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The COPRH Pragmatic Research Plan Workbook
Designing Research for Real World Impact

A participant workbook to supplement the conference:

The Colorado Pragmatic Research in Health (COPRH) Conference: Planning for Real World Impact

A virtual conference hosted by

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PRAGMATIC RESEARCH PLANS

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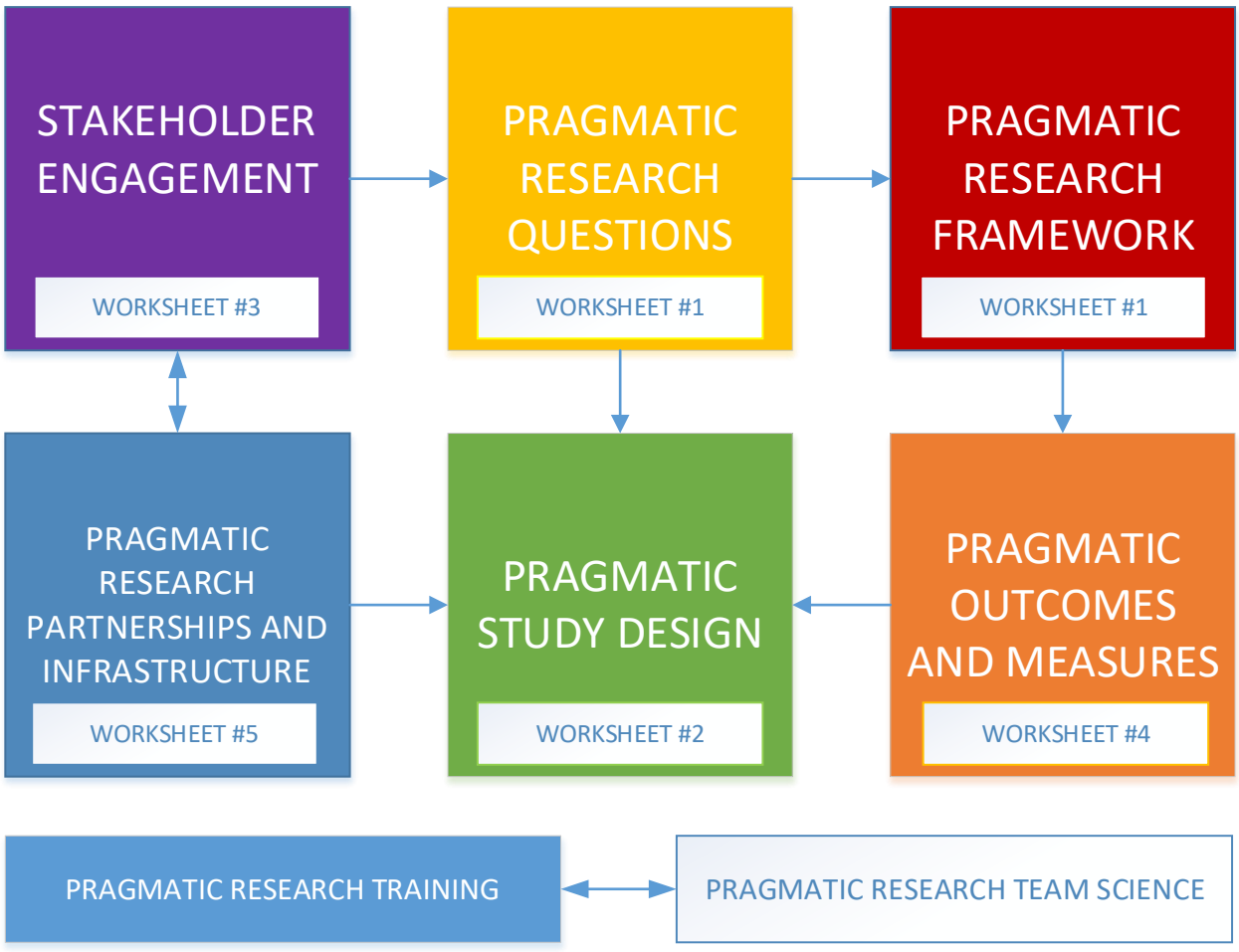
A Guide

To make the most of your COPRH Con experience, we provide a workbook to build a pragmatic research plan for your next grant proposal. Each session at COPRH Con informs one or more components of a plan for research designed for rigor and real world, equitable impact.

