COPRH Con
Colorado Pragmatic Research in Health Conference

IMPLEMENTATION & CONDUCT OF PRAGMATIC RESEARCH:
Ensuring Rigor & Relevance in Practice

Virtual International Conference

May 24-26, 2021 | 10 am - 3 pm (MT)

CONFERENCE PROGRAM

Featured Distinguished Speakers

Megan Branda, MS
University of Colorado

Fan Li, PhD
Yale University

Brian Mittman, PhD
Kaiser Permanente

Graham Moore, PhD
Cardiff University (UK)

Julia E. Moore, PhD
The Center for Implementation (CAN)

Monica Perez Jolles, PhD
University of Southern California

Noy Phimphasone-Brady, PhD
University of Colorado

Andrea Troxel, ScD
NYU Langone

David Vock, PhD
University of Minnestoa

A special thank you to all of our invited speakers, without whom this event would not have been possible.

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Welcome to COPRH Con 2021
Implementation and Conduct of Pragmatic Research: Ensuring Rigor and Relevance in Practice

We are delighted you are able to join us for the second Colorado Pragmatic Research in Health Conference (COPRH Con).

There are a variety of ways of conceptualizing pragmatic research – from pragmatic clinicaltrials to drug trials focused on real-world evidence to dissemination and implementation research. For COPRH Con, we conceptualize pragmatic research as research designed to be conducted in the real world using usual care settings, resources, and structures.
Pragmatic research is intended to help support a decision by service and care providers – and policy makers, patients, and other stakeholders – on whether and in what context to adopt, deliver, or make use of an intervention. COPRH Con brings both established and emerging pragmatic methods, measures, and models, many of which come from the blossoming field of dissemination and implementation (or 'D&I') science. These methods helpto ensure that pragmatic research is not seen as messy or poorly done research, but rather relevant AND rigorous.

Of great importance is the fact that conducting research in diverse, real world settings helpsto ensure that our evidence can be applied successfully across different populations and contexts – which is critical for promoting health equity.

COPRH Con is a three-year conference series funded by the Agency for HealthcareResearch and Quality (R13HS027526). The aims of the conference series are to:
Describe and promote **use of pragmatic research methods, models, and measures** tosupport translation of evidence-based practices, policies, and guidelines to clinical, community, and public health settings.
Build capacity for pragmatic research through use of web-based **tools, templates, andguidance materials** for application of pragmatic research methods.
Foster **team science** in use and testing of pragmatic research methods through creationand support of a **virtual learning community**.

The COPRH Con series follows the Evidence Life Cycle (Figure 1). Year 1 focuses on PhaseI – pragmatic research conceptualization, planning and getting funded. Year 2 will focus on Phase II – conduct and
implementation of pragmatic research, with topics such asaccessing learning health system infrastructure, adaptation, ethics, and human subjects research considerations. Year 3 will focus on Phases III and IV – with topics such as dissemination, sustainment, commercialization, and de-implementation.

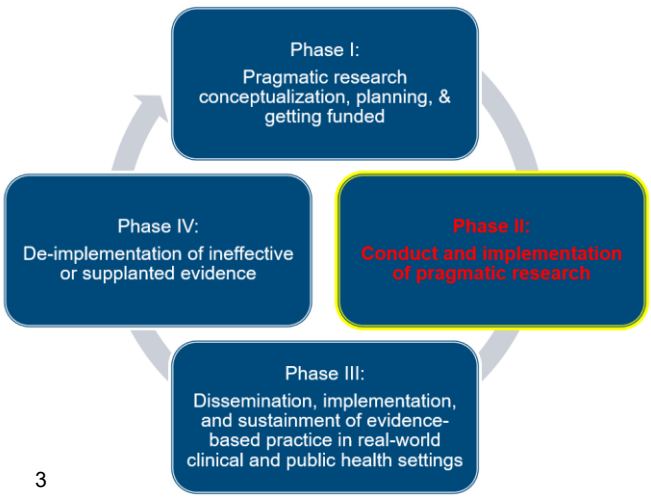


Figure 1. The COPRH Con Evidence Life Cycle

Conference Planning Committee


Bethany Kwan, PhD, MSPH
(Conference Chair)


Russell Glasgow, PhD


Allison Kempe, MD, MPH


Amy Huebschmann, MD, MPH, FACP


Borsika Rabin, PhD, MPH, PharmD


Elizabeth Juarez-Colunga, PhD

Sponsors: The University of Colorado School of Medicine's Adult and Child Consortium for Health Outcomes Research and Delivery Science (ACCORDS) and the Colorado Clinical and Translational Sciences Institute (CCTSI)

Day One: May 24, 2021

Time (MDT)	**Title**	**Speakers**	**Type**
9-10 MT	***Pre-Conference Special*: Welcome and Orientation for Patient and Community Stakeholder Representatives**	Bethany Kwan, PhD, MSPH	Live Session
10–10:15 MT	**Conference Welcome and Overview**	Allison Kempe, MD, MPH; Bethany Kwan, PhD, MSPH	Welcome Address (live)
10:15–11 MT	**Implementation and Conduct of Pragmatic Trials: The Intersection of Quality Improvement, Learning Health Systems, and System Level Change**	Brian Mittman, PhD	Keynote Session (recorded)
15-minute break			
11:15–12 MT	**Pragmatic Research with Real-World Clinical and Community Settings: Challenges, Opportunities, and Recommendations for Success**	Brian Mittman, PhD; Amy Huebschmann, MD; Bryan Garner, PhD; Erin Kenzie, PhD, James Pittman, PhD; Nicole Stadnick, PhD, Shelley Vanderhout, PhD	Panel Discussion (live)
12–12:30 MT	**The Zoom Hallway: See Who Might Be Passing Through!**	Bethany Kwan, PhD, MSPH	Networking Lunch
12:30-1 MT	**An Introduction to Pragmatic Trials: A View into the Rationale and Process of Real-Life interventions**	Megan Branda, MS	Plenary Address (live)
1-1:45 MT	**Track 1: Dissemination and Implementation**		
	Stakeholder Engagement in Complex Environments: One Size Does Not Fit All	Mónica Pérez Jolles, PhD	Plenary Address (live)
	Track 2: Data Science and Biostatistics		
	Recent Developments in Statistical Methods for Pragmatic, Stepped Wedge Cluster Randomized Trials	Fan Li, PhD	Plenary Address (live)
15-minute break			
2-3:15 MT	**Track 1: Implementation and Engagement Strategies**		

2-2:35 MT	Implementation Mapping: A Promising and Innovative Method to Design and Select Implementation Strategies for Firearm Safety Promotion in Pediatric Primary Care *Rinad Beidas, PhD*	Choosing Appropriate Stakeholder Engagement Methods: The Stakeholder Engagement Navigator Webtool *Matthew Decamp, MD; Brad Morse, PhD; Kate Ytell, MPH*		Breakout Session (live)
2:40-3:15 MT	Planning for Practice Facilitation in Your Research Proposal: What You Need to Know *Jeanette Waxmonsky, PhD; Robyn Wearner, MA; Stephanie Kirchner, MSPH*	Juggling the Various Components of Stakeholder Engagement: A Hands-on Approach *Mónica Pérez Jolles, PhD*		
2-3:15 MT	**Track 2: Data Analysis for Pragmatic Research**			
2-2:35 MT	Analyzing Correlated Data: Basics of the Linear Mixed Effects Model *John Rice, PhD*	Clinical Prediction Models *Krithika Suresh, PhD; Katie Colborn, PhD*		Breakout Session (live)
2:40-3:15 MT	Interrupted Time Series with Individual Level Data *Elizabeth Juarez-Colunga, PhD; Angela Moss, MS*	Causal Inference via Trial Emulation *Nandita Mitra, PhD*		

*****CONTINUE TO NEXT PAGE FOR DAY 2*****

Day Two: May 25, 2021

Time (MDT)	**Title**		**Speakers**	**Type**
10-10:30 MT	**The Benefits and Challenges of Leveraging Existing and Secondary Data for Pragmatic Research: A Case Study of Evaluating the Effect of Living Kidney Donation on Long-Term Outcomes**		David Vock, PhD	Keynote Session (live)
15-minute break				
10:45-12 MT	**Track 1: Assessing Context and Fit in Usual Care Settings**			
10:45-11:20 MT	Identifying Multilevel Contextual Factors *Christina Studts, PhD*	PRECIS-2-PS: A Tool for Developing Implementation Trials with Purpose and Intent *Wynne Norton, PhD*		Breakout Session (live)
11:25-12 MT	Assessing Multilevel Contexts *Bryan Weiner, PhD*	Patient Reported Measures: On the Ground Collection, Implementation and Clinical Workflows *Rodger Kessler, PhD, ABPP*		
10:45-12 MT	**Track 2: Managing Real World Data**			
10:45-11:20 MT	Building the Tower of Babel – Tricks and Traps in Harmonizing EHR Data *Lisa Schilling, MD, MSPH; Patrick Hosokawa, MS*	Using Population-Based Data in Secondary Analysis *Allison Kempe, MD; Art Davidson, MD*		Breakout Session (live)
11:25-12 MT	Opportunities for Using Healthcare Claims Data for Pragmatic Sustainability Assessments *Mark Gritz, PhD*	Digital Health Data Access, Management, and Use *Susan L. Moore, PhD, MSPH*		
15-minute lunch break				

12:15-1 MT	**Cultural Adaptations of Evidence-Based Interventions to Fit to Context**		Noy Phimphasone-Brady, PhD	Plenary Address (live)
1-1:50 MT	**Poster Sessions A**		*Various*	Poster Sessions (live)
10-minute break				
2 - 3:15 MT	**Track 1: Measuring Dissemination and Implementation Outcomes**			
2 - 2:35 MT	Assessing and Enhancing Reach and Representativeness *Russell Glasgow, PhD; Meredith Fort, PhD*	Measuring Implementation Outcomes *Cara C. Lewis, PhD*		Breakout Session (live)
2:40-3:15 MT	Process Evaluation and Adaptations in Complex Trials *Graham Moore, PhD*	Methods for Reporting and Aligning Implementation Strategies with Implementation Outcomes *Brittany Rudd, PhD*		
2 - 3:15 MT	**Track 2: Analyzing Real World Data**			
2 - 2:35 MT	Data Quality Assessment Issues and Methods for Secondary Data Use *Michael Kahn, MD, PhD*	Methods for Linking Records Across Disparate Data Sources *Toan Ong, PhD; Jenna Reno, PhD*		Breakout Session (live)
2:40-3:15 MT	Watson: Attics, Guesswork and Clay. Sleuthing Your Way into Biomedical Natural Language Processing *Seth Russell, MS*	Mining and Analyzing Data from Social Media Data Sources *Bethany Kwan, PhD; Jenna Reno, PhD*		

*****CONTINUE TO NEXT PAGE FOR DAY 3*****

Day Three: May 26, 2021

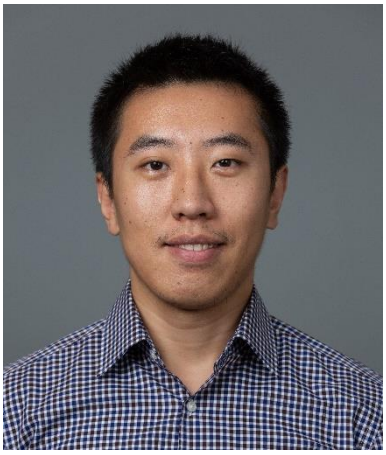
Time (MDT)	**Title**		**Speakers**	**Type**
10 - 11 MT	**Implementing Pragmatic Trials via Electronic Platforms: Practical and Ethical Considerations for Consent, Participation, and Analysis**		Andrea Troxel, ScD	Plenary Session (live)
15-minute break				
11:15 - 12 MT	**Understanding and Adapting to Complexity in Real-World Contexts**		Graham Moore, PhD	Keynote Session (live)
15-minute break				
12:15 – 1 MT	**Poster Sessions B**		*Various*	Poster Session (live)
12:15 – 1 MT	**Building D&I Capacity Around the Globe: A Review of D&I Centers and Programs**		Clare Viglione; Borsika Rabin, PhD	Panel Discussion (live)
1 - 1:45 MT	**Map2Adapt: A Roadmap to Plan for Adaptations**		Julia Moore, PhD	Plenary Address (live)
15-minute break				
2 - 2:45 MT	**Track 1: Adaptation Methods**			
	Using Frame and MADI Frameworks to Guide and Track Adaptations *Shannon Wiltsey Stirman, PhD*	Reconceptualizing Sustainability and Adaptation: From Static to Dynamic *David Chambers, DPhil*		Breakout Session (live)
	The Form and Function Matrix Approach to Adapting Complex Interventions to Local Context *Brian Mittman, PhD*	Multi and Mixed Methods Approaches for Documenting and Analyzing Adaptations in Real-World Studies *Jodi Holtrop, PhD; Borsika Rabin, PhD*		
2:45 - 3 MT	**Looking Towards COPRH Con 2022: Dissemination, Sustainment, and De-Implementation**		Bethany Kwan, PhD, MSPH	Closing Address (live)
End of COPRH Con 2021				

Keynote and Plenary Speakers

Megan Branda, MS
Plenary Address

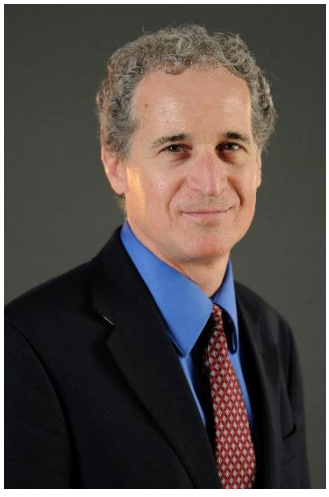
Mrs. Branda has planned and managed clinical trials for over 15 years. She has been a member of three national cancer cooperative groups by planning and analyzing phase I - III randomized clinical trials. She supports the research endeavors of the Mayo Clinic's KER Unit by collaborating on the design and analysis of practice-based interventions as well as pragmatic clinical trials. She is the associate editors for Trials Journal as well as the instructor of a graduate course on clinical trials design at the University of Colorado.

Fan Li, PhD
Plenary Address



Dr. Li is an Assistant Professor in the Department of Biostatistics at the Yale School of Public Health. I am also a faculty member in the Center for Methods in Implementation and Prevention Science (CMIPS) and the Yale Center for Analytical Sciences (YCAS). My research focuses on statistical methodology to evaluate comparative effectiveness with real-world data arising from pragmatic clinical trials, observational studies or a combination of both. I am an expert in the design, monitoring, analysis and interpretation of parallel-arm, crossover and stepped-wedge cluster randomized studies, which are increasingly common in pragmatic trials embedded in the health care delivery systems. I have also been developing new propensity score methods to enable causal inference with real-world observational data, with a focus on improving overlap and internal validity.

Brian Mittman, PhD
Keynote Address



Brian Mittman, PhD is a Senior Scientist at Kaiser Permanente Southern California with additional affiliations at USC and UCLA, where co-leads the UCLA CTSI Implementation and Improvement Science initiative. He co-founded the IOM Forum on the Science of Quality Improvement and Implementation and the journal Implementation Science. He previously chaired the NIH peer review panel on Dissemination and Implementation Research in Health and directed VA's Quality Enhancement Research Initiative. He currently serves on the PCORI Methodology Committee, AAMC Advisory Panel on Research, NHLBI Board of External Experts and advisory committees for several additional research and training programs.

Graham Moore, PhD
Keynote Address

Graham Moore, PhD joined the Cardiff University School of Social Sciences in 2005 as a Research Assistant, while completing an MSc in the University of Bristol. Dr. Moore completed his ESRC funded PhD within the school in 2010, subsequently taking up a post-doctoral role, before obtaining an MRC funded personal fellowship. He was appointed as a Senior Lecturer in 2016 and achieved promotion to Reader in 2018 then to Professor in 2020. Within his current role, Moore is Deputy Director & Health Public Policy programme lead in the Centre for Development Evaluation Complexity and Implementation in Public Health Improvement (DECIPHer) funded by Health & Care Research Wales. Moore is also an investigator, and Wales academic lead, on a large UKPRP funded consortium focused on commercial determinants of health and health inequalities (Shaping Public hEalth poliCies To Reduce ineqUalities and harM; SPECTRUM). Further, he is an investigator (and workstream co-lead) on the new Wolfson Centre for Young People's Mental Health to be established in 2020.

Julia E. Moore, PhD
Plenary Address

Julia E. Moore, PhD, Executive Director of The Center for Implementation, is internationally known for her ability to communicate complex implementation science concepts in clear and actionable ways. Dr. Moore's experience in the field spans more than a decade and includes working on over 100 implementation projects in 8 countries. Her passion for supporting the real-world use of implementation science is shown through her commitment to the spread and scale of accessible training: Dr. Moore has led and designed tailored courses and workshops for over 2500 professionals from a wide range of fields. She also developed the popular online mini-course, Inspiring Change: Creating Impact with Evidence-based Implementation, which has been completed by over 5000 professionals from around the globe.

Mónica Pérez Jolles, PhD
Plenary Address

Mónica Pérez Jolles, PhD, MA, health service and implementation scientist is seeking to close the health gap through team-based science. Her focus brings together scientists from various backgrounds to support Federally Qualified Health Centers (FQHCs) in their efforts to implement and evaluate complex interventions; particularly patient/family-centered and trauma-informed care. Projects include a PCORI-funded Eugene Engagement Award developing a toolkit to increase the capacity of behavioral health care providers to engage in Patient-Centered Outcomes Research (PCOR). Based on her previous work in NC, she recently completed a multi-site pilot study in Los Angeles County exploring the acceptability and feasibility of the concept of health activation among individuals who experienced homelessness and currently live in permanent supportive housing.

Noy Phimphasone-Brady, PhD
Plenary Address

Phoutdavone “Noy” Phimphasone-Brady, PhD (preferred name Noy; preferred pronoun she/her/hers) is a Senior Instructor in the Department of Psychiatry at the University of Colorado, School of Medicine. She is a current K12 Scholar with the NIH-funded Building Interdisciplinary Research Careers in Women’s Health (BIRCWH) Program through the Center for Women’s Health Research. As a clinical health psychologist, her expertise is in the area of women’s health and mental health across in integrated care settings, specifically perinatal mental health, reproductive health, polycystic ovarian syndrome, type 2 diabetes, and weight management. As an integrated psychologist-researcher, her program of research seeks to understand and address 1) sex and gender differences in the development of mental illness in chronic medical conditions, and 2) individual, system, and cultural level determinants to the implementation, adaptation, and sustainability of mental health interventions while managing chronic medical diseases, especially for women of color.

Andrea Troxel, ScD
Plenary Address

Andrea Troxel, ScD is the Director of Biostatistics and Professor of Population Health at New York University. I have extensive experience in the design, implementation, and analysis of clinical trials of all phases, including both pragmatic and adaptive randomized trials. I collaborate with investigators in a wide range of clinical areas, including oncology, cardiology, chronic disease, and behavioral economics. I am also heavily involved in educational activities in biostatistics and clinical trials.

David Vock, PhD
Keynote Address

David Vock, Ph.D., is an associate professor and McKnight Presidential Fellow in the Division of Biostatistics, University of Minnesota. Dr. Vock is an expert in methods to mine electronic health data, assess the causal effect of (time-varying) interventions, and to develop personalized treatment strategies. He collaborates extensively with outcomes researchers in a variety of areas including solid organ transplant, smoking cessation, adolescent depression, and obesity.

Supporting Presenters

**denotes COPRH Con Planning Committee Member*

Rinad Beidas, PhD
Director, Penn Implementation Science Center Psychiatry, Medical Ethics, and Health Policy, Perelman School of Medicine, University of Pennsylvania

Rinad Beidas, PhD, is a leading implementation scientist who has published over 150 articles. She has a strong record of NIH-funded implementation research serving as MPI or PI of nine NIH grants totaling approximately 23 million dollars since 2012. Her research program is designed to improve the quality of health and mental health services through implementation science. To conduct this work, Beidas collaborates closely with key stakeholders, including patients, clinicians, health system leaders, payers, and policymakers, to develop natural laboratories in which to answer questions of interest.

Katie Colborn, PhD
Assistant Professor Department of Surgery, University of Colorado

Katie Colborn, PhD, MSPH is an Assistant Professor in the Department of Surgery and holds a secondary appointment in the Department of Biostatistics and Informatics at the University of Colorado Anschutz Medical Campus. She also co-directs the Surgical Outcomes and Applied Research (SOAR) Program in the Department of Surgery. In her role as SOAR co-director, she collaborates with investigators conducting surgical outcomes and health services research and mentors surgeon faculty, residents, and other graduate students. Her research currently focuses on development and validation of statistical methodologies for clinical prediction models. These lines of inquiry typically involve machine learning and high dimensional model selection. She also leads the Data Informatics and Statistics Core of the Palliative Care Research Cooperative Group. She has received extramural funding for her research and has collaborated on numerous extramural research grants.

David Chambers, DPhil
Deputy Director for Implementation Science, DCCPS

David Chambers, DPhil is Deputy Director for Implementation Science in the Office of the Director in the Division of Cancer Control and Population Sciences (DCCPS) at the National Cancer Institute (NCI). Dr. Chambers manages a team focusing on efforts to build and advance the field of Implementation Science (IS) through funding opportunity announcements, training programs, research activities, dissemination platforms, and enhancement of partnerships and networks to integrate research, practice and policy. He publishes on strategic research directions in implementation science and serves as a plenary speaker at numerous scientific conferences.

Art Davidson, MD, MSPH
Director of Public Health Informatic, Epidemiology, and Preparedness, Denver Public Health

Art Davidson, MD, MSPH is a graduate of State University of New York Brockport (chemistry) and Albert Einstein College of Medicine and was a resident in family medicine at the University of Colorado, where he also received an MSPH (epidemiology) in 1988. He has practiced family medicine and public health at Denver Health since 1982. With University of Colorado appointments in the School of Public Health (Biostatistics and Informatics) and Medicine (Family Medicine), he has been a Primary Care Research Fellowship co-director since the 1990's.

Matthew Decamp, MD, PhD
Associate Professor Center of Bioethics and Humanities; Division of General Internal Medicine; University of Colorado

Matthew DeCamp, MD, PhD, is an Associate Professor in the Center for Bioethics and Humanities and Division of General Internal Medicine. A practicing internist, health services researcher and philosopher, Dr. DeCamp employs both empirical and conceptual methods to identify and solve cutting edge problems at the interface of health care, policy and bioethics. Special emphases of his research include engaging patients in health care organizational decision-making, ethical issues in the use of social media, “Big Data,” and global health (with a focus on short-term global health ethics).

Meredith Fort, PhD
Research Assistant Professor Colorado School of Public Health

Meredith Fort, PhD, MPH, is a Research Assistant Professor in the Colorado School of Public Health in the Department of Health Systems, Management and Policy and the Centers for American Indian and Alaska Native Health. Currently, she is a K12 scholar in the University of Colorado’s IMPACT (IMPlementation to Achieve Clinical Transformation) program. Dr. Fort is dedicated to community-engaged research aimed at improving chronic disease prevention and care and works with community, public health and primary care partners in Central America, Mexico, and the United States. Her current research focuses on: systems science approaches to design and implement multi-level and multi-sectoral interventions to prevent cardiovascular disease; hypertension control in Guatemala’s public primary care system; diabetes prevention and care in Urban Indian Health Organizations; and regenerative foodscapes that promote food sovereignty and support healthy, equitable and sustainable diets and the environment.

Russell Glasgow, PhD*
Director of the Dissemination and Implementation Program The Adult and Child Consortium for Health Outcome Research and Delivery Science

Russell E. Glasgow, PhD, is Research Professor in the Department of Family Medicine, School of Medicine at the University of Colorado and Director of the Dissemination and Implementation Program of the Adult and Child Consortium for Health Outcome Research and Delivery Science there. His research focuses on issues of designing for implementation and sustainability, understanding and assessing adaptations to programs, and development and evaluation of pragmatic models and measures. Russell is a behavioral scientist who specializes in the development and assessment of chronic illness prevention and self-management programs.
Russell has 15 years of experience in implementation science and over 25 years of experience in intervention and health outcomes research. He has over 450 peer reviewed publications, most of them related to applied research issues, evaluating and enhancing generalizability of research, pragmatic research methods and frameworks, and ways to enhance implementation and dissemination.

Mark Gritz, PhD
Director of Operations, Adult and Child Consortium for Health Outcomes Research and Delivery Science

R. Mark Gritz, PhD, is Director of Operations for ACCORDS, an Associate Professor and Head of the Division of Health Care Policy and Research, and Director of Operations at the Farley Health Policy Center. He received his PhD in Economics from Stanford and has over 30 years of experience in directing and managing demonstrations, evaluations, research, and technical assistance projects designed to improve economic, health and other outcomes affecting the well-being of economically-disadvantaged and vulnerable populations. Many of these projects have involved youth, women from low-income families, veterans, elderly, and other targeted populations, including several research and evaluation efforts examining the needs and experiences of low-income youth, unemployed workers, working single mothers, socio-economically

disadvantaged populations, and disabled veterans. His current work focuses on healthcare value and its association with socio-economics factors with an eye towards rapidly responding to research and policy analysis needs of government agencies.

