GETTING D&I

DISSEMINATION & IMPLEMENTATION IDEAS FUNDED

ANSCHUTZ MEDICAL CAMPUS
June 21st and 22nd

SPEAKERS INCLUDE

Enola Proctor, PhD
Washington University
Center for Mental Health Services Research

Paul Estabrooks, PhD
University of Nebraska Medical Center
College of Public Health

Russell Glasgow, PhD
University of Colorado
Anschutz Medical Campus

TOPICS INCLUDE

Expert advice on getting your grant funded
Identifying funding sources that fit your research area
Separate learning tracks for Beginner and Intermediate/Advanced attendees

AN INTERACTIVE PRAGMATIC WORKSHOP

PARTICIPANT GUIDE

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About this participant guide and workbook

A letter from ACCORDS

Welcome!

Preparing a high quality proposal and demonstrating capacity to conduct a proposed study is essential if we are to be successful in securing funding to conduct dissemination and implementation (D&I) research.

This D&I Training Workshop is sponsored by the Adult and Child Consortium for Health Outcomes and Research Delivery Science (ACCORDS), with co-sponsorship by Colorado Clinical and Translational Sciences Institute (CCTSI), The Veteran's Administration (VA) The Center of Innovation (COIN), Geriatric Research Education and Clinical Center (GRECC), and Triple Aim QUERI (TAQ).

We have designed this workbook as a resource tool for you. We like to think of it as a D&I interactive workbook.

The content is divided into three sections:

- Day 1
- Day 2
- D&I resources

In each section we point you to key references and resources to aid you in further study and application.

We are excited about the national D&I experts who are part of our inaugural training program.

We look forward to your feedback and the D&I community we are forging together in Colorado!

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Bryan Ford

Presenters

Keynote Speaker

Paul Estabrooks, PhD

Dr. Estabrooks is the Harold M. Maurer Distinguished Chair and Professor in the Department of Health, Promotions, Social & Behavioral Health at the University of Nebraska Medical Center. His work focuses on dissemination and implementation research that emphasizes testing innovative physical activity, nutrition, and weight control programs, policies, and practice interventions. Dr. Estabrooks also studies health promotion initiatives that can be adopted, implemented, and sustained in typical community and clinical settings, at a reasonable cost—with a focus on achieving health equity. Dr. Estabrooks is the author of nearly 200 publications, mostly focusing on how best to integrate evidence-based practice into typical community and clinical settings.

Keynote Speaker

Enola Proctor, PhD

Dr. Proctor directs the Center for Dissemination and Implementation for the Institute for Public Health, and the Dissemination and Implementation Research Core (DIRC) of Washington University's Institute for Clinical and Translational Science. Dr. Proctor's teaching and research are motivated by the question: How do we ensure that people receive the very best possible care? In social work, public health and health care settings ranging from hospitals to community agencies, she studies the processes through which organizations and individual providers can adopt and deliver the most effective programs and interventions. Her research and training programs through the Center for Mental Health Services Research have been funded continuously by the National Institute of Mental Health (NIMH) since 1993. Dr. Proctor also leads several national initiatives to advance the science of dissemination and implementation research, including the NIMH-funded Implementation Research Institute (IRI), which trains researchers from across the nation in implementation science for mental health.

David B. Buller, PhD

Dr. Buller is Senior Scientist and Director of Research at Klein Buendel, Inc., a health communication research and media development firm in Golden, Colorado. His research on community-based health communication interventions to prevent cancer and other chronic diseases has been funded by numerous R01 and SBIR grants from the National Cancer Institute (NCI), the Eunice Kennedy Shriver National Institute on Child Health and Human Development (NICHD), the National Institute on Drug Abuse (NIDA), the National Institute on Alcohol Abuse and Alcoholism (NIAAA), and the Centers for Disease Control and Prevention (CDC). Dr. Buller has studied the implementation, and cost of transferring evidence-based interventions from efficacy/effectiveness trials to wide-scale dissemination in randomized trials enrolling organizations from employer to schools to retailers. Specifically, Dr. Buller has studied the implementation, scalability, and cost of an occupational sun protection policy and training intervention with over 200 public and private employers in a series of R01 grants from NCI; implementation and cost of school policies for sun protection of students in over 100 public elementary schools with an R01 grant from NICHD; the conversion of an online responsible beverage service training program into Spanish for predominately Spanish-speaking premises in New Mexico and Texas with an SBIR grant from NIAAA; and the transfer of responsible sales practice training from the alcoholic beverage market to the new recreational marijuana industry in Colorado, Oregon, and Washington State in an SBIR grant from NIDA.

Russell E. Glasgow, Ph.D.

Dr. Glasgow focuses on issues of designing for implementation and sustainability, adaptations to programs, pragmatic models and measures, and the development of dissemination plans. He is Research Professor at the Department of Family Medicine, School of Medicine at the University of Colorado and the Director of the Dissemination and Implementation Program of the Adult and Child Consortium for Health Outcome Research and Delivery Science, as well as Co-Director of the Evaluation Hub at the Department of Family Medicine at the University of Colorado. Dr. Glasgow is the primary developer of the RE-AIM framework for planning and evaluation, he has over 450 publications and has been the recipient of over 20 grants from NIH, AHRQ, CDC and foundations including the Robert Wood Johnson Foundation.

Ed Havranek, MD

Dr. Havranek is the Director of Denver Health's Department of Medicine and a Professor of Medicine at the University of Colorado School of Medicine. He has been a cardiologist at Denver Health since 1991. He graduated from the University of Vermont College of Medicine, with subsequent training in internal medicine at the University of Colorado Health Sciences Center and in cardiology at the University of Wisconsin Hospital. He has experience in large-scale quality improvement as a clinical coordinator for the National Heart Care project, a nationwide quality improvement effort in heart failure and acute myocardial infarction sponsored by the Centers for Medicare & Medicaid Services (CMS). Dr. Havranek has been a site principal investigator in numerous multicenter clinical trials in cardiovascular disease, including in heart failure, atrial fibrillation and myocardial infarction. His current research focuses on health disparities based on race/ethnicity – particularly the effects of bias and stereotyping – and on redesign of healthcare delivery to improve quality and reduce cost.

Jodi Summers Holtrop, PhD, MCHES

Dr. Holtrop is an Associate Professor in the Department of Family Medicine and Senior Implementation Scientist with the Adult and Child Consortium for Health Outcomes Research and Delivery Science (ACCORDS) and the Center on Aging at the University of Colorado Denver School of Medicine. She is additionally Senior Scientist for the American Academy of Family Physicians National Research Network. Dr. Holtrop has extensive experience as a principal or co-investigator on NIH, AHRQ, PCORI, RWJF and other funded studies. Her expertise is in the use of qualitative and mixed methods, including the use of theoretical models and frameworks to understand how implementation works and to produce generalizable findings regarding the how, why, who and what of interventions. Additionally, she is a master certified health education specialist (MCHES) with expertise in patient education and health behavior change. Her own research is focused on how to make health promotion and disease prevention an integrated part of primary care.

Amy Huebschmann, MD, MS, FACP

Dr. Huebschmann is an Associate Professor in the University of Colorado School of Medicine with the Division of General Internal Medicine and the Center for Women's Health Research. She is funded by a K23 career development award from the National Heart Lung Blood Institute of the National Institutes of Health and was previously funded by a KL2 award from the Colorado Clinical and Translational Sciences Institute. Her overarching research goal is to reduce the burden of cardiovascular disease in people with type 2 diabetes by overcoming barriers to physical activity and by optimally controlling other cardiovascular risk factors such as hypertension. To achieve this overarching goal, Dr. Huebschmann seeks to work with clinics and communities to implement evidence-based programs to promote physical activity for people with type 2 diabetes.

Bethany M. Kwan, PhD, MSPH

Dr. Kwan is a social health psychologist and an Assistant Professor in the Department of Family Medicine at the University of Colorado School of Medicine. She is a dissemination and implementation scientist in ACCORDS, where she also serves as Education Program lead. She is the dissemination core lead for the CU Data Science to Patient Value (D2V) initiative. Dr. Kwan's work includes health services research and evaluation, patient-centered outcomes research, and dissemination and implementation of evidence-based interventions in health care settings. She has a particular interest and expertise in the application of psychological theory and health information technology (HIT) to the study of chronic disease self-management and health behavior change.

Daniel D. Matlock, MD, MPH

Dr. Matlock is the Director of the Shared Decision Making Core at ACCORDS (The Adult and Child Consortium for Outcomes Research and Delivery Science). He is board certified in Internal Medicine, Geriatrics, and Palliative care. His research is aimed at fundamentally changing and improving how patients make decisions around invasive cardiovascular technologies. He has been funded under an NIH career development award, three NHLBI R01s (two Co-I, one PI), and three PCORI projects studying shared decision making among older adults making decisions around invasive technologies. He has participated in the American College of Cardiology's shared decision making task force and he is also an active participant of the International Patient Decision Aid Standards writing committee. Recently, he has also been named Director of Implementation Research for the Denver Veterans Affairs Geriatric Research, Education, and Clinical Center.

Demetria M. McNeal, PhD, MBA, CPLP

Dr. McNeal is an academically trained health communication scientist with prior corporate healthcare experience as well as clinical experience. Her unique skillset positions her to advance the field of dissemination and implementation science through novel approaches to improve patient outcomes and health care delivery. Dr. McNeal is a Postdoctoral Fellow in the University of Colorado Adult and Child Consortium for Health Outcomes Research and Delivery Science (ACCORDS) D&I Program and the School of Public Health, Department of Health Systems Management & Policy. As a rising Dissemination & Implementation Scientist, her research goals are to increase health equity and reduce health disparities in chronic disease management, such as diabetes, in the African American population. Dr. McNeal strives to implement sustainable health interventions in institutional and community healthcare settings.

Elaine Morrato, DrPH, MPH

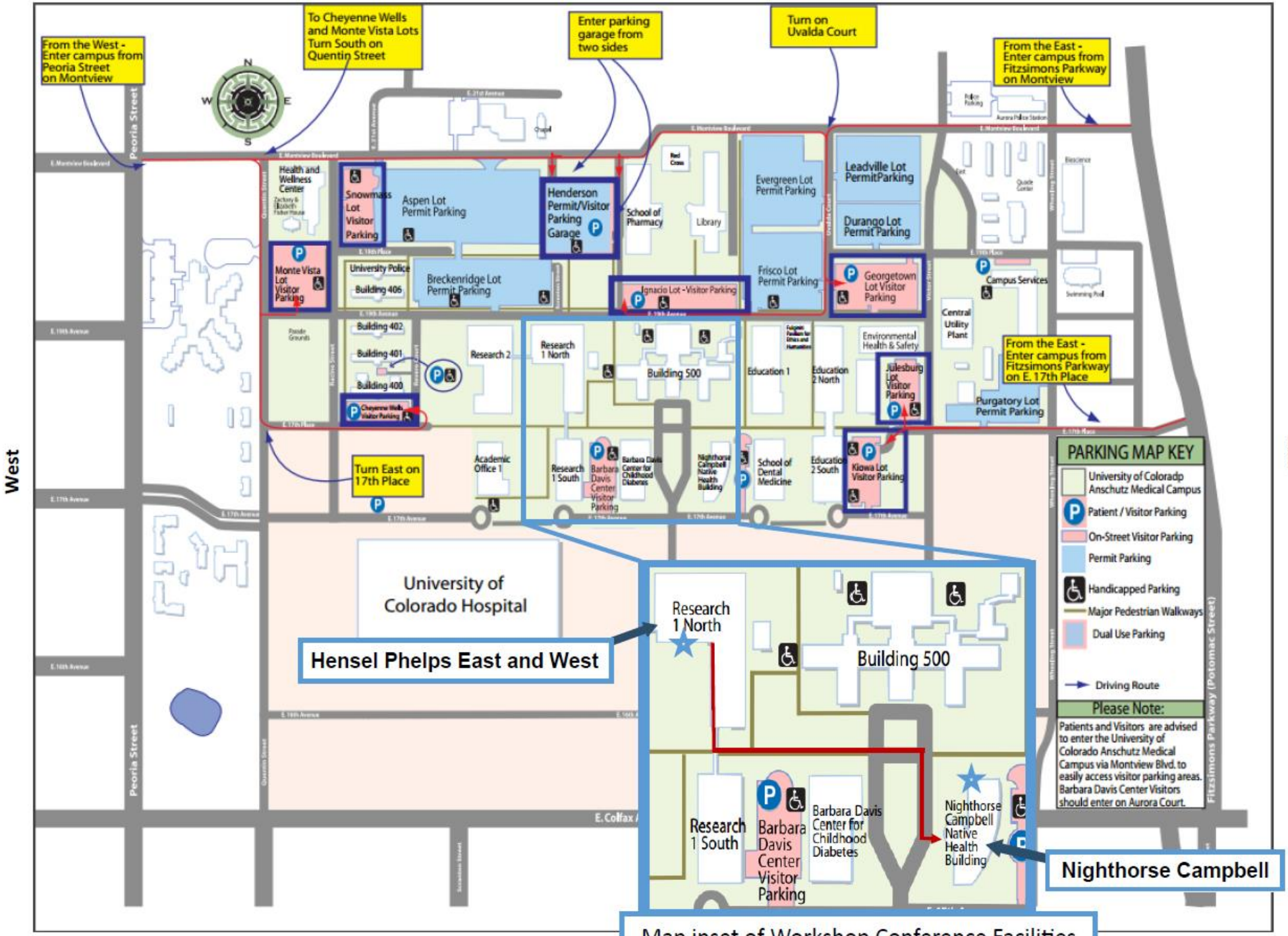
Dr. Morrato is the Interim Dean and Associate Dean for Public Health Practice at the Colorado School of Public Health. Dr. Morrato is a senior dissemination and implementation scientist at the Adult & Child Consortium for Health Outcomes Research and Delivery Science (ACCORDS). Her research focuses on accelerating the translation of medical innovation and drug warnings into clinical practice. Dr. Morrato's 15-year tenure in Procter & Gamble's healthcare division launching new drugs and indications informs her implementation research and practice. She advises the FDA on drug safety and risk management implementation. Dr. Morrato also directs the Pragmatic Trials and Dissemination and Implementation Research program in the Colorado Clinical & Translational Sciences Institute (CCTSI). She is Site-PI for two NCATS initiatives: Dissemination Core Director for the Accrual to Clinical Trial (ACT) program and the Innovation-Corps (I-Corps™) commercialization training program.