On day 1, we begin with a focus on defining pragmatic research in health, study design features that make a study more or less pragmatic, and exploring frameworks useful for planning pragmatic research.

On day 2, we dig into the foundation of pragmatic research: stakeholder engagement – and then selecting outcomes that matter to stakeholders and pragmatic measures. Pragmatic research is a collective effort, done in partnership with communities, health systems, and scientists from a variety of disciplines. Take note of what training, collaborations, and partnerships you may need to develop.



PRAGMATIC RESEARCH

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Characteristics of Pragmatic Research

EXERCISE BEFORE YOU BEGIN

Bear in mind the following characteristics of pragmatic research:

The research question of interest...

…tests if an intervention is effective in routine practice or service settings, often compared to well-defined usual care or existing programs and/or other comparator interventions. What intervention(s) will you test?

…considers the organization (and its existing personnel and infrastructure) – What organization type(s) are relevant? Are the resources and expertise required for program delivery available in typical delivery settings?

The settings studied are…

…typical delivery settings (e.g., typical workplaces, schools, or communities rather than highly specialized types of these settings).

The population of interest (in a highly pragmatic study) will include...

….broad eligibility criteria to represent "typical real-world" recipients of this program

…a recruitment path identified in typical ways for clinical/community settings (e.g., registry data, best practice alerts, other)

On the next page, outline these key consideration for your pragmatic research.

RELEVANCE TO YOUR WORK

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Learning happens best when applying new content to your own work. As the conference begins, please take a moment to identify at least one project you are working on that may be relevant to pragmatic research methods. Answer the following questions to help get you started on your pragmatic research plan.

- What are the research questions?

- What makes this research "pragmatic"? That is, in what sense is it designed to produce evidence relevant to real-world health issues, populations, and health care settings?

- What intervention(s) will be tested? How will the intervention(s) be implemented, ideally making use of existing service structures, systems, and processes?

- What is the level of evidence for the intervention? Will this be a pilot effectiveness study or is it ready for a dissemination and/or implementation (D&I) study?

- What level(s) of change are relevant? (e.g., individual, provider, setting, policy levels)

- What characteristics of the setting or context are relevant to the research questions?

- What is the timeframe for your project?

YOUR PLANNING FRAMEWORK(S)

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Worksheet #1

Selecting, Combining, Adapting, Using, and Measuring Pragmatic Research Planning Frameworks

Use this worksheet with the following sessions:

⇒ Day 1 Opening Keynote and Plenary Planning Pragmatic Research

⇒ Day 1 Tour of Frameworks for Planning Pragmatic Research

⇒ Day 1 Discussion Forum, Frameworks for Planning Pragmatic Research: How to Select, Combine, Adapt, Use, and Measure

- What pragmatic research planning frameworks reflect levels of change and contextual or setting characteristics relevant to your research? Tip: Visit dissemination-implementation.org to explore frameworks

- How might the selected framework(s) guide the process of planning pragmatic research – such as engaging stakeholders, identifying settings for conducting research, adapting and refining interventions and study protocols, and establishing implementation, dissemination, and sustainability plans?

- How might the selected framework inform the outcomes and measures (including intermediate or process outcomes, mechanisms of change, or determinants/factors related to implementation) to be studied?

Continued next page

YOUR PLANNING FRAMEWORK(S)

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Worksheet #1 continued

- Selection of models and frameworks to guide your pragmatic research plan can be informed by a logic model or diagram that highlights the health issues, activities, and constructs in your project. Sketch a logic model here.
    - For guidance on creating a logic model visit the Plan section of the D&I webtool: https://dissemination-implementation.org/content/plan.aspx

- Do you need to combine frameworks? Which might you combine, and for which purposes?
    - There are many occasions when selecting just one model will not address all your needs for guiding the planning, design, implementation, and evaluation activities. Nilsen classified D&I models into five broad categories based on their primary purpose: process models, determinant frameworks, classic theories, implementation frameworks, and evaluation frameworks. When one model does not suffice, you might decide to select multiple models and combine them. Helpful guidance on how to combine models is included in the Combine section of the D&I Models webtool: https://dissemination-implementation.org/content/combine.aspx

- Do you need to adapt frameworks? What adaptations might be needed?
    - Bear in mind, there is likely no comprehensive model that will perfectly fit your study, so it may be necessary to further adapt the model or models you identified for your study. Learn more about strategies and considerations to adapt models in the Adapt section of the D&I Models webtool: https://dissemination-implementation.org/content/adapt.aspx

