McMaster University

Family Medicine

David Braley Primary Care Research Collaborative

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Implementation Science and Applications in Primary Care Research

Watch a recording of the session here

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June 18th, 2024

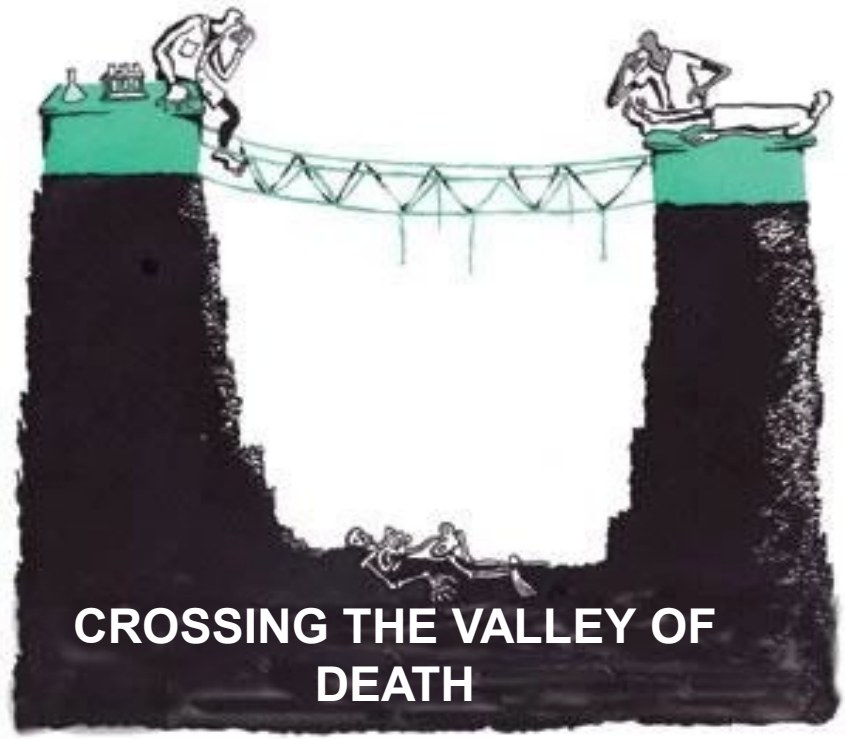
Michael G. DeGroote SCHOOL OF MEDICINE

Objectives

- Review implementation science, its definition, methods, and challenges
- Highlight commonly used theories, models and frameworks
- Panel of speakers: share applications in primary care research
  - Jennifer & Rebecca: RE-AIM Framework
  - Jessica: Normalization Process Theory
  - Gina: Proctor's Framework

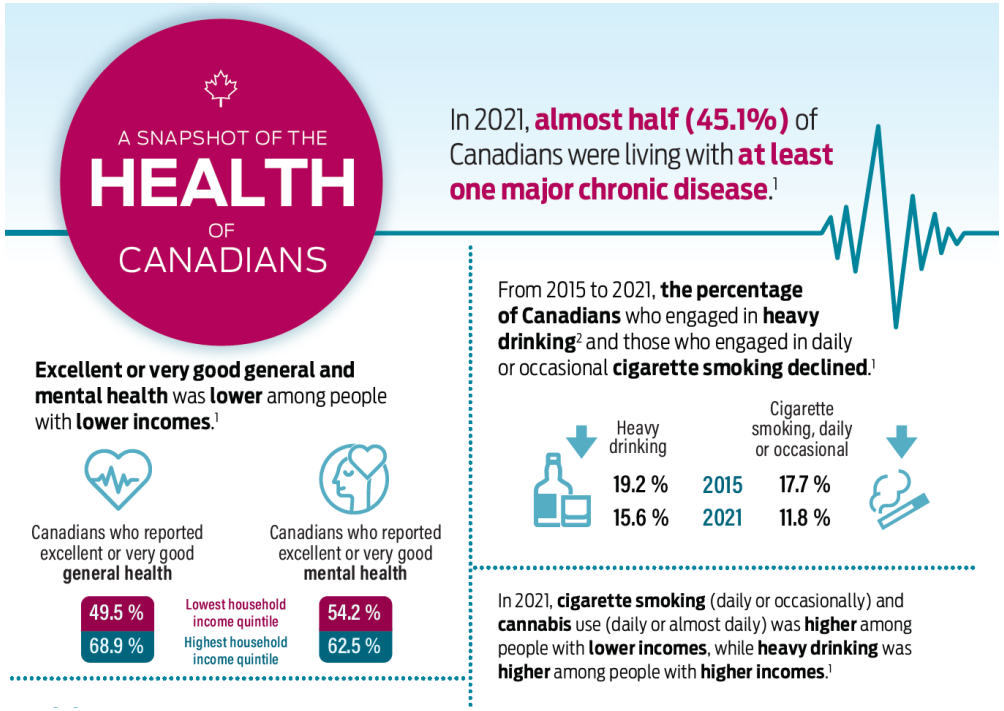
‘Why’ of Implementation Science

Close the research-to-practice gap



Butler D. Translational Research: Crossing the Valley of Death. Nature 2008;453:840-842.

Improve patient and population health



Statistics Canada. A Snapshot of the Health of Canadians. November 29, 2023. Available: https://www150.statcan.gc.ca/n1/pub/11-627-m/11-627-m2023066-eng.htm

Implementation Science

Defined as:

"The scientific study of methods to promote the systematic ***uptake of research findings and other evidence-based practices (EBPs) into routine practice***, and, hence, to improve the ***quality and effectiveness*** of health services. It includes the study of influences on healthcare professional and organizational behaviour."