Debra P. Ritzwoller, PhD

Dr. Ritzwoller is a health economist and senior investigator at the institute for Health Research, Kaiser Permanente Colorado (KPCO IHR). She has over two decades of experience leading or collaborating on numerous large, complex multi-site NIH-funded projects. Much of her research has been related to consulting and cost-effectiveness of behavioral interventions, and she has authored or co-authored more than a dozen manuscripts related to economic analysis and dissemination and implementation research. Specifically, the focus of this work had been on the implementation costs associated with the broad dissemination of effective interventions within and across heterogeneous community practices.

Contents

Map of Workshop Conference Facilities



Map inset of Workshop Conference Facilities

Getting Dissemination and Implementation (D&I) Science Ideas Funded – An Interactive, Pragmatic Workshop

Day 1 -- Wednesday, June 21

Day 1 Objectives:

- Clarify the distinct features of a D&I grant proposal versus a clinical grant proposal with D&I components versus other types of proposals
- Identify key tips, strategies, and important steps in the development of innovative and high quality D&I grant proposal ideas

Day 1 Agenda Location: Hensel Phelps East Auditorium

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Topic	Title	Time	Speakers	Activity
Registration & Continental Breakfast		7- 8:30 am		Network with colleagues
Welcoming Remarks		8:30 -9 am	Elaine Morrato, DrPH and Russell Glasgow, PhD	Brief welcome and introduction to the conference from ACCORDS (Dr. Morrato) and overview of D&I case example and workbook (Dr. Glasgow)
Keynote Address	***Writing D&I grants: Getting started in a fast-moving field***	9:00 – 10 am	Enola Proctor, PhD	Introduce the audience to D&I grant writing --how the field is changing and how funding is also evolving.
BREAK		10-10:20 am		
Learning Track – Session 1	*Beginner/Intermediate D&I Track*: ***Recognize key ingredients to include when starting a D&I grant proposal*** *Advanced D&I Track*: ***Specialized Tips and Strategies to refine an existing D&I grant idea into a fundable proposal***	10:20-11:30 am	Demetria McNeal, PhD, MBA (Ben Nighthorse Campbell Building – Room 110, Shore Family Forum room) Amy Huebschmann, MD, MS (Hensel Phelps East)	Participants will be guided step-by-step to complete a work sheet related to their personal D&I grant proposal ideas – these presentations will incorporate the learning case example from the welcoming remarks and will demonstrate use of the CU ACCORDS D&I website to guide the process

PICK UP BOX LUNCHES/BREAK		11:30 -12 pm		Pick up lunch for breakout sessions
INTERACTIVE LUNCH BREAKOUT SESSIONS:	*Overarching goal of lunch sessions:* ***To recognize how key methodologic aspects may be applied to a case example D&I grant proposal***	12 -1:20 pm	Workshops: ***See full list of the 5 workshops below***	These 20-minute interactive sessions repeat at noon, 12:30 pm, and 1 pm, in order to allow people to select 3 separate sessions to attend

Lunch breakout session schedule:

RC1-North rooms	12 noon	12:30 pm	1 pm
Hensel Phelps East	**D&I frameworks – what are they and how to choose? -Jodi Holtrop, PhD (pg. 29)**	**Hybrid D&I RCT designs – balancing effectiveness and implementation measures -Dan Matlock, MD, MPH (pg. 31)**	**D&I frameworks – what are they and how to choose? -Jodi Holtrop, PhD (pg. 29)**
Room 1103	**Selecting Pragmatic outcomes for D&I research that are relevant to stakeholders -Bethany Kwan, PhD (pg.32)**	**Selecting Pragmatic outcomes for D&I research that are relevant to stakeholders -Bethany Kwan, PhD (pg.32)**	**Selecting Pragmatic outcomes for D&I research that are relevant to stakeholders -Bethany Kwan, PhD (pg.32)**
Room 1104	**Balancing necessary adaptations and modifications in D&I research with fidelity – the Adaptome model by David Chambers -Amy Huebschmann, MD, MS (pg. 33)**	**Balancing necessary adaptations and modifications in D&I research with fidelity – the Adaptome model by David Chambers -Amy Huebschmann, MD, MS (pg. 33)**	**Balancing necessary adaptations and modifications in D&I research with fidelity – the Adaptome model by David Chambers -Amy Huebschmann, MD, MS (pg. 33)**
Room 1105	**Assessing replication costs and economic outcomes for D&I research -Deb Ritzwoller, PhD (pg.34)**	**Assessing replication costs and economic outcomes for D&I research -- -Deb Ritzwoller, PhD (pg.34)**	**Assessing replication costs and economic outcomes for D&I research -- Deb Ritzwoller, PhD (pg.34)**
Room 1107	**Sustainability – how do you design programs to support sustainability? -Elaine Morrato, DrPH (pg.35)**	**Sustainability – how do you design programs to support sustainability? -Elaine Morrato, DrPH (pg.35)**	**Sustainability – how do you design programs to support sustainability? -Elaine Morrato, DrPH(pg.35)**

BREAK	1:20-1:45 pm	

Learning Track – Session 2	*Beginner/Intermediate D&I Track:* ***How to Use the Pragmatic Explanatory Continuum Indicator Summary (PRECIS-2) tool to guide your D&I research design*** *Advanced D&I Track*: ***How to incorporate RE-AIM into your CONSORT diagram – the rationale and application of the expanded CONSORT diagram***	1:45 - 2:30pm	Bethany Kwan, PhD (Ben Nighthorse Campbell Building – Room 110, Shore Family Forum room) Russell Glasgow, PhD (Hensel Phelps East)	Speakers will apply the concepts to the learning case example: PRECIS-2 and the rationale for the expanded CONSORT diagram.
BREAK		2:30-2:45 pm		
Plenary demonstration	***Don't Just "Google It": Effective, evidence-based D&I Resources***	2:45-3:15 pm	Dan Matlock, MD, MPH	Speaker will demonstrate the uses of several D&I website resources with regard to the learning case example.
Plenary discussion	Campfire Chat: a review of common themes and ideas across sessions	3:15-4 pm	Panel: Drs. Glasgow, Proctor, and Estabrooks	Feedback

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Getting Dissemination and Implementation (D&I) Science Ideas Funded – An Interactive, Pragmatic Workshop

Day 2-- Thursday, June 22

Day 2 Objective:

- To compare the evolving priorities and opportunities for funding for Career Development Awards (e.g., K-awards or similar) and for Independent research awards (e.g., R01 or similar) of several prominent D&I research funders: National Institutes of Health- including SBIR, AHRQ, VA QUERI program, and PCORI.

Day 2 Agenda

Location: Hensel Phelps East Auditorium

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Topic	Title	Time	Speaker	Activity
Continental Breakfast		7:00-8 am		Networking
Keynote Address	***Practical use of D&I outcomes, theories, and research designs***	8:00-9 am	Paul Estabrooks, PhD	
	Where's the Money? Applying for Funding Through Common & Uncommon Sources	9:00-10 am	**Moderator:** Amy Huebschmann, MD, MS Panelists: **PCORI** (Bethany Kwan, PhD) **SBIR/STTR** (David Buller, PhD) **VA QUERI** (Marina McCreight, MA) **AHRQ** (Jodi Holtrop, PhD) **NIH** (Ed Havranek, MD and Russ Glasgow, PhD)	
BREAK		10:00-10:15 am		
Learning Track – Session 3	*Beginner/Intermediate track* – ***To recognize how to utilize D&I research approaches to improve health disparities***	10:15-11 am	Paul Estabrooks, PhD and Demetria McNeal, PhD, MBA (Hensel Phelps West)	
	Advanced track – ***Advanced approaches to utilizing Mixed Methods in D&I research***		Jodi Holtrop, PhD (Hensel Phelps East)	

Behind the Curtain Study Section — a grant review skit	11-11:45 am	Chair: Dr. Estabrooks; Reviewers 1-3: Drs. Glasgow, Holtrop, and Matlock	To understand common grant reviewer critiques of D&I grants
CONCLUSION/Wrap-up	11:45-noon	Dr. Glasgow	
Working Lunch – Group D&I Consultations (selected participants ONLY) **Rooms 1103, 1104, 1105, 1107**		12:00 noon – 2:00 pm	The attendees whose D&I grant concept ideas were accepted will pick up their box lunch and then discuss their proposed ideas with D&I experts (2 experts and up to 4 attendees per small group).

Dissemination and Implementation

as defined by the National Institutes of Health…

"Dissemination *is the targeted distribution of information and intervention materials to a specific public health or clinical practice audience. The intent is to spread ("scale up") and sustain knowledge and the associated evidence-based interventions.*

Implementation *is the use of strategies to adopt and integrate evidence-based health interventions and change practice patterns within specific settings....*

Dissemination and implementation research *intends to bridge the gap between public health, clinical research, and everyday practice by building a knowledge base about how health information, interventions, and new clinical practices and policies are transmitted and translated for public health and health care service use in specific settings."*

Source: Department of Health and Human Services. *Part 1 Overview Information Dissemination and Implementation Research in Health* (R01). http://grants.nih.gov/grants/guide/pa-files/PAR-13-055.html.

Evidence-based intervention

The objects of D&I activities are interventions with proven efficacy and effectiveness (i.e., evidence-based). Interventions within D&I research should be defined broadly and may include programs, practices, processes, policies, and guidelines. More comprehensive definitions of evidence-based interventions are available elsewhere. In D&I research, we often encounter complex interventions (e.g., interventions using community-wide education) where the description of core intervention components and their relationships involve multiple settings, audiences, and approaches.

Adoption

Adoption is the decision of an organization or community to commit to and initiate an evidence-based intervention.

Sustainability

Sustainability describes the extent to which an evidence-based intervention can deliver its intended benefits over an extended period of time after external support from the donor agency is terminated. Most often sustainability is measured through the continued use of intervention components; however, Scheirer and Dearing suggest that measures for sustainability should also include considerations of maintained community or organizational-level partnerships, maintenance of organizational or community practices, procedures, and policies that were initiated during the implementation of the intervention, sustained organizational or community attention to the issue that the intervention is designed to address, and efforts for program diffusion and replication in other sites. Three operational indicators of sustainability are: (1) maintenance of a program's initial health benefits, (2) institutionalization of the program in a setting or community, and (3) capacity building in the recipient setting or community.

Reinvention/adaptation

For the success of D&I, interventions often need to be reinvented or adapted to fit the local context (i.e., needs and realities). Reinvention or adaptation is defined as the degree to which an evidence-based intervention is changed or modified by a user during adoption and implementation to suit the needs of the setting or to improve the fit to local conditions. The need for adaptation and understanding of context has been called Type 3 evidence (i.e., the information needed to adapt and implement an evidence-based intervention in a particular setting or population). Ideally, adaptation will lead to at least equal intervention effects as is shown in the original efficacy or effectiveness trial. To reconcile the tension between fidelity and adaptation, the core components (or essential features) of an intervention (i.e., those responsible for its efficacy/effectiveness) must be identified and preserved during the adaptation process.

Dissemination strategy

Dissemination strategies describe mechanisms and approaches that are used to communicate and spread information about interventions to targeted users. Dissemination strategies are concerned with the packaging of the information about the intervention and the communication channels that are used to reach potential adopters and target audiences. Passive dissemination strategies include mass mailings, publication of information including practice guidelines, and untargeted presentations to heterogeneous groups. Active dissemination strategies include hands on technical assistance, replication guides, point-of-decision prompts for use, and mass media campaigns. It is consistently stated in the literature that dissemination strategies are necessary but not sufficient to ensure wide-spread use of an intervention.

For additional terms see Rabin, B.A. and Brownson, R.C. (2012). Developing the terminology for dissemination and implementation research in health. In Brownson, R.C., Colditz, G.A., & Proctor, E.K. (Eds.), *Dissemination and Implementation Research in Health: Translating Science to Practice*. New York: Oxford University Press or visit http://makeresearchmatter.org/glossary.aspx

DAY 1 (TAB)

D&I workshop case vignette and worksheet:

Adapting the Diabetes Prevention Program for implementation with pregnant women

The Diabetes Prevention Program (DPP) is a highly effective and robust lifestyle counseling intervention that was originally designed to compare the effectiveness of intensive behavioral dietary and physical activity counseling on outcomes of incident type 2 diabetes for adults with a diagnosis of prediabetes. Prediabetes is a measurement of impaired glucose metabolism that is linked to obesity and sedentary behavior, as well as genetic predisposition or a past history of gestational diabetes during pregnancy.

The DPP was highly successful—it lowered the incidence of type 2 diabetes mellitus by >60% in participants randomized to the lifestyle intervention group as compared to the usual care group, and the lifestyle intervention was also more effective than the pharmacological (metformin) group. Due to its success, the DPP has been adapted for implementation in many different populations, including culturally sensitive adaptations developed through community-based participatory research that adapt the intervention to incorporate cultural preferences. In addition, the DPP has been adapted by businesses such as Omada Health, and in YMCAs across the country in ways that seek to enhance its scalability.

For this workshop, we will utilize a case vignette of a researcher who is seeking to adapt the DPP for implementation ***with pregnant women in a safety-net health system***. We will consider the range of D&I perspectives that are relevant for this researcher, including the type of D&I framework to utilize, considering potential adaptations to the standard DPP program to enhance its adoption and maintenance by the clinical organizations that serve the target population of pregnant women, and the research design methods that are appropriate to measure the program's effectiveness in the target population (pregnant women) and the program's impact – both positive and negative— on the organizations that deliver the program.