Amy Huebschmann, MD, MS, FACP*
Associate Professor, Division of General Internal Medicine; University of Colorado School of Medicine

Amy Huebschmann, MD, MS, FACP began her education at the University of Illinois at Urbana-Champaign, earning a BS in Environmental Engineering. She earned her medical degree in 2000 from Vanderbilt University School of Medicine and completed her residency at the University of Colorado School of Medicine. Continuing her education, most recently she earned an MS in Clinical Sciences in 2015 at the University of Colorado. Dr. Huebschmann is an Associate Professor at 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.

Patrick Hosokawa, MS
Biostatistician, Analyst Adult and Child Consortium for Health Outcomes Research and Delivery Science

Patrick Hosokawa, MS joined COHO in 2007. He has a Master of Science in Biostatistics from the University of Colorado Denver and was previously a web and database developer. Currently he provides statistical support for the SOAR and Invested initiatives as well as the department of Neurosurgery.

Elizabeth Juarez-Colunga, PhD*
Assistant Professor, Colorado School of Public Health

Elizabeth Juarez-Colunga, PhD, is an Assistant Professorin the Colorado School of Public Health. She received her BS in Applied Mathematics and MSc in Statistics in Mexico, and her doctoral degree in Statistics from Simon Fraser University in Canada. Elizabeth's areas of expertise and interest include: (i) analysis of data with dependencies at different levels including longitudinal and clustered data, which builds upon generalized linear and nonlinear mixed models, (ii) analysis of repeated events data such as pulmonary exacerbations, which evolve as extension of survival analysis methods, (iii) joint modeling of multiple outcomes, and (iv) analysis of observational data. She has been involved in the design and analysis of several health outcomes research studies, including for instance, The Scalable Architecture for Federated Translational Inquiries Network (SAFTINet) project, a pragmatic trial to assist weight loss in a low-income population, and several observational studies in surgical outcomes.

Michael Kahn, MD, PhD
Emeritus Professor, Department of Pediatrics, University of Colorado

Michael Kahn, MD, PhD is an Emeritus Professor of Informatics and Data Science in the Department of Pediatrics at the University of Colorado Anschutz Medical Campus. Formerly, Kahn was Medical Director of Research Informatics at Children's Hospital Colorado (CHCO), Translational Informatics Core Director in the Colorado Clinical and Translational Sciences Institute (CCTSI), and formerly Director of the Health Data Compass Multi-Institutional Research Data Warehouse housed within the Colorado Center for Personalized Medicine (CCPM). As active faculty, I held joint appointments in the School of Medicine, School of Public Health, College of Nursing and Graduate School at the University of Colorado. He has been co-chair of the national NIH funded Clinical and Translational Sciences Award (CTSA) Informatics Key Function Committee, which represents the informatics core directors for all 60 CTSA grantees.

Allison Kempe, MD, MPH*
Founding Director of ACCORDS Professor of Pediatrics at the University of Colorado School of Medicine and the Colorado School of Public Health

Allison Kempe, MD, MPH is the founding Director of ACCORDS. She is a tenured Professor of Pediatrics at the University of Colorado School of Medicine and the Colorado School of Public Health and has conducted health services, outcomes, and implementation/dissemination research for over thirty years. She has extensive experience in conducting pragmatic trials, in program evaluation and in the conduct of surveys, with over 200 publications focusing on improving health care and health care delivery. Finding and testing methods of improving immunization rates and other preventive care delivery and decreasing disparities in health and health care delivery for children have been the major focus of her own research. She has received numerous R01 level grants from NIH, AHRQ, and the CDC throughout her career. Additionally, Dr. Kempe has played a major mentorship role for many fellows and junior faculty. She directed two federally funded primary care research fellowships for over 10 years and developed a fellowship for surgical and subspecialty faculty who wish to become outcomes or health services researchers. Currently, she is a Co-Director of a K12 from NHLBI that focuses on implementation and dissemination science.

Rodger Kessler, PhD, ABPP
Associate Professor, Department of Family Medicine, University of Colorado

Rodger Kessler, PhD, MSPH, is a health psychologist practicing in Family Medicine for over 25 years. While he is often associated with integrated behavioral health, is current do is advanced models of community and primary care integration. His work also, focuses on EHR use and patient reported outcomes, such as quality of life, to assist decision support to promote improved care outcomes.

Stephanie Kirchner, MSPH, RD
Director of Practice Transformation

Stephanie Kirchner, MSPH, RD has been working in quality improvement and practice transformation since 2006, collaborating with partners and stakeholders associated with the Comprehensive Primary Care Initiative, Advancing Care Together, EvidenceNOW, Transforming Clinical Practice Initiative, Colorado State Innovation Model, and the Colorado Behavioral Health Task Force.

Bethany Kwan, PhD, MSPH*
Director, ACCORDS Education Program
Associate Professor, Department of Family Medicine, University of Colorado

Bethany Kwan, PhD, MSPH is an Associate Professor in the Department of Family Medicine at the University of Colorado School of Medicine, Anschutz Medical Campus. She received her PhD in social psychology from the University of Colorado Boulder in 2010, following a MSPH from the University of Colorado Health Sciences Center in 2005. She holds a BS in Chemistry and Psychology from Carnegie Mellon University (’01). As an investigator in the University of Colorado’s Adult & Child Consortium for Health Outcomes Research and Delivery Science (ACCORDS), she conducts pragmatic, patient-centered research and evaluation on health and health care in a variety of areas. With an emphasis on stakeholder engagement and dissemination and implementation (D&I) methods, her work addresses the integration of physical and behavioral health, chronic disease self-management, improving processes and systems of care to achieve the Quadruple Aim, pragmatic trials using electronic health data, and enhancing quality of life for patients and care partners. She works with patients and other stakeholders at all phases of research, from prioritization, to design, implementation, and dissemination of research. She mentors and teaches students, trainees, and fellow faculty on Designing for Dissemination to ensure that research innovations are efficiently and effectively adopted, used, and sustained in real world settings to improve health and well-being for all. Dr. Kwan directs the ACCORDS Education program as well as theColorado Clinical & Translational Sciences Institute (CCTSI) Dissemination & Implementation Research Core.

Cara Lewis, PhD
Associate Investigator, Kaiser Permanente Washington Health Research Institute

Cara C. Lewis, PhD is a clinical psychologist, associate investigator at Kaiser PermanenteWashington Health Research Institute and affiliate faculty in the Department of Psychiatry and Behavioral Sciences at the University of Washington. She is Past President of the Society for Implementation Research Collaboration and co-founding Editor-in-Chief of the proposed SIRC journal. Her research focuses on advancing pragmatic and rigorous measures and methods for implementation science and practice, and informing tailored implementation of evidence-based practices. She is also a Beck Scholar with expertise in Cognitive Behavioral Therapy.

Nandita Mitra, PhD
Professor of Biostatistics Department of Biostatistics, Epidemiology, and Informatics; University of Pennsylvania

Nandita Mitra, PhD, is Professor of Biostatistics and Vice-Chair of Faculty Professional Development in the Department of Biostatistics, Epidemiology, and Informatics at the University of Pennsylvania. She is also the Chair of the Graduate Group in Epidemiology and Biostatistics and Co-Director of the Center for Causal Inference at Penn. Her primary research area is causal inference with a focus on developing propensity score, instrumental variables, and sensitivity analysis methods for observational data with applications in cancer, health policy, and health economics. Dr. Mitra is Editor-in-Chief of Observational Studies and serves on the editorial board of the International Journal of Biostatistics. She is an elected Fellow of the American Statistical Association.

Susan L. Moore, PhD, MSPH
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Brad Morse, PhD earned his Ph.D. in Technology, Media, and Society from the ATLAS Institute at the University of Colorado Boulder. A Masters degree in Cultural Anthropology was obtained before finishing his terminal degree. His current academic interests include userexperience (UX) research, human-centered design, mHealth, qualitative research design, qualitative methods, ethnography, community engagement, and collaborative video development.

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Wynne E. Norton, PhD, is a Program Director in Implementation Science in the Division of Cancer Control and Population Sciences at the National Cancer Institute. Her research interests include de-implementation of ineffective interventions, evidence-based cancer care delivery, and pragmatic trials of implementation strategies. Dr. Norton serves as faculty for the NCI Training Institute for Dissemination and Implementation in Cancer (TIDIRC) and is a program scientist on three NCI Cancer Moonshot(SM) Initiatives.

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Borsika Rabin, PhD, MPH, PharmD is an Assistant Professor at the Department of Family Medicine and Public Health at the School of Medicine, University of California San Diego where she also serves as the co-Director of the UC San Diego D&I Science Center. Dr. Rabin serves as the co-lead of the Implementation Core for the Triple Aim QUERI Program for Denver VA and an Implementation Scientist at the Center of Excellence in Stress and Mental Health at the San Diego VA. She is a member of the ACCORDS Dissemination and Implementation Science Program at the University of Colorado. Her research focuses on dissemination and implementation (D&I) of evidence-based interventions, adaptations, measurement, and the evaluation and development of interactive, web-based interventions and tools with a special emphasis on tools that can support planning for D&I interventions. She designed and developed a number of web- based resources including the D&I Models in Research and Practice (https://dissemination-implementation.org/ websites.

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Seth Russell, MS has been involved in the crucial effort of improving health care and reducing health care costs through the appropriate use of information technology. Some of his works include the R package "Pediatric Complex Chronic Conditions" a tool for scoring pediatric patients based on chronic conditions, big data education materials for non-technical audiences: "Co-Designing Learning Materials to Empower Laypersons to Better Understand Big Data and Big Data Methods", privacy protection through synthetic data generation, and most recently working on some top-secret NLP information extraction tools and the National COVID Cohort Collaborative. While at CU Anschutz, Mr. Russell has been part of Data Science to Patient value Analytics Core and the ACCORDS Data Science Program.

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Lisa Schilling, MD, MSPH, Professor of Medicine at the University of Colorado Department of Medicine, is board-certified in Internal Medicine and Clinical Informatics. She is a practicing general internist with the University of Colorado, and Co-Director of the Data Science to Patient Value Program. She has over a decade of experience with distributed clinical data research networks, common data modeling, and data quality frameworks and assessments. She is currently a co-PI of the pSCANNER project, a distributed data network of over 50 million persons, and the Rapid Response Data Discovery for COVID-19 Clinical Consultations Using Patient Observations (R2D2-CP30) Project.

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Christina Studts, PhD, MSPH, LCSW is an Associate Professor in Pediatrics at the University of Colorado Anschutz Medical Campus, and an implementation scientist with the ACCORDS Dissemination & Implementation Science Program. Her training background is in social work and public health, and her mixed methods research focuses on the systematic adaptation and implementation of evidence-based health promotion interventions with underserved populations--particularly to increase access to parenting interventions in low-resource contexts. In addition to leading her own program of community-engaged research, Dr. Studts serves as an implementation scientist on teams addressing a variety of topical areas, including lung cancer screening, nutrition and physical activity practices in child care settings, sexual risk reduction, diagnostic testing after failed newborn hearing screens, and others. She co-teaches courses on D&I research in health and on context and adaptation in the D&I Science Graduate Certificate Program at the University of Colorado**.**

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Jeanette Waxmonsky, PhD is an Associate Professor in the University of Colorado (CU) Department of Family Medicine and Colorado School of Public Health and an investigator at the CU Adult and Child Consortium for Outcomes Research and Delivery Science (ACCORDS). She has over 20 years' experience in clinical operations, health systems, technology enabled behavioral health services, and academic research focused on the development, implementation, and evaluation of innovative integrated behavioral health services for a variety of patient populations with medical and psychiatric conditions. She also has considerable expertise in the use of evidence-based implementation strategies (e.g., Replicating Effective Programs [REP]) to improve the uptake of evidence-based behavioral health and health behavioral change programs. Dr. Waxmonsky has directed the implementation and evaluation of multiple integrated behavioral health projects, procuring over $22 million in research funding with her collaborators to support these efforts, and has numerous peer reviewed publications based on her work.

Robyn Wearner, MA, RDN
Instructor University of Colorado

Robyn Wearner, MA, RDN, enjoys helping primary care teams work on continuous quality improvement as much as I enjoy working on implementing projects as a research team member. Practice facilitation is the bridge that allows me to bring these two roles together. My background and skills as a Registered Dietitian, Instructional Designer and Project Management Professional have supported numerous programs and research projects at the University of Colorado since 2004.

Bryan Weiner, PhD
Professor Departments of Global Health and Health Services, University of Washington

Bryan Weiner, PhD, is Professor in the Departments of Global Health and Health Services at the University of Washington. Dr. Weiner's research focuses on the implementation of innovations and evidence-based practices in healthcare. Over the past 24 years, he has examined a wide range of innovations including quality improvement practices, care management practices, and patient safety practices; as well evidence-based clinical practices in cancer and cardiovascular disease. His research has advanced implementation science by creating knowledge about the organizational determinants of effective implementation, developing new theories of implementation, and improving the state of measurement in the field.

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Shannon Wiltsey Stirman, PhD, is a clinical psychologist and implementation scientist at the VA National Center for PTSD and in the Department of Psychiatry and Behavioral Sciences at Stanford University. She is the co-director of the Stanford Mental Health Technology and Innovation Hub, and has served on the boards of the Society for Implementation Research Collaboration and the American Psychological Association. Her work focuses on sustainability, adaptation, fidelity and training, and has been funded by NIMH, the VA, and private foundations.

Kate Ytell, MPH
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Kate Ytell, MPH works as a PRA for the D2V initiative, where she supports various research and evaluation efforts including the Stakeholder Engagement Core and the Post-Acute Care Research and Team Science group. Her research interests include refugee health, culturally effective research, and stakeholder engagement.

Implementation and Conduct of Pragmatic Trials: The Intersection of Quality Improvement, Learning Health Systems, and System Level Change

Brian Mittman, PhD

This opening keynote to COPRH Con will set the stage for this year's conference theme, implementation and conduct of pragmatic research. As pragmatic research ideally occurs in real world clinical, public health, and community settings, it is ideal for research protocols to align with existing processes, personnel, and data sources.

[Notes]

Monday, May 24, 2021 – 11:15 AM to 12:00 PM Panel Discussion

Pragmatic Research with Real-World Clinical and Community Settings: Challenges, Opportunities, and Recommendations for Success

- Amy Huebschmann, MD, MSc, Session Organizer and Co-moderator
- Brian Mittman, PhD, Session Co-moderator

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[1] Prevalence and Factors Associated with Patient-Reported Outcomes in Pragmatic Randomized Controlled Trials

Presented by Shelley Vanderhout, PhD, RD, University of Ottawa

Theme 2: Dissemination and Implementation Science Methods | Best of COPRH Con

Background: Patient-reported outcomes (PROs) are subjective measures of health and well-being that come directly from patients and commonly used to measure patient experience, quality of life, and symptoms. Given that pragmatic trials aim to provide evidence to inform clinical care decision making, PROs seem well suited to pragmatic trials; however, their use and reporting in pragmatic trials have not been described. We sought to review pragmatic trials to describe (1) the prevalence and types of PROs used; (2) whether the use of PROs varied across trial characteristics; and (3) how sample sizes and target differences were determined for trials with PROs.

Methods: An electronic search filter in MEDLINE was used to identify primary reports of pragmatic randomized controlled trials in health research published 2014-2019, that were registered in ClinicalTrials.gov and

self-identified as pragmatic. Trial descriptors were downloaded from ClinicalTrials.gov; information about PROs and sample size calculations were extracted from each report. Data were summarized descriptively. Chi-squared, Cochran-Armitage and Wilcoxon rank-sum tests were used to examine associations between trial characteristics and use of PROs.

Results: Of 415 trials which met inclusion criteria, 235 (57%) measured PROs (144 (35%) at least as primary/co-primary and 91 (22%) as only secondary outcomes). Primary PROs were symptoms (64; 44%), health behaviours (36; 25%), quality of life (8; 13%), functional status (16; 11%), and patient experience (10; 7%). Studies published in higher impact journals or funded by industry were less likely to use PROs as

primary/co-primary outcomes, whereas individually (vs. cluster) randomized studies, those conducted in Europe, and those which tested dietary or behavioural interventions were more likely to use PROs as

primary/co-primary outcomes. Patient engagement was not associated with use PROs as primary/co-primary outcomes. For the 144 trials with a PRO as primary or co-primary outcome, 126 (88%) reported a sample size calculation for that outcome. No justification was provided for the target difference in 53 (42%); patient or stakeholder opinion was rarely used to justify the target difference (8, 6%).

Conclusions: PROs are not routinely selected as outcomes in pragmatic trials, and patient and stakeholder engagement in determining target differences and sample sizes is rare. Institutions, funding bodies, and scientific journals can encourage the use of PROs in pragmatic trials by creating incentives, providing methodological support, and establishing policies for pragmatic trialists.

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[2] The Substance Abuse Treatment to HIV Care (SAT2HIV) Project: An example of a completed dual-randomized type 2 hybrid trial

Presented by Bryan R. Garner, PhD, RTI International

Theme 1: Pragmatic Trial Examples | Best of COPRH Con

Background: To help "speed the translation of research findings into routine practice" Curran and colleagues (2012) codified three types of hybrid trial designs (i.e., Type 1, Type 2, and Type 3). As part of type 2 hybrid trials they proposed "dual testing of clinical and implementation interventions/strategies." Despite their note about using the term test in a "liberal manner" (i.e., the clinical and implementation interventions/strategies need not all be tested with randomized, strongly powered designs), in 2014 the National Institute on Drug Abuse funded a dual-randomized type 2 implementation-effectiveness hybrid trial called the Substance Abuse Treatment to HIV care (SAT2HIV) Project. Consistent with theme area 1 (Pragmatic Trial Examples), this presentation/poster will provide a concrete example of what Landes, McBain, and Curran (2019) highlighted as a "rarer" type 2 hybrid trial example.

Setting/Population: Thirty-nine HIV service organizations, 78 HIV service organization staff, and 824 people with HIV and a comorbid substance use disorder.

Methods: A dual-randomized type 2 implementation-effectiveness hybrid trial, which simultaneously included: 1) a 39-site cluster-randomized implementation trial focused on testing the effectiveness of the team-focused Implementation & Sustainment Facilitation (ISF) Strategy as an adjunct to the staff-focused Addiction Technology Transfer Center.

(ATTC) Strategy, and 2) a multisite randomized controlled trial testing the effectiveness of a motivational interviewing-based brief intervention for substance use as an adjunct to HIV service organization's usual care for substance use disorders. Both staff-level outcomes and client-level outcomes were examined.

Results: The ISF Strategy had a significant impact on implementation effectiveness (i.e., the consistency and the quality of implementation; ? = .65, p = .01), but not on time-to-proficiency (? = ?.02), or level-of-sustainment (? = .09). Additionally, the ISF Strategy had a significant impact on intervention effectiveness (i.e., the effectiveness of the MIBI), at least in terms of significantly decreasing the odds (odds ratio = 0.11, p = .02) of clients using their primary substance daily during follow-up.

Conclusions: Although not for the faint of heart, dual-randomized type 2 hybrid trials can be successfully completed with the right infrastructure and team. Building upon the SAT2HIV Project, the SAT2HIV-II Project is a type 3 hybrid trial that was recently funded by the National Institute on Drug Abuse that is focused on testing a pay-for-performance (P4P) strategy as an adjunct to the ATTC+ISF Strategy found to be most effective as part of the original SAT2HIV Project.

All Authors and Affiliations

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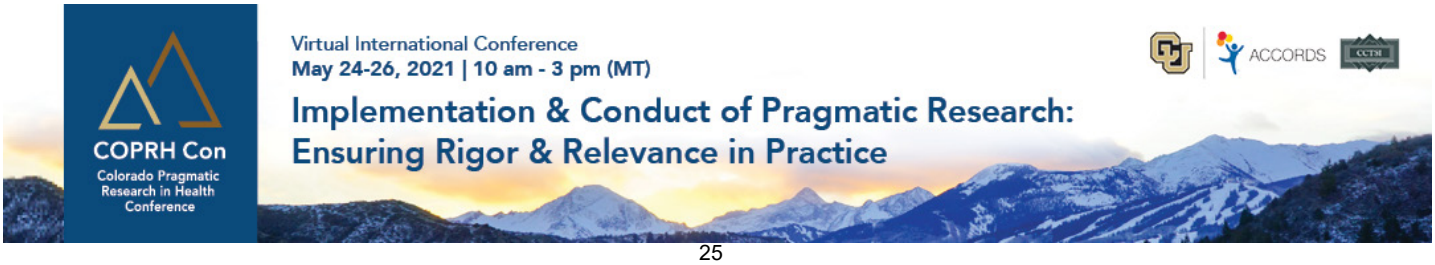

[3] Combining Qualitative Interviewing with Systems Science to Understand How Practice Facilitators Tailor Implementation Support to Context

Presented by Erin Kenzie, PhD, Oregon Health & Science University

Theme 2: Dissemination and Implementation Science Methods | Best of COPRH Con

Background: A complex array of factors affect the ability of primary care clinics to successfully integrate evidence-based practices into routine care. Models like i-PARIHS (integrated Promoting Action on Research Implementation in Health Services) identify factors related to the intervention, recipients (motivation, skill), and multiple levels of context including local (workflows, past experience), organization (culture, structure), and external (policy drivers). To effectively support clinics, practice facilitators-individuals trained to build the capacity of primary care practices-must accurately assess clinics' needs and identify corresponding means of implementation support. Examining how this tailoring happens is key to evaluating program outcomes and maximizing program success.

Setting: This research is being conducted as part of the ANTECEDENT study, an AHRQ-funded EvidenceNOW unhealthy alcohol use project led by the Oregon Rural Practice-based Research Network (ORPRN). In ANTECEDENT, ORPRN practice facilitators provide technical assistance and supportive services to primary care clinics to adopt or improve evidence-based methods of addressing unhealthy alcohol use through screening, brief intervention, and medication assisted treatment (MAT). Efforts are aligned with the state's Medicaid quality incentive metric for SBIRT (screening, brief intervention, and referral to treatment) and in partnership with SBIRT Oregon (www.sbirtoregon.org).

Methods: In this mixed methods evaluation, we combine qualitative interviews with causal-loop diagramming, a systems science method for describing complex interrelationships. This poster will outline how we are using causal-loop diagramming to enhance our qualitative analysis and structure our understanding of how practice facilitators respond to clinic needs. We will describe our approach for generating causal-loop diagrams illustrating practice facilitators' mental models of practice change from qualitative interviews.

Results: Preliminary results from baseline analyses will be presented by illustrating causal-loop diagrams of practice facilitators' mental models of practice change and tailoring implementation support to context. By analyzing the structure and content of the diagrams, insight can be gained about the range of perspectives held by practice facilitators. Strengths and limitations of this approach to modeling from qualitative data will be identified.

Conclusions: System dynamics, and causal-loop diagramming in particular, is well suited for enhancing qualitative analysis. Our novel approach provides a framework to specify documented or assumed cause-and-effect relationships. This approach can illustrate the mental models of practice facilitators or researchers and help improve evaluation as well as implementation outcomes.

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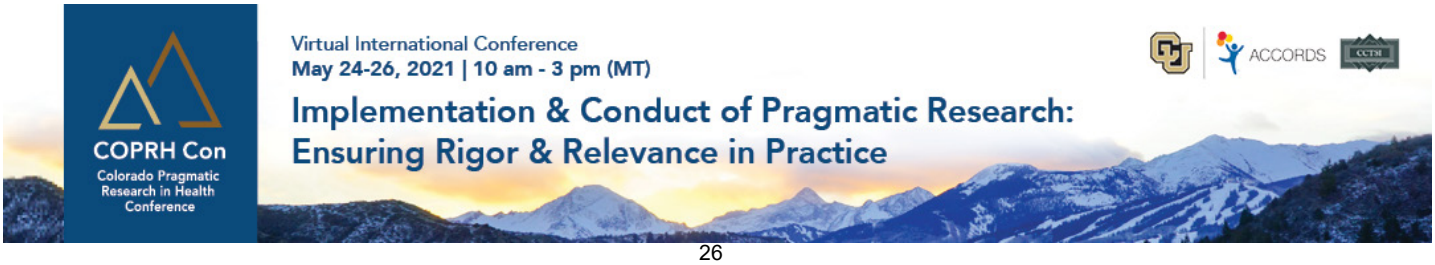

[4] Adaptation of a Quality Improvement Approach to Implement eSceening in VHA Healthcare Settings

Presented by James Pittman, University of California San Diego, VA San Diego Center of Excellence for Stress and Mental Health

Theme 2: Dissemination and Implementation Science Methods | Best of COPRH Con

Background: The Veterans Health Administration (VHA) developed a comprehensive mobile screening technology (eScreening) that provides customized and automated self-report health screening via mobile tablet forveterans seen in VHA settings. There is agreement about the value of health technology, but limited knowledge of how best to broadly implement and scale up health technologies. Quality improvement (QI) methods may offer solutions to overcome barriers related to broad scale implementation of technology in health systems. We aimed to develop a process guide for eScreening implementation in VHA clinics to automate self-report screening of mental health symptoms and psychosocial challenges.

Setting/Population: Stakeholders within the VHA.