- Eccles MP et al (2006)

Eccles, MP. Welcome to Implementation Science. Implementation Science. 2006;1:1.

Health Impacts: Traditional Distinctions

Efficacy trials

- Ideal circumstances
- Optimize validity

Effectiveness trials

- Real-world
- Optimize generalizability

Moving Research to Practice: Numerous Concepts

https://healthresearchbc.ca/news_article/translating-knowledge-translation/

Implementation Science vs. Quality Improvement

Implementation Science

- Evaluate the process of implementation and its impacts on EBP
- Use and quality of use of EBP
- Established evaluation methods
- Develop generalizable knowledge that can be widely applied beyond the individual system or setting

Quality Improvement

- Specific problem in a specific healthcare system or setting
- Design and trial strategies to improve
- Established QI approaches
- Improve the specific problem for the specific healthcare system or setting

Bauer, MS et al. An Introduction to Implementation Science for the Non-Specialist. BMC Psychology. 2015; 3:32.

Implementation Studies

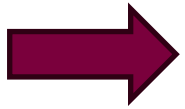
- **Evaluation studies**
  - Quantitative data
  - Qualitative data
  - Multiple levels of inquiry
  - Fidelity is a key component
  - Guided by theories, models and frameworks

Fidelity and Implementation

Available: https://www.youtube.com/user/MelanieBarwick/videos

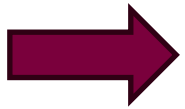
Goals of Implementation Studies

Evaluate the process of implementation and its impact on the EBP of interest



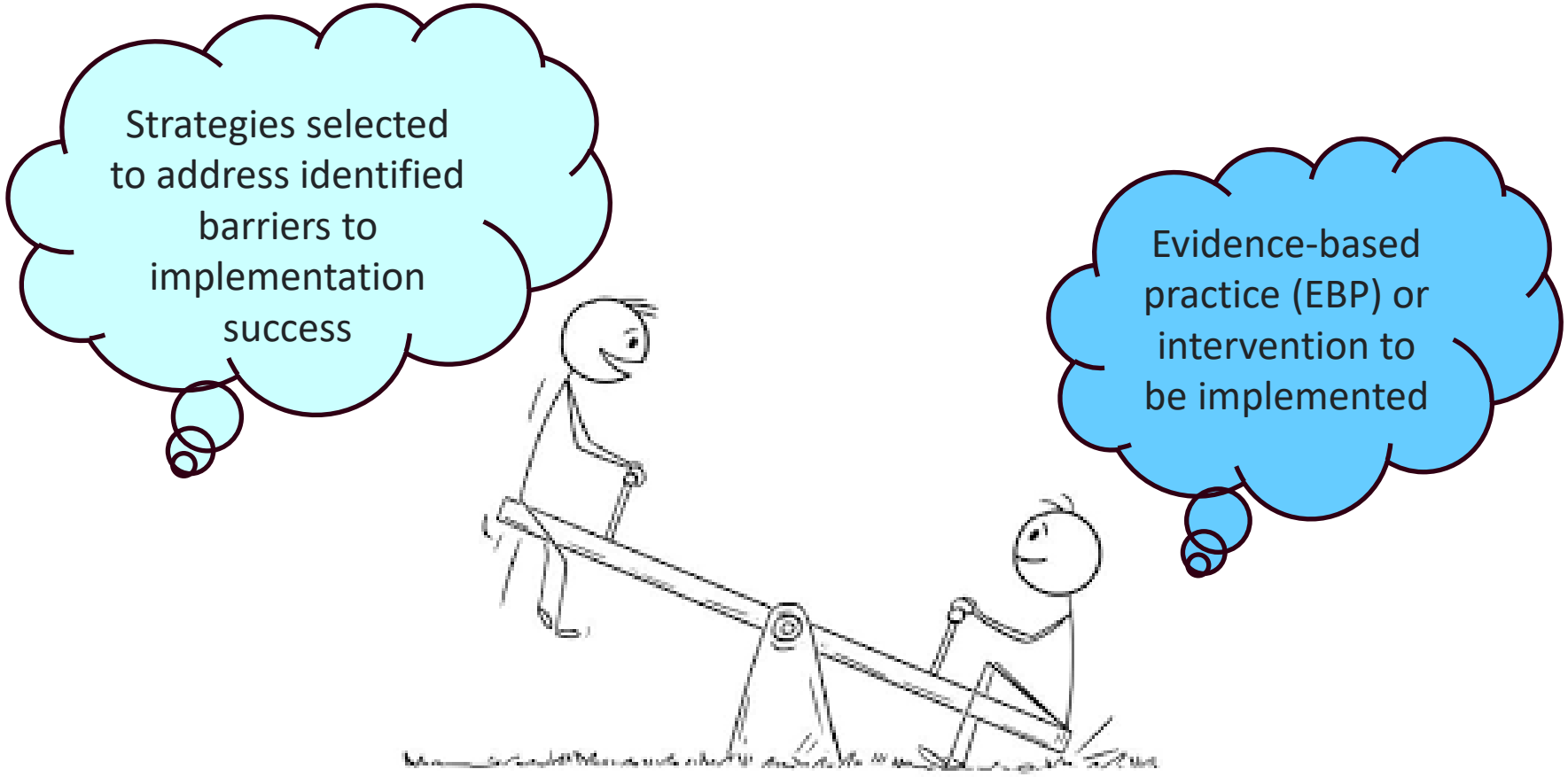
Implementation outcomes: use and quality of use of EBP

Use theories, models and frameworks to build knowledge about what works, where and why



Understand the context or other aspects to optimize adoption (uptake) of EBPs

Process of Implementation vs. EBP



Bauer, MS et al. An Introduction to Implementation Science for the Non-Specialist. BMC Psychology. 2015; 3:32.