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Worksheet #1 continued

Key resources:

1. D&I Models Webtool: http://dissemination-implementation.org/
2. T-CaST: an implementation Theory Comparison and Selection Tool: https://impsci.tracs.unc.edu/tcast/
3. Moullin, J.C., Dickson, K.S., Stadnick, N.A. et al. Ten recommendations for using implementation frameworks in research and practice. Implement Sci Commun 1, 42 (2020). https://doi.org/10.1186/s43058-020-00023-7

Notes:

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Worksheet #2

Selecting Pragmatic Research Study Design Features

Use this worksheet with the following sessions:

⇒ Day 1 Keynote on Pragmatic Research

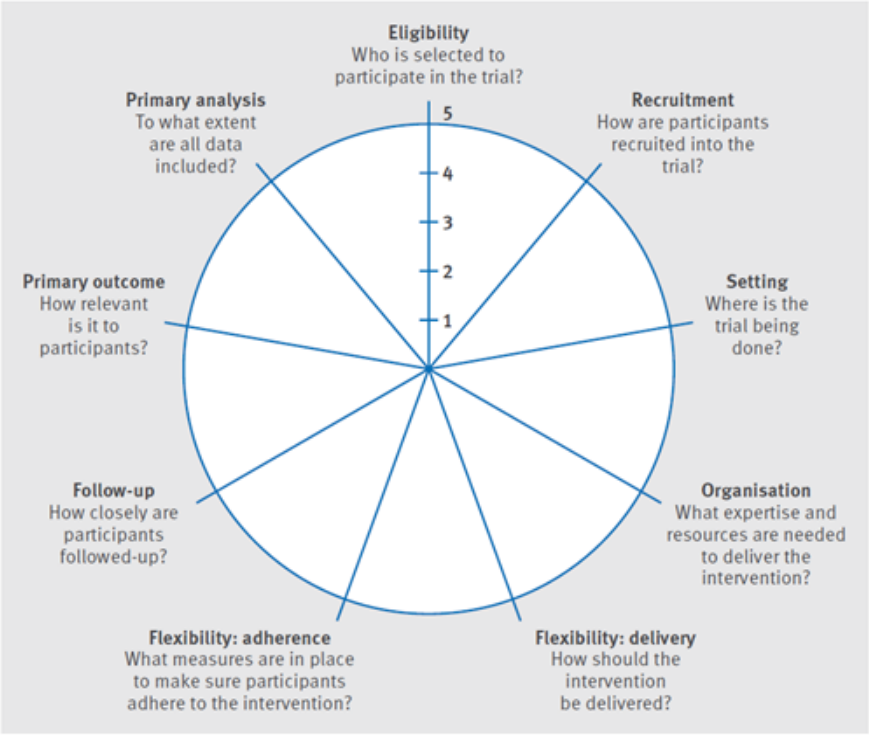
⇒ Day 1 Plenary on Planning Pragmatic Research and the PRECIS-2 framework

⇒ Day 1 Plenary on the Multiphase Optimization Strategy (MOST) Approach

⇒ Day 1 Tour of Pragmatic Study Design and Panel Discussion

The Pragmatic-Explanatory Continuum Indicator Summary (PRECIS-2)

The PRECIS-2 framework can be used a) as a study planning tool, b) to report on studies, and c) to rate the pragmatism of published studies as part of a systematic review. This latter approach may assist the selection of potential pragmatic and effective interventions. The PRECIS-2 has nine domains reflecting key design features of clinical trials. Each element of a study design is given a rating between 1 and 5 on each domain relative to usual care, with 1 representing a very explanatory (or efficacy-focused) trial and 5 representing a very pragmatic trial. For interactive rating tools, see the PRECIS-2.org website.



The PRagmatic-Explanatory Continuum Indicator Summary 2 (PRECIS-2) wheel.