Methods: This was a two-phase, mixed methods implementation project building on an adapted quality improvement method. In phase one, we adapted and conducted a Rapid Process Improvement Workshop (RPIW)to develop a generalizable process guide for eScreening implementation (eScreening Playbook). In phase two, we integrated the eScreening Playbook and RPIW with additional strategies of training and facilitation tocreate a multicomponent implementation strategy (MCIS) for eScreening.

We then piloted the MCIS in two VHA sites. Quantitative eScreening pre-implementation survey data and qualitative implementation process"mini interviews" were collected from individuals at each of the two siteswho participated in the implementation process. Survey data were characterized using descriptive statistics, and interview data were independently coded using a rapid qualitative analytic approach.

Results: Pilot data showed overall satisfaction and usefulness of our MCIS approach and identified some challenges, solutions, and potential adaptations across sites. Both sites used the components of the MCIS, butsite 2 elected not to include the RPIW. Survey data revealed positive responses related to eScreening from staff at both sites. Interview data exposed implementation challenges related to the technology, support, andeducation at both sites. Workflow and staffing resource challenges were only reported by site 2.

Conclusions: A RPIW can be an important factor in the adoption of health technology, but organizational factors also need to be addressed. Throughour experience implementing eScreening, we have found that successful adoption of health technology needs to be flexible and contain multiple components. Overall, our use of RPIW and other QI methods to both develop a playbook and an implementation strategy for eScreening has created a testable implementation process to employ automated, patient-facing assessment. The efficient collection and communication of patient information has the potential to greatly improve access to and quality of healthcare.

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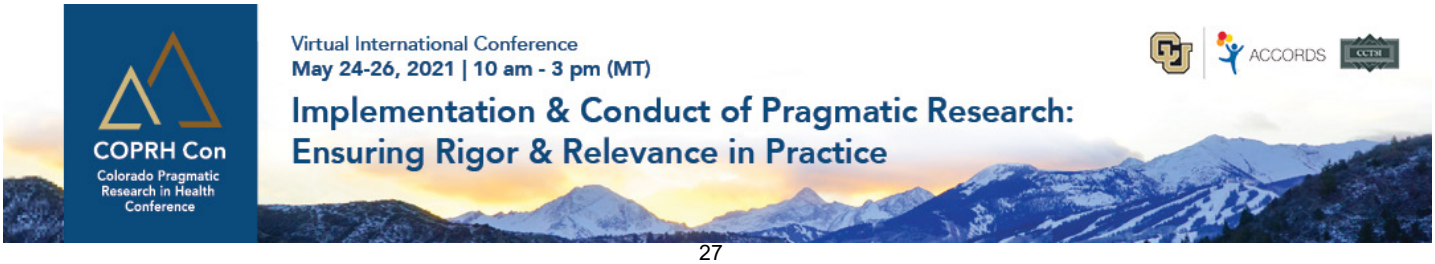

Monday, May 24, 2021 – 11:15 AM to 12:00 PM Panel Discussion

Pragmatic Research with Real-World Clinical and Community Settings: Challenges, Opportunities, and Recommendations for Success

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[5] Using Meaningful Community Engagement Methods to Advance COVID-19 Testing and Vaccine Uptake in Underserved Communities

Presented by Nicole Stadnick, University of California San Diego

Theme 2: Dissemination and Implementation Science Methods | Best of COPRH Con

Background: In response to the alarming health disparities experienced by underserved communities related to the COVID-19 pandemic, the National Institutes of Health (NIH) heavily invested in community engagement research efforts to eliminate disparities in testing, clinical trial participation, access to care, and vaccination. We describe the use of a Theory of Change process to meaningfully engage community members from or supporting underserved communities in two NIH-funded implementation science projects aimed at promoting equitable access to COVID-19 prevention and care services.

Setting/population: Both projects focused on underserved Latinx, Black, and immigrant and refugee communities in South/Central San Diego and/or individuals accessing care at a federally qualified health center (FQHC) near the US/Mexico border.

Methods: A Community Advisory Board (CAB) was established for each project with 11 and 22 members. CAB members included community organizers, promotores, FQHC providers and administrators, and public health researchers. The Global Action Research Center (ARC) led the recruitment of CAB members and facilitated each meeting. The Global ARC is a non-profit social change organization committed to bridging academic and community conversations to support community-driven solutions to public health priorities. The CABs were guided through a six-session Theory of Change, focused on identifying necessary conditions that must exist for a community-identified issues of concern along with specified actions to create those conditions and a blueprint for assessing the efficacy of those actions. Each session lasted two hours hosted over Zoom and was augmented by interactive web-based activities. Each CAB member was offered $100 for their participation in each meeting. There was a live interpreter who facilitated participation of Spanish-speaking CAB members.

Results: A Theory of Change for each project was completed in approximately four months. A total of nine necessary conditions were identified across both projects. Cross-cutting conditions related to 1) accessible and available resources and services, 2) culturally and linguistically competent programming and materials, 3) investment in trusted community and faith leaders to convey accurate information, 4) social safety net to provide ancillary resources/services to support families. Corresponding actions to create these conditions were operationalized by the CAB members along with measures to indicate success in creating these necessary conditions.

Conclusions: We used a CAB-led Theory of Change process facilitated by our community partner, the Global ARC, to comprehensively assess and co-create necessary conditions, actions, and measures to eliminate disparities in COVID-19 prevention and intervention. While resource-intensive, these methods yielded a rich opportunity to equitably engage diverse groups that typically are not invited to inform these processes.

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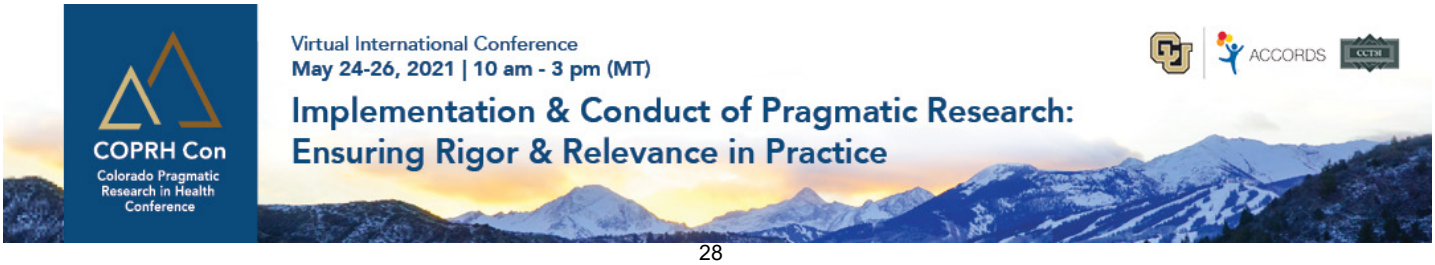

An Introduction to Pragmatic Trials: A View Into the Rationale and Process of Real-Life Interventions

Plenary Address by Megan Branda, MS

Learning Objectives:

1. Describe the evolution of the efficacy trial to the pragmatic.
2. Use systematic approaches to design and evaluate pragmatic trials.
3. Describe practical approaches and resources to ensure administrative, clinical and patient preferences in design.

References for Pragmatic Trials

1. NIH Pragmatic and Group Randomized Trials in Public Health and Medicine course (7 parts) https://prevention.nih.gov/resources-for-researchers/nih-methods-training/grt
    a. This is the online series of courses offered by the NIH. If you have no experiencethen it could be helpful. A section is on issues other researchers have experienced and what they did to address them.
2. For I., Norrie J. Pragmatic Trials. N Engl J Med 2016;375:454-63. DOI: 10.1056/NEJMra1510059
    a. This is a nice overview of pragmatic trials. It addressed several issues andexplained things in an easy to obtain manner.
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4. Patsopoulos NA. A pragmatic view on pragmatic trials. Dialogues in Clinical Neuroscience - Vol13 . No. 2 . 2011
    a. This paper explains where pragmatic trials started from and some of the changes and tools to use currently.
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    a. This is two examples of pragmatic trials in primary care and addresses some of the issues.

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    a. This paper is more statistically driven but I thought it was a great review ofdesign/planning issues when planning a trial and provides solutions.

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    a. A look at the ethical implications as well as the regulatory issues that may arrise.
9. Weinfurt K.P, Hernandez A.F., Coronado G.D. Pragmatic clinical trials embedded in healthcare systems: generalizable lessons from the NIH Collaboratory. BMC Medical Research Methodology (2017) 17:144. DOI 10.1186/s12874-017-0420-7
10. Rachel L Richesson, Beverly B Green, Reesa Laws, Jon Puro, Michael G Kahn, Alan Bauck, Michelle Smerek, Erik G Van Eaton, Meredith Zozus, W Ed Hammond, Kari A Stephens, Greg E Simon, Pragmatic (trial) informatics: a perspective from the NIH Health Care Systems Research Collaboratory, *Journal of the American Medical Informatics Association*, Volume 24, Issue 5, September 2017, Pages 996–1001, https://doi.org/10.1093/jamia/ocx016

An Introduction to Pragmatic Trials: A View Into the Rationale and Process of Real-Life Interventions

Plenary Address by Megan Branda, MS

11. Emily Pfaff, Adam Lee, Robert Bradford, Jinhee Pae, Clarence Potter, Paul Blue, Patricia Knoepp, Kristie Thompson, Christianne L Roumie, David Crenshaw, Remy Servis, Darren A DeWalt, Recruiting for a pragmatic trial using the electronic health record and patient portal: successes and lessons learned, *Journal of the American Medical Informatics Association*, Volume 26, Issue 1, January 2019, Pages 44–49, https://doi.org/10.1093/jamia/ocy138
    a. This study shows the assessment of different methods for contacting a patientfor recruitment.
12. DeBar L, Benes L, Bonifay A, et al. Interdisciplinary team-based care for patients with chronicpain on long-term opioid treatment in primary care (PPACT) - Protocol for a pragmatic cluster randomized trial. *Contemp Clin Trials*. 2018;67:91-99. doi:10.1016/j.cct.2018.02.015
    a. Example of a pragmatic trial of a complex intervention.
13. Burch T. Patient Commentary: Added Value and Validity to Research Outcomes ThroughThoughtful Multifaceted Patient-Oriented Research. Patient. 2020
    a. Strategies on collaborating with patients.

Below are two tools, first to assess bias in a cluster randomized trial and the second to gage 'how pragmatic is your trial'. PRECIS-2 seems to be the current standard (https://www.precis-2.org) - PRECIS-2 is coming soon.

14. Caille A, Kerry S, Tavernier E, Leyrat C., Eldridge S, Giraudeau B. Timeline cluster: a graphical tool to identify risk of bias in cluster randomized trials. BMJ 2016; 354:i4291.

15. Loudon Kirsty, Treweek Shaun, Sullivan Frank, Donnan Peter, Thorpe Kevin E, Zwarenstein Merrick et al. The PRECIS-2 tool: designing trials that are fit for purpose BMJ 2015; 350 :h2147

[Notes]

Stakeholder Engagement in Complex Environments: One Size Does Not Fit All

Plenary Address by Mónica Pérez Jolles, PhD

The use of pragmatic trials and calls for stakeholder engagement during trial implementation have common goals -- increase diversity of views and contributions, co-creation during the implementation process, and sustainment of evidence-based practices in real-world clinical and community settings. Early calls for the value of pragmatic trials can be traced back to 1967 with Schwarts and Lelouch'si call for 'pragmatic attitudes' during clinical trials. The younger field of implementation science with an emphasis on contexts and faster translation of evidence into routine practices in real-world settings can greatly contribute to the achievement of pragmatic trial goals. I will first provide an overview of the concept of implementation strategies and their role in pragmatic trials, as well as an overview of the state of the literature. Then, I will discuss stakeholder engagement using the 7 P's Stakeholder Matrix by highlighting the role of context on shaping engagement within and across stakeholder categories. Last, I will advocate for the inclusion of engagement strategies that can foster co-creation, and social justice and inclusion, as promising avenues to increase health equity in the United States. My overall goal is that this discussion will enable a shift, from linear and formulaic approaches to engagement with diverse communities, to a context-dependent and health equity approach.

[i] Schwartz D, Lelloch J. Explanatory and pragmatic attitudes in therapeutic trials. Journal of Chronic Disease. 1967; 20:637–48.

Learning Objectives:

1. Learn the concept of implementation strategies and its role in pragmatic trials
2. Identify state of the literature on approaches to stakeholder engagement in pragmatic trials, limitations, and future research
3. Analyze stakeholder engagement taxonomies (7 P'S Stakeholder Matrix) as context dependent
4. Learn various ways to incorporate stakeholder engagement in grant applications and scientific publications
5. Advocate for concrete ways to co-create and incorporate a lens of social justice and inclusion in stakeholder engagement efforts

Thought Questions

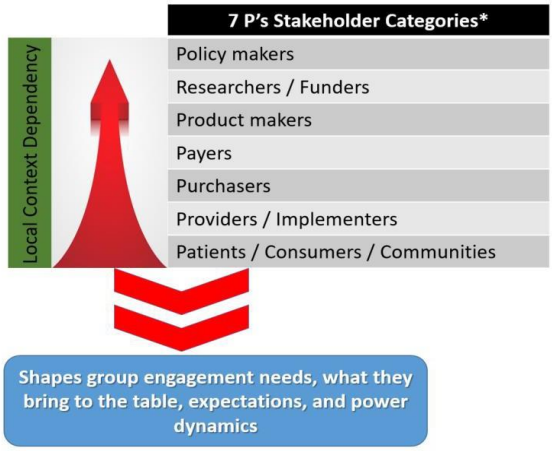
1. How can you increase tracking and reporting of engagement activities throughout the study?
2. What is your take on the statement that stakeholder engagement is context dependent? Do you agree or disagree and why?
3. How can stakeholders in your community benefit from engagement in the research process?

Stakeholder Engagement in Complex Environments: One Size Does Not Fit All

Plenary Address by Mónica Pérez Jolles, PhD

Key Points

- Active stakeholder engagement increases the quality of the research, and the success of the implementation, and sustainment of EBPs
    - I will summarize the literature and provide an example (A 2020 systematic review on patient involvement gave our study the highest rating of quality.)
- Several systematic literature reviews highlight the comprehensiveness of stakeholder engagement during pragmatic trials, as well as limitations related to lack of tracking and reporting of engagement activities
- The field of implementation science can address some of these gaps by:
    - Leveraging tested implementation strategies (definition and classification)
    - Conceptualizing stakeholder engagement as context dependent (complexity)



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

- It is important to showcase pre-implementation engagement in grant proposal and to include community partners as co-authors in peer reviewed publications
- Stakeholder engagement benefits communities by promoting a co-creative process rooted in social justice and inclusion
    - I plan on incorporating short video interview clips (1min or less each), from community and research partners, on their take on this key point, from their perspective and experience
        - Partners will represent: An outpatient community clinic in North Carolina, two Federally Qualified Health Center systems, and a Permanent Supportive Housing Agency in Southern California

Stakeholder Engagement in Complex Environments: One Size Does Not Fit All

Plenary Address by Mónica Pérez Jolles, PhD

Resources

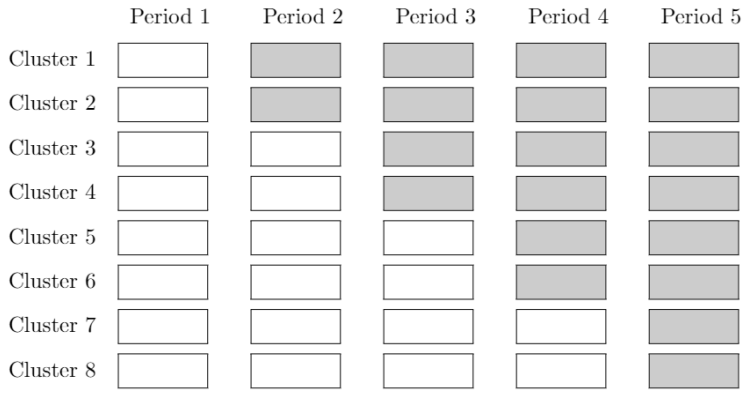
1. Brownson R. C., Colditz, G. A. & Proctor, E. K. (Eds.) (2018). *Dissemination and Implementation Research in Health: Translating Science to Practice* (Second edition). Oxford; New York: Oxford University Press.
    a. See pages 31-34; Chapter 15 – Implementation Strategies for a deeper review of the concept of implementation strategies, a list of evidence-based strategies (ERIC list) and efforts by Powell and colleagues in classifying stakeholder engagement strategies (12.4% of that ERIC list).
2. Concannon TW, Meissner P, Grunbaum JA, et al. A New Taxonomy for Stakeholder Engagement in Patient-Centered Outcomes Research. J Gen Intern Med.
3. 2012;27(8):985-991.
    a. Provides additional information on the 7 P's stakeholder taxonomy.
4. Gesell, S., Halladay, J., Mettam, L., Sissine, M., Staplefoote-Boynton, B., Duncan, P. (2020). Using REDCap to track stakeholder engagement: A time-saving tool for PCORI- funded studies. *Journal of Clinical and Translational Science, 4*(2), 108-114.
    a. This recent paper emphasizes the use of technology to better track and report on stakeholder engagement in research studies.
5. Maar, M., Yeates, K., Barron, M. *et al.* I-RREACH: an engagement and assessment tool for improving implementation readiness of researchers, organizations and communities in complex interventions. (2015). *Implementation Science,* **10(**64). https://doi.org/10.1186/s13012-015-0257-6
6. Bombard, Y., Baker, G.R., Orlando, E. *et al.* Engaging patients to improve quality of care: a systematic review. *Implementation Sci* **13,** 98 (2018). https://doi.org/10.1186/s13012-018-0784-z
    a. These two papers provide a review of relevant approaches and contextual factors to maximize patient engagement during intervention development and implementation, and an assessment tool.

[Notes]

Recent Developments in Statistical Methods for Pragmatic, Stepped Wedge Cluster Randomized Trials

Plenary Address by Fan Li, PhD

A **Stepped Wedge Cluster Randomized Trial** (SW-CRT) uses a design that allows for phased implementation of an intervention. In a SW-CRT, clusters are randomized to intervention sequences that differ by the time points when the intervention starts to roll out. There are three major types of SW-CRTs, **cross-sectional, closed-cohort and open-cohort**, depending on whether the same set of participants are followed over time. As in a Parallel-Arm CRT, cluster randomization leads to positively correlated individual responses, both within and between time periods. Appropriate statistical methods (such as mixed models or GEE) should be considered for design and analysis.



The **advantage** of SW-CRTs is logistical convenience. Another attractive feature is that all clusters eventually receive the intervention, which can help facilitate recruitment when cluster stakeholders perceive the intervention to be beneficial. The **challenge** of SW-CRTs is that it may take longer to finish, and requires additional data collection effort (for example, in a closed-cohort design).

Unlike in a Parallel-Arm CRT, the design and analysis of SW-CRTs are mostly model-based, and requires accounting for secular trend and more complex **intraclass correlation coefficients** (ICCs). For example, the essential ingredient of a mixed model expresses the mean outcome as the sum of [secular trend] + [intervention effect] + [heterogeneity]. Variations of each components exist to address different complications arising from SW-CRTs. Different specifications of the [heterogeneity] component induces different ICC structures, that differentiates **within-period ICC, between-period ICC,** and **longitudinal autocorrelation,** depending on specific design variant. Compared to Parallel-Arm CRTs, sample size determination in SW-CRTs requires more ICC parameters as well as sensitivity analysis. Software tools are available in SAS, R and Stata to facilitate these calculations.

Analysis of SW-CRTs should adequately adjust for secular trend and ICC structures. Two mainstream model-based approaches are **conditional models (mixed models)** and **marginal models (GEE),** the latter of which carries a straightforward **population-averaged** interpretation. Software for mixed models is widely accessible, whereas more advanced tools for GEE analysis of SW-CRTs has been recently developed to address computational challenges with large cluster sizes and complex ICC structures. It is strongly advocated to estimate ICCs in analyzing SW-CRTs, for better reporting practice as well as efficiency considerations.

Recent Developments in Statistical Methods for Pragmatic, Stepped Wedge Cluster Randomized Trials

Plenary Address by Fan Li, PhD

Notes:

Track 1: Implementation and Engagement Strategies

Implementation Mapping: A Promising and Innovative Method to Design and Select Implementation Strategies for Firearm Safety Promotion in Pediatric Primary Care
Rinad Beidas, PhD

Learning Objectives:
1. The participants will be able to describe the implementation mapping method.
2. The participants will learn the strengths and weaknesses of this approach for designing and/or selecting implementation strategies.
3. The participants will be able to apply principles of implementation mapping to their own work.

Planning for Practice Facilitation in Your Research Proposal: What You Need to Know
Jeanette Waxmonsky, PhD; Robyn Wearner, MA; Stephanie Kirchner, MSPH

Learning Objectives:
1. Describe how practice facilitation can be used in research projects.
2. Identify components of practice facilitation that impact project plans.

Choosing Appropriate Stakeholder Engagement Methods: The Stakeholder Engagement Navigator Webtool
Matthew DeCamp, MD; Brad Morse, PhD; Kate Ytell, MPH

Learning Objectives:
1. Describe the untapped potential of stakeholder engagement for enhancing your research.
2. Explain two unmet research needs for improving stakeholder engagement.
3. Feel comfortable using the Stakeholder Engagement Navigator webtool as described in the demonstration.

Juggling the Various Component of Stakeholder Engagement: A Hands-On Approach
Mónica Pérez Jolles, PhD

Learning Objectives:
1. Understanding of the concept of stakeholder engagement as a multi-component, dynamic concept during the implementation of a pragmatic trial.
2. Awareness of practical approaches/methods for stakeholder engagement.
3. Learning of challenges and lessons learned from an illustration on the use of CBPR in a PCORI-funded pragmatic trial.

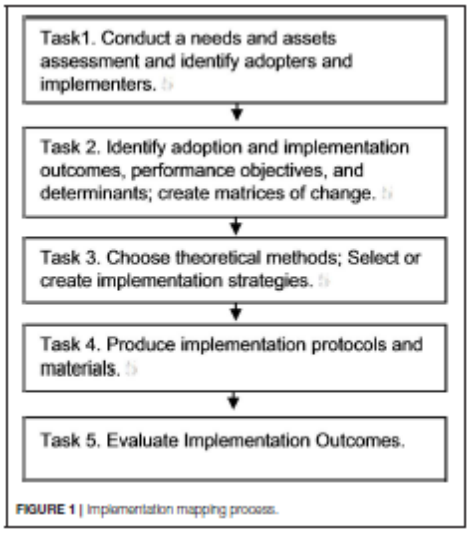
Implementation Mapping: A Promising and Innovative Method to Design and Select Implementation Strategies

Rinad S. Beidas, PhD; University of Pennsylvania

Key points

1. Findings with regard to which implementation strategies are most effective have been equivocal. These results may largely be due to the manner in which implementation strategies were designed and selected in earlier work.
2. Implementation mapping is a promising method through which to select and tailor implementation strategies with an eye towards targets and mechanisms.
3. We illustrate the process of applying implementation mapping via the use case of selecting strategies for a comparative effectiveness trial of firearm safety promotion in pediatric primary care.
4. We review the benefits of using this approach and future directions.

Figure 1. Implementation Mapping Process



Reproduced from Fernandez et al (2019).

Questions

1. What are challenges to using implementation mapping to derive implementation strategies?
2. What are other structured methods to develop implementation strategies?

References

Fernandez, M., ten Hoor, G., van Lieshout, S., Rodriguez, S., Beidas, R., Parcel, G., Ruiter, R., Markham, C., & Kok, G. (2019). Implementation mapping: Using intervention mapping to develop implementation strategies. *Frontiers in Public Health*.

Powell, B., Beidas, R., Lewis, C., Aarons, G., McMillen, J., Proctor, E., & Mandell, D. (2017). Methods to improve the selection and tailoring of implementation strategies. *Journal of Behavioral Health Services Research.*

Powell, B., Fernandez, M., Williams, N., Aarons, G., Beidas, R., Lewis, C., McHugh, S., & Weiner, B (2019). Enhancing the impact of implementation strategies in healthcare. *Frontiers in Public Health*.

Planning for Practice Facilitation Checklist

You've got a great project in mind and would like to incorporate practice facilitation. What can you do to help make your project go as smoothly as possible? The "buckets" below will help you think through how to plan for practice facilitators based on your research or project.

☐ **Timeline**
-How long is the intervention and how much PF support will your project require?

☐ **Dose**
-What expectations does your project have for PF interaction with practices?

-How often will the PF visit each practice site?

-How long will practice site visits be?

-Will there be practice connections between site visits (email check ins, phone calls, webinars, etc.)?

☐ **Milestones**
-What objectives drive outcomes in your project?

-How can those large objectives be broken down into manageable goals at the practice level?

-Are there phases of progression in practice milestones to move practices towards the desired outcome of objective?

-Consider how each of these milestones will be implemented and measured

-Consider how to move practices through these milestones that align with your project timeline and PF dosing

☐ **Measurement**
-What outcomes are you measuring?

-How will individual practices measure those outcomes?

-How often will practices report measures to the project?

-How will practices use their own data to measure progress and drive quality improvement?

☐ **Training**
-How will PFs be trained to support practices in accomplishing the project goals/objectives/milestones?