Taxonomy of Theories, Models and Frameworks Used in Implementation Science

Table 1 Five categories of theories, models and frameworks used in implementation science

Category	Description	Examples
Process models	Specify steps (stages, phases) in the process of translating research into practice, including the implementation and use of research. The aim of process models is to describe and/or guide the process of translating research into practice. An action model is a type of process model that provides practical guidance in the planning and execution of implementation endeavours and/or implementation strategies to facilitate implementation. Note that the terms "model" and "framework" are both used, but the former appears to be the most common	Model by Huberman [40], model by Landry et al. [41], model by Davies et al. [43], model by Majdzadeh et al. [44], the CIHR Model of Knowledge Translation [42], the K2A Framework [15], the Stetler Model [47], the ACE Star Model of Knowledge Transformation [48], the Knowledge-to-Action Model [13], the Iowa Model [49,50], the Ottawa Model [51,52], model by Grol and Wensing [53], model by Pronovost et al. [54], the Quality Implementation Framework [27]
Determinant frameworks	Specify types (also known as classes or domains) of determinants and individual determinants, which act as barriers and enablers (independent variables) that influence implementation outcomes (dependent variables). Some frameworks also specify relationships between some types of determinants. The overarching aim is to understand and/or explain influences on implementation outcomes, e.g. predicting outcomes or interpreting outcomes retrospectively	PARIHS [5,64], Active Implementation Frameworks [63,68], Understanding-User-Context Framework [62], Conceptual Model [17], framework by Grol et al. [22], framework by Cochrane et al. [59], framework by Nutley et al. [21], Ecological Framework by Durlak and DuPre [57], CFIR [60], framework by Gurses et al. [58], framework by Ferlie and Shortell [61], Theoretical Domains Framework [66]
Classic theories	Theories that originate from fields external to implementation science, e.g. psychology, sociology and organizational theory, which can be applied to provide understanding and/or explanation of aspects of implementation	Theory of Diffusion [107], social cognitive theories, theories concerning cognitive processes and decision making, social networks theories, social capital theories, communities of practice, professional theories, organizational theories
Implementation theories	Theories that have been developed by implementation researchers (from scratch or by adapting existing theories and concepts) to provide understanding and/or explanation of aspects of implementation	Implementation Climate [116], Absorptive Capacity [117], Organizational Readiness [118], COM-B [119], Normalization Process Theory [120]
Evaluation frameworks	Specify aspects of implementation that could be evaluated to determine implementation success	RE-AIM [124]; PRECEDE-PROCEED [125]; framework by Proctor et al. [126]

ACE Academic Center for Evidence-Based Practice, *CFIR* Consolidated Framework for Implementation Research, *CIHR* Canadian Institutes of Health Research Knowledge, *COM-B* Capacity-Opportunities-Motivation-Behaviour, *Conceptual Model* Conceptual Model for Considering the Determinants of Diffusion, Dissemination, and Implementation of Innovations in Health Service Delivery and Organization (full title), *K2A* Knowledge-to-Action, *PARIHS* Promoting Action on Research Implementation in Health Services, *PRECEDE-PROCEED* Predisposing, Reinforcing and Enabling Constructs in Educational Diagnosis and Evaluation-Policy, Regulatory, and Organizational Constructs in Educational and Environmental Development, *RE-AIM* Reach, Effectiveness, Adoption, Implementation, Maintenance.

Nilsen et al (2015). Making sense of implementation theories, models and frameworks.

