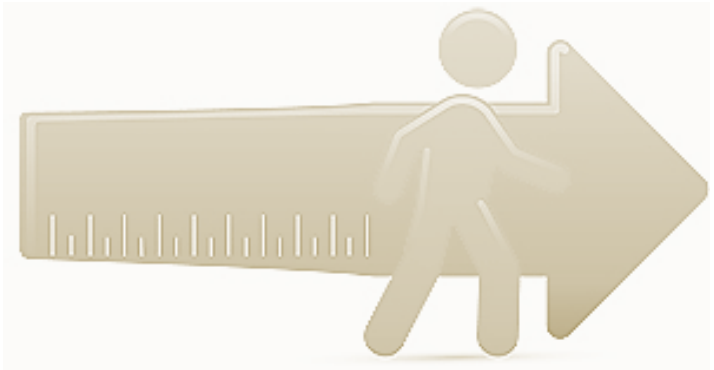
	15	Methods of analysis (with reasons for that choice)	
	16	Any a priori subgroup analyses (such as between different sites in a multicentre study, different clinical or demographic populations) and subgroups recruited to specific nested research tasks	
Results	**17**	Proportion recruited and characteristics of the recipient population for the implementation strategy	Proportion recruited and characteristics (if appropriate) of the recipient population for the intervention
	18	Primary and other outcome(s) of the implementation strategy	Primary and other outcome(s) of the intervention (if assessed)
	19	Process data related to the implementation strategy mapped to the mechanism by which the strategy is expected to work	
	20	Resource use, costs, economic outcomes, and analysis for the implementation strategy	Resource use, costs, economic outcomes, and analysis for the intervention
	21	Representativeness and outcomes of subgroups including those recruited to specific research tasks	
	22	Fidelity to implementation strategy as planned and adaptation to suit context and preferences	Fidelity to delivering the core components of intervention (where measured)
	23	Contextual changes (if any) which may have affected outcomes	
	24	All important harms or unintended effects in each group	
Discussion	**25**	Summary of findings, strengths and limitations, comparisons with other studies, conclusions and implications	
	26	Discussion of policy, practice and/or research implications of the implementation strategy (specifically including scalability)	Discussion of policy, practice and/or research implications of the intervention (specifically including sustainability)
General	**27**	Include statement(s) on regulatory approvals (including, as appropriate, ethical approval, confidential use of routine data, governance approval), trial or study registration (availability of protocol), funding, and conflicts of interest	

*Implementation strategy refers to how the intervention was implemented.
†Intervention refers to the healthcare or public health intervention that is being implemented.
Note: A key concept is the dual strands of describing (*a*) the implementation strategy and (*b*) the clinical, healthcare, or public health intervention that is being implemented. These strands are represented as two columns in the checklist. The primary focus of implementation science is the implementation strategy (column 1) and the expectation is that this will always be completed. The evidence about the impact of the intervention on the targeted population should always be considered (column 2) and either health outcomes reported or robust evidence cited to support a known beneficial effect of the intervention on the health of individuals or populations. While all items are worthy of consideration, not all items will be applicable to or feasible within every study.

Pragmatic Outcomes and Measures



Pragmatic Measures (see handout)

1. **Required Criteria**
   - Important to stakeholders
   - Burden is low to moderate
   - Broadly applicable, has norms to interpret
   - **Sensitive to change**
2. **Additional Criteria**
   - **Actionable**
   - Low probability of harm
   - Addresses public health goal(s)
   - Related to theory or model
   - "Maps" to "gold standard" metric or measure

Glasgow, RE & Riley, WT. Pragmatic measures… *Am J Prev Med* 2013;45(2):237–243)

EXAMPLE PRAGMATIC STUDY: My Own Health Report (MOHR) Study

Cluster randomized pragmatic trial of web-based, brief health behavior and mental health assessment and intervention in nine diverse pairs of primary care practices to test whether they could implement My Own Health Report (MOHR).