Training would include overview of grant/project, learning the intervention or innovation, plan for dose, timeline, milestones, plan for monitoring

☐ **Budget**
-How you define each of the elements discussed should be considered in proposed budget

-How much will it cost to field a PF to do all of the work as you have defined, including:

- Travel
- Planning time
- Documentation

☐ **Personality Characteristics/Background of Practice Facilitators[1]**

-Demonstrate empathy and understanding of others' needs

-Communicate in a genuine, positive, and respectful way to establish and maintain relationships

-Know when to speak, when to listen, and know how to handle criticism

-Communicate in a timely manner, assuring prompt response to stakeholder feedback to achieve project milestones

-Need to be flexible, adapting their efforts and response to local context, including needs and resources

-Need to be self-confident, innovative and resourceful, as well as exhibit energy and enthusiasm

-Need to be credible, approachable, and accessible

-Also need the appropriate knowledge and skills to support implementation

-Has basic knowledge of implementation science, quality improvement, and organizational change processes, as well as the organizational policies, structures, and contexts that can affect implementation

☐ **Practice Facilitator 5 Core Competencies identified by Richie et al.[2]**

Can the Practice Facilitator:

- Build relationships with and between others and create a supportive environment for change?

- Help change the system of care and the structure and processes that support it?

- Transfer knowledge and skills and create infrastructure support for ongoing learning?

- Plan and lead change efforts?

- Assess people, processes, and outcomes and create infrastructure for program monitoring?

References:
[1] Ritchie MJ, Dollar KM, Miller CJ, Smith JL, Oliver KA, Kim B, Connolly, SL, Woodward E, Ochoa-Olmos T, Day S, Lindsay JA, Kirchner JE. Using Implementation Facilitation to Improve Healthcare (Version 3). Veterans Health Administration, Behavioral Health Quality Enhancement Research Initiative (QUERI), 2020. Available at: https://www.queri.research.va.gov/tools/implementation/Facilitation-Manual.pdf
[2] Ritchie MJ, Parker LE, Kirchner JE. From novice to expert: a qualitative study of implementation facilitation skills. Implement Sci Commun. 2020;1(1):7. https://doi.org/10.1186/s43058- 020-00006-8

Choosing Appropriate Stakeholder Engagement Methods: **The Stakeholder Engagement Navigator Webtool**

Matt DeCamp, MD, PhD; Brad Morse, PhD; Kate Ytell, MPH

Introduction

The Stakeholder Engagement Navigator (https://DICEmethods.org/) is an interactive website that helps researchers by (1) providing information about various methods for engaging different types of stakeholders in research, via the Education Hub, and (2) helping researchers select engagement strategies based on their specific needs and constraints, via the Stakeholder Engagement Selection Tool. This worksheet is focused on this second component, the Stakeholder Engagement Selection Tool. It will help you think about stakeholder engagement in the context of your project so that you will be prepared to answer the questions posed by the tool.

Research stage: During which stage or stages of your research do you plan to engage stakeholders? This could include multiple stages, from planning, to implementing, to disseminating.

☐ Planning ☐ Implementing ☐ Disseminating

Purpose: Why do you want to engage stakeholders? What do you hope to achieve through stakeholder engagement?

Budget: Engaging stakeholders in a meaningful way requires some resource commitment (not just for paying stakeholders, but also for rooms, food, staff FTE, stipends, transportation, childcare, etc). What budget do you expect to have for engagement activities?

Number of interactions: Over what period of time do you expect to engage your stakeholders?

Time per interaction: How much time do you expect from your stakeholders in any given interaction?

Staffing/expertise: What types of staffing and expertise are available to you?

Use this space to keep a record of which engagement strategies come to the forefront when using the Stakeholder Engagement Selection Tool:

Engagement Strategy	Notes

Juggling the Various Components of Stakeholder Engagement: A Hands On Approach

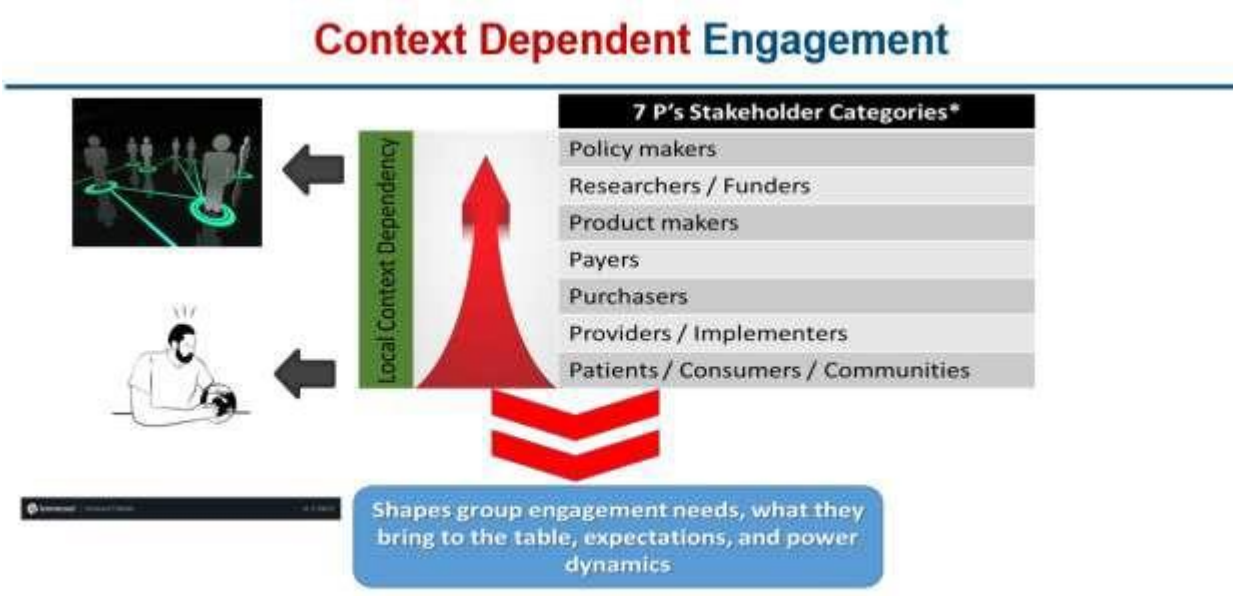
Mónica Pérez Jolles, PhD

Learning Objectives

1. Understanding of the concept of stakeholder engagement as a multi-component, dynamic concept during the implementation of a pragmatic trial
2. Awareness of practical approaches/methods for stakeholder engagement
3. Learning of challenges and lessons learned from an illustration on the use of CBPR in a PCORI-funded pragmatic trial

Now that we are rolling out the pragmatic trial, how do I keep stakeholders engaged/meaningfully involved?

Framework



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

Juggling the Various Components of Stakeholder Engagement: A Hands On Approach

Mónica Pérez Jolles, PhD

Interactive Activity #1 – "Padres Efectivos: PCORI-Funded Research Project Leads to Sustained Partnerships" (https://youtu.be/9Ri_oYz1mvc)

Interactive Activity #2 – Discussion Questions

1. What human, financial, and concrete resources would you need to have inplace to meet the various needs of your stakeholders?
2. What could make stakeholder engagement more challenging in dynamic,diverse, and complex settings?
3. If stakeholders' needs and priorities change throughout the implementationprocess, how can you maintain their engagement while still meeting your study set goals and milestones?
4. What concrete engagement activities could best lead to a co-created groupprocess?
5. In your view, how can this context dependent engagement lens promote socialjustice and equity?

Resources / Readings

1. Patient-Centered Outcomes Research Institute (PCORI) Engagement Tool andResource Repository (Filter: Implementation Phase): https://www.pcori.org/engagement/engagement-resources/Engagement-Tool- Resource-Repository?f%5B0%5D=field_engage_award_phases%3A1897
2. PCORI (Patient-Centered Outcomes Research Institute): PCORI EngagementRubric, Published February 4, 2014, Updated June 6, 2016 http://www.pcori.org/sites/default/files/Engagement-Rubric.pdf
3. Salloum, R.G., Shenkman, E.A., Louviere, J.J. *et al.* (2017). Application of discrete choice experiments to enhance stakeholder engagement as a strategy for advancingimplementation: a systematic review. *Implementation Science,* **12,** 140. https://doi.org/10.1186/s13012-017-0675-8

Juggling the Various Components of Stakeholder Engagement: A Hands On Approach

Mónica Pérez Jolles, PhD

4. Interactive Online Tool created by a community-led stakeholder group: Patient- Centered Outcomes Research (PCOR) Toolkit for Community Behavioral HealthOrganizations Serving Latinos: http://pcor-toolkit.elfuturo-nc.org/

[Notes]

Track 1: Implementation and Engagement Strategies

[Notes]

Track 2: Data Analysis and Pragmatic Research

Analyzing Correlated Data: Basics of the Linear Mixed Effects Model
John Rice, PhD

Learning Objectives:

1. Explain what longitudinal/clustered data is and some of its advantages and disadvantages
2. Simple approaches to analyzing longitudinal data
3. Understand what a mixed model is and when it may be useful
4. Example mixed model analysis

Interrupted Time Series with Individual Level Data
Elizabeth Juarez-Colunga, PhD; Angela Moss, MS

Learning Objectives:

1. To understand what an interrupted time series analysis (ITS) is
2. Identify when it is appropriate
3. List advantages/disadvantages
4. Interpret results in a specific example

Clinical Prediction Models
Krithika Suresh, PhD; Katie Colborn, PhD

Learning Objectives:

1. When is a prediction model appropriate?
2. Process for designing, developing, and validating a prediction model
3. Examples of predictive models commonly used in clinical settings
4. Methods for assessment and validation
5. Caveats and considerations when developing prediction models

Causal Inference Via Trial Emulation
Nandita Mitra, PhD

Learning Objectives:

1. Participants will learn about the potential outcomes framework and directed acyclic graphs (DAGs).
2. Participants will understand the challenges to making causal claims using observational data.
3. Trial emulation will be described as a framework for obtaining causal inference from observational studies. Participants will learn about target trial components such as trial eligibility, treatment assignment procedures, defining study follow-up, and determining outcomes. Finally, causal contrasts of interest will be described along with the need for careful analytic plans.

Analyzing Correlated Data: Basics of the Linear Mixed Effects Model

John Rice, PhD

What is clustered/correlated data?

- **Correlated observations:** arise when pairs or clusters of observations are related and thus are more similar to each other than to observations outside of that pair/cluster
  - Multiple (longitudinal) measurements on the same subject
  - Observations of multiple items on the same subject (e.g., left and right eye data)
  - Sibling, twins, members of the same household
  - Patients from the same practice or provider
- **Repeated measures** are another kind of correlated data
  - Could also be viewed as multiple measurements on a unit (cluster)
  - For example, standardized test scores from students in the same classroom in same school

Advantages and disadvantages of correlated data:

- Advantages
  - Only longitudinal data gives information on individual patterns of change
  - Longitudinal studies economize on subjects (fewer patients needed for similar power, e.g.)
- Disadvantages
  - More complicated analyses are often necessary
  - Have to deal with missing data
  - Interpretation of results may be more difficult

Simple approaches to analyzing correlated data:

(Not recommended in general)

- Change score as outcome
- Baseline as covariate
- Hybrid

Linear mixed models are the preferred approach to analyzing correlated data:

- Similar framework to classical linear regression methods
  - Assumes normality of residuals (but extensions to other distributions also exist)
  - Regression coefficients have similar interpretations
  - Estimation methods are similar
  - Testing/inference is based on the same statistics (e.g., ratios of coefficient estimates to estimated standard errors)
- Additional specification is required (Need to describe the correlation structure of the data within each cluster/unit)
- **Covariance pattern models** specify a correlation structure for the outcome (e.g., independence, compound symmetry, etc.)
- **Random effects models** specify a set of random coefficients

Clinical Prediction Models

Katie Colborn, PhD; Krithika Suresh, PhD

Learning Objectives

- When is a prediction model appropriate?
- Process for designing, developing, and validating a prediction model
- Examples of predictive models commonly used in clinical settings
- Methods for assessment and validation
- Caveats and considerations when developing prediction models

Activity

- Participants will be asked to review this paper: https://pubmed.ncbi.nlm.nih.gov/33090219/
- We will discuss the TRIPOD checklist accompanying this paper

Resources

Clinical Prediction Models by Ewout Steyerberg
http://link.springer.com/book/10.1007/978-0-387-77244-8

EQUATOR Network
https://www.equator-network.org/

TRIPOD statement on Annals of Internal Medicine
https://www.acpjournals.org/doi/10.7326/m14-0697

[Notes]

The Benefits and Challenges of Leveraging Existing and Secondary Data for Pragmatic Research

David M. Vock, PhD

Through a handful of case studies, we explore some of the benefits and drawbacks of leveraging existing and secondary data in pragmatic research. Existing/secondary data present an important resource which can be used at many points in the lifecycle of pragmatic research including for planning and trial design, participant recruitment, endpoint ascertainment, calibration of treatment effects, among others. However, we argue that existing/secondary data should be interrogated for not only what it includes but also what it systematically does not capture. When possible, the limitations of existing/secondary data should be ameliorated in the design and analysis plan. Finally, we argue that many perceived weaknesses of existing and secondary data such as patient heterogeneity, measurement error of covariates, etc. should be reframed as strengths for pragmatic research.

Key Thought Questions:

1) What are some key barriers to using existing and secondary data in your research? How can they be overcome?
2) How can the limitations of existing and secondary data be rephrased as relative strengths of the sources?
3) What can methodologists do to improve the suite of available methods to make using existing and secondary data more

Key Points

1) Existing/secondary data can and should be used at many points in the lifecycle of pragmatic research (e.g., planning, participant recruitment, endpoint ascertainment, calibration of treatment effects, etc.)
2) Any source of data should be interrogated for the not only what it includes but also what it does not capture.
3) Using existing and secondary data requires a data integration and security plan.
4) The limitations of existing/secondary data should be ameliorated in the design and analysis plan.
5) Many perceived weaknesses of existing and secondary data should be reframed as strengths for pragmatic research.

Resources

1. Cowie MR, Blomster JI, Curtis LH, Duclaux S, Ford I, Fritz F, Goldman S, Janmohamed S, Kreuzer J, Leenay M, Michel A. Electronic health records to facilitate clinical research. Clinical Research in Cardiology. 2017 Jan;106(1):1-9.
2. Sidebottom AC, Sillah A, Vock DM, Miedema MD, Pereira R, Benson G, Lindberg R, Boucher JL, Knickelbine T, VanWormer J. (2018) Assessing the effect of the Heart of New Ulm Project: a population-based program to reduce cardiovascular disease. *Preventative Medicine* **112**:216-221. doi: 10.1016/j.ypmed.2018.04.016 PMID: 29634974
3. Sidebottom AC, Sillah A, Boucher J, Vock DM, Pereira R, Benson G, Knickelbine T, Miedema MD, VanWormer J. (2016) Changes in cardiovascular risk factors after 5 years of implementation of a population-based program to reduce cardiovascular disease: The Heart of New Ulm Project. *American Heart Journal* 175:66-76. doi: 10.1016/j.ahj.2016.02.006 PMID: 27179725

David M. Vock, PhD

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[Notes]

Track 1: Assessing Context and Fit in Usual Care Settings

Identifying Multilevel Contextual Factors
Christina Studts, PhD

Learning Objectives:
1. Participants will describe contextual factors related to implementation at multiple levels of the socioecological framework.
2. Participants will describe multiple frameworks incorporating multilevel contextual factors.
3. Participants will use one or more frameworks to identify relevant multilevel contextual factors in a case example of implementing an evidence-based intervention.

Assessing Multilevel Contexts
Bryan Weiner, PhD

Learning Objectives:
1. Compare the strengths and limitations of general approaches to assessing context
2. Review current tools for assessing context
3. Discuss common challenges in assessing context

PRECIS-2-PS: A Tool for Developing Implementation Trials with Purpose and Intent
Wynne Norton, PhD

Learning Objectives:
1. Understand how to conceptualize implementation trials along the explanatory-pragmatic continuum
2. Recognize key elements of implementation trials that can make them more explanatory or more pragmatic in overall intent
3. Identify differences between planning for intervention trials along the explanatory-pragmatic continuum or planning for implementation trials along the explanatory-pragmatic continuum
4. Review case studies of implementation trials along the explanatory-pragmatic continuum

Patient Reported Measures: On the Ground Collection, Implementation, and Clinical Workflows
Rodger Kessler, PhD, ABPP

Learning Objectives:
1. List and discuss the core elements of a patient reported measurement and monitoring system
2. Identify current measurement systems used for this purpose
3. Using data report examples, generate work flows for different data clusters

Identifying Multilevel Contextual Factors

Christina Studts, PhD, MSPH, LCSW

Overview of context:

- When, where, how, with whom, under what circumstances, and why does ***this thing*** work?
  - ***This thing*** can be a program, policy, practice, principle, procedure, pill, product, or… implementation strategy.
- Key aspects of context:
  - Multilevel
  - Multiple domains
  - Interactive
  - Dynamic
- Contextual factors at multiple levels can (and do) serve as facilitators or barriers to implementation, and may come into play at different stages of the implementation process
- Contextual factors may be modifiable (or not)
  - "Plasticity and elasticity" (May et al., 2016)

Organizing our conceptualization and understanding of context:

- Many contextual frameworks have been developed, adapted, combined
- Let's start with a relatively simple framework that reflects the key aspects of context (the Socioecological Framework) and compare it with a much more complex framework (Greenhalgh et al's Diffusion of Innovations in Service Organizations)
- In between these extremes are numerous contextual frameworks that add nuance and complexity to the basic idea of the Socioecological Framework and incorporate theory, constructs, and organizing principles from interdisciplinary fields. Three frequently used examples are:
  - The Consolidated Framework for Implementation Research (CFIR)
  - Exploration, Preparation, Implementation, and Sustainment (EPIS)
  - Practical, Robust Implementation and Sustainability Model (PRISM)

The function of frameworks in identifying multilevel contextual factors:

- Verify what you expected (maybe)
- Consider contextual factors you may not have thought of
- Clarify contextual factors you could target with specific implementation strategies
- Identify contextual changes over time
- Inform adaptations, implementation, sustainment

Key resources and references:

Dissemination-implementation.org

https://episframework.com

cfirguide.org

re-aim.org (PRISM coming soon!)

May, C.R., Johnson, M. & Finch, T. Implementation, context and complexity. Implementation Sci 11, 141 (2016).

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Nilsen P, Bernhardsson S. Context matters in implementation science: a scoping review of determinant frameworks that describe contextual determinants for implementation outcomes. BMC Health Serv Res. 2019 Mar 25;19(1):189.

Kirk, M.A., Kelley, C., Yankey, N. et al. A systematic review of the use of the Consolidated Framework for Implementation Research. Implementation Sci 11, 72 (2015).

An exercise in identifying potential multilevel contextual factors:

Scenario: Low-dose CT lung cancer screening reduces mortality from lung cancer among individuals at high risk for developing lung cancer. Since identified as an evidence-based practice in 2015, LDCT has been inadequately adopted and implemented in community settings (i.e., mostly hospitals). Implementation research on LDCT seeks to understand contextual factors related to adoption, implementation, and eventual sustainment to increase its public health impact.

Within each level of context organized in the Socioecological Framework, *brainstorm possible contextual factors that should be considered in the implementation of LDCT in community settings.*

Level of Socioecological Framework	Potential Contextual Factors
Individual	
Interpersonal	
Organizational	
Community	
Societal/Policy	
Other levels/factors that do not fit into the above	

For an example of ongoing studies on implementation of high quality lung cancer screening, check out: www.KentuckyLeads.org

Assessing Multi-Level Contexts

Bryan J. Weiner, Ph.D.

Three main assessment approaches

- Qualitative
- Quantitative
- Mixed

Assessment tools for commonly used implementation science frameworks

- See resources and references below
- Mostly qualitative, few quantitative, some mixed

Pros and cons of going qualitative

Quick and easy	Few templates for interview guides and codebooks
Works with small samples	Interview guides and codebooks often not available
Potential for richness, depth, and nuance	Challenging to write interview questions for abstract concepts
Builds rapport, fosters empathy	Challenging to code abstract concepts in natural language

Instrumentation issues in implementation science

- Measures are poorly distributed across implementation science constructs
- Many measures have unknown or dubious quality
- Measures exhibit synonymy, homonymy, and instability
- Measures lack practicality
- Measures are hard to find

Key resources and references:

SIRC Instrument Review Project

episframework.com

cfirguide.org

re-aim.org

TICD Checklist

PhenX Toolkit

Systematic Reviews of Methods to Measure Implementation Constructs: SIRC IRP

McCreight MS, Rabin BA, Glasgow RE, Ayele RA, Leonard CA, Gilmartin HM, Frank JW, Hess PL, Burke RE, Battaglia CT. Using the Practical, Robust Implementation and Sustainability Model (PRISM) to qualitatively assess multilevel contextual factors to help plan, implement, evaluate, and disseminate health services programs. Transl Behav Med. 2019 Nov 25;9(6):1002-1011.

Piper KN, Haardorfer R, Escoffrey C, Sheth AN, Sales J. Exploring the heterogeneity of factors that may influence implementation of PrEP in family planning clinics: a latent profile analysis. Impement Sci Commun. 2021 May 4;2(1):48.

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Debono D, Taylor N, Lipworth W, Greenfield D, Travaglia J, Black D, Braithwaite J. Applying the theoretical domains framework to identify barriers and targeted interventions to enhance nurses' use of electronic medication management systems in two Australian hospitals. Implement Sci. 2017 Mar 27;12:42.

Lynch EA, Luker JA, Cadilhac DA, Fryer CE, Hillier SL. A qualitative study using the Theoretical Domains Framework to investigate why patietns were or were not assessed for rehabilitation after stroke. Clinical Rehabilitation. 2017 Jul;31(7):966-977.

Woodward EN, Matthieu MM, Uchendu US, Rogal S, Kirchner JE. The health equity implementation framework: proposal and preliminary study of hepatitis C virus treatment. Implement Sci. 2019 Mar 12;14:26.

Aarons GA, Fettes D, Hulburt M, Palinkas L, Gunderson L, Willging C, Chaffin M. Collaboration, negotiation, and coalescence for inter-agency collaborative teams to scale-up evidence-based practice. J Clin Child Adolesc Psychol. 2014;43(6):915-928.

An exercise in writing interview questions and survey items

Leadership engagement is defined in the Consolidated Framework for Implementation Research as "the commitment, involvement, and accountability of leaders and managers with the implementation" (Damschroder et al 2009, p. 9). Leadership has been shown to be an important factor in implementation success.

Write three to five interview questions to gauge leadership engagement in the implementation of an evidence-based practice in an organizational setting of your choosing. Leadership engagement, as the definition implies, is a multi-faceted construct. Consider how you will capture the fullness of this construct. You are free to write sub-questions follow-up questions to probe more deeply.

Q1:

Q2:

Q3:

Now, write several survey items to assess leadership engagement. Consider how you will capture the fullness of this construct.

Q1:

Q2:

Q3:

Q4:

Q5:

Q6:

PRECIS-2-Provider Strategies (PS)

PRECIS-2-PS: Domains and Key Questions

Domain Name	Key Question
1. Eligibility	To what extent are healthcare providers in the trial similar to those in usual care?
2. Recruitment	How much extra effort is made to recruit healthcare professionals into the trial compared to what is available to encourage their engagement in usual care settings?
3. Setting	How different is the health care or public health setting (e.g., hospital, clinic, health department) in which the trial is conducted compared to usual care settings?
4. Implementation Resources	How different are the resources needed to support the delivery of the provider-focused strategies from resources that are readily available in usual care?
5. Flexibility of Provider Strategies	How different is the flexibility in how provider-focused strategies are delivered in the trial and the flexibility in how provider-focused strategies are likely to be delivered in usual care?
6. Flexibility of Intervention	How different is the flexibility in how the intervention is delivered by healthcare providers to patients and the flexibility in how the intervention would be delivered in usual care?
7. Data Collection	How different is the frequency and intensity of measurement and data collection throughout the trial compared to what is considered routine in usual care?
8. Primary Outcome	To what extent is the trial's primary outcome important to healthcare professionals?
9. Primary Analysis	To what extent are all data included in the analysis of the primary outcome?

Note. 1 = Very explanatory, 5 = very pragmatic. Detailed description of usual care and implementation-as-usual is necessary for understanding and documenting the context in which the trial will occur. Stakeholders involved in trial planning are encouraged to provide as much detail as possible on the context of implementation with respect to the domains above and not be limited to a few brief descriptors. Additional trial information relevant to the score decision-making process can be added as well as changes to trial elements or the context of implementation-as-usual that may occur during the trial. Worksheet includes domain score, rationale, and description of usual care and implementation-as-usual.

Select References

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- Loudon et al. (2015). The PRECIS-2 tool: Designing trials that are fit for purpose. *BMJ*.
- Johnson, K.E., Neta, G., et al. (2016). Use of PRECIS-2 ratings in the National Institutes of Health (NIH) Health Care Systems Research Collaboratory. *Trials*.
- Zwarenstein, M. (2017). Pragmatic and explanatory attitudes to randomized trials. *Journal of the Royal Society of Medicine*.