Methodological Challenges

Fidelity

- Whether the EBP was delivered as intended

Adaptations

- Modifications to the EBP or implementation strategy

Prioritized and planned

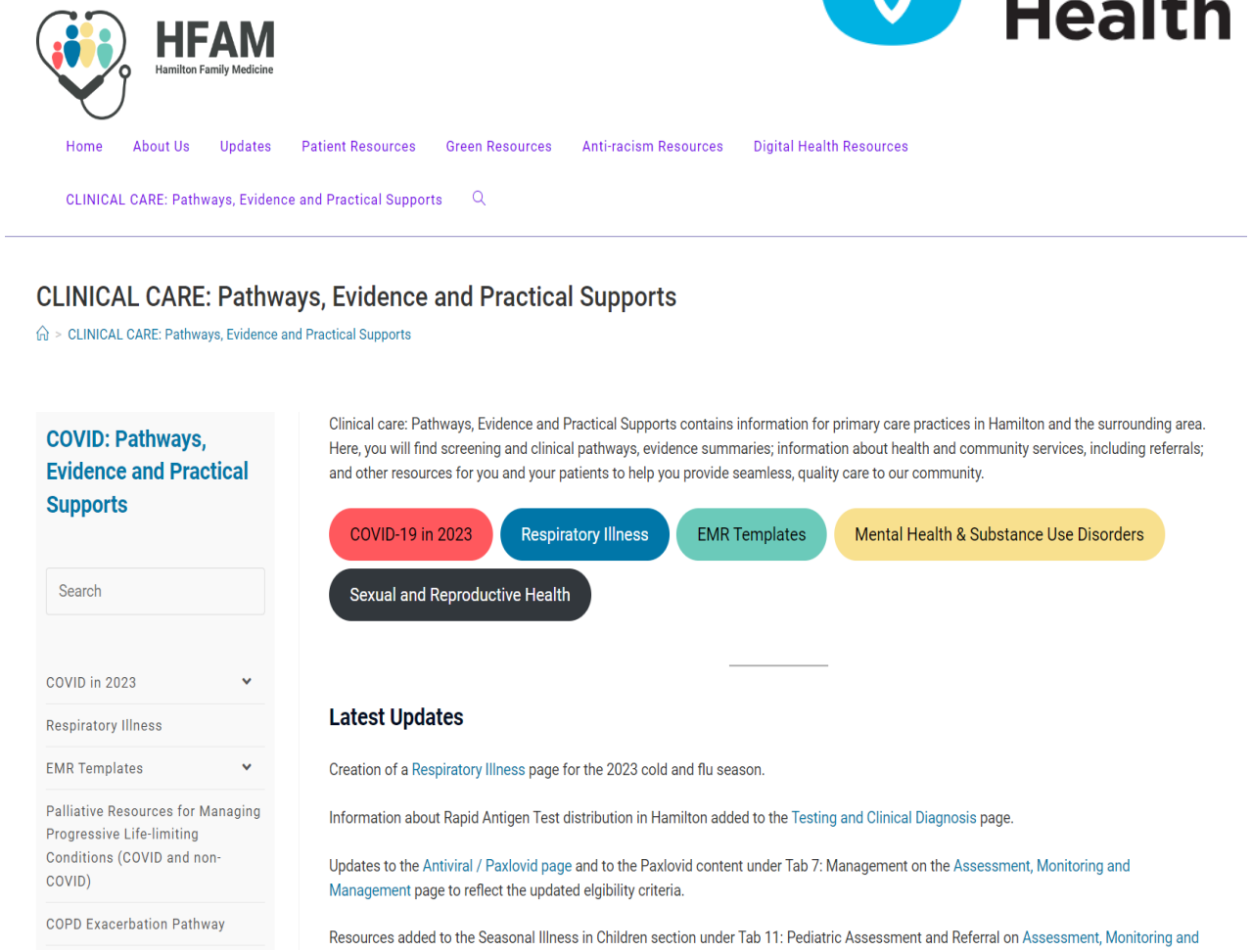
- Monitor and track over the course of the study

Contextual Challenges

- Complexity of implementation strategies
  - Involve multiple components, time-consuming, competing demands
- EBPs are not adopted, or are adopted but in an adapted form
- Need for infrastructure
- Support for continued use
- Institutional memory
- Lack of knowledge, skills and resources

Example: Implementation and Evaluation of the COVID@Home Clinical Care Pathway

- An evidence-based remote monitoring clinical care pathway for the integrated primary care management of COVID-19
  - Online, freely accessible
  - Evidence-based + updates
  - Provider resources
  - Patient resources
  - EMR remote patient monitoring form
  - Pulse oximeters (oxygen saturation monitors)



EMR, electronic medical record

Ontario Health

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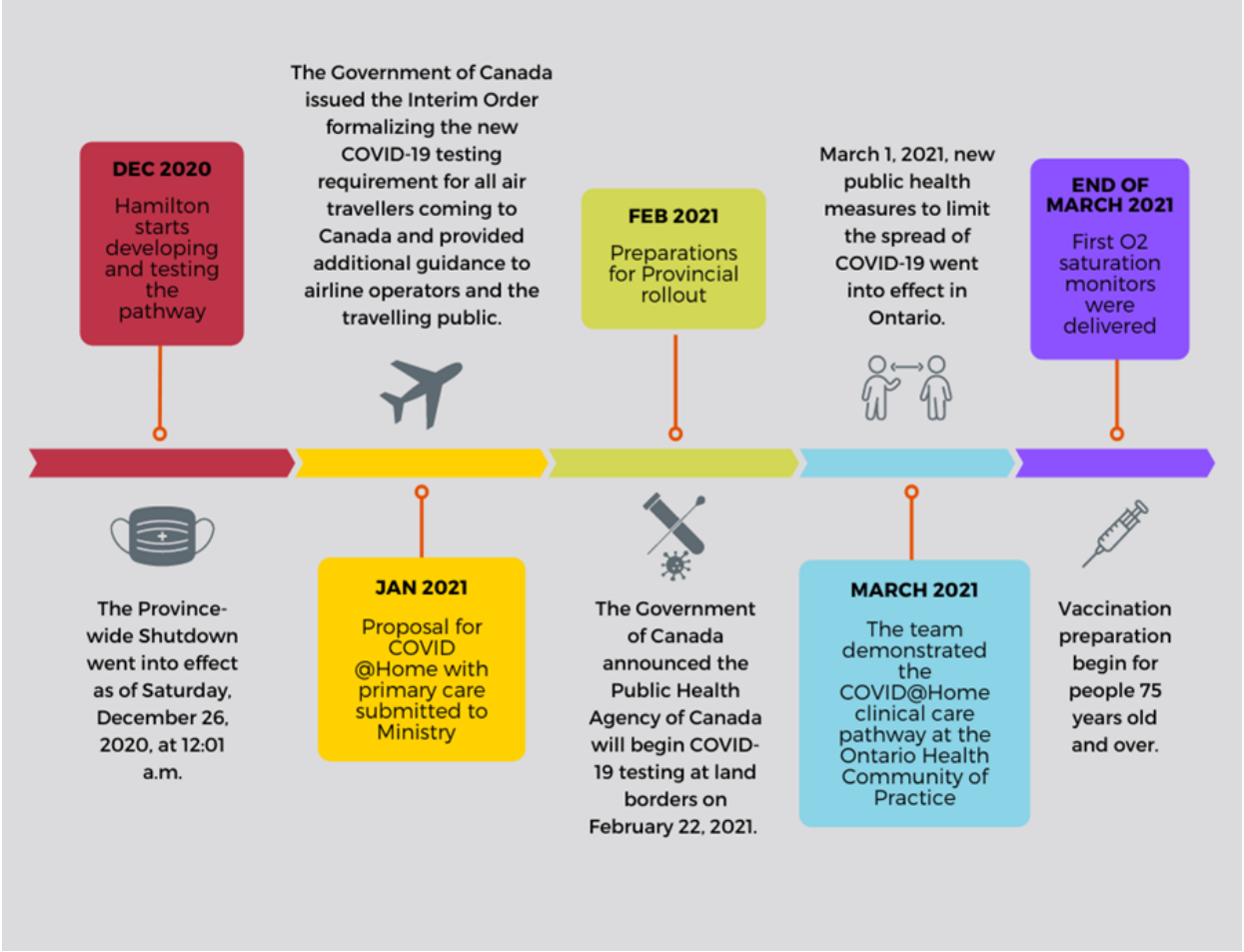
COVID@Home: Results