Acknowledgement: Special thanks to Dr. Kate Sauder, who allowed us to incorporate elements of this vignette from her research.

MY NOTES on this vignette's PURPOSE and CONTENT from Dr. Glasgow's introduction:

Issues to consider while attending D&I workshop presentations- Make notes on *options and choices* for a D&I research design addressing this case vignette in the following areas:

Factors that compose the Pragmatic Explanatory Continuum Indicator Summary – version 2 (PRECIS-2) and RE-AIM dimension criteria:

Eligibility Criteria– the extent to which participants in the trial are similar to those who would potentially receive the intervention in the usual care setting

Recruitment Path – how much extra effort is made to recruit participants over and above what would be used in the usual care setting to engage with patients

Setting and Staff– the difference in the settings and implementing staff of the trial from the usual care setting where the results are likely to be applied

Organization (Feasibility) – the difference between the resources, provider expertise, and the organization of care delivery employed in the intervention arm of the trial and those available in usual care

Flexibility (delivery by intervention staff) – the difference in flexibility of intervention delivery compared to the flexibility anticipated in usual care

Flexibility (adherence) – the difference in the flexibility in how participants engage with the intervention compared to the flexibility anticipated in usual care

Follow-up (how closely are patients followed up) – the difference in the intensity of follow-up of participants during the trial compared to the typical follow-up expected in usual care

Primary Aims and Outcome – the extent to which the trial's primary outcome is directly relevant to participants and other stakeholders

Analysis (Intention-to-Treat; vs. supplemented by per protocol) – the extent to which all data is included in analysis of the primary outcomes

Other external validity factors related to the Reach, Effectiveness, Adoption, Implementation, and Maintenance (RE-AIM) model that were not included in PRECIS-2:

Participant Engagement (the extent to which participants' used all parts of the physical activity intervention, including services/materials)

Adaptation/Change (extent of intervention modifications; corrections during study)

Unintended Effects (extent to which harmful or beneficial consequences were reported)

Monetary Costs of Existing Treatment (extent to which costs of the intervention are costly for a patient-centered medical home type of clinic)

Program Sustainability (extent of efforts to continue behavioral intervention after study)

Rapid developments in the field

How has the field of D&I research advanced in the past decade?

Challenges facing implementation science grant writers?

What factors make implementation science a challenging field to move into?

Tips for grant writing

Through what sections of a grant proposal can you demonstrate your ability to feasibly complete an innovative and rigorously designed study?

Where can you find grant writing resources for implementation science?

Writing implementation research grant proposals: ten key ingredients by Enola K. Proctor, Byron J.Powell, Ana A. Baumann, Ashley M. Hamilton and Ryan L . Santens

I. THE SIGNIFICANCE OF THE RESEARCH QUESTION:

By definition, implementation research in health focuses on a _____ _____ or disease, _____ _____, and particular evidence-based intervention and programs with promise of _____ a _____ in quality of care.

The application must have _____ to advance the science of implementation by yielding _____ knowledge.

Grant proposals must balance _____ with _____ _____.

II. GUIDANCE FROM GRANT PROGRAM ANNOUNCEMENTS:

Grant review focuses on the _____ of proposed aims, impact and innovation, _____ _____ to conduct the study as proposed, and support for the _____ _____ and research design.

The more complex the project, the more important it is to provide evidence of _____ and _____.

Table 1 Ten key ingredients for implementation research proposals

Proposal ingredient	Key question	Review criteria	Check (yes/no)
1. The care gap or quality gap	The proposal has clear evidence that a gap in quality exists?	Significance Impact	
2. The evidence-based treatment to be implemented	Is the evidence for the program, treatment, or set of services to be implemented demonstrated?	Significance Innovation	
3. Conceptual model and theoretical justification	The proposal delineates a clear conceptual framework/theory/ model that informs the design and variables being tested?	Approach Innovation	
4. Stakeholder priorities, engagement in change	Is there a clear engagement process of the stakeholders in place?	Significance Impact Approach Environment	
5. Setting's readiness to adopt new services/treatments/programs	Is there clear information that reflects the setting's readiness, capacity, or appetite for change, specifically around adoption of the proposed evidence-based treatment?	Impact Approach Environment	
6. Implementation strategy/process	Are the strategies to implement the intervention clearly defined, and justified conceptually?	Significance Impact Innovation	
7. Team experience with the setting, treatment, implementation process	Does the proposal detail the team's experience with the study setting, the treatment whose implementation is being studied, and implementation processes?	Approach Investigator team	
8. Feasibility of proposed research design and methods	Does the methods section contain as much detail as possible, as well as lay out possible choice junctures and contingencies, should methods not work as planned?	Approach Investigator team	
9. Measurement and analysis section	Does the proposal clarify the key constructs to be measured, corresponding to the overarching conceptual model or theory?	Approach Investigator team	
	Is a measurement plan clear for each construct?		
	Does the analysis section demonstrate how relationships between constructs will be tested?		
10. Policy/funding environment; leverage or support for sustaining change	Does the proposal address how the implementation initiative aligns with policy trends?	Impact Significance	

References

1. Proctor, E. K., Powell, B. J., Baumann, A. A., Hamilton, A. M., & Santens, R. L. (2012). Writing implementation research grant proposals: ten key ingredients. *Implementation Science,* 7(1), 96-108. doi:10.1186/1748-5908-7-96.

Notes:

Key Ingredients to Writing Successful D&I Research Proposals

Getting Started: Is this a good D&I research question?

- A significant and innovative research question that is appropriate for Dissemination and Implementation science (D&I) is the first and primary ingredient in a successful proposal.
- Programs ready for D&I should show promise of reducing a gap in quality of care. D&I studies should be conducted in real world settings with representative patients and, in general, delivered by regular staff rather than researchers. See "ingredient 1" on the checklist below for more details.
- D&I research in health focuses on a health condition or disease(s) in healthcare or community settings, and particular interventions or policies that are already evidence-based (e.g., in efficacy or effectiveness studies, systematic reviews, clinical care guidelines, etc.). See "ingredient 2" on the checklist below for more details.

10 Key Ingredients Checklist: (especially for new investigators and initial ideas)

Although we have framed this as a checklist, we recognize that it may be impossible to get all 10 ingredients in any given project. Click the box to check each item that you have addressed at least moderately well.

☐ 1. The Quality Gap or Care Gap:

- Provide clear evidence that a modifiable gap in care/quality exists at the population, organization or provider level.
- Include the following types of evidence of a Quality Gap:
  - Wide variation in care delivery, or poor/suboptimal care delivery – cite references in Significance
  - Potential to improve care through the proposed work – present Preliminary Data and/or Significance

☐ 2. The Evidence-Based intervention or policy to be implemented or disseminated:

- Does the evidence demonstrate the efficacy/effectiveness of the program to be implemented?
- Can you support that you are using an evidence-based treatment?
  - Some experts suggest a minimum standard of demonstrated efficacy by at least 2 separate investigators using a manualized intervention.
  - Even stronger evidence would include the use of a program that has been promoted in an evidence-based guideline, systematic review, or promoted by 3rd parties as an effective program: Cochrane Review; CDC list of community health programs, especially related to tobacco and obesity; National Cancer Institute Research Tested Intervention Program related to cancer control/prevention; Canadian Best Practices Portal; Laura and John Arnold Foundation.

☐ 3. Conceptual model/theoretical framework:

- Propose a clear conceptual model or theoretical framework that justifies the key relationships and variables that will be tested.
  - Even studies that address only a subset of variables within a conceptual model need to be framed conceptually, so that reviewers perceive the larger context (and body of literature)
- Present an overarching D&I model or D&I Theory to guide the investigation
  - Consider carefully which model or theory is most appropriate for your work—you may benefit from consultation with an expert D&I consultant
  - Examples of D&I models: Reach, Effectiveness, Adoption, Implementation, Maintenance (RE-AIM); Consolidated Framework for Advancing Implementation Science (CFIR)
  - Examples of D&I theories: Rogers' Diffusion of Innovation theory
- Incorporate the D&I models/theories into the Approach, including measures and analyses – a mere mention of the model will not suffice

☐ 4. Stakeholder priorities and engagement in change:

- Demonstrate that your program has a good fit with the preferences and priorities of those who shape, deliver, and participate in healthcare
    - Minimum requirement: include letters of support from stakeholders that highlight the shared priorities
    - If at all possible, include relevant preliminary qualitative or quantitative data demonstrating that stakeholders are engaged. Even better, publish such data with stakeholders as co-authors.
- Stakeholders may include all of the following, and will vary by project: health system administrators (or community organization leaders), health providers and staff (or community organization staff), patients and families (or community members), policymakers.

☐ 5. Setting's readiness to adopt a new intervention:

- Beyond your specific setting - include citations on any innovations in the organizational and policy context that will influence setting's readiness for change.
- Specific to your sites – include preliminary data regarding your settings' appetite for change concerning the evidence-based practice that you propose. If no data are available, letters can also convey this type of information, albeit less strongly.
- Avoid cherry-picking sites for implementation that you know will adopt intervention well, as reviewers know that this will incompletely inform broader dissemination efforts.

☐ 6. Implementation strategy/process:

- At present, D&I research seeks to go beyond identifying barriers to implementation to "raise the bar" and generate knowledge about the D&I strategies that can overcome such barriers.
- To this end, it is extremely helpful to use existing implementation science strategy models to define proposed mechanisms by which you hypothesize that your implementation strategies will exert their effects, such as the WIDER and SQUIRE models.

☐ 7. Team experience with the setting, treatment, implementation process, and review environment.

- Include an experienced D&I researcher on the research team, as well as other investigators needed to address the methods required for the project (e.g., mixed methods, biostatistician, health economist).
- Convey the team's expertise and the D&I infrastructure in your institution in several places, including the grant narrative, biosketches, budget justification, and the environment sections of the grant.

☐ 8. Feasibility of Proposed Research Design and Methods

- Preliminary data should include data on as many of the following categories as possible:
    - referral flow;
    - participant entry into the study;
    - participant retention;
    - the extent to which key measures are feasible to use, understood by participants, acceptable for use, are sensitive to change, and capture variability
    - demonstrate that the proposed methods are likely to work.

☐ 9. Measurement and Analysis

- Make sure you are measuring each key construct in the guiding theory (see ingredient #3 above-Conceptual Model/Theoretical Framework)
- Ensure measurements of fidelity to key components AND adaptation of the intervention or implementation strategies
- Consider the use of measures from the National Cancer Institute's Grid-Enabled Measures (GEM), the NIH PROMIS measures set; or the Comprehensive Review of D&I Science Instruments supported by the Seattle Implementation Research Conference (SIRC) at the University of Washington

☐ 10. Policy environment will leverage, support, and sustain the change

- Address how the proposal aligns with current and anticipated policy changes, as this enhances the public health significance of the project and likelihood of adoption and sustainability.

June 21, 2017 - **Specialized Tips and Strategies to refine an existing D&I grant idea into a fundable proposal**

Presented by Amy G. Huebschmann, MD, MS *10:20am Hensel Phelps East*

With attribution to Brownson RC,Colditz GA, Dobbins M, Emmons KM, Kerner JF, Padek M, Proctor EK, Stange KC. Concocting that Magic Elixir: Successful Grant Application Writing in Dissemination and Implementation Research. *Clin Transl Sci*, 2015 Dec;8(6):710-6. doi: 10.1111/cts.12356.

Introduction

- Dissemination and Implementation (D&I) Science is a relatively new field — the standing D&I study section for the National Institutes of Health was only established in 2010
- Establishing a common list of core competencies for outstanding dissemination and implementation (D&I) grants may be useful both to applicants and reviewers
- Recently, several authors with a combined 170 years of expertise in D&I grant writing and reviewing, including serving as chair of the standing D&I NIH study section, developed a list of core competencies for writing a successful proposal (Brownson et al., *Clin Transl Sci,* 2015).
- Our D&I core at the University of Colorado Adult and Child Consortium for Outcomes Research and Delivery Science (ACCORDS) has worked with Dr. Brownson to adapt these core competencies into a web-based guide for researchers that I will demonstrate with regard to a case example of implementing the Diabetes Prevention Program into prenatal care for overweight pregnant women.

Methods

- **A group of D&I faculty experts developed a list of D&I grant competencies. A card-sorting activity was conducted with 300 individuals who had received DI training, in order to identify core competencies for successful D&I grant applications.**

Results

- Twelve competencies for successful D&I grants were identified – these were mapped onto the relevant grant sections for National Institutes of Health (NIH) grant applications (Table).
- The authors also expanded these competencies into several specialized tips and strategies for each section of NIH grants — we have adapted these recommendations into a “D&I Grant Preparation Checklist” document in your workbook.
- We are also in the process of developing a web-based tool to use for self-assessment that allows navigation to D&I resources in areas of self-identified need. We would LOVE your feedback on this evolving tool to help make it even better: http://www.crispebooks.org/DIFundingTipsPreview

Application

- In this session, we will utilize the web-based version of the D&I Grant preparation checklist to assess the case vignette example
- **Following this group exercise, there will be time for each of you to self-assess your own current D&I grant idea with regards to the D&I Grant preparation checklist.**

Why is this Important?

- Given the increasing competitiveness of D&I grant funding, it is critical to systematically address the core competencies of D&I grants. Following the recommendations of seasoned D&I proposal reviewers is a helpful guide to improve your chances of competing successfully for D&I funding.

Grant Preparation Checklist – ***accessible online with active web links at:***

http://www.ucdenver.edu/academics/colleges/medicalschool/programs/ACCORDS/sharedresources/DandI/Pages/Getting-Funded.aspx

Rate yourself on a 1-5 scale for how well you have addressed each issue below (1= completely; 3= fairly well; 5 = not clearly or thoroughly). For those areas in which you score 3 or higher you may want to *click on the relevant link for resources* to help you improve this feature**. (this feature not currently available- check back next month).**

General Tips and Issues to Address*:*

- Be clear (have several people read your aims)
- Use tables and figures for key issues such as:
  - Recruitment expectations (expanded CONSORT figure that addresses D&I elements)
  - Components of intervention(s) and comparison condition(s)
  - Key measures/outcomes
- Anticipate challenges- explain your choices nondefensively. Consider using headings to bring attention to sections that you expect reviewers will scrutinize.
- These are *guidelines*, not gospel.