Select Resources

- *PRECIS-2 Website*: PRECIS-2 Toolkit, podcasts, webinars, how-to guide; database of 700+ trials that have been scored using PRECIS-2; www.precis-2.org
- *NIH Collaboratory Living Textbook*: Collection of knowledge from the NIH Health Care Systems Research Collaboratory; chapters on design, conduct, and dissemination of pragmatic clinical trials; training resources, newsletter, webinars; www.rethinkingclinicaltrials.org
- *Pragmatic Trials: A Workshop Handbook*: Adult and Child Center for Health Outcomes Research and Delivery Science (ACCORDS), Colorado Research and Implementation Science Program (CRISP); www.crispebooks.org;
- *edX Massive Open Online Course* (archived): Pragmatic Randomized Controlled Trials in Health Care; www.edx.org/course/pragmatic-randomized-controlled-trials-in-health-c

Patient Reported Measures: On the Ground Collection, Implementation and Workflows

Rodger Kessler Ph.D. ABPP

Rationale

For clinical, regulatory and research purposes, collecting and using patient reported data is both imperative and viable. The challenges to doing so are not about available brief validated measures, whether they are valued by clinicians and patients, or whether such activity is viable in practice, but rather administrative support, and workflows for collection, integration of data into electronic records, and clinical workflows for use of the data.

Background

The author has been involved in collecting patient reported psychiatric symptom data in primary care settings since the precursor of the PHQ, the Prime-MD. While a significant body of literature has critiqued the limited utility of such measures in primary care, their use is ubiquitous. Patients report that what is most important to them is function and quality of life. Both theoretically and on the ground the task must start with de-implementation of such measures and consideration of alternatives. We have developed a strong relationship with John Ware Ph.D. who has spent a career focusing on patient reported Quality of Life (Qol) measures, and, developed a brief 1-3 minute QoL measure designed to both have research integrity and have direct clinical utility. This presentation will report on two projects, one in Arizona and the other in Colorado, focusing on identifying and intervening with patients with and without the COVID virus, who are at significant risk of decreased function and QoL, potentially resulting in poorer outcomes and greater system expense.

We will describe use of Dr. Ware's QoL measures in combination with EHR data to identify such high-risk patients and adaptations to work flow.

Track 1: Assessing Context and Fit in Usual Care Settings

[Notes]

Track 2: Managing Real World Data

Building the Tower of Babel – Tricks and Traps in Harmonizing HER Data
Lisa Schilling, MD, MSPH; Patrick Hosokawa, MS

Learning Objectives:
1. Understand the challenges of using EHR data from multi-sites
2. Understand some pre-cautions to take when using multi-site EHR data

Opportunities for Using Healthcare Claims Data for Pragmatic Sustainability Assessments
Mark Gritz, PhD

Learning Objectives:
1. Identify national and local sources of healthcare claims data from public and private payers in the US
2. Describe the structure and domains of claims data available for pragmatic research
3. Describe general steps for acquiring claims data for pragmatic research

Using Population-Based Data in Secondary Analysis
Allison Kempe, MD; Art Davidson, MD

Learning Objectives:
1. Describe and categorize an array of population-based data resources for use in secondary analyses
2. Describe the attributes, barriers and methods required to access these population-based data resources

Digital Health Data Access. Management, and Use
Susan L. Moore, PhD, MSPH

Learning Objectives:
1. Identify types and sources of non-EHR digital health data
2. Discuss access and security considerations for working with digital health data
3. Review key issues and challenges involved in working with digital health data

Building the Tower of Babel – Tricks and Traps in Harmonizing EHR Data

Patrick Hosokawa, MS; Lisa M. Schilling, MD, MSPH

Prepared May 2021

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3. Preliminary exploratory data analysis of simulated national clinical data research network for future use in annotation of a rare tumor biobanking initiative," A. S. Felmeister *et al*. *2017 IEEE International Conference on Bioinformatics and Biomedicine (BIBM)*, 2017, pp. 2098-2104, doi: 10.1109/BIBM.2017.8217983. https://ieeexplore.ieee.org/abstract/document/8217983
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Using Population-Based Data in Secondary Data Analysis

Presenters: Arthur Davidson, MD, MSPH; Allison Kempe, MD, MPH

Learning Objectives:

- Describe and categorize an array of population-based data resources for use in secondary analyses
- Describe the advantages and disadvantages of secondary datasets and how to access population-based data
- Describe examples of important publicly available datasets

Description of session:

A didactic presentation will describe population-based data resources used to answer research questions, as well as their advantages/disadvantages when used in secondary data research. Access and suitability issues of population-based datasets for research will be described with a short interactive activity (described below).

Interactive Activity:

Think of a research question of interest to you or within your current focus area (*examples below*):

Clinical questions:

- Among patients diagnosed with appendicitis, is hospital readmission higher for those receiving initial antibiotic therapy alone compared with patients receiving initial surgical intervention?
- Have rates of insulin plus oral medication among patients with Type 2 diabetes changed over time?

Policy or population-based questions:

- Do states with more restrictive personal exemption policies for childhood immunizations have higher rates of completion of recommended immunizations for 19-35 month old children?
- What trends in obesity prevalence have been observed in US youth and adults, by sex and age, during the past decade?

Considerations:

1. What key features of a population-based database are needed to answer this question? Think of the unit of analysis, frequency of data collection, granularity and/or longitudinality.
2. Assess public availability (yes/no); What barriers might exist to access these data? Who would be key partners?
3. What regulatory or legal issues should an investigator weigh to obtain and then analyze these types of data?

Analytic Plan Template – *Course Material (Annotated)*

Date:
Working Paper/Study Title/Grant application:

Lead Investigator(s):
Project Team Members:

Note: This is the right time and place to begin the discussion around authorship and position in the listed authors. First and last should probably be defined early.

Specific Aim(s): *Specify which specific aim this manuscript addresses (if applicable)*

Resources:

Note: Important to define whether the resources are readily available and how to tactically and tactfully acquire this support. May require rethinking who are the team members.

Who are the statistician and data analyst for this manuscript?

Note: Do you have the qualitative or quantitative skills to conduct and analyze the study?

Do you need additional resources (e.g., additional programming, database management)?

Note: What types of data will you be using? Is there someone skilled in acquiring data from a secondary source? How easy will access to those secondary data sources be? What is the track record working with data from this source? What is the format for data received and how will that make use easier/harder?

Research Objective(s): *State your research question(s) or goals*

Note: Is this a real research study or a quality improvement effort? How would one or the other influence the need for regulatory review? Different from specific aims, the research objectives are typically less structured and more a narrative of the intent of the work.

Study Design:

Note: There may be an iterative relationship between the qualitative and the quantitative elements of your research design. These are not clearly accounted for in this analytic plan. How might this document change to achieve that? A few resources to review various study designs:

Study Designs in Epidemiology
Secondary Data Analysis: A Method of which the Time Has ...
An Introduction to Secondary Data Analysis - National Center ...

Time Frame (e.g., cross-sectional, longitudinal, retrospective cohort, cohort):

RCT or Observational:

Other comments:

PATIENT COHORT AND SUBJECTS: Describe the patients who are part of this manuscript. Specify **inclusion** and **exclusion** criteria and **study site(s)**.

Note: A principle in clinical trials is that the analysis must take into account the level at which randomization occurred. The number of observations in the analysis should match the number of 'units' that were randomized. In a simple parallel group design for a clinical trial, participants are individually randomized to one of two intervention groups, and a single measurement for each outcome from each participant is collected and analyzed.

Note: Variations on this design:

- *groups of individuals were randomized together to the same intervention (i.e. cluster-randomized trials);*
- *individuals undergo more than one intervention (e.g., in a cross-over trial, or simultaneous treatment of multiple sites on each individual); or*
- *multiple observations for the same outcome (e.g., repeated measurements, recurring events, measurements on different body parts).*

Note: Are we discussing patients, providers, systems or a combination of all of these? What is the fundamental unit of analysis?

Inclusion Criteria

Exclusion Criteria

Study Site

DATA SOURCES (identify existing data and additional data needed):

Note: All sources should be linked to the dependent and independent variables below

HYPOTHESES: State key hypotheses explicitly. If there is no specific hypothesis (e.g., descriptive) simply state what is proposed.

H1:
H2:
H3:

VARIABLES FOR ANALYSIS *(link these to each research question or hypothesis to be tested):*

Note: If a variable is both in the dependent and independent variable list, it probably is worthwhile to parse them out into several tables after each hypothesis.

Note: Adding which hypotheses are associated with these variable helps to assure all variables have a clear purpose related to SA and hypotheses

Dependent Variables

Variable	Description	Type	Source	Hypothesis
Primary Outcomes				

Secondary Outcomes				

Note: Mark the hypothesis to which the variable is related both here in the dependent and below in the independent variable tale.

Independent Variables *(identify as main exposure variable, covariates, potential confounders) modify as needed)*

Note: Which of the following fairly common variables are part of your study, which variables are totally unique to your study?

Example table:

Variable	**Description**	**Type**	**Source**	**Hypothesis**
Age	Created variable using DOB and enrollment date (in years)	continuous	administrative	
Gender	Male=1; female=0	dichotomous	administrative	
Race/ethnicity	Recode from administrative data, collapse into Latino=1, African American=2, Non-Hispanic white=3, Others?	categorical		
comorbidities	Apply case-finding algorithms – use individually or count	From ICD-9 codes	Sum of comorbidities from eligible visits	
Insurance	Private Federal -Medicaid, Medicare State – CIPC/uninsured	From last visit		
Intervention group	1=intervention, 0=controls			
time	Time since enrollment (in months, days?)			
BMI	BMI = (Weight in Pounds / (Height in inches x Height in inches)) x 703		Calculated	
Add as many				

as necessary to describe your study variables….				

Note: Might want to describe the case finding process in detail here to assure clearly documented

DATA ANALYSIS

Some general analytic approaches (expand and modify as needed).

Note: How does your study fit with items a-e? Are there other topics that you should consider for your study or more broadly for all studies in your domain?

1. *Setting and subjects.* Usually start by describing the sample and addressing issues of external and internal validity
    a. Generate frequency distributions and summary statistics (e.g., means, standard deviations, median, rates) on outcome variables, sociodemographic and clinical variables, and other relevant variables of interest. For continuous outcomes, examine distributions to determine whether normality assumptions hold or if transformations or other approaches may be needed.
    b. Are the patients in this clinic similar to target population?
        i. Usually start by computing descriptive statistics for sample – frequencies, means (sd)
    c. Are people who refuse similar to participants?
        i. If possible, compare participants to non-participants: t-tests, chi-square tests, or just compute 95% CI on means and proportions for participants
    d. Are dropouts similar to completers (longitudinal designs)?
        i. Compare dropouts to completers and assess for differences in baseline covariates and outcomes using chi-square tests, t-tests, Kendall's tau
        ii. Also determine whether there is differential dropout by study group. For longitudinal designs this will help determine whether the data are 1) MCAR = Missing completely at random, 2) MAR= missing at random: ignorable,3) MNAR= missing not at random: missingness related to something you may not observe The first two are ignorable but analytic requirements differ; the last is non-ignorable. Variables related to missingness need to be included in the analysis.
    e. If an RCT, compare treatment groups on key baseline variables using chi-square tests and t-tests
        i. This will help determine which covariates are potential confounders and need to be included in the analysis.
2. Bivariate analyses (parametric/nonparametric, correlations vs. categorical statistics)
3. Multivariate analyses
    a. Choice of model and rationale (e.g., logistic regression, linear regression, survival analysis, factor analysis)
    b. Strategy for c*ovariate identification and selection.* Screen by domains (e.g., sociodemographic or clinical) and retain all independent variables that are associated

with the outcome at ≈ p<.20 for inclusion in initial multivariate models. Final models will include covariates that are associated with missingness (if longitudinal), treatment group, or the outcome (at ≈ p<.15 in multivariate models, depending on sample size).

c. Assessment of appropriateness/fit of model
d. Strategies to validate model (split sample, separate sample, etc.)

Analyses to address study questions/hypotheses. *Some text here will help with writing later on. This would be a good place to mention specific analyses (e.g., multivariate linear regression, etc) and highlight pros and cons or issues that need to be addressed.* The primary outcome for this analysis is XXX.

H1.
H2.
H3.

Include empty, mocked up tables, if possible

Note: Imagine the final product or manuscript. What would be your 4 or 5 tops tables or figures? Create shell tables to visualize how your analytic approach will create a summary that communicates your intended output and that will address your primary research question.

Next steps, meetings, assignment of responsibilities, etc:

Note: Create a work breakdown structure that allows you to define all the steps, dependencies, priorities and timelines.
Note: Use the plan to drive accountability and forward momentum

An abbreviated description of some secondary datasets

Examples of some publicly available datasets from the National Center for Health Statistics (www.cdc.gov/nchs/)

- **National Health Interview Survey (NHIS)**
  - Data on a broad range of health topics are collected through personal household interviews
  - Multipurpose survey: health, illness, services
  - Complex sample design with clustering and stratification
  - Sample representative of non-institutionalized US civilian population living at addressed dwellings
  - Administered annually since 1957
  - Approximately 100k respondents/year from 1986 – 2021
  - Typical measures:
    - demographics,
    - employment,
    - health status,
    - activity limitations,
    - healthcare utilization
- **National Health and Nutrition Examination Survey (NHANES)**
  - Program of studies designed to assess the health and nutritional status of adults and children in the US
  - Unique in that it combines interviews and physical examinations
  - Complex sample design with clustering and stratification
  - Sample representative of non-institutionalized US civilian population living at addressed dwellings
  - Administered 1971-'80, 1988-'94, 1999-current
  - Approximately 30K respondents/year earlier period, now about 5K/year
  - Typical Measurements:
    - physiological,
    - diet & nutrition,
    - blood and urinary labs,
    - alcohol and tobacco use
- **National Ambulatory Medical Care Survey (NAMCS)**
  - National survey designed to meet the need for objective, reliable information about the provision and use of ambulatory medical care services in the US

- Findings are based on a sample of visits to non-federal employed office-based physicians who are primarily engaged in direct patient care
- age, sex, race, ethnicity, and visit characteristics such as patient's reason for visit, physician's diagnosis, services ordered or provided, and treatments, including medication therapy
- data about the physician and their practice characteristics are collected during a survey induction interview (~2K/year followed)
- 1973 – present (public use)

- **National Immunization Survey (NIS)**
  - List-assisted random-digit-dialing telephone survey followed by a mailed survey to children's immunization providers
  - Began data collection to monitor childhood immunization coverage
  - Target population for the NIS is children between the ages of 19 and 35 months living in the United States at the time of the interview
  - Added teen-focused surveys 13-17 years in 2006
  - COVID surveys in adults (>18 years)
  - 1994 – present (children surveyed annually)
- **National Hospital Discharge Survey**
  - National probability survey designed to meet the need for information on characteristics of inpatients discharged from non-Federal short-stay hospitals in the United States
  - Used to examine important topics of interest in public health and for a variety of activities by governmental, scientific, academic, and commercial institutions
  - Contains over 266,000 records from a sample of hospital discharge records
  - Conducted annually since 1965 to 2010
  - More recently, converted to National Hospital Care Survey integrates inpatient data formerly collected by the NHDS with the emergency department (ED), outpatient department (OPD), and ambulatory surgery center (ASC) data collected by the National Hospital Ambulatory Medical Care Survey (NHAMCS).
- **National Survey of Ambulatory Surgery**
  - The only national study of ambulatory surgical care in hospital-based and freestanding ambulatory surgery centers
  - Conducted from 1994-1996, 2006
  - Now efforts to integrate with the National Hospital Ambulatory Medical Care Survey (NHAMCS)
- **National Nursing Home Survey/ National Study of Long-Term Care Providers**
  - A continuing series of national sample surveys of nursing homes characteristics, their residents, services, and staff
  - All nursing homes included in this survey had at least three beds and were either certified (by Medicare or Medicaid) or had a state license to operate as a nursing home
  - Conducted 1973-'74, 1977, 1985, 1995, 1997, 1999, 2004
  - 1500 nursing homes were selected in 2004
  - NSLTCP includes inpatient rehabilitation facilities and long-term care hospitals,adult day services centers, assisted living and similar residential care communities, home health agencies, hospices, and nursing homes

- 2012 – current NSLTCP

Data Set/Source	Description	Variables
Behavioral Risk Factor Surveillance System (BRFSS) **NCHS**	CDC telephone survey designed to collect state-specific general population data on behaviors that are related to the leading causes of premature death. The basic philosophy is to collect data on actual behaviors, rather than on attitudes or knowledge, to support risk reduction and disease prevention activities. Data collection began in 14 states in 1984 and all states have been participating in this survey since 1994, which allows states to compare risk factor prevalence with other states and monitor the effects of interventions over time, as well as permits the assessment of geographic patterns of risk factor prevalence.	Risk Factors • Acute drinking • Cholesterol awareness • Chronic drinking • Cigarette use • Drinking and driving • Exercise • Hypertension • Hypertension awareness • Overweight • Safety belt usage • Smokeless tobacco Disability • Physical inactivity/activity Race/ethnicity

Data Set/Source	Description	Variables
Healthcare Cost and Utilization Project (HCUP) **AHRQ**	AHRQ-sponsored family of administrative, longitudinal databases, web-based products, and software tools developed as part of a Federal- State-Industry partnership to build a standardized, multi-state health data system. HCUP is based on data collected by individual states and provided to AHRQ by the states. These data are used for research on hospital utilization, access, charges, quality and outcomes. They are used to describe patterns of care for uncommon as well as common diseases, analyze hospital procedures, including those that are performed infrequently, and study the care of population sub-groups such as minorities, children, women, and the uninsured. Researchers and policymakers use HCUP data to identify, track, analyze ~~and compare hospital~~ statistics at the national, regional and state levels. **HCUPnet** gives you easy access to nation~~al statistics and trends and se~~lected state statistics about hospital stays. **HCUPnet** generates statistics using the 1997 data from the Nationwide Inpatient Sample (NIS) and from the State Inpatient Databases (SID) for those states that have agreed to participate.	***NIS*** Discharge-Level • Linkage elements • Physician identifiers • Data source identifiers • Area identifiers • Patient demographics • Clinical information • Days and dates • Admission/discharge status • Payment information Hospital-Level • Linkage elements • Sampling stratum characteristics • Weights ***SID*** Discharge-Level • Linkage elements • Physician identifiers • Data source identifiers • Area identifiers • Patient demographics • Clinical information • Days and dates • Admissions/discharge status • Payment information State-specific (varies across states) • Physician specialty • Readmission indicator • Diagnoses present at admission • Type of admission • Birth weight • Detailed charges • Expected payer • Encrypted patient zipcode • Encrypted patient code Hospital-Level: • Linkage elements No survey but rather compilation of administrative longitudinal databases and user-friendly software

Data Set/Source	Description	Variables
Medical Expenditure Panel Survey (MEPS) **AHRQ**	Four surveys in one: • Household component • Insurance component • Medical provider component • Nursing home component AHRQ survey designed to continually provide policymakers, health care administrators, businesses, and others with timely and comprehensive information about health care use, health care costs in the United States, and to improve the accuracy of their economic projections. MEPS collects data on the specific health services that Americans use, how frequently they use them, the cost of these services and how they are paid for, as well as the data on the cost, scope, and breadth of private health insurance held by and available to the U.S. population. MEPS can link data on health services spending and health insurance to the demographic, employment, economic, health status, and other characteristics of survey respondents. NMCES 1977-87 (periodic); MEPS began in 1996 (continuing longitudinal).	<u>Household Component</u> • Health care use • Expenditures • Sources of payment • Insurance status • Functional limitations and disabilities • Restricted activity days • Access to care • Acute and chronic conditions Insurance Component • Health insurance plans • Premiums, deductibles, co-pays Medical Provider Component • Expenditure data from hospitals, home health providers, pharmacies, office-based physicians providing care to household component respondents Survey instruments: www.meps.ahrq.gov/survey.htm

Data Set/Source	Description	Variables
National Ambulatory Medical Care Survey (NAMCS) **NCHS**	NTIS national probability sample survey of patient visits to the offices of non-federally employed office- based physicians who are primarily engaged in office-based, direct patient care, but not in the specialties of anesthesiology, pathology, or radiology. The survey includes information on patient, physician and visit characteristics. The survey measures health care utilization across a variety of providers. The NAMCS was conducted annually from 1973-81, again in 1985, and resumed as an annual survey in 1989.	**Patient characteristics:** • Age • Sex • Race/ethnicity • Whether the patient currently smokes cigarettes **Physician characteristics:** • Physician specialty • Professional identity • Geographic location **Visit characteristics:** • Patient's reason(s) for visit • Injury-related visits • Cause of injury • Physician's diagnoses • Expected source(s) of payment • Ambulatory surgical procedures performed • Diagnostic/screening services • Therapeutic/preventive services • Medication/injections ordered supplied, or administered • Providers seen • Referral status • Prior visit status • Disposition • Duration

Data Set/Source	Description	Variables
National Hospital Ambulatory Medical Care Survey (NHAMCS) **NCHS**	NCHS (CDC) survey designed to collect data on the utilization and provision of ambulatory care services in hospital emergency and outpatient departments. Findings are based on a national sample of visits to the emergency departments and outpatient departments of non-institutional general and short-stay hospitals, exclusive of Federal, military, and Veterans Administration hospitals, located in the 50 States and the District Columbia. The survey uses a four-stage probability design with samples of geographically defined areas, hospitals within these areas, clinics with hospitals, and patient visits within clinics.	• Patient demographics • Expected source of payment • Reason for visit • Cause of injury • Physician diagnoses • Diagnostic/screening services • Procedures • Medications • Providers seen • Disposition • Information on selected hospital characteristics

Data Set/Source	Description	Variables
National Health and Nutrition Examination Survey (NHANES I, II, III) **NCHS**	NCHS (CDC) survey designed to collect information about the health and diet of people in the United States. This survey combines a home interview with health tests that are done in a Mobile Examination Center (MEC virtual tour). NHANES I (NHEFS – epidemiologic follow-up study): Investigates the relationship between clinical, nutritional, and behavioral factors assessed in the first National Health and Nutrition Examination Survey and subsequent morbidity, mortality, and hospital utilization, as well as changes in risk factors, functional limitations and institution- alization. NHANES III: • estimates the national prevalence of selected diseases and risk factors • estimates national population reference distributions of selected health parameters • documents and investigates reasons for secular trends in selected diseases and risk factors • contributes to an understanding of disease etiology • investigates the natural history of selected diseases	**NHANES III**-- Target diseases/conditions • Cardiovascular disease • COPD • Diabetes • Kidney disease • Gallbladder disease • Osteoporosis • Arthritis • Infectious diseases • Substance abuse • Dental health • Allergy • Cancer • Mental health • Hearing • Nutrition • Monitoring • Risk factors • Physical activity • Reproductive health • Tobacco • Child health • Health of older Americans • Occupational health • Environmental health • Longitudinal follow-up • Storage of biologic specimens

Data Set/Source	Description	Variables
National Home Care and Hospice Survey (NHCHS) **NCHS**	NCHS (CDC) is a continuing series of surveys of home and hospice care agencies in the United States (probability sample). Information was collected about agencies that provide home and hospice care and about their current patients and discharges. The survey includes all types of agencies that provide home health and hospice care without regard to whether they are Medicare certified or whether they are licensed. Home health agencies and hospices are usually defined in terms of the type of care they provide. Home health care is provided to individuals and families in their place of residence for the purpose of promoting, maintaining, or restoring health or for maximizing the level of independence while minimizing the effects of disability and illness, including terminal illness. Hospice care is defined as a program of palliative and supportive care services providing physical, psychological, social, and spiritual care for dying persons, their families, and other loved ones. Hospitce services are available in both home and inpatient settings. Data are collected through personal interviews with administrators and staff.	Agency File • Agency identifier code • Number of current patients • Type of ownership • Affiliation • Certification status • Staff hours • Services available Current Patient File • Patient demographics • Current living arrangements • Referral source • Diagnoses at admission and at time of survey • Surgical and diagnostic procedures related to admission • Type of care received • Primary care giver/relationship • Aids used • Vision and hearing status • Activities of daily living • Instrumental activities of daily living • Services provided • Service providers • Number of visits • Amount billed for care/dates • Sources of payment Discharge Patient File – same as current patient file plus: • Living arrangements at discharge • Dxs at admission and discharge • Reason for discharge

Data Set	Description	Variables
National Health Interview Survey (NHIS)	NCHS (CDC) is the collection and analysis of morbidity data on health and disability, current major health issues, and conditions for the civilian non-institutionalized U.S. population by various socioeconomic and demographic characteristics. Continuous data collection since 1957, survey redesigned in 1997 to collect data on all household members through household interviews by US Census Bureau interviewers. Cross- sectional, complex multi-stage area probability sample design, and linkage to the National Death Index. E-coding for injuries, including medical and therapeutic misadventures, began in 1993. Since 1985, over sampling of black and Hispanic persons has been done in various data years.	• Housing characteristics • Family structure and living arrangements • Relationships/social contacts • Health care utilization • Health conditions/impairments • Functional status, assistance with basic activities • Occupation and retirement • Health opinions • Health insurance • Access to health care/transportation • Behaviors (tobacco, physical activity, alcohol) • Use of assistive devices/medical implants • Immunizations • AIDS