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Worksheet #2 continued

PRECIS-2 Domains and Ratings for your Study		
PRECIS-2 Domain	**My Study Design**	**Pragmatic-Explanatory Rating**
Eligibility criteria		
Recruitment path		
Setting		
Organization		
Flexibility: delivery		
Flexibility: adherence		
Follow-up		
Primary outcome – relevance to participants		
Primary analysis		

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Worksheet #2 continued

Selecting Pragmatic Study Design Types

Use the following questions to help determine appropriate study design types for your pragmatic research. When we refer to an intervention, we mean any program, treatment, service or policy that will be tested in the setting in which it is intended to be used or delivered. *Contact a biostatistician (and possibly other experts such as a health economist; qualitative analysis expert; social network or systems analyst) early to discuss appropriate study designs and analytic techniques.*

- Will your design type be:

☐ Participant-level randomized trial

☐ Cluster randomized trial (level of randomization: _____; level(s) of outcome data: _____)

☐ Stepped wedge design (level of randomization to rollout: _____)

☐ Quasi-experimental design (Type: _____)

☐ Observational design (Type: _____)

☐ Factorial (full or partial) design

☐ SMART design

☐ Adaptive design

Comments:

- Will your study be focused on effectiveness only, implementation only, or both effectiveness and implementation outcomes (suggesting a hybrid trial may be appropriate)?

☐ Clinical effectiveness trial only (no implementation outcomes)

☐ Implementation trial only (no health outcomes)

☐ Hybrid Type I: Primary aim: clinical effectiveness (secondary aim: context for implementation, acceptability and feasibility)

☐ Hybrid Type II: Coprimary aims: clinical effectiveness and implementation (adoption, fidelity)

☐ Hybrid Type III: Primary aim: utility of an implementation strategy (secondary aim: clinical outcomes)

Comments:

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Worksheet #2 continued

Selecting Pragmatic Study Design Types

To decide, consider the following:

- Is randomization to condition possible, ethical, and feasible? Why or why not?

- For non-randomized designs
  - Consider an observational, quasi-experimental design, or natural experiment.

- For randomized designs
  - Will randomization be at the participant level or provider/site/cluster level? Why?

    Consider a cluster randomized trial or stepped wedge design if there is the possibility of contamination or pragmatic challenges with participant level randomization (e.g., an organization or provider would be unable to deliver an intervention more than one way at a time due to resources)

  - Is the recruitment rate likely to be constant across time?

    If no, consider cluster randomized rather than stepped wedge to mitigate study delays when recruitment is low.

  - How feasible is it to implement the intervention for all randomization units at the same time?

    If not feasible, consider a stepped wedge to distribute the implementation at clusters at different time points.

  - Are more than two interventions being compared?

    If yes, consider a cluster randomized trial or a participant-level randomized trial instead of a stepped wedge design.

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Worksheet #2 continued

Selecting Pragmatic Study Design Types

◊ Do the intervention(s) to be tested have multiple components that need to be optimized in terms of combination, sequence, dose, or tailoring?

If yes, an adaptive trial design (e.g., SMART) or factorial design may be appropriate. Also considered a MOST approach for iterative design and testing of an optimized intervention strategy.

♦ Other considerations

◊ Power and Sample Size Estimation

Pragmatic trials with an active comparator may anticipate a small effect size difference, which requires more participants to achieve adequate statistical power. What is your anticipated effect size difference for your study? Do you have access to the required sample size in your partnering sites?

◊ Analysis

Standard methods for analysis of individually randomized trials may not be appropriate. Statistical analysis must incorporate the study design features, such as hierarchical dependency of data and temporal trends. What analytic approach(es) might be appropriate?

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Worksheet #2 continued

Key resources and references:

1. PRECIS-2 website: https://www.precis-2.org/
2. Loudon et al., The PRECIS-2 tool: designing trials that are fit for purpose: *BMJ* 2015;350:h2147.
3. Luoma K., Leavitt I. et al., How Can Clinical Practices Pragmatically Increase Physical Activity for Patients With Type 2 Diabetes? A Systematic Review. TBM, 2017.
4. Ali SA, Kloseck M, et al. Evaluating the design and reporting of pragmatic trials in osteoarthritis research. *Rheumatology (Oxford)*. 2018;57(1):59-63.
5. Brown CH, Curran G, et al. Overview of Research and Evaluation Designs for Dissemination and Implementation. *ARPH*, 2017
6. Thorlund K, Haggstrom J, et al.. Key design considerations for adaptive clinical trials: a primer for clinicians. *BMJ*, 2018
7. Curran GM, Bauer M, et al.. 2012. Effectiveness-implementation hybrid designs: combining elements of clinical effectiveness and implementation research to enhance public health impact. *Med. Care* 50:217–26
8. Brown et al 2017. An Overview of Research and Evaluation Designs for Dissemination and Implementation. *Annual Review of Public Health*
9. Hussey MA, Hughes JP. Design and analysis of stepped wedge cluster randomized trials. *Contemp Clin Trials*. 2007;28(2):182-191.
10. Hemming K, Lilford R, Girling AJ. Stepped-wedge cluster randomised controlled trials: a generic framework including parallel and multiple-level designs. *Statist Med*. 2015;34(2):181-196.
11. Campbell, M.K., Mollison, J. and Grimshaw, J.M. (2001), Cluster trials in implementation research: estimation of intracluster correlation coefficients and sample size, Statistics in Medicine, 20, 391-399.
12. Campbell MJ, Donner A, Klar N. Developments in cluster randomized trials and *Statistics in Medicine*. Statistics in Medicine. 2007 Jan 15;26(1):2-19.
13. Eldridge, S.M, Ashby, D., Feder, G.S., Rudnicka, A.R. and Ukomunne, O.C. (2004) Lessons for cluster randomized trials in the twenty-first century: a systematic review of trials in primary care Clinical Trials 1:80-90