Self-rating (1-5)	**Abstract:** • Include key content relevant to funder and review group; • Summarize aims, study design, key outcomes, number and characteristics of subjects, and implications for public health/impact/funder mission. • This section should help non-experts to understand your project and communicate how your proposal relates to key funder interests or mechanisms
Self-rating (1-5)	**Specific Aims:** (1 page) • Provide a brief rationale—state the quality gap and how this application addresses the quality gap; • Specify what is proposed- design; measures; settings/subjects; • Include 2-4 well-articulated aims (what outcomes on what variables, compared to what). • Communicate what is innovative and important implications for impact on public health/clinical practice. • Consider including a brief rationale for each aim • Consider following each aim with a sentence on the methods used to accomplish this aim and the importance of the anticipated findings. • Aims should be related but not contingent upon each other • *Come back to aims in various sections*- measures, analyses, etc. to show how the aims are addressed
Self-rating (1-5)	**Significance/Background**: • Specify need for this research- and how this proposal addresses them • BRIEFLY describe the state of the science, include key references, especially classic and recent ones; • Address how this fits the priorities of the funding mechanism and funder. • Keep BRIEF (~1 page) to allow room for detailed APPROACH
Self-rating (1-5)	**Innovation**: • BRIEFLY describe the novel products that will stem from this proposal, such as implementation toolkits; • Does this advance theory, methods, impact, and/or application in high risk populations (hopefully more than one of these). • Address how this work fits with recent or upcoming changes in health policy, reimbursement or clinical practice. • Keep BRIEF (~1/2 page) to allow room for detailed APPROACH

Self-rating (1-5)	**Approach – general requirements**: • Well-reasoned and appropriate overall strategy, methodology, and analyses; • Are potential problems, alternative strategies, and benchmarks for success presented? • If the project is in the early stage of development, will this proposal establish feasibility and how will potentially risky aspects be managed? • See below for additional recommendations for particular aspects of the Approach
Self-rating (1-5)	**Preliminary Studies:** • Focus on your own work; • If studying an evidence-based program, then the supporting evidence-e.g., if any Cochrane or systematic reviews, recommendations or guidelines, followed by your pilot feasibility work and overall expertise, experience, capabilities of your team in this research area; • Include experience and synergy of your team- how members have worked together. • Again, keep relatively brief (~1/2-1 page of preliminary data for each aim)

APPROACH: This is the **most important and heavily weighted** section in reviews; be thorough and clear. Use a logical sequence that maps back to your aims; include tables and figures to break up and clarify text. Show what is innovative about your approach- in terms of theory, methods, intervention, impact, and setting. See tips for writing your approach.

Self-rating (1-5)	**Conceptual Framework/Theory:** • Select one or at most two theories or models, usually for both the intervention (if applicable) and the evaluation. • Make sure your selected theory/model(s) fits your problem, context, aims, and level(s) of analysis. • Use the model throughout- show how it explains results, is integrated into intervention components, implementation strategies, measures, hypotheses, and analyses. • Show you understand the model and implications- not just giving lip service. See also: On-line interactive Framework selection tool.
Self-rating (1-5)	**Recruitment:** • Selection of sample at **each level** of *setting(s), staff, and patients*. • How did you sample, how many and what type are you recruiting; • How many and characteristics of those invited are estimated to participate- at each of above levels. • Be realistic; base estimates on prior work. • Convince reviewers that you are sensitive to the need to include high-risk populations and sensitive to potential sources of recruiting bias, delays, etc. (Most proposals do not meet recruitment goals on time) • How will you approach participants at each level above to educate, inform, engage them- and maintain their participation? See sample 'Extended CONSORT' recruitment Figure
Self-rating (1-5)	**Research Design**: • Specify and provide the rationale for the design selected as most appropriate for this question in this setting. • How does this design address potential threats to internal *and external validity*? • What are the strengths and limitations of this design compared to alternative choices you might have selected (or that reviewers might be expecting)? See Designs for D&I research. • What challenges may come up- e.g. contamination, policy changes disrupting the program, secular trends, etc. and how will they be dealt with?

	• Especially if your design is for a pragmatic trial or comparative effectiveness research, demonstrate how- using the PRECIS-2 wheel or other criteria- your design is pragmatic. • If a comparative study, consider carefully and justify your choice of a comparison condition (e.g., if comparative effectiveness research, then both or all alternative interventions need to be 'real world' alternatives'. See CER that will translate. • Consider mixed methods or qualitative research to help design or refine the intervention, and to understand how and why program effects came about (or did not). • See NIH mixed methods resource. If a PCORI or patient engagement application, demonstrate how your design and approach will substantially involve stakeholders (who may be diverse and have quite different perspectives) throughout the project in a meaningful way; not just an initial focus group.
Self-rating (1-5)	**Intervention:** (if applicable): • Specify details- e.g., who will deliver, what, when, and how. • Is there a core set of components, or minimum 'dose' required (have you or others demonstrated this level of implementation before?). • How appropriate and *feasible* for this setting is this intervention? • How is it different from or build upon, improve upon earlier research with this type of interventions? • WHY should settings; staff; and patients participate-what is in it for them? • Do current or upcoming policies, reimbursement; guidelines, or requirements support or interfere with this program?
Self-rating (1-5)	**Implementation Strategy(ies):** • Distinguish strategies for implementation from the *content of the intervention* above. • How will the intervention program be introduced, explained, presented, facilitated, supervised, and incentivized; • What strategies will be used to monitor progress, provide feedback on performance, guide adaptations made? See implementation strategies.
Self-rating (1-5)	**Fidelity and Adaptation**: • For D&I, one generally wants a balance between fidelity (to core or essential intervention elements) and adaptation (to local circumstances, populations, resources). In diverse, real world settings, not all adaptations are bad! See adaptation articles and models. • Explain exactly how you will measure implementation and fidelity to critical elements of program delivery. • How will you record and report adaptations that occur (and encourage staff and others to report rather than suppress/hide adaptations)? • What rules or guidelines will be used to guide –or restrict adaptations?
Self-rating (1-5)	**Measures and Outcomes.** • Clearly specify a primary aim (and power your analyses on this outcome). • Do not have too many key outcomes or aims (reviewers rebel, even if this is the case in the real world :-) • Justify (briefly) the reliability, validity, and appropriateness of your chosen measures for THIS project. If you are not choosing measures that may be other reviewers' favorites (e.g., PROMIS measures; ones your reviewers may have developed but that are impossible to use in real world settings) justify this respectfully. See pragmatic measures resources • Show how your measures relate to both your theory and your aims

Self-rating (1-5)	**Analyses:** • Explicitly link your analyses to your aims – in the order listed. • Consider restating each aim and then the analyses relevant to this. • Show how your proposed analyses are relevant to address the question at hand, and can address likely challenges, such as dropout, incomplete data, contamination, secular trends, etc. • Most grants require the participation of an experienced statistician. • Consider issues of clustering, violation of assumptions, and how your analyses account for the complexity of the problems addressed such as possible confounding variables. • Demonstrate you have at least power of 80% (preferably 85-90%) given reasonable assumptions about effect size, dropouts, variability, multiple comparisons, etc. Base these estimates on data wherever possible
Self-rating (1-5)	**Cost, Resources Required and Burden:** • If possible, estimate the costs and burden required at the relevant levels involved in your study- setting (clinic or hospital), staff (clinical team) and patient/family. • Not all studies require cost or cost-assessment analyses (and some funders, especially PCORI do not allow formal cost-effectiveness analyses, but are interested in intervention costs and burden). For a D&I study, unless it is to have national policy implications, you generally do not need a comprehensive analysis of societal costs or cost-benefit. However, questions about staff time and costs are usually one of the first things that potential adopting settings and participants ask. • Focusing on *replication costs,* understanding costs and resources required (usually time, equipment and travel resources) from the perspective of different stakeholders, and estimating predicted costs under different future scenarios (sensitivity analyses) can be quite helpful. See assessing costs in D&I

OTHER KEY APPROACH ISSUES:

- Make sure there is clear linkage, consistency, clarity of how your specific aims relate to theory, methods, measures, analyses, etc.
- Use figures and tables to illustrate and clarify any things difficult to explain or that go against convention;
- 'Show your work'- there are often not right or wrong decisions, but reviewers want to know you considered alternatives.
- On the National Cancer Institute's Implementation science website, see examples of successful D&I grants from reviews of funded D&I projects (https://cancercontrol.cancer.gov/is/)

Self-rating (1-5)	**Implications, Dissemination, and Future Research:** Leave enough room for these usually final, important sections (cut the intro/significance, preliminary studies if need to create space). Explain where, if successful (and if not, what you will do) and how you will take this research to the next step, broaden its distribution, be applied to a more challenging or broader population, and explain how this current study will inform that. What specific methods to disseminate results will you use? (presentations and journal articles do NOT cut it in D&I, even if in Nature, JAMA, or Science). How will you work with potential users, settings, etc. to package your results, provide trainings, workshops, or ongoing consultations, develop and test guidelines, toolboxes, FAQs, etc.?
Self-rating (1-5)	**Final Paragraph Summary, Strengths and Limitations.** Briefly summarize the key contributions and strengths, acknowledge limitations that all studies have (and if possible here and in more detail in the Approach sections above, how you will anticipate, minimize and address them). Repeat key points in your aims, rationale and why this is a critically important issue, yours is an innovative approach, and why your team is the best group to do this.

Summary of Ratings:

Add all of your scores above, divide by 17, and provide your average score here: _____

If this score is more than 3.0, consider if your proposal is not ready for a D&I study or a dramatically different approach and methodology is needed.

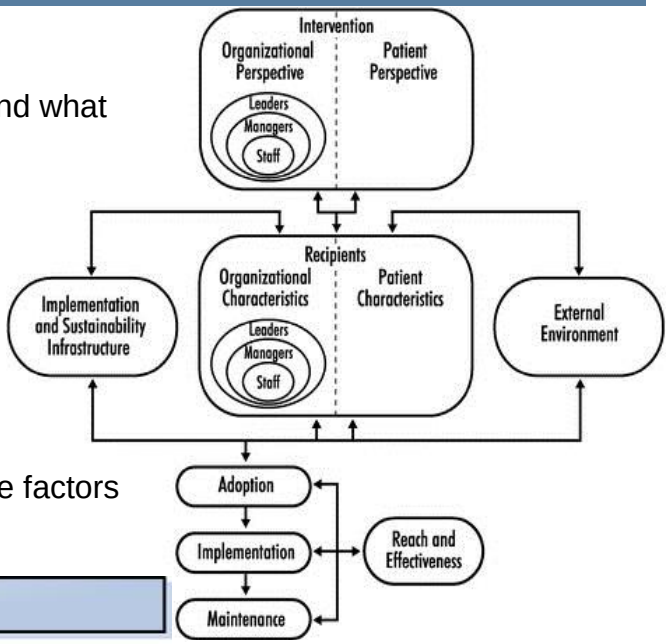
In any case, you may want to go back over the areas which you rated 3 or higher, review some resources, and talk with colleagues about their feedback and ideas regarding these sections.

Notes:

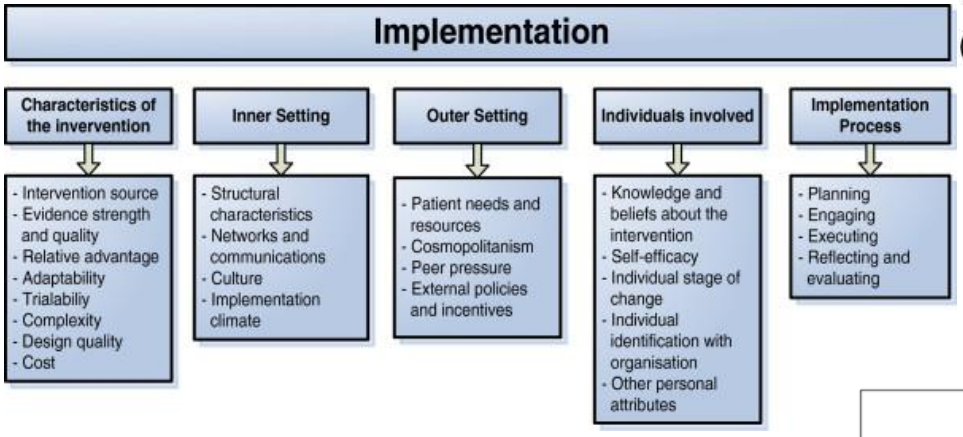
June 21, 2017 – Interactive Lunch Breakout sessions - **D&I frameworks – what are they and how to choose?**

Presented by Jodi Summers Holtrop, PhD, MCHES *12pm & 1pm Hensel Phelps East*

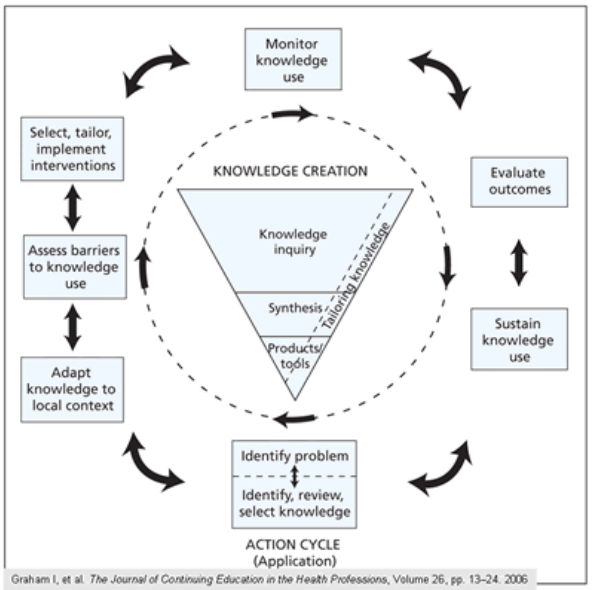
I. RE-AIM or PRISM
- Addresses the questions – how should we plan and what should we evaluate?
- RE-AIM = Reach, effectiveness, adoption, implementation, maintenance (re-aim.org)
- PRISM = Practical, robust implementation and sustainability model



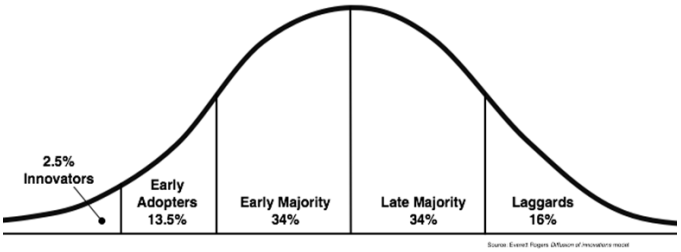
II. CFIR = Consolidated Framework for Implementation Research (cfirguide.org)
- Addresses the question – what are all the possible factors that might impact implementation?