- **A Report for the Ontario Ministry of Health**
  - Evaluation: The Ontario COVID@Home Clinical Pathway for Primary Care of Acute COVID Illness
- **Previous Research Knowledge and Skill Builder (RKSB) Webinar**
  - DFM Research > Training and Resources > Research Knowledge and Skill Builder Sessions > Implementation Science > Video link
- **Publications**
  - Mangin D, Salerno J, Clark R, Datta J, Lawson J, Dempsey M, Elston D, Hafid S et al. The Implementation and Evaluation of the Ontario COVID@Home Clinical Care Pathway. Family Practice.

Quantitative Evaluation

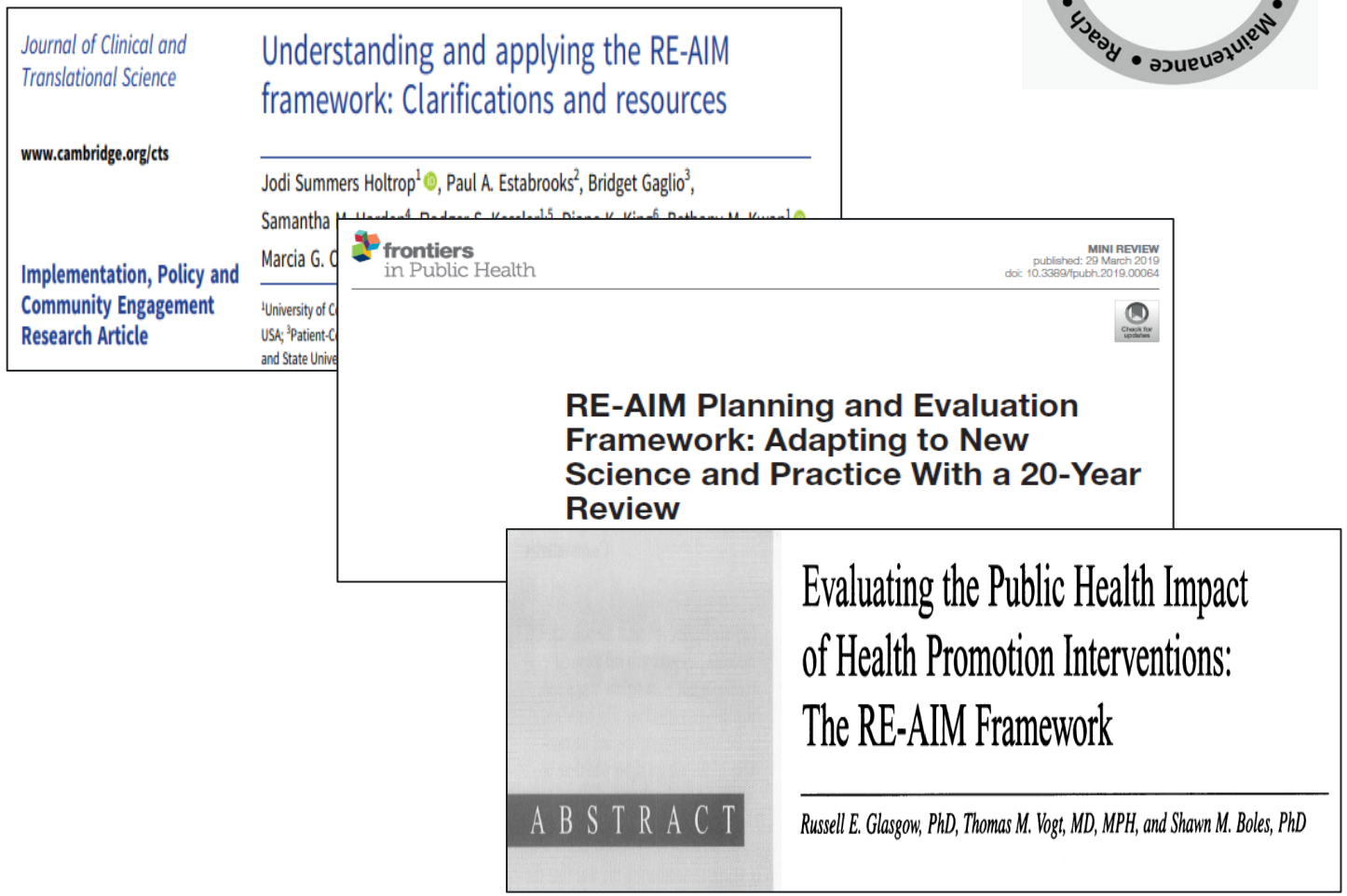
- Examine the effectiveness of the Pathway and assess the rapid widespread implementation of the COVID@Home Pathway
- Data collection
  - Clinical patient cohort (e.g., EMR patient monitoring form)
  - Ontario cohort