Data Set/Source	Description	Variables
National Survey of Family Growth (NSFG) **NCHS**	NCHS (CDC) is a multipurpose survey based on personal interviews with a national sample of women aged 15 to 44 years in the civilian non-institutionalized population of the United States. Its main function is to collect data about factors affecting pregnancy and women's health in the United States. Studies were conducted in 1973, 1976, 1982, 1988, 1990, and in 1995.	• Number of children women have had/number they expect in the future • Intended and unintended births • Sexual intercourse • Marriage and cohabitation • Contraceptive use • Infertility, impaired fecundity, and sterilization operations • Breastfeeding, maternity leave, and child care • Adoption, stepchildren, and foster children • Health insurance coverage • Family planning and other medical services • Smoking by women 15-44 • HIV testing • Pelvic inflammatory disease • Sex education

Data Set/Source	Description	Variables	
American Community Survey **Census**	American Community Survey (ACS) is an ongoing survey that provides vital information on a yearly basis about our nation and its people. Information from the survey generates data that help determine how more than $675 billion in federal and state funds are distributed each year. Through the ACS, we know more about jobs and occupations, educational attainment, veterans, whether people own or rent their homes, and other topics. Public officials, planners, and entrepreneurs use this information to assess the past and plan the future. ACS data help communities plan for hospitals and schools, support school lunch programs, improve emergency services, build bridges, and inform businesses looking to add jobs and expand to new markets, and more.	• Age • Ancestry • Citizenship Status • Commuting (Journey to Work) and Place of Work • Disability Status • Educational Attainment and School Enrollment • Employment Status • Fertility • Grandparents as Caregivers • Health Insurance Coverage • Hispanic or Latino Origin • Income and Earnings • Industry, Occupation, and Class of Worker	/ • Language Spoken at Home • Marital History, Marital Status • Migration/Residence 1 Year Ago • Period of Military Service • Place of Birth • Poverty Status • Race • Relationship to Householder • Sex • Undergraduate Field of Degree • VA Service-Connected Disability • Status • Veteran Status • Work Status Last Year • Year of Entry

[Notes]

Ensuring fit to cultural context to improve health equity: Cultural Adaptation Frameworks

Noy Phimphasone-Brady, PhD

Cultural Adaptations

- The aim is to protect the scientific integrity of evidence-based treatments (EBTs) and promote dissemination by promoting the external and ecological validity of studies. The ultimate aim is to reduce heath disparities by making EBTs broadly available to diverse cultural groups.
- Cultural adaptations integrates multicultural and EBTs to consider culture and context systematically (historical, economic, ecological, and political influence)

For a comprehensive list of cultural adaptation frameworks: Domenech Rodríguez, M. M., & Bernal, G. (2012). *Frameworks, models, and guidelines for cultural adaptation.* In G. Bernal & M. M. Domenech Rodríguez (Eds.), Cultural adaptations: Tools for evidence-based practice with diverse populations (p. 23–44). American Psychological Association. https://doi.org/10.1037/13752-002

1. **Cultural Sensitivity Framework** (Resnicow et al. 1999)
    a. A combination of quantitative and qualitative approaches as well as the use of existing databases and conducting new research to inform your adaptations of targeted health promotion, materials, and programs.
    b. Determine if the design, delivery, and evaluation should involve:
        i. Surface structure adaptations - adapting the materials to look like and sound like your target group. This could involve changing the visuals of the materials, intervention content, and some of your main messages as well as considered where you might deliver the intervention
        ii. Deep level structure - adapting on the predictors that could have influence on the change processes, so this may be socio-historical predictors, environmental, and psychological

2. **Cultural Adaptation Process Model** (Domenech Rodríguez et al. 2004)
    a. Phase 1: Setting the Stage
        i. Collaborate on intervention fit between developer and cultural adaptation specialist (CAS)
        ii. CAS determines if there is a fit within the literature and key community leaders and a needs assessment is conducted (e.g., focus groups or interviews with community leaders)
    b. Phase 2: Initial Adaptation
        i. Tailor the intervention a priori and evaluate the measures for theoretical and cultural appropriateness
        ii. Conduct and observe cultural adaptations in the field and revise iteratively
    c. Phase 3: Adaptation Iterations
        i. Capture any adaptations in new version of the treatment
        ii. Finalize measures for cultural appropriateness and field test
        iii. Attend to (acceptability, compatibility, appropriateness, feasibility):
            1. Language
            2. Who is delivering it?
            3. Common metaphors, languages, or symbols
            4. Content reflects common values or issues
            5. Concepts that are relevant to cultural and context
            6. Context issues like migration and acculturation stress

3. **Cultural Adaptation Framework** (Barrera et al. 2013)
    1. Information gathering
        i. Determine whether an adaptation is necessary and if so, what intervention components should be modified.
        ii. Conduct a literature search and/or conducting focus groups and interviews with target group and/or engage stakeholders.
    2. Preliminary adaptation design
        i. Integrate information from stage one to inform preliminary modifications of the original interventions. Core components are not altered unless there is considerable evidence from stage one to suggest alterations.
        ii. Conduct qualitative research to gather opinions/beliefs on intervention materials and activities
    3. Preliminary adaptation tests
        i. Pilot test the adapted intervention to assess the efficacy of the preliminary version of the adapted EBI.
        ii. Continue to refine based on process features, such as who delivered the intervention, where was it delivered, what was the ethnocultural group's experience during delivery – as well as the outcomes, how was a health outcome achieved, how effective was the intervention
    4. Adaptation refinement
        i. Use information and feedback from third stage to further revise the intervention
    5. Cultural adaptation trial
        i. Conduct a randomized controlled trial of the revised intervention to determine whether the adaptation had the predicted outcomes
        ii. Conduct indepth interviews of participants and those who delivered the intervention to inform further modifications

Cross cutting themes

- Conduct a needs assessment with target ehtnocutural group, literature review, and seek feedback
- Process is iterative on designing and testing culturally adapted intervention using multiple methods
- Pilot test and seek feedback to refine and improve for subsequent larger trial with the target ethnoculturl group
- Culturally adapted interventions to improve fit and compability can be easily disseminated to improve accessibility and engagement with undergroups, with the ultimate goal of achieving health equity

Key References:

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Cultural Adaptations of Evidence-Based Interventions to Fit to Context

Plenary Address by Noy Phimphasone-Brady, PhD

Learning Objectives:

1. Explain the importance of and need to culturally adapting evidence-based interventions to fit to context, paying attention to target populations' language, culture, and context.
2. Describe and integrate appropriate cultural adaptations frameworks for studying the processes and impact of adaptations on intervention adoption, implementation, and effectiveness.

[Notes]

Track 1: Measuring Dissemination and Implementation Outcomes

Assessing and Enhancing Reach and Representativeness
Russell Glasgow, PhD; Meredith Fort, PhD

Learning Objectives:
1. Describe concepts of reach and representativeness and how to operationalize them
2. Summarize challenges to assessment of reach and representativeness; and how to overcome these challenges
3. Identify how reach and representativeness relate to health equity
4. Examine potential trade-offs between reach and effectiveness

Process Evaluation and Adaptations in Complex Trials
Graham Moore, PhD

Learning Objectives:
1. The importance of process evaluation within studies of effectiveness in real world settings;
2. Key elements of the UK MRC guidance for process evaluation of complex interventions and apply them to examples of real-world effectiveness studies
3. The role of process evaluation data in adapting effective interventions, either over time in the same setting, or in new external settings

Measuring Implementation Outcomes
Cara C. Lewis, PhD

Learning Objectives:
1. Delineate key implementation outcomes
2. Summarize the state of the science for measurement of implementation outcomes
3. Articulate critical parameters of implementation outcome measurement

Methods for Reporting and Aligning Implementation Strategies with Implementation Outcomes
Brittany Rudd, PhD

Learning Objectives:
1. Discuss the importance of specifying implementation strategies in clinical and implementation research.
2. Describe methods for specifying implementation strategies in clinical and implementation research.
3. Apply methods for reporting implementation strategies to their own clinical or implementation research.

Assessing and Enhancing Reach and Representativeness

Russell Glasgow, PhD; Meredith Fort, PhD

Reach

How are you operationalizing Reach (individual level) in your project or program? What data sources will you use?

How are you defining your denominator?

Based on past experience, have the intervention/implementation strategies had limited reach? If so, why? What are the multiple levels and domains of influence on participation?

What barriers may prevent some people from participating (distance, cost, lack of representation among delivery staff, historical or ongoing racial/ethnic discrimination, social exclusion, work/family commitments, language, documentation status, etc.)? How can the project address those barriers to enhance reach?

How will you conduct recruitment to enhance reach?

Are there other levels of reach/adoption you are concerned with (e.g. setting or community level)? If yes, how will you operationalize and enhance participation at these other levels?

Assessing and Enhancing Reach and Representativeness

Russell Glasgow, PhD; Meredith Fort, PhD

Representativeness
How are you operationalizing Representativeness (individual level) in your project or program? What dimensions or characteristics are most important?

Based on past experience, are there some groups that tend to be less represented? How can the intervention/implementation strategies be adapted to enhance representativeness? What are the long-term implications of not designing the intervention/implementation strategies to encourage representativeness?

What data sources will you use (consider use of secondary, administrative and publicly available data – e.g. census and survey data) to measure representativeness?

What other levels (if any) are important to consider (e.g. staff, local site, larger multi-site organization, neighborhood, community, region, etc.). What characteristics are a) most important and b) feasible to collect? Is the intervention favoring sites that are more resourced? If so, what will the implications be for equity and sustainability?

How will you enhance representativeness at these various levels?

Complexities and Challenges to Address: (e.g., reach and representativeness over time; unintended consequences and trade-offs to consider for other outcomes; adequacy of resources; ongoing monitoring issues)

Assessing and Enhancing Reach and Representativeness

Russell Glasgow, PhD; Meredith Fort, PhD

Tips to Consider to Enhance Reach and Representativeness

1. Build relationships with your community and target population. *Ongoing and in-depth* stakeholder engagement and CBPR.
2. In your assessments, be sure to include both current users of your services and non-users. Recruitment will be more effective if you rely on potential users to guide you. Ask them what is most likely to motivate people like them and what information sources they consider valuable and credible. You will likely *need to iterate.*
3. Determine what recruitment materials are *feasible and best* for your program. Your target audience will be extremely helpful in developing promotional content and identifying appropriate reading levels for recruitment materials.
4. *Go to where the target population is* and don't make them come to you for recruitment materials. There are many community settings that you can and should use as recruitment locations.
5. Communicate in the language(s) that the population you aim to include in your study is most comfortable using.

Key References and Resources

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Potential Data Sources

1. https://www.cdc.gov/datastatistics/index.html (and epidemiological surveillance agencies in other countries)
2. https://www.census.gov/data.html (and census and Ministry of Health data in other countries)
3. Social determinants of health: Individual PRO level: *The Accountable Health Communities Health-Related Social Needs Screening Tool*. Innovation.cms.gov. (2020). Retrieved from: https://innovation.cms.gov/files/worksheets/ahcm-screeningtool.pdf.

Process Evaluation and Adaptation in Complex Trials

Graham Moore, PhD

While real-world effectiveness is important, UK MRC guidance for process evaluation recognize that “effect sizes do not provide policy makers with information on how an intervention might be replicated in their specific context, or whether trial outcomes will be reproduced” (Moore et al. 2015). Hence, for evidence of effectiveness to meaningfully inform continued practice in the same context, or to inform transference to new contexts, we need to understand more than effects. We need to understand issues such as what was delivered (by whom and how), *how* did it work, and what are the contextual contingencies necessary for successful implementation and effects.

Prospectively designing process evaluations

Think about an intervention in your area of research which is going to be, or is currently being, evaluated using a randomized controlled trial, or other outcomes evaluation design.

To provide evidence to inform decisions on how this intervention should (if effective) be maintained in practice or used in other contexts, what might we need to ask about:

- Implementation/delivery
- Mechanisms
- Contextual contingencies?

What methods might we use, alongside an RCT, to understand these questions?

Figure 1. MRC Process Evaluation Framework (Moore et al. 2015)

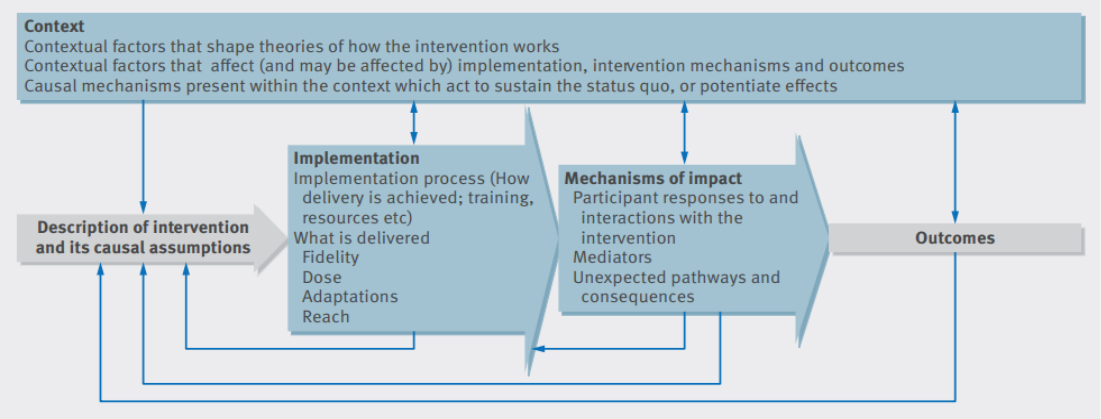


Fig 1 | Key functions of process evaluation and relations among them (blue boxes are the key components of a process evaluation. Investigation of these components is shaped by a clear intervention description and informs interpretation of outcomes)

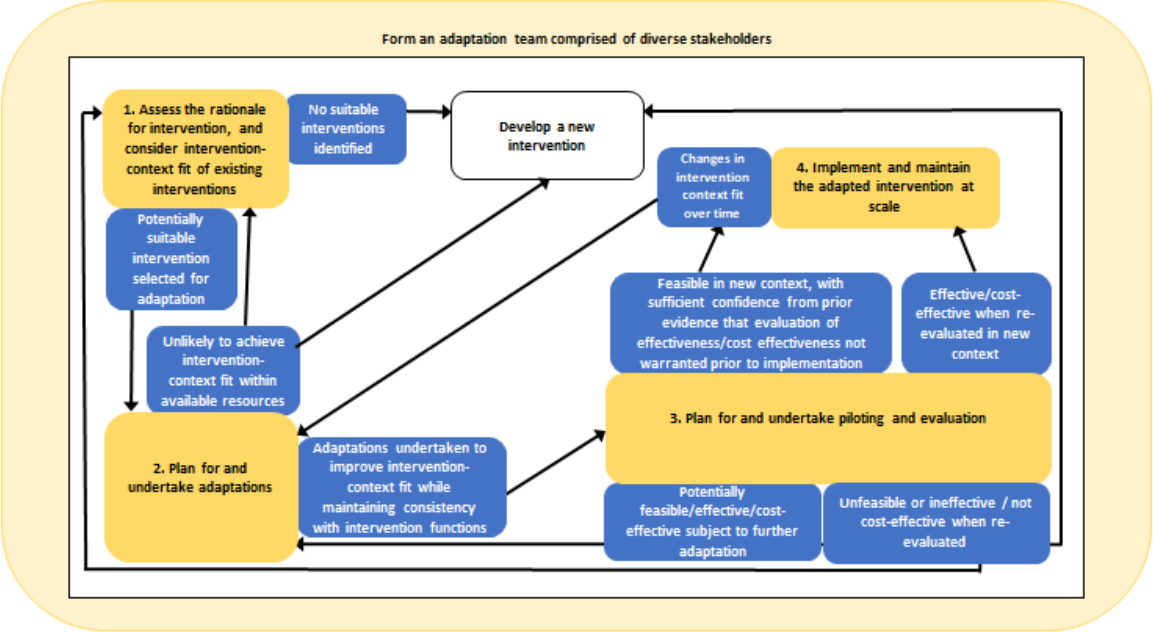
Using process evaluation data to inform adoption and adaptation decisions in a new context.

As described above, a key role for process evaluation is to provide data which enables teams in other contexts to make informed judgements on whether an 'effective' intervention might also be valuable in their context.

Looking at this from the other perspective, imagine you have identified an 'effective' intervention. What evidence would you look for (from the original evaluation, and in your own context) in order to understand:

- Are the mechanisms through which the intervention works relevant to my context?
- Are the contextual features necessary for successful implementation, and for the activation of intended mechanisms, present in my context?

Figure 2. ADAPT guidance framework (Moore et al 2020)



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Measuring Implementation Outcomes

Cara C. Lewis, PhD

Learning Objectives:

1. Delineate key implementation outcomes
2. Summarize the state of the science for measurement of implementation outcomes
3. Articulate critical parameters of implementation outcome measurement

Breakout Activity:

- Identify a construct or outcome you are interested in measuring for an ongoing or future project.
- Define the construct or outcome, draw on established theory wherever possible.
- What are possible synonyms for this construct or outcome? What are similar terms that reflect different constructs?
- At what level of analysis is this construct/outcome measured?
- In what phase of implementation should this construct/outcome be measured?
- Is this a latent or manifest variable?
- What are some example ways to measure this construct/outcome?

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Methods for Reporting and Aligning Implementation Strategies with Implementation Outcomes

Brittany N. Rudd, PhD

Using the Pragmatic Implementation Reporting Tool

When to Use:

When using implementation strategies in your work. This includes clinical research where implementation strategies are used to support the use of the intervention but the goal is to evaluate the efficacy or effectiveness of the intervention and implementation research where implementation strategies are under evaluation.

How to Use:

Can be used to support grant writing or reporting. For more details, see: Rudd, B.N., Davis, M. & Beidas, R.S. Integrating implementation science in clinical research to maximize public health impact: a call for the reporting and alignment of implementation strategy use with implementation outcomes in clinical research. *Implementation Sci* **15,** 103 (2020). https://doi.org/10.1186/s13012-020-01060-5

Why to Use:

1. To support theory development
2. To improve replication
3. Facilitate research to practice implementation
4. Design with implementation and sustainment in mind
5. Accelerate translational science

What to include:

Aligns with Proctor et al. (2013) and Presseau et al. (2019): **Actor** - the individual(s) who perform(s)/enact(s) the Action(s)

Per Proctor et al. (2013): **Dose** - dosage of implementation strategy, when relevant

Aligns with Proctor et al. (2013) "Temporality" and Presseau et al. (2019) "Time": **Temporality** - when the strategy is used and aligns with implementation process frameworks (e.g., Nilsen et al., 2015)

Per Proctor et al. (2011): **Justification** - the empirical, theoretical, or pragmatic justification for the choice of implementation strategies

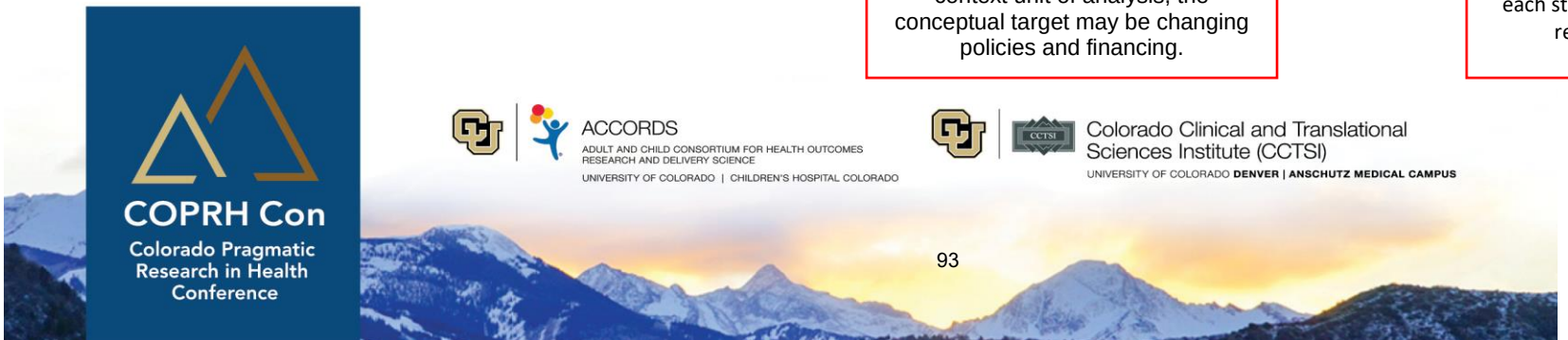
Operationalize It								
Action	Actor	Context	Dose	Action Target		Temporality	Implementation Outcome	Justification
				Conceptual	Unit of Analysis			

Aligns with Proctor et al. (2013) and Presseau et al. (2019): **Action** - use verb statements to specify the discrete observable behaviors enacted that encompass the

Per Presseau et al. (2019): **Context** - the physical location, emotional context, or social setting in which an action is performed

Aligns with Proctor et al. (2013) and Presseau et al. (2019): **Action Target** - specify targets according to **Conceptual** models of implementation (e.g., Nilsen et al., 2015 for review) and identify the **Unit of Analysis** for measuring implementation outcomes. The unit of analysis is also "target" in Presseau et al. (2019). The Action Target should mechanistically align with the Implementation Outcome. As an example, and using Damschroder et al.'s (2009) framework (see useful website), at the individual unit of analysis, the conceptual target may be attitudes or knowledge. At the inner-context unit of analysis, the conceptual target may be culture or leadership engagement, and at the outer context unit of analysis, the conceptual target may be changing policies and financing.

Per Proctor et al. (2013): **Implementation Outcome** - where one identifies the implementation outcomes likely to be affected by each strategy. Consider aligning with an evaluation framework (see Nilsen et al., 2015 for review), and linking to the CONSORT Outcomes section. Note that Presseau et al.'s (2019) framework can be used to detail implementation outcomes affected by each strategy, when relevant.



Track 1: Measuring Dissemination and Implementation Outcomes

[Notes]

Track 2: Analyzing Real World Data

Data Quality Assessment Issues and Methods for Secondary Use
Michael Kahn, PhD

Learning Objectives:
1. Identify data quality challenges across the data lifecycle from initial collection to analytics
2. Describe key dimensions for health data quality assessment prior to use in pragmatic research
3. Identify resources needed for data quality assessment

Watson: Attics, Guesswork and Clay. Sleuthing Your Way into Biomedical Natural Language Processing
Seth Russell, MS

Learning Objectives:
1. A general idea of what Natural Language Processing (NLP) is.
2. A knowledge of the ethical implications of data reuse in NLP.
3. Knowledge of where to get text for NLP.
4. How to use and learn more about some basic NLP techniques.

Methods for Linking Records Across Disparate Data Sources
Toan Ong, PhD; Jenna Reno, PhD

Learning Objectives:
1. Define opportunities to use record linkage methods for healthcare research
2. Understand and describe steps to perform data linkage in healthcare
3. Identify barriers and challenges to conducting record linkage

Mining and Analyzing Data from Social Media Data Sources
Bethany Kwan, PhD; Jenna Reno, PhD

Learning Objectives:
1. Identify audiences and potential uses of social media in pragmatic research
2. Identify approaches to mining data from social media and the web for research
3. Describe quantitative and qualitative analysis methods appropriate for social media data

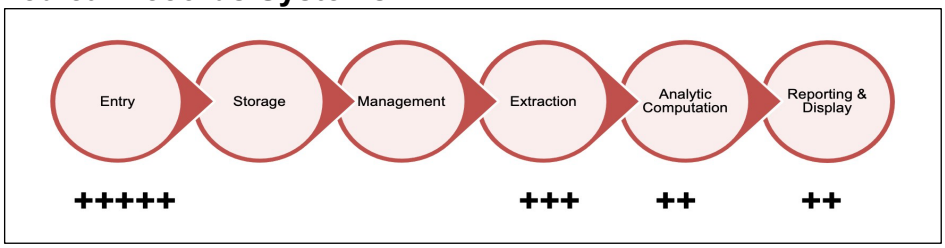
Data Quality Assessment Issues and Methods for Secondary Data Use

Michael G. Kahn MD, PhD (Michael.Kahn@cuanschutz.edu)

Handout, slides, example DQ reports, other links @
https://drive.google.com/drive/folders/11iJIG0AoS1KwgOjJM5RxPzqVaunZ6Kt9?usp=sharing

Sources of Quality Issues in Medical Records Systems

- The data lifecycle:
- Secondary data users rarely have access to source data systems.
- Operational systems focus on user efficiency, not data quality



Some key data quality "lingo" for framing your thinking & DQ activities

- Global data quality (DQ): A look at data quality across the entire data set irrespective of specific data use/analytics
- Fit for Use (F4U DQ) also called Fit for Purpose (F4P): A more-narrow view of data quality that is tailored to intended use/analytics.
    - F4U focuses on variables used to define cohort, exposure, outcomes, covariate.

- Intrinsic data quality: A look at DQ that doesn't depend on external data sources.
- Typically use local knowledge to determine data quality
- Extrinsic data quality: A look at DQ that compares DQ findings against some other data source (gold standard, relative gold standard, peer groups).
    - Peer group comparisons are common in multi-institutional data networks
      "How does my institution's data look compared to our peers"

- Data quality dimensions: An organizational model to break down of the wide range of data quality features that you could consider if relevant to your use case. The field uses terms inconsistently (sigh). I provide one attempt to try to harmonize DQ dimensions.
- Data quality measures: The actual computations used to quantify a specific data quality measure. The field has yet to develop a robust, reusable set of tools that is not dependent on the structure of a particular data set (sigh).
- Data quality rules: A set of "acceptance criteria" that if not met, will trigger a warning to investigate the data in more detail. These rules might be applied to global DQ measures or F4U DQ measures. The acceptance criteria can be different.
    - For a chronic renal disease study, it might be OK to have 100% missingness for psychiatric patients whereas this is (obviously) not so for a schizophrenia study.