III. KTA = Knowledge to Action Framework
- Addresses the question – what processes and knowledge generation inform actions?



IV. Diffusion of Innovations
- Addresses the question – how, why and at what rate do new ideas spread?



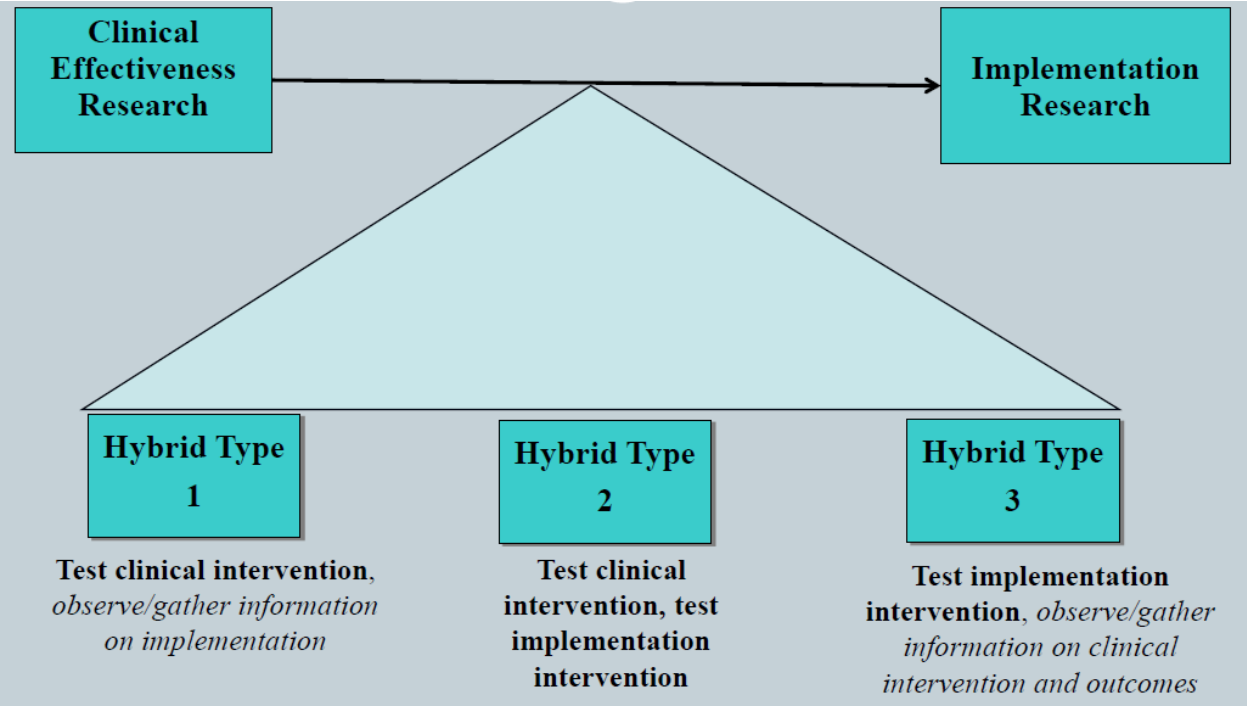
Session Summary Questions

	RE-AIM or PRISM	CFIR	KTA	D of I
At what point in your research might you use each model?				
In what situation might you want to use each model? What criteria would you use to decide?				
Can you use the models in combination? Why or why not?				
Other notes of importance				

References
1. Feldstein AC, Glasgow RE. A practical, robust implementation and sustainability model (PRISM) for integrating research findings into practice. Jt Comm J Qual Patient Saf. 2008;34(4):228-43.
2. Gaglio B, Phillips SM, Heurtin-Roberts S, Sanchez MA, Glasgow RE. How pragmatic is it? Lessons learned using PRECIS and RE-AIM for determining pragmatic characteristics of research. Implement Sci. 2014;9:96. doi: 10.1186/s13012-014-0096-x.
3. Gaglio B, Shoup JA, Glasgow RE. The RE-AIM framework: a systematic review of use over time. Am J Public Health. 2013;103(6):e38-46.
4. Damschroder LJ, Aron DC, Keith RE, Kirsh SR, Alexander JA, Lowery JC. Fostering implementation of health services research findings into practice: a consolidated framework for advancing implementation science. Implement Sci. 2009;4:50. doi: 10.1186/1748-5908-4-50.
5. Tabak RG, Khoong EC, Chambers D, Brownson RC. Models for dissemination and implementation research. Am J Prev Med . 2012 September ; 43(3): 337–350. doi:10.1016/j.amepre.2012.05.024.
6. Field B, Booth A, Ilott I, Gerrish K. Using the knowledge to action framework in practice: a citation analysis and systematic review. Implement Sci. 2014 Nov 23;9:172. doi: 10.1186/s13012-014-0172-2. Review.
7. Rogers, Everett. Diffusion of Innovations, 5th edition. 2003. Simon and Schuster.

June 21, 2017 – Interactive Lunch Breakout sessions - **Hybrid D&I RCT designs – balancing effectiveness and implementation measures**
Presented by Dan Matlock, MD, MPH *12:30pm Hensel Phelps East*

Overview: This session will serve as a bridge for traditional research and implementation science. Studying effectiveness and studying implementation do not have to be mutually exclusive. The model of effectiveness/implementation hybrid designs developed by Curran et al. is a highly useful way of thinking about models where one can explore aspects of both effectiveness and implementation simultaneously.



This session will provide a brief overview of hybrid designs. Then, using one case example, the participants will collectively develop a trial in each one of these hybrid designs to see how they compare and contrast. This will leave the participant with a full understanding of the model and a beginning understanding of different designs for exploring aspects of implementation science.

References

1. Curran GM, Bauer M, Mittman B, Pyne JM, Stetler C. Effectiveness-implementation hybrid designs: combining elements of clinical effectiveness and implementation research to enhance public health impact. Med Care. 2012;50(3):217-226.

June 21, 2017 – Interactive Lunch Breakout sessions - ***Selecting Pragmatic Outcomes for D&I Research That Are Relevant to Stakeholders***
Presented by Bethany Kwan, PhD, MSPH *12pm, 12:30pm, & 1pm Room 1103*

Selecting pragmatic outcomes (and data sources) for D&I research involves several steps:

1. Identifying and engaging stakeholders

2. Eliciting stakeholder goals, processes, decisions, and outcomes of interest

3. Identifying feasible data sources & reliable measures

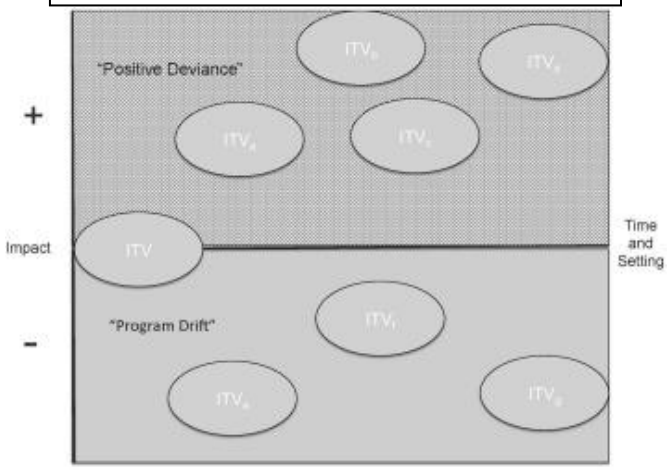
4. Establishing plans for stakeholder engagement in interpretation and dissemination of findings

In this breakout session, we will briefly discuss the rationale and methods for each of these steps. Then, we will practice applying these methods to the case vignette of "Adapting the Diabetes Prevention Program for implementation with pregnant women" using a stakeholder matrix based on the 7Ps Framework of Stakeholder Engagement.

References

1. Glasgow, R. E., & Riley, W. T. (2013). Pragmatic measures: what they are and why we need them. *American Journal of Preventive Medicine*, *45*(2), 237-243.
2. Concannon, T. W., Meissner, P., Grunbaum, J. A., McElwee, N., Guise, J. M., Santa, J., … & Leslie, L. K. (2012). A new taxonomy for stakeholder engagement in patient-centered outcomes research. *Journal of general internal medicine*, *27*(8), 985-991.
3. Reeve, B. B., Wyrwich, K. W., Wu, A. W., Velikova, G., Terwee, C. B., Snyder, C. F., ... & Lyons, J. C. (2013). ISOQOL recommends minimum standards for patient-reported outcome measures used in patient-centered outcomes and comparative effectiveness research. *Quality of Life Research*, *22*(8), 1889-1905.
4. Frank, L., Basch, E., & Selby, J. V. (2014). The PCORI perspective on patient-centered outcomes research. *Jama*, *312*(15), 1513-1514.

Figure 1. Two Responses to Adaptation: "Positive Deviance" and Negative "Program Drift "



I. Tension between Fidelity and Adaptations in D&I research

- Traditional assumption: Evidence-based interventions shall be delivered with fidelity to the original manualized intervention at each step of translation (Efficacy->Effectiveness->Implementation).
- D&I experts are increasingly challenging this assumption:
  - Implementation requires flexibility to setting needs
  - Some adaptations do lead to worse outcomes (i.e., "Program Drift"), but other adaptations may lead to better outcomes (Figure 1)

II. Key categories of intervention adaptation have been characterized (Chambers et al., Stirman et al.)

III. Methods to Balance Fidelity and Adaptation have been developed

- Dynamic Adaptation Process Model, characterized by Aarons et al. and drawing upon the CFIR framework:
  - Identify intervention core components – deliver these with fidelity
  - Identify the adaptable characteristics — fidelity not required for these elements)
  - Be open to changing the adaptable characteristics in response to certain stimuli:

IV. Developing an Adaptome – Dr. Chambers proposes developing a data repository ("Adaptome") that provides further insight as to the impact of certain types of adaptations for certain types of interventions.

V. Application: Group Discussion of how these concepts could be applied to the Workshop Case Vignette on Implementing the Diabetes Prevention Program into prenatal visits for obese pregnant women

References

1. The Adaptome: Advancing the Science of Intervention Adaptation. Chambers, DA & Norton, WE. Am J Prev Med. 2016 June 28. S0749-3797(16)30181-7. doi:10.1016/j.amepre.2016.05.011.

2. S.W. Stirman, C.J. Miller, K. Toder, A. Calloway Development of a framework and coding system for modifications and adaptations of evidence-based interventions, Implement Sci, 8 (2013), p. 65. http://dx.doi.org/10.1186/1748-5908-8-65

3. G.A. Aarons, A.E. Green, L.A. Palinkas, *et al.* Dynamic adaptation process to implement an evidence-based child maltreatment intervention Implement Sci, 7 (2012), p. 32 http://dx.doi.org/10.1186/1748-5908-7-32

June 21, 2017 – Interactive Lunch Breakout sessions - **Assessing implementation/replication costs for D&I research**
Presented by Debra P. Ritzwoller, PhD *12pm, 12:30pm, & 1pm Room 1105*

I. Optimizing implementation requires an understanding of the resources and costs needed for replication.

- Understanding the resources required for the implementation, delivery, and replication of" pragmatic implementation trial D&I studies and trials is key.
- Policy makers, payers and practices need information regarding financial requirements (e.g. personnel costs, reimbursement rates, etc.) associated implementing behavioral change services.

II. Selecting your framework and/or methods

- What were the outcomes of interest (e.g. decrease in HbA1C or BMI, increase in PA, other)
- What is the perspective – practice (safety net vs not), payer, health department, other?
  - Patient travel & participation time is important
- What is the target population (e.g. all pregnant women, diabetes, other)
  - Participation and completion rates - % contacted who enrolled
  - How were study participants identified and/or recruited – "if you build it will they come?"
- Who delivered what components of the intervention (MD, RNs, MA, MPH, other)
  - What training and supervision was required – would it vary by setting & infrastructure (EHR or no).
- How long did the intervention last – how many contacts, maintenance, etc.

III. Capture of intervention resources and cost transformation

- In collaboration with project leaders, develop a user friendly resource/time capture instrument and process, that is tailored to practice level or setting;
  - Identify intervention core components – and ensure fidelity across site and over life of the study
  - Minimize the burden on subjects and research staff
- Need to differentiate research and development costs from recruitment and *implementation* costs
  - Determine optimal survey or capture intervals – beginning, middle, and end of study
- Transform time and resources to standardized cost - e.g. market wages, fair value of other components

IV. Cost Analysis: Report cost as a function of primary outcome

- Incremental cost per in incremental change in outcome of interest - Change in HbA1C vs BMI vs QALYs, or other
- Conduct a sensitivity analyses – e.g. change in target population, setting, infrastructure, etc.