RE-AIM Framework - Key Resources

Publications

- Seminal paper (1999)
- Clarifying concepts (2019, 2021)



Website: ***https://www.reim.org***

- Videos
- Webinars
- Checklists
- Examples

RE-AIM Framework (*http://www.re-aim.org*)

Goal:

"to encourage program planners, evaluators, readers of journal articles, funders, and policy-makers to pay more attention to essential program elements including external validity that can improve the sustainable adoption and implementation of effective, generalizable, evidence-based interventions"

RE-AIM: Moving Research into Practice

- **R:** Reach
- **E:** Effectiveness
- **A:** Adoption
- **I:** Implementation
- **M:** Maintenance

Reach

Definition	Quantitative Parameter	Data Source
The absolute number, proportion, and representativeness of **individuals who are willing to participate** in a given initiative, intervention, or program, and reasons why or why not.	❑ Patient clinical characteristics ▪ *Age, sex, chronic conditions, risk level* ❑ Health equity ▪ *Oxygen saturation monitors across Ontario (rural, urban, income)* ❑ Web-based Pathway ▪ *Unique website users, access to the clinical care pathway*	• Electronic medical records (EMR) • EMR patient monitoring form • Government data • Web analytics

hfam.ca website: https://hfam.ca/clinical-pathways-and-evidence/

Effectiveness

Definition	Quantitative Parameter	Data Source
The **impact of an intervention on important individual outcomes**, including potential negative effects, and broader impact including quality of life and economic outcomes; and variability across subgroups (generalizability or heterogeneity of effects).	❑ Patient clinical care outcomes ▪ *Hypoxia, HR, BP, symptoms, psychosocial needs, illness education & management* ❑ Patient pathway utilization ❑ Patient mortality ❑ Patient satisfaction (8 questions) ▪ *Comfort, care plan, access, overall* ❑ Provider satisfaction (9 questions) ▪ *Resources, confidence, care provided, relationships with partners and patients*	• EMR patient monitoring form • Provincial reporting • Patient survey • Provider survey

BP, blood pressure; HR, heart rate; hypoxia, low levels of oxygen

Adoption

Definition	Quantitative Parameter	Data Source
The absolute number, proportion, and representativeness of **settings** and intervention agents (**people who deliver the program**), who are willing to initiate a program.	❑ Number of clinics ❑ Number of providers ❑ Practice type ▪ *Team-based care, solo practice*	• Provincial reporting • Provider survey

Implementation

Definition	Quantitative Parameter	Data Source
At the setting level, implementation refers to the intervention agents' **fidelity to the intervention's key functions or components** including consistency of delivery as intended and the time and cost of the intervention. It also includes ***adaptations*** made. At the individual level, implementation refers to **delivery staff's use of the implementation strategies**.	❑ Implementation strategies ▪ *Open-access web-based Pathway* ▪ *Training webinars, CoP* ▪ *Procurement of oxygen saturation monitors* ❑ Fidelity to the Pathway's key components ▪ *Patient monitoring & distribution of oxygen saturation monitors* ❑ Acceptability & feasibility (3 questions) • *Routine practice, familiar, importance of primary care team*	• Web analytics • Provincial reporting • EMR patient monitoring form • Provider survey

CoP, Community of Practice

Maintenance

Definition	Quantitative Parameter	Data Source
At the **setting** level, the extent to which a program or policy becomes institutionalized or part of the routine organizational practices and policies. At the **individual** level, maintenance has been defined as the long-term effects of a program on outcomes after 6 or more months after the most recent intervention contact.	❑ Web-based Pathway ▪ *Unique website users at 12-months after active implementation and scale up*	• Web analytics

Takeaways

- Context was an urgent health crisis e.g., COVID-19 pandemic
  - Leveraged existing infrastructure, pragmatic data collection, data limitations
- RE-AIM framework
  - Robust, organized multiple sources of data
  - Facilitated comparison of results with other similar studies
- PRISM: addition of contextual factors to RE-AIM
  - **P**ractical **R**obust **I**mplementation and **S**ustainability **M**odel

Example: Implementation and Evaluation of the COVID@Home Clinical Care Pathway - Qualitative

- RE-AIM encourage use of qualitative methods for each dimension
  - Helps to understand the ‘why’ behind the quantitative results and adds context
- For COVID@Home
  - Interviewed clinicians, patients and implementors
  - Interview guide, survey questions and analysis were created based on the RE-AIM framework

Reach

- Goal: To understand reach/recruitment

- Context captured indirectly:

1. Can you describe what the program looks like in your community and/or practice?

Effectiveness

- Goal: To understand outcomes
- Sample questions:

1. Were there instances where monitoring resulted in medical interventions or avoided interventions? (*e.g., referred to ER due to low O2)*
2. What are things that are working well?
3. What are things that are not working well?