- Non data quality features that impact F4U:
    - Are the data sufficiently timely for my needs (better data in 1 year vs poorer data today)?
    - Can I have access to the data elements I need, can I do the analytics I want, and can I present/publish as I wish (licensing and collaboration considerations)?
    - Can I afford access to the data and can I retain access as long as I need?

Getting Started

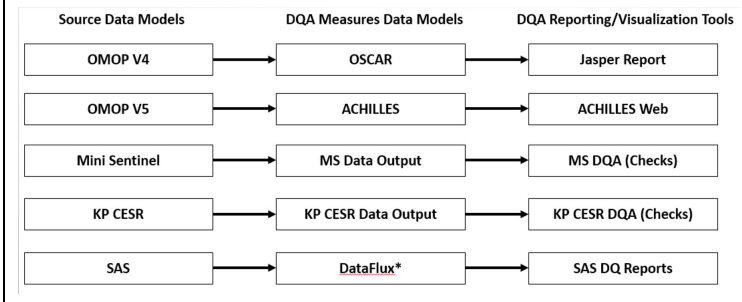
DQ Assessment is a big task. Align scope with resources. A rarely funded activity despite its importance in ensuring analytic validity. One (of many) data quality framework to use to scope your thinking/activities:

> Kahn MG, Callahan TJ, Barnard J, Bauck AE, Brown J, Davidson BN, et al. A Harmonized Data Quality Assessment Terminology and Framework for the Secondary Use of Electronic Health Record Data. eGEMs (Generating Evidence & Methods to improve patient outcomes) [Internet]. 2016 Sep 11 [cited 2016 Sep 12];4(1). Available from: https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5051581/pdf/egems1244.pdf

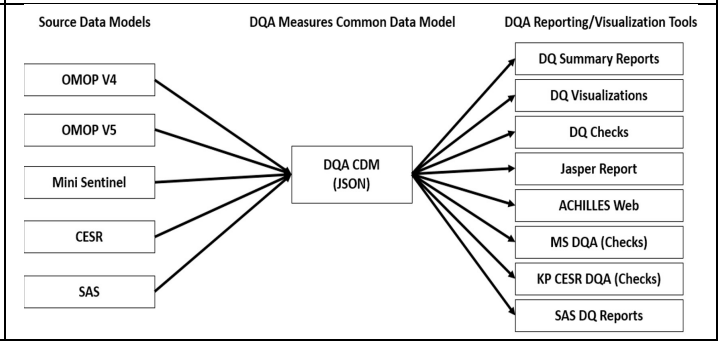
Focus on variables that matter: Work backwards from analytic plan. Consider interaction terms. List key variables on spreadsheet row. List data quality dimensions you feel are most impactful across columns. Start small, you can always grow. Convert DQ dimensions into DQ measures. Consider acceptability threshold (real world data never 100% clean so be realistic in your thresholds). Code or look for tools.

Finding Re-usable Tools: Not so easy

What we are today…..



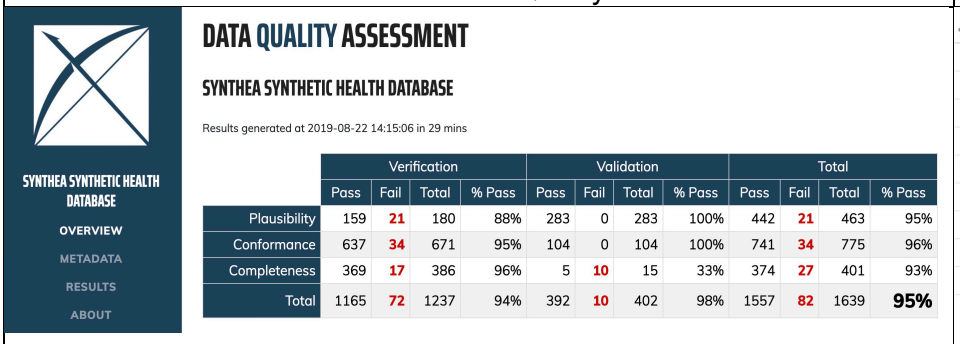
Where we want to be…..



- Many commercial tools (expensive): https://www.gartner.com/reviews/market/data-quality-solutions
  - New movement from "buy a tool" to "use a web service" ("DQ as a service"). Evolving but worth watching
- Open-source tools focused on health data.
  Large data networks have created E-X-T-E-N-S-I-V-E data quality tools. If you can use data in one of these formats, you can leverage their free (open access) DQ tools.
  - FDA Sentinel (claims oriented): https://www.sentinelinitiative.org/methods-data-tools/sentinel-common-data-model/data-quality-review-and-characterization-programs
  - PCORnet (medical records oriented): https://pcornet.org/data/
    SAS code @ https://github.com/PCORnet-DRN-OC/PCORnet-Data-Curation
  - OMOP (medical records oriented): https://github.com/OHDSI/DataQualityDashboard
  - A zillion "generic" (not health care focused) DQ tools on Github (https://github.com).
    Search "data quality" or "data profiling".
  - Other resources posted @
    https://drive.google.com/drive/folders/11iJIG0AoS1KwgOjJM5RxPzqVaunZ6Kt9?usp=sharing

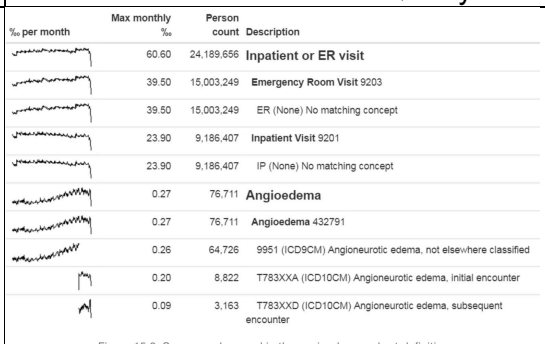
Data Quality Dashboard (OMOP) by Clair Blacketer: https://www.medrxiv.org/content/10.1101/2021.03.25.21254341v1.full.pdf

Global Data Quality



	Verification				Validation				Total			
	Pass	Fail	Total	% Pass	Pass	Fail	Total	% Pass	Pass	Fail	Total	% Pass
Plausibility	159	21	180	88%	283	0	283	100%	442	21	463	95%
Conformance	637	34	671	95%	104	0	104	100%	741	34	775	96%
Completeness	369	17	386	96%	5	10	15	33%	374	27	401	93%
Total	1165	72	1237	94%	392	10	402	98%	1557	82	1639	**95%**

Fitness for Use Data Quality



‰ per month	Max monthly ‰	Person count	Description
	60.60	24,189,656	Inpatient or ER visit
	39.50	15,003,249	Emergency Room Visit 9203
	39.50	15,003,249	ER (None) No matching concept
	23.90	9,186,407	Inpatient Visit 9201
	23.90	9,186,407	IP (None) No matching concept
	0.27	76,711	Angioedema
	0.27	76,711	Angioedema 432791
	0.26	64,726	9951 (ICD9CM) Angioneurotic edema, not elsewhere classified
	0.20	8,822	T783XXA (ICD10CM) Angioneurotic edema, initial encounter
	0.09	3,163	T783XXD (ICD10CM) Angioneurotic edema, subsequent encounter

Figure 15.8: Source codes used in the angioedema cohort definition.

Attics, guesswork and clay. Sleuthing your way into Biomedical Natural Language Processing

Seth Russell

This presentation, handout, and some example code is available at https://github.com/magic-lantern/coprh-nlp-2021

ACM Code of Ethics and Professional Conduct

Association for Computing Machinery, 2018

“Computing professionals' actions change the world. To act responsibly, they should reflect upon the wider impacts of their work, consistently supporting the public good. The ACM Code of Ethics and Professional Conduct ("the Code") expresses the conscience of the profession...”

Natural Language Processing is comprised of areas such as:

- Document Retrieval
- Information Extraction
- Knowledge Representation
- Word/Concept/Abbreviation disambiguation
- Automated reasoning
- Classification
- Sentiment Analysis

Common Natural Language Processing techniques

- Regular expressions
- Syntactical Analysis
- Stemming
- Lemmatization
- Stop word removal
- Word to vector representations
- Deep Learning & Language Models

Additional Resources

- "Clinical Natural Language Processing" Laura K. Wiley, PhD Asst Prof @ CU Anschutz https://www.coursera.org/learn/clinical-natural-language-processing
- "Natural Language Processing Specialization" https://www.deeplearning.ai/program/natural-language-processing-specialization/
- "A Code-First Introduction to Natural Language Processing" https://www.fast.ai/2019/07/08/fastai-nlp/
- https://towardsdatascience.com/introduction-to-clinical-natural-language-processing-predicting-hospital-readmission-with-1736d52bc709
- Medical Transcription Classification: https://www.kaggle.com/ritheshsreenivasan/clinical-text-classification

Analyzing Real World Data: Methods for Linking Records Across Disparate Data Sources

Toan Ong, PhD; Jenna Reno, PhD

Learning Objectives
1. Define opportunities to use record linkage methods for healthcare research
2. Understand and describe steps to perform data linkage in healthcare
3. Identify barriers and challenges to conducting record linkage

Record linkage: a process to determine if two or more records belong to the same entity.

Getting Started
When planning a research study that uses record linkage, start by answering the following questions:
See workbook for more info

1a. What is the research question?

1b. What data are needed to answer the question?

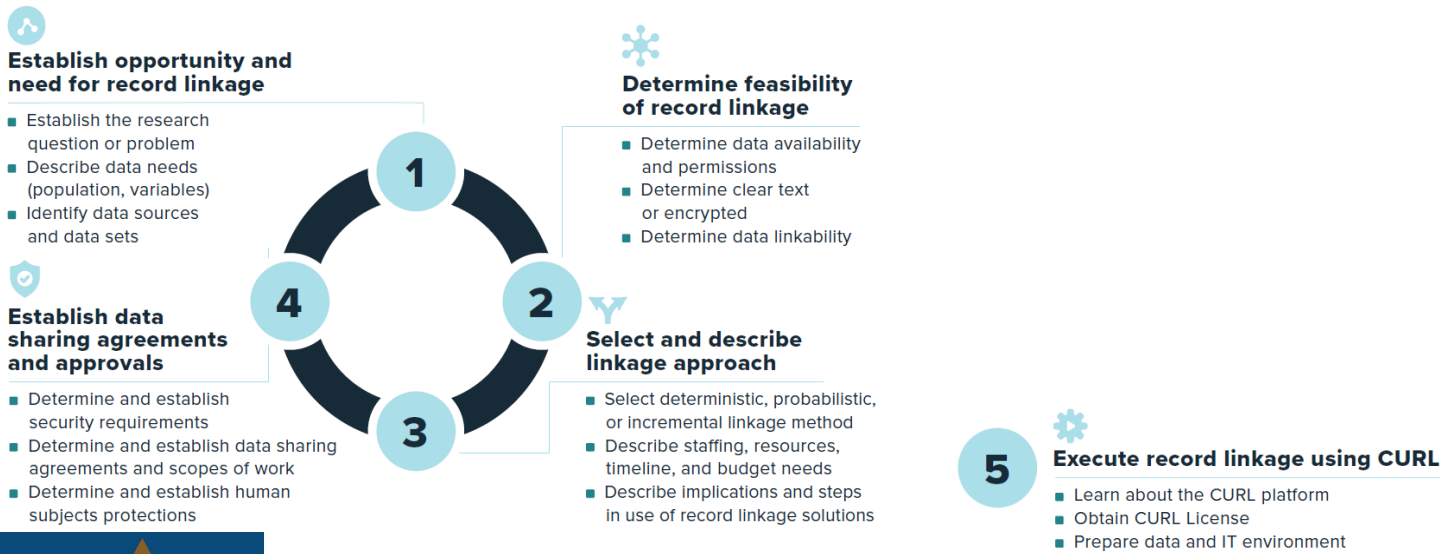
1c. What are sources of these data?

1d. What data sets or variables do you want to link (i.e., the type and scope of the data) and can they be linked together?

1e. For what purpose might data sets be linked (deduplication, data enrichment, cohort identification)?

1f. Describe the limitations of a single data source or data set that can be addressed by linking across populations, settings, or data types.

CU Record Linkage Planning Workbook for Investigators



Mining and Analyzing Data from Social Media for Pragmatic Research

Bethany Kwan, PhD, MSPH; Jenna Reno, PhD
University of Colorado Anschutz Medical Campus

Learning Objectives

1. Identify audiences and potential uses of social media in pragmatic research
2. Identify approaches to mining data from social media and the web for research
3. Describe quantitative and qualitative analysis methods appropriate for social media data

Use of Social Media in Pragmatic Research

Implementation and conduct of research

- Stakeholder and community engagement or "citizen science"
- Dissemination and messaging channels
- Recruitment and outreach

Source of data for research

- "Secondary use"
- Communication research
- Network analysis
- Ethnographic research
- Public health surveillance
- Patient-generated health outcomes data

Mining Data from Social Media

- Manual approaches
- Connection via an Application Programming Interface (API)
    - Free on Twitter – search and download tweets (but limited to 1% of tweets)
- Third party vendors
    - Licensed with the platform for broader access (can be expensive)
    - Symplur: https://www.symplur.com/products/signals/
    - Social listening tools
- Named entity recognition and normalization (automated and manual)
    - Named entity recognition: identification of entities such as drugs, diseases, and medical events
    - Normalization: Mapping to predefined categories or standard medical ontologies
    - Dictionary lookup
- Text mining techniques (extracting features of free-text for further analysis)
    - N-gram, word embedding, sentence-dependency-based parse tree, Latent Dirichlet Allocation (LDA) topic modeling

Analysis of Data from Social Media

- Network analysis
- Qualitative content analysis
- Supervised and unsupervised machine learning
- Hypothesis testing
- Facebook message testing

Activity #1: Know Your Audience

- Pick one of the “uses of social media for pragmatic research”
- State a specific hypothetical or real example of how you might use social media in one or more ways in your research
- Who is your audience?
  - Consider adopters, influencers, potential saboteurs
- Where might you find this audience on social media?
- How do they use social media?
- Who are the influencers on social media?
- How might you partner with existing online communities?

Activity #2: Social media data mining and analysis plan

- Consider the audience, social media platform, and research topic you considered in Activity #1.
- What data types might be available from that social media platform?
  - Text data
  - Structural data
  - Metadata
  - Other?
- How might you mine the data?
- How might you analyze the data?
- Who do you need on your team?

References and Resources

1. Ru B, Yao L. A literature review of social media-based data mining for health outcomes research. Social Web and Health Research. 2019:1-4.
2. Taylor J, Pagliari C. Mining social media data: how are research sponsors and researchers addressing the ethical challenges? Research Ethics. 2018 Apr;14(2):1-39.

[Notes]

Implementing Pragmatic Trials via Electronic Platforms: Practical and Ethical Considerations

Andrea B. Troxel, ScD

Pragmatic trials often aim to take advantage of technology for outreach and implementation, with the goals of broadening outreach and reducing burden on participants. One benefit of such approaches is the reduction in barriers presented by in-person consent processes. Different methods of outreach and consent, however, result in different subpopulations of participants who enroll; both of these features can influence the estimates of treatment effectiveness that may result. We will discuss examples of how these approaches influence outcomes and analytic results, as well as ethical concerns.

Learning Objectives

- Review features of pragmatic clinical trials
- Understand the kinds of electronic platforms available to facilitate pragmatic trials
- Describe real-world examples
- Address the effect of different outreach and consent approaches on participation

Key Points

- Proliferation of technology in health care
- Consider the intersection of technology and human behavior
- Electronic platforms for trial implementation and patient care/communication
- Use of electronic health records in pragmatic trials

Thought Questions

- How can an electronic platform or system enhance the reach of a trial and/or its generalizability?
- How can we reduce the burden of participation on both patients and providers?
- How can we incorporate interventions into existing workflows to enhance their impact?
- How can technical innovations be harnessed in the service of care and research?
- How can we optimize our interventions to meet the needs of stakeholders?

[Notes]

Understanding and Adapting to Complexity in Real-World Contexts

Keynote Address by Graham Moore, PhD

Complex systems approaches to intervention science are increasingly advocated. However, despite a growing abundance of conceptual publications, there have to date been few attempts to consider in practical terms what a complex systems lens means for intervention researchers. This talk discusses the influence of complex systems thinking within historical and ongoing guidance development for intervention researchers. It will argue that whole systems evaluations may be neither attainable, nor necessary and that acknowledgment of complexity does not mean that real-world evaluations must investigate all facets of complexity. However, a systems lens may add value to intervention science through framing issues such as how fidelity is conceived, aspects of context which matter for intervention effects to transfer across contexts, and how intervention effects may build or diminish over time in real world settings. The talk will introduce new MRC-NIHR funded ADAPT guidance, which draws upon complex systems perspectives to provide guidance in thinking through and undertaking the adaptation of interventions for new contexts.

By the end of this session, participants will have been introduced to:

1. Definitions of a complex systems perspective, including i) what is meant by the terms 'complex intervention', ii) a 'complex system" iii) intervention as an 'event within a complex system'
2. The influence of complex systems perspectives in guidance development for health intervention research;
3. Practical implications of complexity for development, evaluation and implementation of interventions, with an emphasis on adaptation of interventions across contexts

References:

1. Hawe P, Shiell A, Riley T. Theorising interventions as events in systems. *American journal of community psychology* 2009;43(3-4):267-76.
2. Moore GF, Evans RE, Hawkins J, et al. From complex social interventions to interventions in complex social systems: future directions and unresolved questions for intervention development and evaluation. *Evaluation* 2019;25(1):23-45.
3. Moore GF, Evans RE. What theory, for whom and in which context? Reflections on the application of theory in the development and evaluation of complex population health interventions. *SSM-population health* 2017;3:132-35.
4. Graham Moore, Mhairi Campbell, Lauren Copeland, Peter Craig, Ani Movsisyan, Pat Hoddinott, Hannah Littlecott, Alicia O'Cathain, Lisa Pfadenhauer, Eva Rehfuess, Jeremy Segrott, Penelope Hawe, Frank Kee, Danielle Couturiaux, Britt Hallingberg, Rhiannon Evans (2020) Adaptation of interventions for implementation and/or re-evaluation in new contexts: The ADAPT Study guidance (v1.0). https://decipher.uk.net/portfolio/the-adapt-study/

Understanding and Adapting to Complexity in Real-World Contexts

Keynote Address by Graham Moore, PhD

[Notes]

Map2Adapt: A Roadmap to Plan for Adaptations

Plenary Address by Julia E. Moore, PhD

Pragmatic research answers the question, “Does it work in typical clinical care settings?” Ultimately, the goal of pragmatic research is to inform the implementation, spread, and scale of evidence in clinical settings to improve patient outcomes. There has been an increasing recognition that adaptations are the reality when implementing interventions in clinical settings. This change has been accompanied by a rapidly growing body of research on adaptations, which has accelerated in response to environmental demands from COVID-19. Unfortunately, this growing evidence base is not yet ready for use by the people responsible for leading change in organizations. In an effort to bridge this gap between the research on adaptations and the practice of adaptations in clinical settings, we developed a practical roadmap, Map2Adapt, to guide decision-making and planning for adaptations. Map2Adapt is a practical tool that highlights key concepts of adaptations and identifies strategies to systematically approach adaptations by applying existing literature that have exemplified ways to categorize and document adaptations in interventions, programs, or policies. Map2Adapt can be used collaboratively by pragmatic researchers and implementers to understand, plan for, track, and evaluate the impact of adaptations. This workshop will illustrate how pragmatic researchers, implementation scientists, and implementers can work collaboratively to better plan for adaptations.

Learning Objectives:

1. Provide concrete and practical guidance to bridge the gap between adaptations in research and adaptations in practice
2. Describe key concepts related to adaptations
3. Use strategies to systematically approach adaptations
4. Classify different types of adaptations and the reasons for making those adaptations

Thought Questions

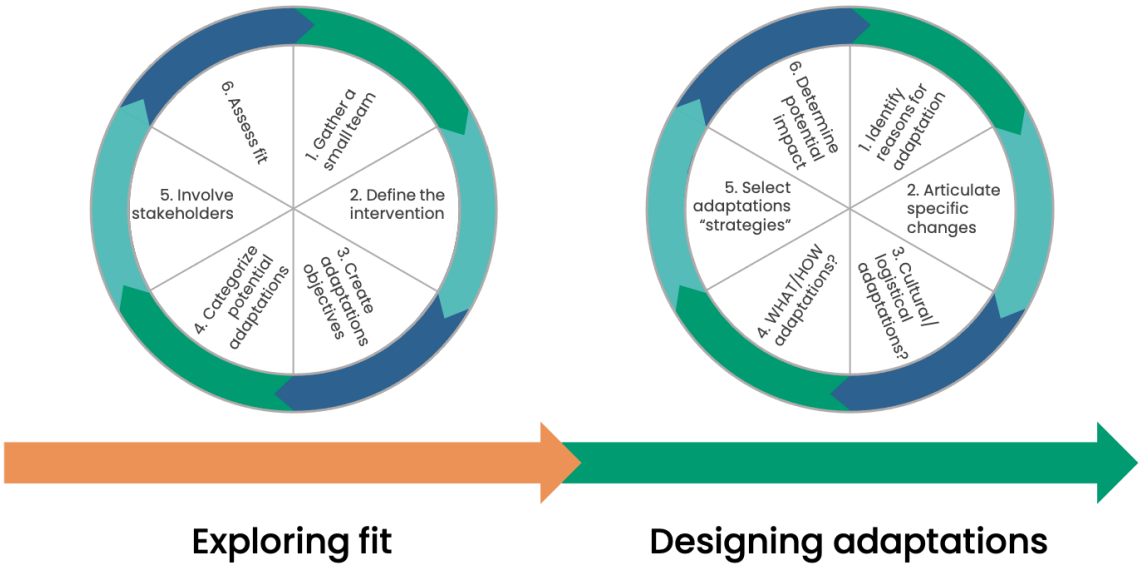
1. How do you navigate questions from stakeholder pushing for adaptations or fidelity?
2. How can you better plan for adaptations?
3. What are potential ways to embed equity into decision-making for adaptations?

Map2Adapt: A Roadmap to Plan for Adaptations

Plenary Address by Julia E. Moore, PhD

Adaptations refer to changes that are made to an intervention in order to increase its relevance or fit to a given context (Kirk, 2020). The purpose of adaptations is to enhance fit and feasibility of implementing programs and practices, improve implementation outcomes, increase relevance of implementation strategies, as well as sustain interventions over time (Kirk, 2020). There is existing evidence to support how adaptations lead to better outcomes than interventions that are not tailored to a setting or population. Although, positive outcomes are not assured. There are many other factors embedded in the adaptation process that can impact the level and quality of outcomes, along with impact. For this reason, we focus on systematically approaching the planning and decision-making that goes into adaptations. The nature of adaptations calls for the application of implementation theory, models, frameworks, and approaches. Using implementation theory, models, frameworks, and approaches can help make adaptations more systematic, intentional and maintain responsiveness to the needs of a project.

To that end, we developed Map2Adapt. Map2Adapt is a process model that was created based on other existing adaptation frameworks. The idea behind the Map2Adapt is to provide a practical roadmap that can guide practitioners in making adaptations during the early phases of the project. It includes two phases: (1) exploring fit; and (2) designing adaptations. Within each phase, there are activities that can help guide your adaptations by considering different levels related to your intervention. Emphasis is placed on stakeholder engagement, as well as using adaptation frameworks to identify the WHAT and HOW of your intervention, adaptation objectives, and categorize potential adaptations by multiple ecological levels.



Plenary Address by Julia E. Moore, PhD

References

1. Bernal, G. E., & Domenech Rodríguez, M. M. (2012). Cultural adaptations: Tools for evidence-based practice with diverse populations (pp. xix-307). American Psychological Association.
2. Escoffery, Cam, et al. (2018). A systematic review of adaptations of evidence-based public health interventions globally. Implementation Science 13(1):125. https://doi.org/10.1186/s13012-018-0815-9.
3. Kirk, A. (2020). Chapter 13: Adaptation In Nilsen, P. & Birken, S Handbook on Implementation Science. United Kingdom: Edward Elgar Publishing, Inc.
4. Roscoe, J. N., Shapiro, V. B., Whitaker, K., & Kim, B. E. (2019). Classifying changes to preventive interventions: Applying adaptation taxonomies. The Journal of Primary Prevention, 40(1), 89-109. doi: 10.1007/s10935-018-00531-2.
5. Stirman, S. W., Baumann, A. A., & Miller, C. J. (2019). The FRAME: An expanded framework for reporting adaptations and modifications to evidence-based interventions. Implementation Science, 14(1), 1-10. https://doi.org/10.1186/s13012-019-0898-y.