V. Application: Group Discussion of how these concepts could be applied to the Workshop Case Vignette on Implementing the Diabetes Prevention Program into prenatal visits for obese pregnant women

References

1. Herman WH, Hoerger TJ, Brandle M, Hicks K, Sorensen S, Zhang P, Hamman RF, Ackermann RT, Engelgau MM, Ratner RE; Diabetes Prevention Program Research Group. The cost-effectiveness of lifestyle modification or metformin in preventing type 2 diabetes in adults with impaired glucose tolerance. Ann Intern Med. 2005 Mar 1;142(5):323-32.
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4. Dodoo MS, Krist AH, Cifuentes M, Green LA. Start-up and incremental practice expenses for behavior change interventions in primary care. Am J Prev Med. 2008 Nov;35(5 Suppl):S423-30.PMID: 18929990

RE-AIM Framework: Maintenance

Definition: The extent to which a program or policy becomes institutionalized or part of the routine organizational practices and policies. Maintenance also refers to adherence at the individual level.

Planning Questions for Improving Maintenance:

Individual Level

1. What evidence is available to suggest the intervention effects can be maintained 6+ months after it is completed? How confident are you that the program will produce lasting benefits?
2. What are the barriers to adherence? What do you plan to do to support initial success and prevent or deal with relapse of participants?
3. What resources (financial, social) are available to provide long-term support for individuals?

Community or Organizational Level

1. How confident are you that your program will be sustained in your setting 12+ months after implementation support and grant funding ends?
2. What do you see as the greatest challenges to organizations continuing their support?
3. Do you have key stakeholder commitment to continue the program if it is successful? What benefits do you need to demonstrate in order to achieve their commitment?
4. How can the intervention be integrated into routine practice?
5. What are your plans for intervention financial sustainability? What is the business model?

Product Design Principles: Unique Value Proposition

Definition: A business or marketing statement that a company uses to summarize why a consumer should buy a product or use a service. This statement convinces a potential consumer that one particular product or service will add more value or better solve a problem than other similar offerings.

For _____ (target customer)
who _____ (statement of the need or opportunity)
our (product/service name) is _____ (product category)
that (statement of benefit) _____ better (be specific) than (alternative) _____.

Planning Questions for Identifying a Sustainable Value Proposition :

Customer Discovery

1. Who are your target customers (users) for your intervention? What are their "jobs"? "pains"? "gains"? What are "must have" needs vs. "nice-to-have" needs?
2. Who are the stakeholders and how do they relate to one another in your user's ecosystem? Who are the "influencers"? "champions"? "saboteurs"?

Problem-Solution Fit. You have a problem worth solving. You have a solution better than current alternatives.

1. Is the problem your intervention addressing currently unworkable? unavoidable? urgent? underserved?
2. Net Promoter Score. What percent would highly (9/10) recommend your product/service to a colleague (on a scale of 1-to-10) less the percent who are negative/neutral (1-6)?

Product-Market Fit. Your product/service satisfies a strong market demand.

1. The 40% rule – do enough customers care? What percent consider the product or service a "must have"? What percent would be "very disappointed" if no longer have access?

Sources: Value Proposition Design (2014); http://re-aim.org/ Elaine.Morrato@ucdenver.edu | June 21, 2017

I. PRAGMATIC TO EXPLANATORY (EFFICACY) TRIALS

- What aspects of study design make a study more pragmatic versus more explanatory? (Krist et al., 2013)

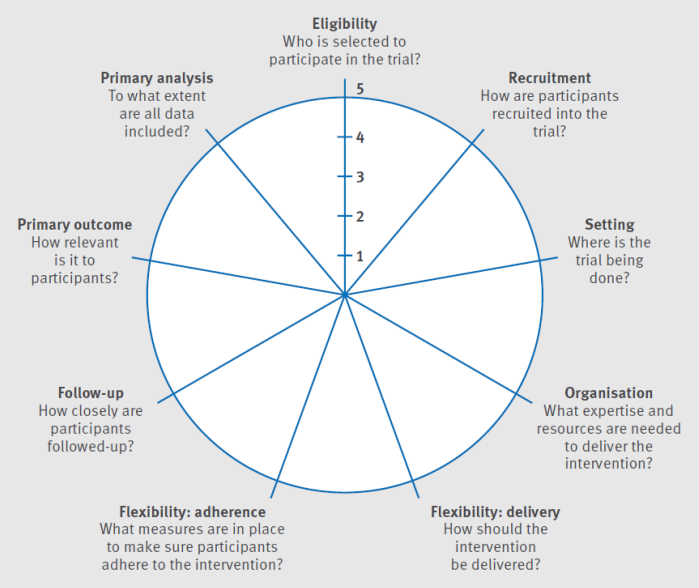
Table 1 Distinguishing differences between pragmatic and traditional clinical efficacy trials

	Pragmatic study	Traditional clinical efficacy
Stakeholder involvement	Engaged in all study phases including study design, conducting the study, collecting data, interpreting results, disseminating findings	Limited engagement, often in response to investigator ideas or study subjects
Research Design	Includes internal and external validity, design fidelity and local adaptation, real life settings and populations, contextual assessments	Focus on limiting threats to internal validity, typically uses randomized controlled trial, participants and settings typically homogenous
Outcomes	Reach, effectiveness, adoption, implementation, comparative effectiveness, sustainability	Efficacy, mechanism identification, component analysis
Measures	Brief, valid, actionable with rapid clinical utility, feasible in real world and low-resource settings	Validated measures that minimize bias, focus on internal consistency and theory rather than clinical relevance
Costs	Assessments include intervention costs and replication costs in relation to outcomes	Often not collected or reported
Data Source	May include existing data (electronic health records, administrative data) and brief patient reports.	Data generation and collection part of clinical trial
Analyses	Process and outcome analyses relevant to stakeholders and from different perspectives	Specified a priori and typically restricted to investigator hypotheses
Availability of findings	Rapid learning and implementation	Delay between trial completion and analytic availability

- Importance of stakeholder engagement in design of pragmatic trials

II. PRECIS-2

- History and motivation
- The wheel and its 9 domains (Loudon et al., 2015)
- Steps to applying PRECIS-2
- Interactive tools
  i. https://www.precis-2.org/
  ii. http://www.crispebooks.org/Pragmatic Trials/workbook-1627-1845R.html



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

III. APPLICATION TO CASE EXAMPLE

- Workshop participants will each plot the design features of the DPP case example on the PRECIS-2 wheel, and discuss rationale for the ratings and implications for dissemination and implementation of the DPP

References

1. Krist, A. H., Glenn, B. A., Glasgow, R. E., Balasubramanian, B. A., Chambers, D. A., Fernandez, M. E., . . . Phillips, S. M. (2013). Designing a valid randomized pragmatic primary care implementation trial: the My Own Health Report (MOHR) project. *Implementation Science, 8*(1), 73.
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June 21, 2017 – **How to incorporate RE-AIM into your CONSORT diagram – the rationale and application of the expanded CONSORT diagram**
Presented by Russell Glasgow, PhD *1:45pm Hensel Phelps East*

(with contributions from Amy Huebschmann, MD, MS)

Introduction:

- There are major problems with failure to replicate at all levels of research.
- Part of the problem - failure to specify conditions and context of a study.
- This is especially true when conducting research in real world settings where context is not artificially reduced and constrained.

The Consolidated Standards of Reporting Trials (CONSORT) criteria have been widely used and shown to improve quality of reporting. This session will discuss and illustrate an expansion or extension of the basic CONSORT criteria to concisely report additional contextual and implementation factors.

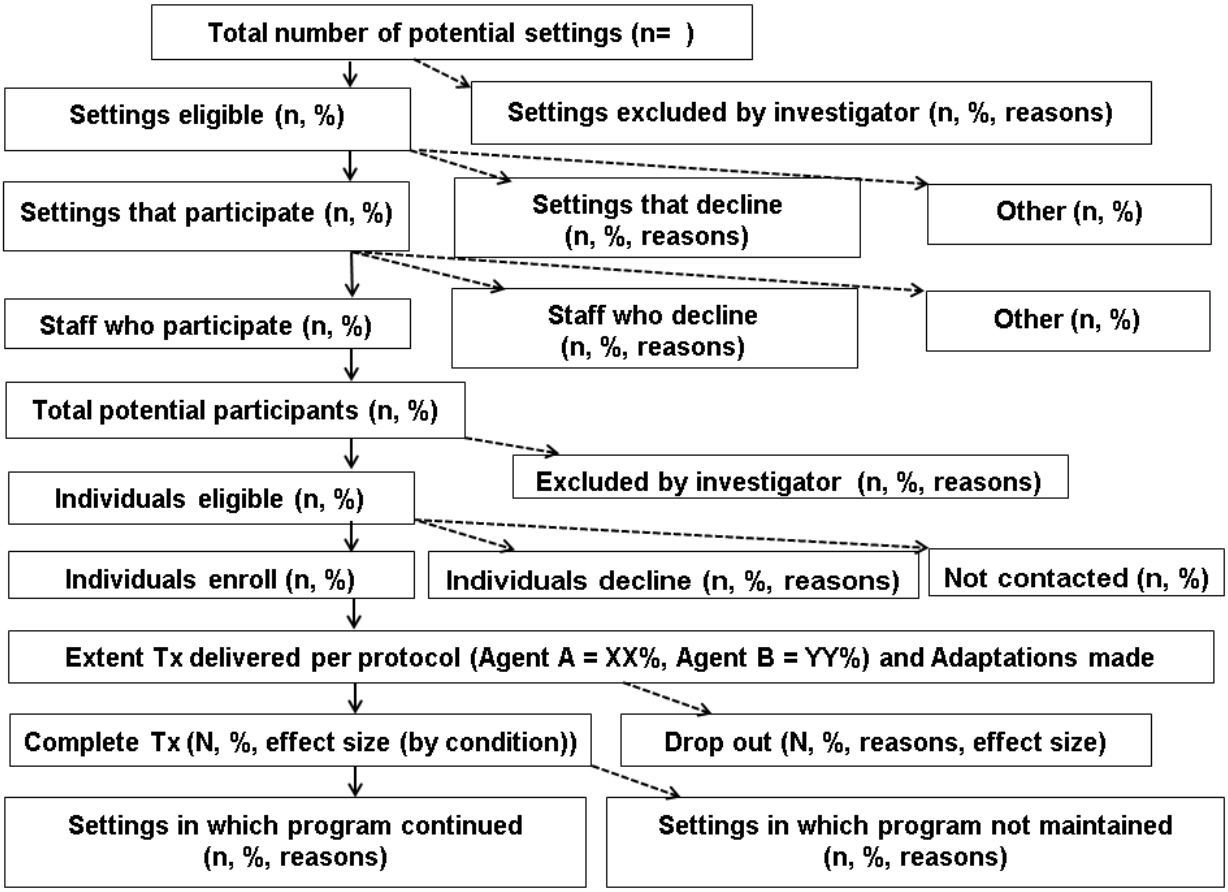
Content and Examples:

- A key issue in D&I research- and for understanding replication (or failure to replicate) is understanding procedures and results around recruitment and participation, at multiple levels. The current CONSORT diagram and reporting starts with individual participants, and ends with loss to follow-up.

But… research occurs in a **context**:

- Setting and staff/ intervention agents are an important part of the mix
- Sustainability of the program after the study ends is also important.
- To better understand context and conditions related to outcomes, we need to focus on and use methods to investigate and report these factors.
- The Reach, Effectiveness, Adoption, Implementation, Maintenance (RE-AIM) framework provides a model to categorize these contextual factors, in order to address replication issues and enhance transparent reporting.
- These categories can be diagrammed in an expanded version of the CONSORT figure (see Figure below). These additional issues include, sequentially:
    - ***Adoption*** level 1: health systems, hospitals, worksites, clinics that are invited to participate in a program or policy; and which participate and why)
    - ***Adoption*** level 2: which staff and providers are invited to participate; what percent do; how representative are they; and reasons for declining
    - ***Reach*** level: the number of potential participants excluded due to investigator exclusion criteria, as well as the percent and representativeness of participants and reasons eligible participants decline
    - ***Implementation*** level issues: The extent to which the treatment is delivered with fidelity to the protocol by: various staff/providers; across settings; over time; and how often, what type and why adaptations are made
    - ***Maintenance*** level: The degree to which settings elect to continue (or intend to continue) a program or policy after research is complete

Expanded CONSORT Figure (see http://re-aim.org/wp-content/uploads/2016/09/consort.pdf)



Discussion: Consistent reporting and use of RE-AIM or similar frameworks and the accompanying Expanded CONSORT diagram can fill an important reporting need. This should help with the scientific replication problem by helping to understand the context and conditions under which results are obtained. The Expanded CONSORT figure and reporting is an efficient way to increase attention to these important contextual issues in planning, conducting, reporting and understanding a D&I intervention.

Summary: Basic principles to address at multiple levels: inclusion/exclusion criteria; participation rate, representativeness, and reasons.
Why is this important?

a) to increase transparency of reporting and reasons for replication or failure to replicate; and

b) to help answer the '***Ultimate Use'*** goal of D&I research: what program or policy components, delivered to which populations, in which settings, by which delivery agents (staff), under what conditions, produce what outcomes, in what time frame, through what processes, and how and why are these results obtained?

June 22, 2017 - **Don't Just "Google It": Effective, evidence-based D&I Resources**
Presented by Dan Matlock, MD, MPH *2:45pm Hensel Phelps East*

Overview: There are a small but growing handful of true "Implementation Science" experts. For many of the rest of us working in the field, we have gravitated to and gained expertise in implementation science driven by interest in some other clinical question. Luckily, several of the experts have created online resources to make the science more accessible to those who may be learning the field. This session will be an interactive session briefly viewing many of the resources that are available online for D&I research.