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Worksheet #3

Selecting Stakeholder Engagement Method(s)

Use this worksheet with the following sessions:

Day 2 Plenary on Pragmatic Challenges of Engaging Stakeholders

Day 2 Breakout sessions on a Tour of Stakeholder Engagement Methods

Identifying your stakeholders, engagement purposes, resources and assets:

- What types of stakeholders have you or do you plan to engage? Who else might be important to engage? (Consider multiple socio-ecological levels, e.g., community members/patients; setting staff; setting leaders; policymakers)

  On page 17, use the 7Ps stakeholder matrix to brainstorm different stakeholder types and specific individuals or organizations you will approach for engagement.

- What are the relevant purposes of engagement? (e.g., research planning, implementation, conduct, dissemination)

- Where are you in the process of developing and implementing your study protocol? Are you open to redirection from your stakeholders at this point?

- What resources (including time) do you have available to support your engagement efforts?

- What assets do you have to support your engagement efforts – such as existing stakeholder, community or patient partners, or technical expertise and experience?

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Worksheet #3 continued

Selecting an engagement method:

- Considering the pragmatic research planning framework you have selected, in what phases or stages of your research will you engage stakeholders? What strategies, if any, does the framework specify for how, when, and for what purposes to engage stakeholders in the planning process?

- Will you convene a stakeholder panel or community advisory board? What will their responsibilities be and for how long? How will you identify and invite them to participate? How will you fund their time?

- What strategies (e.g., group facilitation techniques) will you use to elicit the perspectives of your stakeholders?

- What will be the role of your stakeholders in decision making? Will consensus be required? How will you establish consensus?

- How will you assess the extent to which your stakeholders agree that your pragmatic study design features reflect real world systems, structures, and processes of care?

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Worksheet #3 continued

Key Resources and References or Stakeholder Engagement

1. Concannon TW, Meissner P, Grunbaum JA, McElwee N, Guise JM, Santa J, Conway PH, Daudelin D, Morrato EH, Leslie LK. A new taxonomy for stakeholder engagement in patient-centered outcomes research. Journal of general internal medicine. 2012 Aug 1;27(8):985-91.
2. https://cdn.ymaws.com/www.iap2.org/resource/resmgr/pillars/Spectrum_8.5x11_Print.pdf
3. https://www.pcori.org/sites/default/files/Engagement-Rubric.pdf
4. https://www.pcori.org/engagement/engagement-resources
5. The Engage2020 Action Catalogue: http://engage2020.eu/news/action-catalogue-an-online-method-tool-that-lets-you-find-the-exact-method-you-are-searching-for/
6. Deliberative Democracy Institute Wiki: http://www.delib.org/wiki/index.php?title=Main_Page
7. CSU Center on Public Deliberation: https://cpd.colostate.edu/what-is-deliberation/
8. Participedia: https://participedia.net/en/methods/deliberation
9. National Coalition for Dialogue and Deliberation: http://ncdd.org/
10. Liberating structures: http://www.liberatingstructures.com/

Notes:

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7 P'S STAKEHOLDER MATRIX

Adapted from: Concannon TW, Meissner P, Grunbaum JA, et al. A New Taxonomy for Stakeholder Engagement in Patient-Centered Outcomes Research. J Gen Intern Med. 2012;27(8):985-991.