[Notes]

Track 1: Adaptation Methods

Using Frame and MADI Frameworks to Guide and Track Adaptations
Shannon Wiltsey Stirman, PhD

Learning Objectives:
1. Describe two frameworks for guiding and tracking adaptations
2. Discuss how to apply MADI to understand adaptation impacts
3. Explain strategies to apply the FRAME to track adaptations

The Form and Function Matrix Approach to Adapting Complex Interventions to Local Context
Brian Mittman, PhD

Reconceptualizing Sustainability and Adaptation: From Static to Dynamic
David Chambers, DPhil

Learning Objectives:
1. Understanding traditional approaches to sustainability and adaptation and their limitations
2. Reconceptualizing sustainability and adaptation as dynamic approaches to improving fit between intervention and setting
3. Identifying opportunities to study sustainability and adaptation in the context of implementation

Multi and Mixed Methods Approaches for Document and Analyzing Adaptations in Real-World Studies
Jodi Summers Holtrop, PhD; Borsika Rabin, PhD

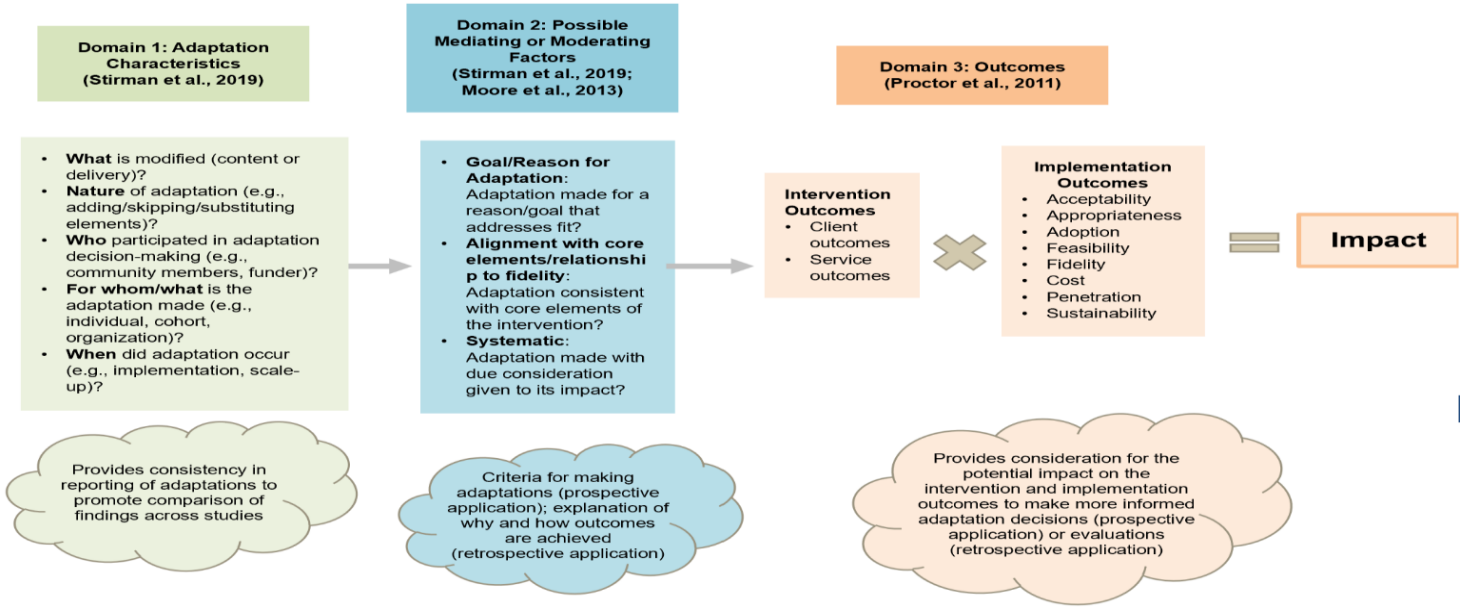
Learning Objectives:
1. Provide an understanding of key concepts of adaptations as they relate to the documentation and analysis of adaptations
2. Review and compare key strategies for documenting adaptations pre-implementation, during implementation, and during sustainment
3. Identify approaches to analyze adaptations and their impact pre-implementation, during implementation, and after implementation

Using Frame and MADI Frameworks to Guide and Track Adaptations

Shannon Wiltsey Stirman, PhD

FRAME and Frame-IS Resources available at: https://med.stanford.edu/fastlab/research/adaptation.html
MADI information and resources available at: https://madiguide.org/about/

MADI (https://implementationscience.biomedcentral.com/articles/10.1186/s13012-020-01021-y)



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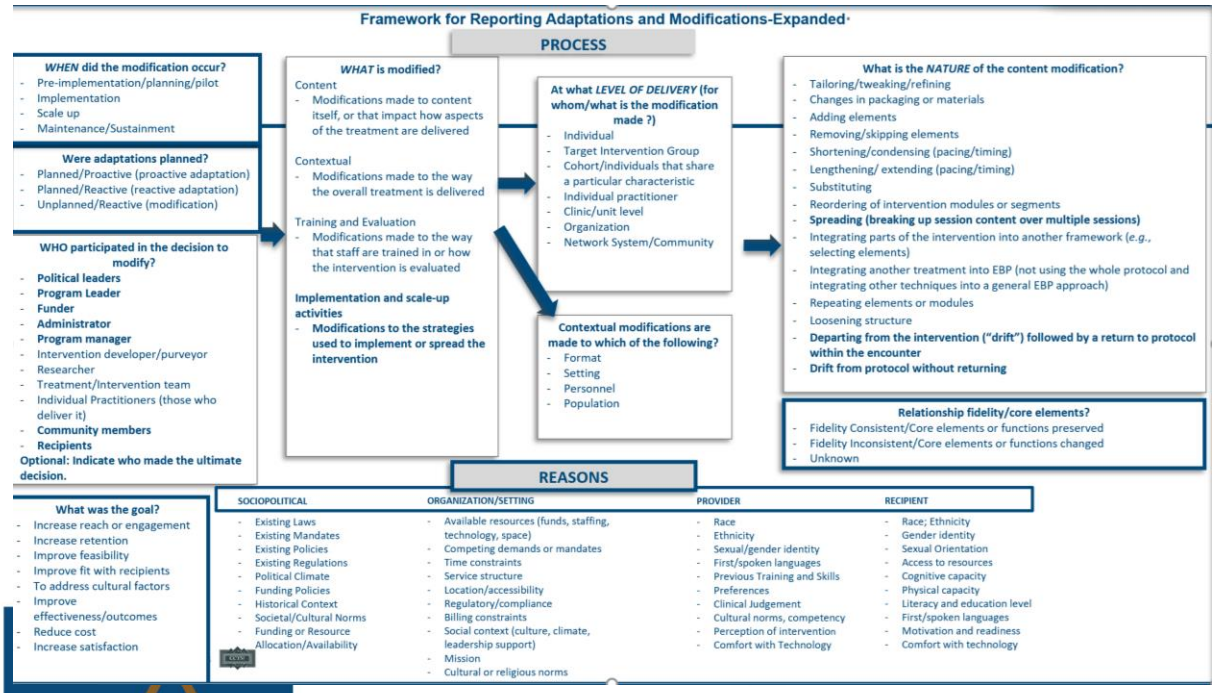


A Dynamic Approach to Sustainability and Adaptation

David Chambers, DPhil

Definitions (from Chambers et al, 2013, "The Dynamic Sustainability Framework")

Table 1 Definitions of key terms used in this paper

Term	Definition
Implementation	The process of putting to use or integrating evidence-based interventions within a setting [9].
Sustainability	To what extent an evidence-based intervention can deliver its intended benefits over an extended period of time after external support from the donor agency is terminated [9].
Sustainment	The continued use of an intervention within practice [10].
Voltage drop	The phenomenon in which interventions are expected to yield lower benefits as they move from efficacy to effectiveness and into real world use (adapted from [11]).
Program drift	The phenomenon whereby deviation from manualized protocols in real-world delivery of interventions is expected to yield decreasing benefit for patients (adapted from [12]).

Key Questions:

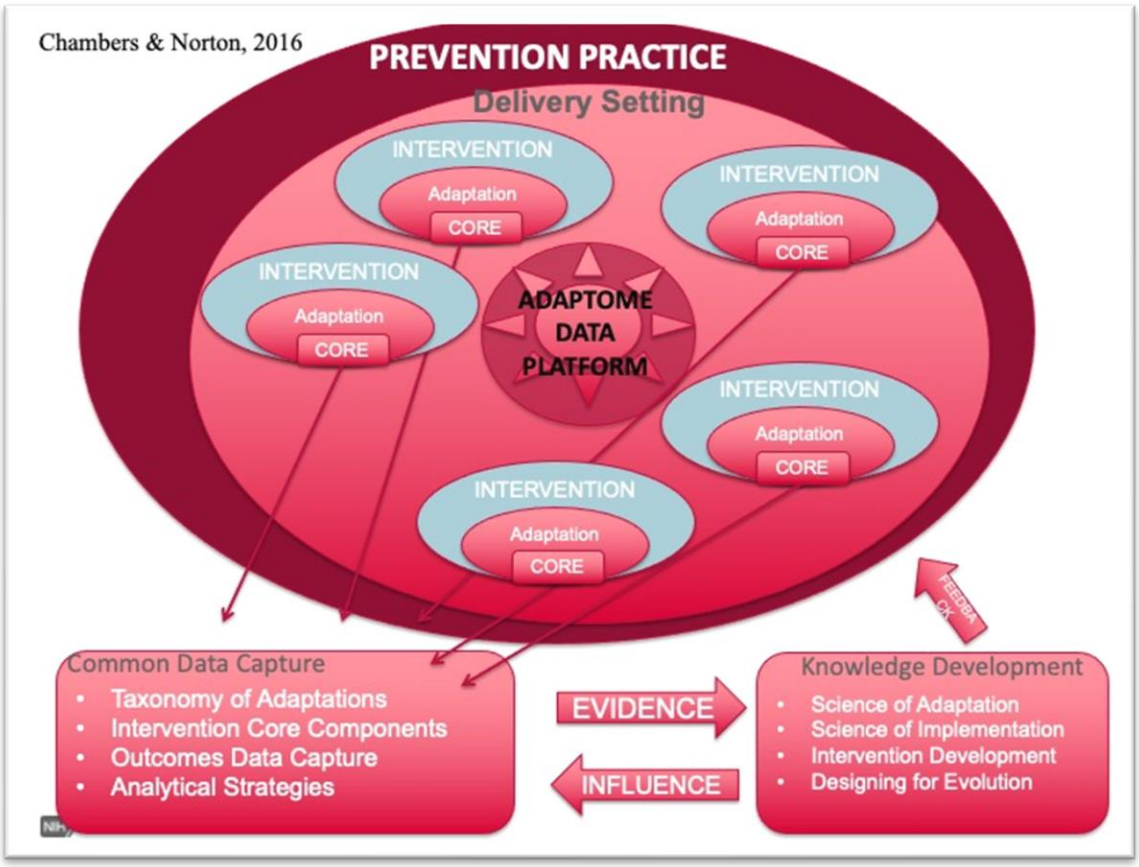
1. What is the intervention that you are planning to sustain?
2. What is the timeframe for sustainability?
3. What strategies are needed to sustain?
4. What is likely to change during this phase:
    - Intervention?
    - Context?
    - Needs?
    - Evidence?
    - Policy?

A Dynamic Approach to Sustainability and Adaptation

David Chambers, DPhil

Considering Ongoing Adaptation (ref: The Adaptome, Chambers and Norton, 2016)

Moving from traditional study of Adaptation (via a clinical trial comparing adaptation to base version of an intervention) to the concept that adaptation is part of ongoing learning (see below figure)



Activity: Discuss potential adaptations likely to emerge during implementation
Sample Intervention: Care management for depression
Key Questions:

- What kinds of adaptations do you expect to happen over a 5 year period?
- What would you want to measure?
- How can we build a common set of lessons from these experiences?
- What designs might you use?

A Dynamic Approach to Sustainability and Adaptation

David Chambers, DPhil

References:

Shelton RC, **Chambers DA**, Glasgow RE. An Extension of RE-AIM to Enhance Sustainability: Addressing Dynamic Context and Promoting Health Equity Over Time. Front Public Health. 2020 May 12;8:134. doi: 10.3389/fpubh.2020.00134. PMID: 32478025; PMCID: PMC7235159.

Johnson, A.M., Moore, J.E., **Chambers, D.A**. *et al.* How do researchers conceptualize and plan for the sustainability of their NIH R01 implementation projects?. *Implementation Sci.* 14**,** 50 (2019) doi:10.1186/s13012-019-0895-1.

Chambers DA, & Norton WE. (2016). The Adaptome: Advancing the Science of Intervention Adaptation. *American Journal of Preventive Medicine*, *51*(4 Suppl 2), S124–S131. http://doi.org/10.1016/j.amepre.2016.05.011

Chambers DA, Glasgow RE, Stange KC. (2013) The dynamic sustainability framework: addressing the paradox of sustainment amid ongoing change. *Implementation Science* 8:117.

[Notes]

Multi and mixed methods approaches for documenting and analyzing adaptations in real-world studies

Borsika Rabin, PhD, MPH, PharmD, Jodi Summers Holtrop, PhD, MCHES

Learning Objectives

1. Provide an understanding of key concepts of adaptations as they relate to the documentation and analysis of adaptations
2. Review and compare key strategies for documenting adaptations pre-implementation, during implementation, and during sustainment
3. Identify approaches to analyze adaptations and their impact pre-implementation, during implementation, and after implementation

	Timing of Adaptation - Point in the Study		
Focus of Adaptation	**Planning Pre-implementation**	**During Implementation**	**Following Sustainment**
Intervention			
Implementation Strategy			
Context			

Data Collection Methods to Assess Adaptations

Qualitative

- Observational techniques/observation
- Interviews and/or focus groups
- Field notes from coaching/facilitation, process maps

Quantitative

- Questionnaires/surveys
- Checklists (fidelity assessments)
- Other data sources such as study or clinical databases (electronic medical records, program logs)

Data Analysis Methods to Assess Adaptations

- Traditional qualitative analysis (grounded theory, thematic, content analysis, etc.)
- Basic descriptive statistics (frequencies, cross tabs/co-occurrence)
- Cluster analysis (statistics)
- Mixed methods: Joint display analysis, configurational comparative methods (QCA, CNA)

Track 1: Adaptation Methods

[Notes]

Conference Notes

[Notes]

Conference Notes

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About ACCORDS

Adult and Child Consortium for Health Outcomes Research and Delivery Science

The Adult and Child Consortium for Health Outcomes Research and Delivery Science (ACCORDS) encompasses T3-T4 research across the life spectrum for the University of Colorado (CU) Anschutz Medical Campus, with infrastructure support provided jointly from the Dean's Office of the School of Medicine and Children's Hospital Colorado (CHCO). The program was first established in 1998 as the Colorado Health Outcomes program (COHO). In 2014, COHO merged with the Children's Outcomes Research (COR) program, with **Allison Kempe, MD,** named the Program Director. The name highlights the focus on the entire life spectrum as well as on "delivery science," encompassing comparative effectiveness, patient-centered outcomes, and dissemination and implementation research.

ACCORDS is a group of investigators from multiple disciplines. Some have primary offices on campus, while a much larger group maintain off-site research homes. Currently, over 50 investigators, 15 biostatisticians/analysts, 39 research assistants, four instructors, and 11 administrative personnel have office space with ACCORDS. In FY2019, 32 grants were awarded totaling $14 million, reflecting a 38 percent success rate for submitted proposals. ACCORDS provided 490 consultations to 28 departments/division in the School of Medicine and assisted with 63 faculty recruitments. ACCORDS houses two fellowship programs focusing on primary and subspecialty clinician scientists, and currently has a K12 training grant focused on dissemination and implementation science. During FY2019, ACCORDS hosted four seminar series, two distinguished lecturers, and four educational workshops.

ACCORDS brings together T3-T4 researchers from across the CU Anschutz campus. Collaborating investigators represent all School of Medicine departments, as well as the Colorado School of Public Health, the Skaggs School of Pharmacy and Pharmaceutical Sciences, and the College of Nursing. ACCORDS also has strong research affiliations with the Colorado Clinical and Translational Sciences Institute (CCTSI), Denver Health, Kaiser Permanente, U.S. Department of Veterans Affairs, Colorado Department of Public Health and Environment, and the Colorado Department of Health Care Policy and Financing. ACCORDS is as an incubator for research ideas, fosters interdisciplinary collaboration, and develops focused areas of research of national prominence.

The mission of ACCORDS is to improve health, locally and nationally, by supporting state-of-the-art outcomes and community translational research to guide clinical practice and health policy.

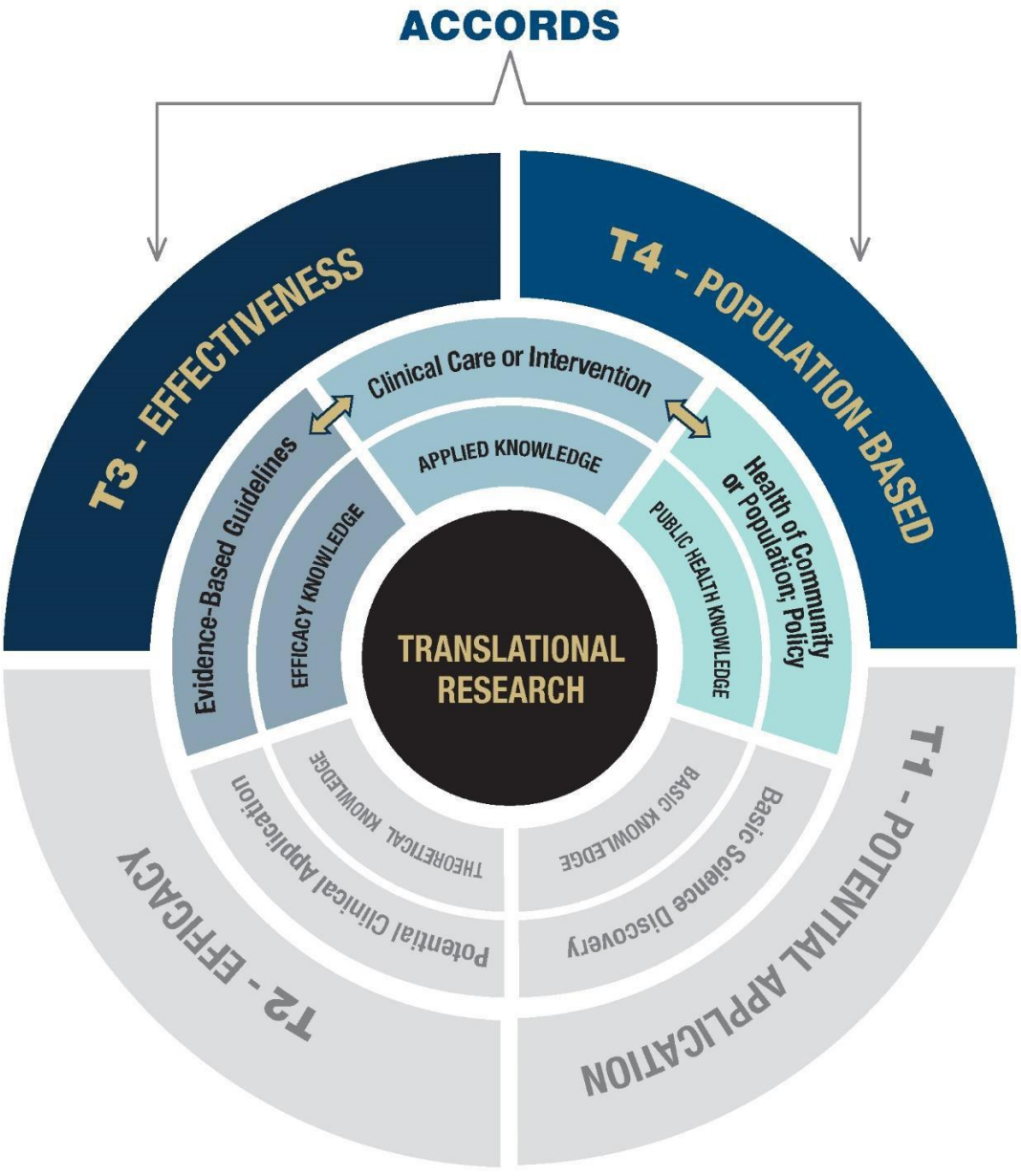
The objectives of ACCORDS are to

- Increase competitiveness of the School of Medicine/CHCO for funding from multiple research, education and training program sponsors, especially Patient-Centered Outcomes Research Institute, Agency for Healthcare Research and Quality, and the National Institutes of Health
- Strengthen affiliations with key external partners, including Denver Health, U.S. Department of Veterans Affairs, Kaiser Permanente, and the Colorado Department of Public Health and Environment, to increase access to populations and collaborators necessary for certain grants
- Improve faculty development for both senior and junior faculty interested in outcomes and delivery research by providing an interdisciplinary home for developing research, a mentored training ground, and substantial educational activities
- Improve the ability of the School of Medicine/CHCO to recruit senior and junior faculty interested in health outcomes, health services research, dissemination and implementation science, comparative effectiveness, and patient-centered outcomes research
- Achieve greater national visibility for the School of Medicine/CHCO as leaders in the areas of health outcomes, dissemination and implementation science, comparative effectiveness research, and training

ACCORDS is organized into programmatic areas: (1) Dissemination and Implementation Science; (2) Education; (3) Research Training and Mentorship; (4) Patient-Centered Decisions; (5) Data Science, and (6) Community Engagement and Outreach.

ACCORDS also has methodological cores in qualitative and mixed methods, practice-based research networks, biostatistics and analysis, economic analysis, and health informatics/mobile health. These cores provide support to the programmatic areas and consultative support to investigators. A major focus of these cores is to provide support for the development of new projects and grant proposals.

For more information, please visit https://medschool.cuanschutz.edu/accords



About CCTSI

The Colorado Clinical and Translational Sciences Institute

Accelerating Research to Improve Health

A collaboration between the University of Colorado Anschutz Medical Campus, the University of Colorado Denver, the University of Colorado Boulder and Colorado State University, the CCTSI includes six affiliated hospitals and health care organizations as well as multiple community organizations--all with the goal of building resilient research teams of the future and accelerating the translation of research discoveries into improved patient care and public health. The CCTSI partner health care institutions include University of Colorado Hospital, Children's Hospital Colorado, National Jewish Health, Denver Health and Hospitals, Denver Veterans Affairs Medical Center and Kaiser Permanente Colorado.

The CCTSI is a National Institutes of Health (NIH/NCATS)-funded research institute at CU Anschutz. It is part of the national consortium of 62 CTSA institutional hubs throughout the United States and is one of the largest federal research grants awarded in the state of Colorado. The CCTSI also receives considerable institutional support from CU Anschutz, CU Boulder, CSU and the affiliated hospitals. The CCTSI has nearly 7,000 individual members who benefit from its services, funding sources and programs.

The **vision** of the CCTSI is to accelerate and catalyze the translation of innovative science into improved health and patient care. To reach this vision, the mission of the CCTSI is to:

- Catalyze and enhance scientific discovery, innovation, dissemination and translation across the lifespan;
- Educate and sustain a resilient, innovative and diverse translational science workforce;
- Promote and ensure an efficient, safe, collaborative and integrated research environment;
- Engage stakeholders and communities across the entire translational spectrum.

The CCTSI is led by **Ronald J. Sokol, MD**, and a team of talented associate directors and administrative staff. For further information on our programs, services and funding opportunities, go to CCTSI.cuanschutz.edu.

D&I Graduate Certificate Program

The Dissemination and Implementation (D&I) Science Graduate Certificate at the University of Colorado was designed to address a local and national need for rigorous training in D&I Science in health services research.

D&I science is the study of methods and strategies to facilitate the spread, adoption, implementation, and sustainment of evidence-based practices, interventions and policies in real world and diverse health settings. As a transdisciplinary scientific field, D&I science can address multiple cross-cutting research topics (e.g., reducing disparities in access to and quality of care; use of innovative technologies and data science to improve routine care) and health conditions (e.g., mental health, cancer and cardiovascular disease morbidity and mortality, geriatric care) of high priority. D&I Science also has the potential to make precision health more actionable and relevant and can make the translation of discoveries in this and other high priority areas more rapid.

The D&I Science Graduate Certificate Program is designed to provide pragmatic training to researchers who want to develop competencies in D&I science and practice which can be applied across multiple topic areas and settings in health services, clinical and community health, and public health research.

The program is intended to provide researchers with solid foundational skills in D&I science, as well as intermediate and advanced skills in select D&I competency areas.

The D&I Science Graduate Certificate Program has two sponsoring units: the Adult and Child Consortium for Health Outcomes Research and Delivery Science (ACCORDS) acts as the primary sponsor and the Colorado Clinical and Translational Sciences Institute (CCTSI) at the University of Colorado Anschutz Medical Campus acts as the secondary sponsor. It is coordinated through the ACCORDS Dissemination and Implementation Science Program.

For questions about the D&I Certificate program content please contact Amy Huebschmann, the program director.

2022 Colorado Pragmatic Research in Health Conference

SAVE THE DATE!

COPRH Con is a three-year national conference series focused on pragmatic methods for health services research.

In May 2022, COPRH Con will focus on Phase III and IV of the Evidence Life Cycle (dissemination, sustainment, and de-implementation).

Mark your calendars now!