Objectives:

1) To become aware of online resources supporting research in dissemination and implementation.
2) To develop an idea using online resources and to think about gaps in this area and how you might contribute to this goal (or evaluate current sites)

Website resources:

General D&I

- Access to D&I tools on CU ACCORDS website: http://www.ucdenver.edu/academics/colleges/medicalschool/programs/ACCORDS/sharedresources/DandI/Pages/Dissemination%20and%20Implementation.aspx - general D&I issues and upcoming events, articles and opportunities
    - http://www.crispebooks.org/PragmaticTrials/Landing-1627-179R3.html - general interactive elearning book on D&I basics and **terms**)
    - http://www.crispebooks.org/PragmaticTrials/workbook-1627-1845R.html
- https://societyforimplementationresearchcollaboration.org/ - national society that facilitates communications and collaborations amongst implementation science research teams, researchers, and community members
- https://cancercontrol.cancer.gov/is/
- https://impsci.tracs.unc.edu/

Theories

- Dissemination-Implementation.org - selecting and adapting theories for D&I
- www.Re-aim.org - website with resources and details on use of RE-AIM D&I framework
- www.Cfirguide.org - website with resources and details on use of the CFIR D&I framework
- www.precis-2.org - website with resources on using the Pragmatic Explanatory Continuum Indicator Summary tool to assist research trialists to portray visually how pragmatic or explanatory their trial design is

D&I and Pragmatic Measures

- https://www.gem-measures.org/public/MeasureList.aspx?cat=2 and the SIRC website above

NOTES:

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Day 2 (Tab)

- Practical use of D&I outcomes

- Practical use of D&I theories

- Practical use of D&I design

Russell Glasgow, PhD, discussing the National Cancer Institute (NCI): The National Cancer Institute has been and continues to be one of the strongest funders of and leaders in Dissemination and Implementation Science. They sponsor activities including ongoing discussions of key and evolving issues in D&I, strong support of training, the annual NIH/Academy Health/VA research meeting (https://cancercontrol.cancer.gov/IS/training-education/index.html#conference) in December, and their website (https://cancercontrol.cancer.gov/is/). The primary funding mechanism used by the NCI for D&I funding is the NIH-wide PAR-16-238. Other funding mechanisms are also announced periodically and they have a major repository (RTIPS) of over 175 evidence-based interventions that researchers and program developers can use for research and practice.

Ed Havranek, MD, discussing the National Heart Lung Blood Institute (NHLBI): The role of the National Heart, Lung, and Blood Institute has grown in recent years, starting with creation of the Center for Translational Research and Implementation Science in 2014. The Center has coordinated activities with NHLBI's divisions, focusing on hypertension, asthma, and sickle cell disease initially. More recently, NHLBI has convened a workshop on implementation science in critical care medicine and has issued an RFA for creation of K12 research career development programs in T4 implementation research (https://grants.nih.gov/grants/guide/rfa-files/RFA-HL-17-016.html).

Marina McCreight, MPH, discussing VA QUERI: VA research is different from research sponsored by other federal research agencies. Specifically, VA Research is the only research program focused entirely on Veterans' needs. VA Research is intramural, meaning only VA employees can conduct research under VA's sponsorship. Typically, VA researchers collaborate with academic institutions. This is an exceptional benefit because it allows VA Research to identify the direct needs of patients at chair and bed side, and to find discoveries and innovations directly in-step with these needs. In addition, the creation of the VA'S Quality Enhancement Research Initiative (QUERI) has allowed the VA healthcare system to support the application of critical evidence into practice. QUERI rapidly translates research findings and evidence-based treatments into clinical practice therefore positioning the VA healthcare system as a leader in implementation science.

Bethany Kwan, discussing PCORI: Disseminating and promoting the uptake of research findings is part of PCORI's legal mandate to improve the quality and relevance of evidence available to help patients, caregivers, clinicians, employers, insurers, and policymakers reach better-informed health decisions. In addition, PCORI has specific funding mechanisms related to D&I research. For example, there is a funding announcement for Communication and Dissemination research, in order to study approaches to providing comparative effectiveness research information, empowering people to ask for and use the information, and supporting shared decision making between patients and their providers. In addition, the PCORI Awards for Disseminating and Implementing Research Findings allows PCORI-funded research project teams to propose projects for disseminating findings from their completed studies. Finally, organizations with strong ties to audiences that can use findings from patient-centered outcomes research can apply for Eugene Washington PCORI Engagement Awards. The program's dissemination opportunity provides support for projects to strengthen the infrastructure and relationships necessary to disseminate and implement findings from patient-centered outcomes research.

Jodi Holtrop, PhD, MCHES, discussing AHRQ: The AHRQ mission is to produce evidence to make health care safer, higher quality, more accessible, equitable and affordable, and to work with HHS and other partners to make sure that the evidence is understood and used. Their research priority areas of focus include: 1) Improve health care quality by accelerating implementation of Patient Centered Outcomes Research (PCOR), 2) Make health care safer, 3) Increase accessibility by evaluating expansions of insurance coverage, and 4) Improve health care affordability, efficiency and cost transparency. AHRQ funds R01, R18, and R03 grant applications in these areas, as well as K-awards and R13 (conference grants). The R18 mechanism is the most D & I appropriate in many cases. Specific funding opportunities can be found at: https://www.ahrq.gov/funding/fund-opps/index.html

David Buller, PhD, discussing the NIH Small Business Innovation Research (SBIR) and Small Business Technology Transfer (STTR) programs: The NIH SBIR/STTR funding mechanism is reserved for small businesses, usually in collaboration with university researchers, for supporting D&I through the transfer of evidence-based technology (broadly conceived) to the commercial marketplace. NIH uses the SBIR/STTR mechanism both for investigator-initiated projects and for contract to perform research given high priority by individual institutes and the Centers for Disease Control and Prevention. All projects must have commercial potential and the small business must have a commercialization plan. Funding occurs in two phases, with Phase I ($150,000 for up to 1 year) devoted to demonstrating the feasibility of a research-tested product and Phase II ($1,000,000 for approximately 2 years) focused on development of the product and evaluation of its effectiveness in the potential commercial environment. Phase III devoted to commercialization is the responsibility of the small business. All SBIR/STTR applications are awarded to the small business, which subcontracts with the university. SBIR applications have a Principal Investigator located in the small business while STTR applications have a Principal Investigator located in the university.

Biomedical Laboratory Research & Development (BLR&D)

- BLR&D Merit Review Award (Parent I01)

Clinical Science Research and Development (CSR&D)

- CSR&D Merit Review Award (Parent I01)
- CSR&D Merit Review Award for Deployment Health Research (OEF/OIF/OND)
- CSR&D Merit Review Award for Traumatic Brain Injury (TBI) Research (I01)
- CSR&D Merit Review Award for Research on Amyotrophic Lateral Sclerosis, Parkinson's Disease and Alzheimer's Disease
- CSR&D Merit Review Pilot Project Awards for Research on Amyotrophic Lateral Sclerosis, Parkinson's Disease and Alzheimer's Disease (I21)
- CSR&D Merit Review Award for Clinical Trials (I01)
- CSR&D Career Development Award (CDA-2 [IK2])
- CSR&D Award for Research on Gulf War Veterans' Illnesses (GWVI [I01])
- CSR&D Pilot Projects for Research on Gulf War Veterans' Illnesses (GWVI) (GWVI [I21])
- CSR&D Award for Research on New Treatments for Gulf War Veterans' Illnesses (GWVI [I01])
- CSR&D Merit Review Research Career Scientist (RCS) Award (IK6)
- CSR&D Merit Review Award for Suicide Prevention Research (I01)

Spring & Fall - Basic and Clinical Science March 10th and September 10th

Health Services Research and Development (HSR&D)

- CREATE Project Implementation Supplemental Funding
- HSR&D Merit Review Award (Parent I01)
- HSR&D Merit Review Award Pilot Project Program (I21)
- VA Nursing Research Initiative (NRI)
- HSR&D Targeted Solicitation for Health Services Research on Veteran Suicide Prevention
- HSR&D Targeted Solicitation for Health Services Research on Provider Behavior - A Learning Health Care System Initiative
- Targeted Solicitation for Health Services Research on Data and Measurement Sciences – A Learning Health Care System Initiative
- HSR&D Career Development Award (CDA-2)
- QUERI Partnered Evaluation Initiative ("Parent") Partnered Evaluation Mechanism
- HSR&D Merit Review Research Career Scientist (RCS) Award (IK6)
- HSR&D Targeted Solicitation for Service-Directed Research Award on Health Services Research on the Care of Gulf War Veterans
- QUERI National Evaluation of VA's Innovators Network

Rehabilitation Research and Development (RR&D)

- RR&D Merit Review Award (Parent I01)

Summer & Winter HSR&D and Rehab Science June 10th and December 10th

June 22, 2017 – **Recognize how to utilize D&I research approaches to improve health disparities**

Presented by Paul Eastbrooks, PhD & Demetria McNeal, PhD, MBA 10:15am Hesel Phelps West

Issues to Consider while attending D&I workshop presentations- Make notes on *options and choices* for a D&I research design addressing this case vignette in the following areas:

Factors that compose the Pragmatic Explanatory Continuum Indicator Summary – version 2 (PRECIS-2) and RE-AIM dimension criteria:

Eligibility Criteria– Explicitly define who is the target population (all African American residents? Those receiving care at the FQHC? Lower income? Obese or explicitly at risk for diabetes?). Document the extent to which participants in the trial are similar to the defined target population.

Recruitment Path – Describe potential pathways for recruitment. Determine the relative effort to recruit participants over and above what would be used in the usual care setting to engage with the defined target population (African American residents)

Organization (Feasibility) – Describe the potential organizational delivery settings. Determine the difference between the resources, provider expertise, and the organization of care delivery employed in the intervention arm of the trial and those available in usual care.

Setting and Staff– Explicitly describe the setting and staff that will deliver the intervention. Identify the specific roles of the staff involved. Describe the difference in the settings and implementing staff of the trial from the usual care setting where the results are likely to be applied.

Flexibility (delivery by intervention staff) – Describe the areas of the intervention that are adaptable and to what degree. Describe the difference in flexibility of intervention delivery compared to the flexibility anticipated in usual care.

Flexibility (adherence) – Describe if participants in the intervention will have explicit choice in how and when they receive intervention strategies. Describe the difference in the flexibility in how participants engage with the intervention compared to the flexibility anticipated in usual care.

Follow-up (how closely are patients followed up) – Describe the maintenance/follow-up strategy that will be applied as part of the intervention. Describe the difference in the intensity of the maintenance components of the intervention follow-up during the trial compared to the typical follow-up expected in usual care

Primary Aims and Outcome – Describe the primary aims and outcomes. Describe the extent to which the trial's primary outcome is directly relevant to participants and other stakeholders. Describe the degree to which the primary outcome could be collected pragmatically (i.e., within existing data sources).

Analysis (Intention-to-Treat; vs. supplemented by per protocol) – Describe the extent to which all data is included in analysis of the primary outcomes

Other external validity factors related to the Reach, Effectiveness, Adoption, Implementation, and Maintenance (RE-AIM) model that were not included in PRECIS-2:

Participant Engagement. Describe specific strategies used to retain and increase participant engagement. Describe the extent to which participants' accessed the intervention resources, strategies, and sessions.

Adaptation/Change. Describe the methods that will be used to determine if there are unplanned intervention modifications or corrections during study as a result of lessons learned earlier in the trial.

Unintended Effects. Described methods to capture unintended effects that may occur (e.g., summative qualitative analysis; adverse event tracking)

Monetary Costs of Existing Treatment. Describe how intervention costs will be tracked and used. Determine the extent to which costs of the intervention align with or add to standard practice for a FQHC.

Program Sustainability. Describe plans to promote and/or evaluate program sustainability (or potential for program sustainability). Describe the extent of efforts to continue behavioral intervention after study.

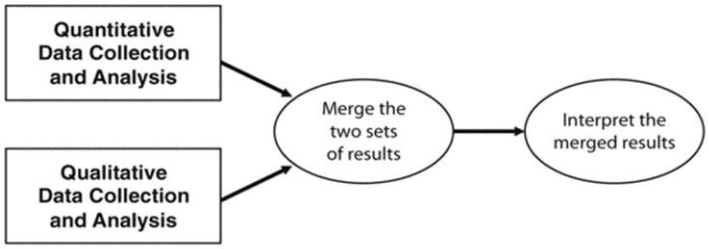
I. Qualitative = words
Data collection examples: Focus groups, interviews, observation
Data analysis examples: Grounded theory, thematic, immersion crystallization

II. Quantitative = numbers
Data collection examples: Surveys (with scales), clinical data (encounters, lab values)
Data analysis examples: Parametric (regression), non-parametric (chi square)

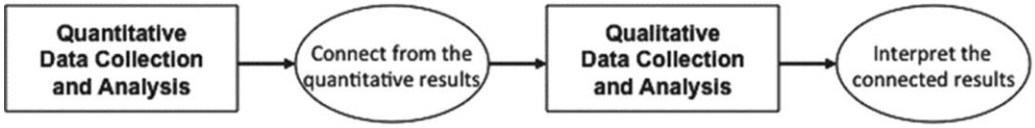
III. Mixed
Using both quantitative and qualitative at some point
Can include data transformation
Three forms of integrating data: merging, connecting, embedding

Four Major Mixed Methods Designs

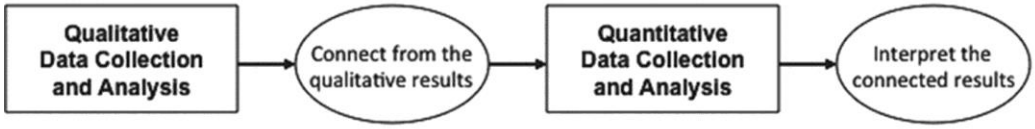
Convergent parallel design



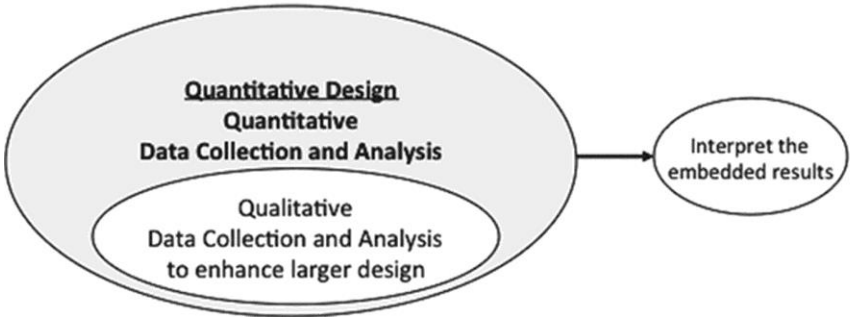
Explanatory sequential



Exploratory sequential



Embedded (example of qualitative embedded within a quantitative design)



Why Use MM in DI research?