			Project Specific		
Stakeholder Category	**Definition**	**Possible Stakeholder Roles**	**What specific groups or individuals will you engage?**	**What needs, contextual factors, and preferences must be considered?**	**How are these stakeholder types engaged in the project?**
Patients and the public	Current and potential consumers of patient-centered health care and population-focused public health, their caregivers, families, and patient and consumer advocacy organizations	Decision to become involved in the program? Identify decisions, questions, benchmarks for success, input agent for QI/evaluation, interpret findings, offer solutions			
Providers	Individuals (e.g., nurses, physicians, mental health counselors, pharmacists, and other providers of care and support services) and organizations (e.g., hospitals, clinics, community health centers, community-based organizations, pharmacies, EMS agencies, skilled nursing facilities, schools) that provide care to patients and populations				
Purchasers	Employers, the self-insured, government and other entities responsible for underwriting the costs of health care				
Payers	Insurers, Medicare and Medicaid, state insurance exchanges, individuals with deductibles, and others responsible for reimbursement for interventions and episodes of care	Decision about paying for program, how to select patients for inclusion in the program, whether to incorporate program into SOP as part of the health plan, how consistent with existing structures and services vs duplicative/overlapping?			

			Project Specific		
Stakeholder Category	**Definition**	**Possible Stakeholder Roles**	**What specific groups or individuals will you engage?**	**What needs, contextual factors, and preferences must be considered?**	**How are these stakeholder types engaged in the project?**
Policy makers	The White House, Department of Health and Human Services, Congress, states, professional associations, intermediaries, and other policy-making entities; public policy makers and policy advocates working in the non-governmental sector.				
Product makers	Drug and device manufacturers; industry partners				
		Funders and investigators can begin immediately to			
Principal investigators	Other researchers and their funders	identify appropriate intermediate and long-term benchmarks for evaluating the effectiveness of engagement, keeping in mind that the optimal organization			

YOUR OUTCOMES AND MEASURES

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Worksheet #4

Selecting Pragmatic Research Outcomes and Measures

Use this worksheet with the following sessions:

Day 1 Frameworks for Planning Pragmatic Research

Day 2 Stakeholder Engagement

Day 2 A Tour of Pragmatic Methods and Measures

In pragmatic research, to the extent possible, the outcomes and measures selected should align with the conceptual, theoretical, and/or process framework(s) guiding the research AND the needs, perspectives, and relevant metrics for success held by patients and other stakeholders. The timing, frequency, and comprehensiveness of data collection is also important, and should be planned with respect to the study design, burden to respondents, research team resources, and consideration of plans to test for mediation, moderation and generalization/ heterogeneity of effects.

- **Stakeholder-centered outcomes.** What outcomes matter most to your stakeholders? What information do they need to inform decisions about what health services to adopt, use, or pay for? If you aren't sure, how will you engage your stakeholders to determine the priority metrics, incentives, or factors influencing decisions? Think about both short term and long term outcomes (refer to your logic model if you have created one).

- **Framework-aligned constructs and outcomes.** What stakeholder-centered outcomes align with the key domains and/or constructs in your conceptual, theoretical, and/or process framework(s)? To answer the next few questions, you may want to refer and complete the exercises on dissemination-implementation.org

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YOUR OUTCOMES AND MEASURES

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Worksheet #4 continued

- **Data sources.** What existing data sources are available to assess these outcomes? To what extent are these data sources pragmatic? That is, to what extent are these data collected in the course of routine practice (e.g., electronic health records), of high quality, and readily accessible to researchers? How will your outcomes be operationalized using these data sources?

- **Data collection methods.** For outcomes that require primary data collection, which types of data collection methods are most appropriate for which outcomes? Qualitative, quantitative, or mixed methods? How often is it feasible to collect repeated measures on a given setting or individual?

- **Pragmatic measures.** Review resources on the next page. What valid, reliable self-report, survey, observational, interview, forced choice experiment, behavioral measures are available? To what extent are these measures pragmatic? If you aren't sure, what literature or measures databases will you review or experts will you consult with?

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YOUR OUTCOMES AND MEASURES

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Worksheet #4 continued

Pragmatic measures are characterized by several key features:

- ◊ Brevity
- ◊ Criterion validity (does it predict what it is supposed to)
- ◊ Reliability (especially test-retest)
- ◊ Sensitivity to change (e.g. ability to detect intervention effects)
- ◊ Actionable and understood by users
- ◊ Quickly and easily scored
- ◊ Broad availability (e.g., validated in multiple languages and applicable across populations)
- ◊ Availability of norms

It can be difficult to find measures that satisfy all of these criteria and align with frameworks and stakeholder priorities. There are also differences across sources, journals, and grant review sections on what constitutes appropriate pragmatic measures, such as the emphasis placed on internal consistency and other 'traditional' psychometric criteria as well as the extent to which a measure is face valid, actionable, and easily understood by users.