Outcomes included:

- ***Reach*** of the MOHR program across patients
- Whether practices would ***adopt*** MOHR
- How practices would ***implement*** MOHR
- ***Effectiveness*** of the MOHR program ***with pragmatic PROs***

Glasgow, et al. (2014). Conducting rapid, relevant, research *American Journal of Preventive Medicine*, August;47(2):212-9.

Krist, et al. (2016). *Translational Behavioral Medicine*, Jun; 6(2):212-9.

Pragmatic EHR Measures for Primary Care

Domain	Final Measure (Source)
1. Overall Health Status	1 item: BRFSS Questionnaire
2. Eating Patterns	3 items: Modified from Starting the Conversation (STC) [Adapted from Paxton AE et al. Am J Prev Med 2011;40(1):67-71]
3. Physical Activity	2 items: The Exercise Vital Sign [Sallis R. Br J Sports Med 2011;45(6):473-474]
4. Stress	1 item: Distress Thermometer [Roth AJ, et al. Cancer 1998;15(82):1904-1908]
5. Anxiety and Depression	4 items: Patient Health Questionnaire—Depression & Anxiety (PHQ-4) [Kroenke K, et al. Psychosomatics 2009;50(6):613-621]
6. Sleep	2 items: Adapted from BRFSS, Neuro-QOL [Item PQSLP04]
7. Smoking/Tobacco Use	2 items: Tobacco Use Screener [Adapted from YRBSS Questionnaire]
8. Risky Drinking	1 item: Alcohol Use Screener [Smith et al. J Gen Int Med 2009;24(7):783-788]
9. Substance Abuse	1 item: NIDA Quick Screen [Smith PC et al. Arch Int Med 2010;170(13):1155-1160]
10. Demographics	9 items: Sex, date of birth, race, ethnicity, English fluency, occupation, household income, marital status, education, address, insurance status, veteran's status. Multiple sources including: Census Bureau, IOM, and National Health Interview Survey (NHIS)

Reactions and Discussion

- **Discuss handout** on Pragmatic measures- compare and contrast most important characteristics from different recommendations

- Handout comparing different recommendations/criteria for pragmatic measures from Kroenke et al. *J Clin Epidemiol*. 2015; 68(9): 1085–1092.

Where do I find pragmatic measures?

(Sample sites to visit!)

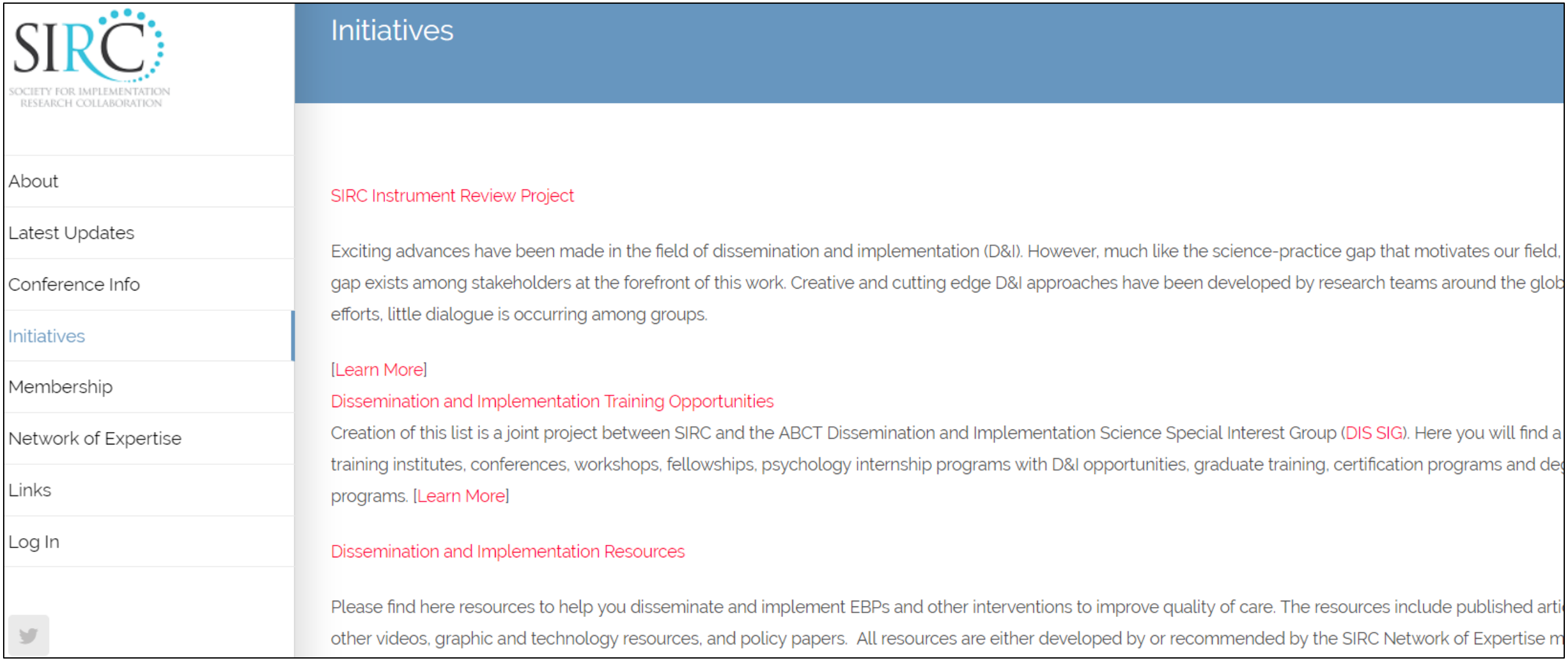
PROMIS website http://www.healthmeasures.net/explore-measurement-systems/promis