1. To measure both intervention and implementation outcomes and understand process
2. To conduct both exploratory and confirmatory research
3) To examine both intervention content and context
4) To incorporate perspectives of stakeholders
5) To compensate for one set of methods by use of another.

Case Study Example

Goal - to adapt the DPP for implementation with pregnant women in a safety-net health system.
Key questions – Consider RE-AIM

- To what extent does the adapted DPP REACH the eligible population? What are their characteristics?
- What are the clinical outcomes (weight, PA) EFFECTIVENESS on the eligible population from the adapted DPP?
- What is the uptake/ADOPTION of the adapted DPP among the possible clinics?
- What factors facilitated or impeded IMPLEMENTATION of the adapted DPP?
- Did the clinics continue to offer the adapted DPP after the study ended? MAINTENANCE

Session Summary Questions

Mixed Methods Approach	**Benefits**	**Drawbacks**	**When to Use**
Convergent Parallel			
Explanatory Sequential			
Exploratory Sequential			
Embedded			
Other			

References

1. Creswell JW, Plano Clark VL. Designing and Conducting Mixed Methods Research 2nd Edition. 2011. Sage Publications, Thousand Oaks, CA.

Notes:

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D&I RESOURCES (Tab)

Table. Core Competencies for D&I grants

Grant Section	Competency	D&I expertise required
Aims* - The Aims page is a ***critically important*** **section —** first impressions matter!		
	Create a ***clear rationale*** and a **realistic action plan** for transforming research questions on D&I into grant proposal aims	Beginner
Significance		
	Identify how to pose an innovative and significant D&I research question, including: • Justify its ***importance –*** how will it improve health and/or eliminate health disparities • Describe the ***knowledge gap*** in the field that it addresses • Connect it to the ***priorities of the funding agency*** (when possible) and the ***goals of the Program Announcement*** (if applicable)	Beginner
	Describe how to ground the proposal in an important quality gap that is addressable through the D&I of an ***evidence-based*** intervention, program, or policy.	Beginner
Innovation		
	Articulate how to identify products from the D&I study, including implementation toolkits, ***to guide practice and policy***	Advanced
	Report on how the proposed practice change (to be addressed in the study) is relevant to ***current policy trends and priorities*****.**	Advanced
Approach		
	Utilize an appropriate ***D&I model or framework*** to organize a proposal and integrate research questions ***throughout the proposal*** with clear and measurable study objectives; aims; measures; and analysis strategies	Intermediate
	Explain how to document or propose ***measurement of the setting's need, appropriateness and readiness*** to implement the practice change required**,** using the D&I strategies proposed	Intermediate
	Identify ***pragmatic measures*** that clearly assess the constructs of interest in the proposed study and are practical to apply in the proposed settings	Intermediate
	Identify how to build your grant team with the ***expertise*** **and experience** needed for the proposed research, including D&I expertise**, *stakeholder engagement*, and other relevant skills (e.g. biostatistics, economics, mixed methods)**	Intermediate
	Create a strategic ***dissemination plan*** for various target audiences that goes beyond the traditional publications and presentation at meetings	Advanced
	Develop an analysis plan that addresses ***each specific aim*****,** the D&I theory you use, and considers the different levels of analyses appropriately: • ***Statistical issues*** involved with cluster-randomized trials and other complex study designs, as well as missing data	Advanced

	• Importance of considering ***mixed methods*** approaches to capture all relevant data from stakeholders (qualitative data) and to also test *a priori* hypotheses (quantitative data)	
Human Subjects		
	Describe the ethical (human subjects) issues that are particular to and relevant for D&I research	Beginner
Table adapted by Amy G. Huebschmann, MD, MS and Russell E. Glasgow, PhD from Brownson RC,Colditz GA, Dobbins M, Emmons KM, Kerner JF, Padek M, Proctor EK, Stange KC. Concocting that Magic Elixir: Successful Grant Application Writing in Dissemination and Implementation Research. *Clin Transl Sci*, 2015 Dec;8(6):710-6. doi: 10.1111/cts.12356		

Key Books and Articles in Dissemination and Implementation Science Research

- Brownson, RC, Colditz, GA, and Proctor, EK., Dissemination and implementation research in health: Translating science to practice. 1st ed. 2012, New York: Oxford University Press
    - Gold standard text on D&I research – currently under revision with new edition expected in 2018.

- Chambers, DA, Glasgow, R., and Stange, KC. (2013) The dynamic sustainability framework: addressing the paradox of sustainment amid ongoing change. *Implementation science*, 8: 117
    - The dynamic sustainability framework identifies key factors that may allow interventions to be sustainable and effective despite changing circumstances: 1) continued learning and problem solving, 2) ongoing adaptation of interventions with a primary focus on fit between interventions and multi-level contexts, and 3) expectations for ongoing improvement as opposed to diminishing outcomes over time.

- Curran GM, Bauer M, Mittman B., et al.(2012) Med Care, Effectiveness-implementation hybrid designs: combining elements of clinical effectiveness and implementation research to enhance public health impact.50(3):217-26.
    - This study proposes methods for blending design components of clinical effectiveness and implementation research. Such blending can provide benefits over pursuing these lines of research independently; for example, more rapid translational gains, more effective implementation strategies, and more useful information for decision makers.

- Damschroeder L., Aron DC, Keith RE, Kirsh SR, Alexander JA, Lowery JC. (2009) Fostering implementation of health services research findings into practice: a consolidated framework for advancing implementation science, *Implementation Science*, 4:50.
    - This is the seminal publication of the Consolidated Framework for advancing implementation science research (CFIR), see also cfirguide.org for more details and for guidance on use of the CFIR framework.

- Gaglio, B., Shoup, JA., and Glasgow, RE. (2013) The RE-AIM framework: a systematic review of use over time. *American journal of public health*. 103(6): e38-46.
    - The RE-AIM framework continues to be widely used as an implementation science framework, and this article identifies how the use of RE-AIM has changed over time. See also the seminal RE-AIM publication: Glasgow RE, Vogt TM, Boles SM (1999). Evaluating the public health impact of health promotion interventions: the RE-AIM framework. Am J Public Health. 1999 Sep 1999; 89(9): 1322-1327.

- Feldstein AC, Glasgow RE. (2008) A practical, robust implementation and sustainability model (PRISM) for integrating research findings into practice. Jt Comm J Qual Patient Saf. 34(4): 228-243.
    - This article describes the PRISM D&I framework —a comprehensive approach to implementation science. PRISM extends RE-AIM by incorporating concepts from Diffusions of Innovation theory and other models that emphasize the importance of context from the perspectives of intervention staff and participants, as well as the importance of building partnerships, and planning for program sustainability.

- Glasgow RE and Riley T (2013). Pragmatic Measures: What They Are and Why We Need Them. *American Journal of Preventive Medicine*, August;45(2):237-43.
    - This article proposes necessary and recommended criteria for pragmatic measures, provides examples of projects to develop and identify such measures, addresses potential concerns about these recommendations, and identifies areas for future research and application.
- Loudon K, Treweek S, Sullivan F., et al. (2015) The PRECIS-2 tool: Designing trials that are fit for purpose. BMJ 350:h2147.
    - This article gives guidance on how to use an improved, validated version, PRECIS-2, which has been developed with the help of over 80 international trialists, clinicians, and policymakers.

Keeping the original simple wheel format, PRECIS-2 now has nine domains scored from 1 (very explanatory) to 5 (very pragmatic), to facilitate domain discussion and consensus.

- Kilbourne, A, Elwy R, Sales A, Atkins D (2016) Accelerating Research Impact in a Learning Health Care System: VA's Quality Enhancement Research Initiative in the Choice Act Era. *Medical Care*.
    - This article describes the Veterans Health Administration (VHA) Quality Enhancement Research Initiative (QUERI) that has supported more rapid implementation of research into clinical practice since 1998. Grounded in implementation science and evidence-based policy, QUERI serves as an example of how to operationalize core components of a Learning Health Care System, notably through rigorous evaluation and scientific testing of implementation strategies to ultimately reduce variation in quality and improve overall population health.

- Proctor EK, Silmere H, Raghavan R., et al. (2011) Outcomes for implementation research: Conceptual distinctions, measurement challenges, and research agenda. Adm Policy Ment Health; 38(2): 65-76.
    - This article proposes a heuristic, working "taxonomy" of eight conceptually distinct implementation outcomes—acceptability, adoption, appropriateness, feasibility, fidelity, implementation cost, penetration, and sustainability—along with their nominal definitions.

- Pinnock, H, Barwick, L, Carpenter, CR. et al. for the StaRI Group. Standards for Reporting Implementation Studies (StaRI) Statement. *BMJ* 2017;356:i6795
    - The StaRI criteria provide guidance for the outcomes that should be reported in D&I research manuscripts.

Recommended Websites

- Dissemination-Implementation.org - selecting and adapting theories for D&I
- https://societyforimplementationresearchcollaboration.org/ - national society that facilitates communications and collaborations amongst implementation science research teams, researchers, and community members
- http://www.ucdenver.edu/academics/colleges/medicalschool/programs/ACCORDS/sharedresources/DandI/Pages/Dissemination%20and%20Implementation.aspx - Access to D&I tools on CU ACCORDS website
    - http://www.crispebooks.org/PragmaticTrials/Landing-1627-179R3.html - general interactive e-learning book on D&I basics and terms)
    - http://www.crispebooks.org/PragmaticTrials/workbook-1627-1845R.html
- http://cufamilymedicine.org/evaluation_hub/
- www.Re-aim.org - website with resources and details on use of RE-AIM D&I framework
- www.Cfirguide.org - website with resources and details on use of the CFIR D&I framework
- www.precis-2.org - website with resources on using the Pragmatic Explanatory Continuum Indicator Summary tool to assist research trialists to portray visually how pragmatic or explanatory their trial design is

Priority Trainings and Meetings

- 4th Biennial Society for Implementation Research Collaborative meeting, Mechanisms of Implementation, What Works and Why? *Opening Pandora's Box,* Sept. 8-9, 2017
    - http://depts.washington.edu/uwconf/wordpress/sirc2017/
- Academy Health/NIH Annual Meeting on Dissemination and Implementation Research. Washington D.C., Dec. 4-6, 2017
    - http://www.academyhealth.org/events/site/10th-annual-conference-science-dissemination-and-implementation-health
- Mentoring Training in Dissemination and Implementation in Cancer (MT-DIRC) is a 2-year training program with a 1-week summer intensive portion supported by additional distance learning activities. Applications are typically due in January.
    - http://mtdirc.org/
- Knowledge Translation Canada trainings – Knowledge Translation is the comparable term to Dissemination and Implementation Science that is used in Canada. There is an application process for annual summer trainings in Knowledge Translation methods
    - http://ktcanada.org/education/kt-training/

Concocting that Magic Elixir: Successful Grant Application Writing in Dissemination and Implementation Research

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Abstract

Background: This paper reports core competencies for dissemination and implementation (D&I) grant application writing and provides tips for writing a successful proposal.

Methods: Two related phases were used to collect the data: a card sorting process among D&I researchers and an expert review among a smaller set of researchers. Card sorting was completed by 123 respondents. In the second phase, a series of grant application writing tips were developed based on the combined 170 years of grant review experience of the writing team.

Results: The card sorting resulted in 12 core competencies for D&I grant application writing that covered the main sections in a grant application to the US National Institutes of Health: (a) *specific aims* that provide clear rationale, objectives, and an overview of the research plan; (b) *significance* that frames and justifies the importance of a D&I question; (c) *innovation* that articulates novel products and new knowledge; and (d) *approach* that uses a relevant D&I model, addresses measurement and the D&I context, and includes an analysis plan well-tied to the aims and measures.

Conclusions: Writing a successful D&I grant application is a skill that can be learned with experience and attention to the core competencies articulated in this paper. Clin Trans Sci 2015; Volume #: 1–7

Keywords: dissemination and implementation research, grant writing, research, grant review, translational research

Link to full article: http://onlinelibrary.wiley.com/doi/10.1111/cts.12356/full

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Writing implementation research grant proposals: ten key ingredients

Enola K Proctor*, Byron J Powell, Ana A Baumann, Ashley M Hamilton and Ryan L Santens

Abstract

Background: All investigators seeking funding to conduct implementation research face the challenges of preparing a high-quality proposal and demonstrating their capacity to conduct the proposed study. Applicants need to demonstrate the progressive nature of their research agenda and their ability to build cumulatively upon the literature and their own preliminary studies. Because implementation science is an emerging field involving complex and multilevel processes, many investigators may not feel equipped to write competitive proposals, and this concern is pronounced among early stage implementation researchers.

Discussion: This article addresses the challenges of preparing grant applications that succeed in the emerging field of dissemination and implementation. We summarize ten ingredients that are important in implementation research grants. For each, we provide examples of how preliminary data, background literature, and narrative detail in the application can strengthen the application.

Summary: Every investigator struggles with the challenge of fitting into a page-limited application the research background, methodological detail, and information that can convey the project's feasibility and likelihood of success. While no application can include a high level of detail about every ingredient, addressing the ten ingredients summarized in this article can help assure reviewers of the significance, feasibility, and impact of the proposed research.

Keywords: Implementation research, Grant writing, Preliminary studies

Link to full article: http://www.implementation science.com/content/7/1/96

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