Key resources for pragmatic measures

A variety of databases exist for identifying measures for pragmatic research. There are two specific resource repositories for pragmatic measures that specifically address how pragmatic a measure is along with information on its psychometric properties (GEM and SIRC).

- ♦ The Grid Enabled Measures resource (https://www.gem-measures.org/Public/Home.aspx) of the National Cancer Institute- see especially sections on a) the Electronic Health Record campaign; and b) the GEM-Dissemination and Implementation initiative 'workspaces'; access these by scrolling on the right hand side of the homepage.
  - ◊ Direct link to D&I measures: https://www.gem-measures.org/public/wsoverview.aspx?cat=8&wid=11&aid=0
- ♦ The Society for Implementation Research Consortium (SIRC) https://societyforimplementationresearchcollaboration.org/sirc-instrument-project/. A subscription is currently required for accessing this information on the SIRC website. On this website, the available measures are specifically scored on a pragmatic rating system, "PAPERS."
- ♦ Information on pragmatic measures is also often included among other more comprehensive sources of information on measures and evaluation procedures in general, such as the Buros mental measurement yearbook). Pragmatic sources of data include existing data sources such as electronic health records, claims data, national surveys (e.g., the Behavioral Risk Factor Surveillance Survey) and Census data.
- ♦ A policy D&I measure database https://www.health-policy-measures.org/
- ♦ UW social determinants of health measure database: https://sdh-tools-review.kpwashingtonresearch.org/

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Worksheet #4 continued

Key References for Pragmatic Measures

1. Glasgow RE, Riley WT. Pragmatic measures: what they are and why we need them. Am J Prev Med. 2013;45:237–43.
2. Weiner BJ, Lewis CC, Stanick CS, Powell BJ, Dorsey CN, Clary AS, et al. Psychometric assessment of three newly developed implementation outcome measures. Implement Sci. 2017;12:1–12.
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Notes:

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Worksheet #5

Training, Partnerships, Funding Opportunities, and Collaborations

Use this worksheet with the following sessions:

Day 1 Networking Lunch: Training and Career Development

Day 2 Networking Lunch: Infrastructure for Pragmatic Science

Day 2 Panel Discussion: Career Paths and a Roadmap to Success

What domains of expertise are needed to successfully plan, obtain funding for, and conduct pragmatic research in your area of health research? Do you personally have - or do you want to obtain - expertise in this area? Do you have - or do you want to establish - a collaboration with an expert in this area? What gaps do you have in your training?

Gap?	Domains	Personal Expertise	Collaborator
	Implementation and Dissemination science		
	Qualitative and mixed methods		
	Practice-based research		
	Stakeholder engagement		
	Statistics/biostatistics		
	Community-engaged research		
	Health equity		
	Electronic health data		
	Health economics/cost analysis		
	Survey measures		
	Systems analysis		
	Policy Research		
	Organizational change		
	Health topic domain expertise		
	Other _____		

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Worksheet #5 continued

Thinking about the settings or contexts in which your pragmatic research will be conducted: What infrastructure do you have access to - or need to connect with - to support research in this context? What gaps do you have in access to partners and settings?

- What partnerships do you have - or need to establish - to conduct this research?
- You need more than just access for success. Have you established clear memoranda of understanding and do you have the support of decision makers?

Gap?	Infrastructure & Partner-ships	Partnership Status (To what extent do you have strong, existing partnerships with supportive contacts?)
	Health system(s)	
	Community organization(s)	
	Database/registry(s)	
	Research network(s)	
	Clinical Translational Science Award (CTSA)	
	Patient, neighborhood or community advocacy group or voluntary association	
	Relevant opinion leaders- formal and informal	
	Other _____	

- What opportunities for training, partnership building, or collaborative team science exist in your gap areas?

- What are three next steps you will take for seeking training, building partnerships or collaborations, or accessing infrastructure for conducting pragmatic research? For instance, **who will you reach out to? What will you write into a career development award? What training programs will you apply to?**

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Worksheet #5 continued

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