National Institute of Nursing Research
https://cde.nlm.nih.gov/form/search?selectedOrg=NINR

GEMS- NCI website
https://www.gem-beta.org/public/MeasureList.aspx?cat=2

My own Health Report (MOHR) project.
http://myownhealthreport.org/

Rabin, B., Lewis, C., Norton, W., Neta, G., Chambers, D., Tobin, J., . . . Glasgow, R. (2016). Measurement resources for dissemination and implementation research in health. *Implementation Science: 11*(1), 42.



https://societyforimplementationresearchcollaboration.org/sirc-instrument-project/

Source for mental health measures from CFIR model especially

National Cancer Institute

U.S. National Institutes of Health | www.cancer.gov

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GEM-Dissemination and Implementation Initiative (GEM-D&I)

Related Constructs & Measures

Add New Construct | Add New Measure | Add Existing Construct/Measure

Constructs▲	Measures	Content Area	Ratings	Documents
Acceptability	Acceptability of Decision Aid Scale	1. Risk and Decision Making 2. Patient Decision Aids	★☆☆☆☆ (average) Rate This!	
Acceptability	Evidence Based Practice Attitude scale	1. not specified	★★★☆☆ (average) Rate This!	
Acceptability	Suicide Prevention Program Rating Profile	1. not specified	★★★☆☆ (average) Rate This!	
Acceptability	Therapists' attitudes toward treatment manuals	1. not specified	not yet rated Rate This!	
Acceptability	Treatment Evaluation Inventory	1. not specified	★★★☆☆ (average) Rate This!	
Acceptability	Residents incorporation of EBM in practice	1. not specified	★★★☆☆ (average) Rate This!	

https://www.gem-beta.org/public/wsmeasures.aspx?cat=8&aid=1&wid=11

Replicability (and generalizability)

- Important to report conditions under which program was delivered

- To what extent is the program **replicable**:
  - ✓ In similar settings?
  - ✓ In different settings?
- Compared to What: what intervention do you compare it to (real world alternative)?

- Bottom Line and **ULTIMATE USE QUESTION**: "***What program/policy components*** *are most effective* for producing ***what outcomes*** for ***which populations/recipients*** when implemented by ***what type of staff using what strategies*** under ***what conditions,*** with ***how many resources*** and ***how/why*** do these results come about?"