Adoption

- Goal: To understand adoption at staff and settling level
- Sample questions:

1. Anecdotal accounts of how the pathway is being used when clinicians describe it

Implementation

- Goal: To understand implementation
- Sample questions:

1. What was your experience implementing COVID@Home?
2. What barriers did you observe for implementation?
3. What facilitators did you observe for implementation?
4. Lessons learned through implementation of COVID@Home.
5. Best and worst aspects of COVID@Home *(patients, providers, implementors)*

Maintenance

- Goal: To understand long term effects at the individual and setting levels
- Sample questions:

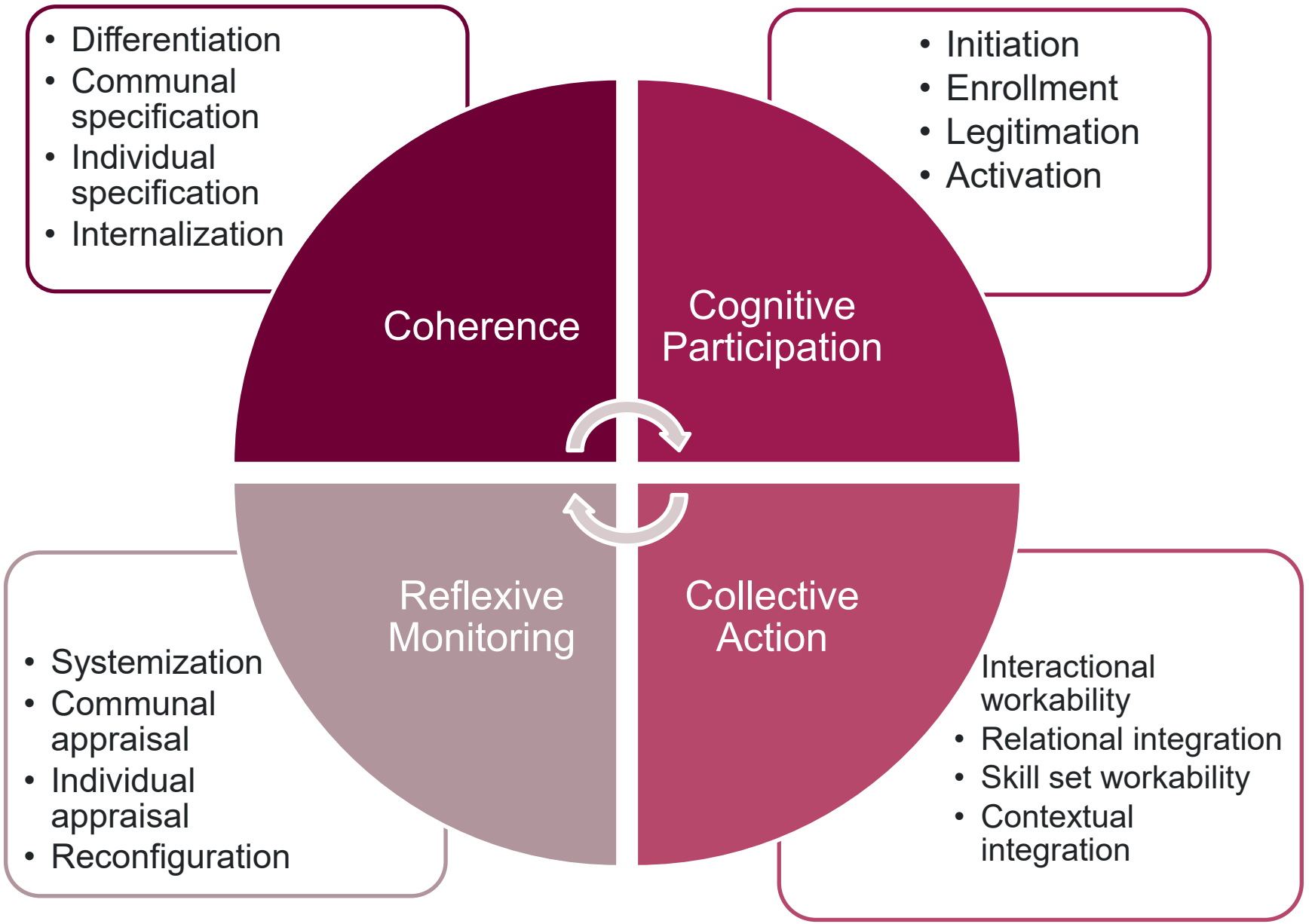
1. What long-term effects, if any, do you feel COVID@Home will have on your practice?
2. What improvements would you suggest for the program for long term implementation?

Normalization Process Theory (NPT)

- Helps explain how a complex intervention has been ***normalized*** into existing practice

- Four key constructs:
  - Coherence (sense-making)
  - Cognitive Participation (enrollment/buy-in)
  - Collective Action (enactment/operationalizing)
  - Reflexive Monitoring (appraisal)

Four Constructs of NPT, and 16 Sub-Constructs



Using NPT: Qualitatively

- NPT was original conceptualized for qualitative work
- Certain considerations:
  - *When* to apply (e.g., primary analysis, secondary analysis)
  - How "low" to go (the four constructs, the 16 sub-constructs?)
  - *How* to apply (your own system; using the new coding manual?)

Implement Sci. 2022; 17: 19.
Published online 2022 Feb 22. doi: 10.1186/s13012-022-01191-x
PMCID: PMC8861599
PMID: 35193611

Translational framework for implementation evaluation and research: a normalisation process theory coding manual for qualitative research and instrument development

Carl R. May,[✉1] Bianca Albers,[2] Mike Bracher,[3] Tracy L. Finch,[4] Anthony Gilbert,[5] Melissa Girling,[4] Kathryn Greenwood,[6] Anne MacFarlane,[7] Frances S. Mair,[8] Christine M. May,[9] Elizabeth Murray,[10] Sebastian Potthoff,[11] and Tim Rapley[11]

New coding manual from NPT team: **Link**

Using NPT: A Qualitative Example

Themes	Elements of the theme
Construct #1: Coherence (sense-making, purpose of the intervention)	
Generating comprehensive assessments of older adults	1. Better information about client's needs, goals, risks, wants obtained through volunteer visits 2. Data collection screening processes improved 3. New patient information generated to support more comprehensive care and follow up
Strengthening health promotion, disease prevention, and self-management for aging at home	1. Care shifting to be more proactive and focused on health promotion and disease prevention 2. Seniors supported to age at home 3. Improvements in self-management 4. Enhancements in health education
Enhancing patient-focused care	1. Caring and open relationship with patients and volunteers as confidantes 2. Patient engagement in care enhanced wherein patients are more connected and have a voice 3. Patients feel valued and cared for by clinic staff
Strengthening interprofessional care delivery	1. Strengthened team-based approach to care 2. Role of volunteers in supporting primary health care explored
Improving coordination of health and community services	1. Knowledge of community resources by patients and team increased 2. Improvements to access to community-based resources
Construct #2: Cognitive Participation (buy-in, engagement)	
Tackling new ways of working	1. Huddle teams experience the biggest changes in ways of working, while those not in the huddle teams experience the least 2. Huddle coordinator facilitates MDs, residents and multi-disciplinary team to contribute new patient information to huddle and coordinate care 3. Volunteer role accepted by patients as part of the health care team, but could be misinterpreted as health professionals by patients
Attaining role clarity	1. Challenges for primary care providers outside of huddles (i.e., MDs, residents) to understand their roles in relation to the huddle team, HT reports and alerts and follow up with patients 2. Lack of clarity by volunteers regarding their role with patients (e.g., advice giving) (for some) 3. Huddle team members learn one another's roles and perceive benefits through increased teamwork and collaboration

Valaitis, R., Cleghorn, L., Dolovich, L. *et al.* (2020). Examining interprofessional team structures and processes in the implementation of a primary care intervention (Health TAPESTRY) for older adults using Normalization Process Theory. *BMC Family Practice 21*, 63. https://doi.org/10.1186/s12875-020-01131-y

Using NPT: Quantitatively

- 23-item **NoMAD** (Normalization Measurement Development)
- 3 items rated 0-10 (on intervention familiarity, currently a normal part of work, will become a normal part of work)
- 20 items based on constructs & sub-constructs

Construct	Sub-Construct	Items
Coherence	*Differentiation*	I can see how the [intervention] differs from usual ways of working
	Communal specification	Staff in this organisation have a shared understanding of the purpose of this [intervention]
	Individual specification	I understand how the [intervention] affects the nature of my own work
	Internalization	I can see the potential value of the [intervention] for my work
Cognitive Participation	*Initiation*	There are key people who drive the [intervention] forward and get others involved
	Legitimation	I believe that participating in the [intervention] is a legitimate part of my role
	Enrolment	I'm open to working with colleagues in new ways to use the [intervention]
	Activation	I will continue to support the [intervention]

Finch, T.L., Girling, M., May, C.R. *et al.* (2018). Improving the normalization of complex interventions: Part 2 - validation of the NoMAD instrument for assessing implementation work based on Normalization Process Theory (NPT). *BMC Med Res Methodol 18*, 135. https://doi.org/10.1186/s12874-018-0591-x

Using NPT: A Quantitative Example

Coherence	Month 1	Month 2
I can see how Health TAPESTRY differs from usual work		
Staff have a shared understanding of Health TAPESTRY		
I understand how Health TAPESTRY affects the nature of my work		
I can see the potential value of Health TAPESTRY for my work		

Cognitive Participation	Month 1	Month 2
Do you feel Health TAPESTRY is a normal part of work?		
There are key people who drive Health TAPESTRY		
Participating in Health TAPESTRY is a legitimate part of my role		
I am open to working with others in new ways to use Health TAPESTRY		
I will continue to support Health TAPESTRY		

- We used it with health care providers implementing Health TAPESTRY
- A secondary validation study
- We added: more structured scoring (Likert-style), & a "traffic light summary"
- Our recommendations:
  - Use max 3 data collection timepoints (early, mid, late implementation)
  - Use alongside qualitative work

Lamarche, L., Clark, R.E., Parascandalo, F. & Mangin, D. (2022). The implementation and validation of the NoMAD during a complex primary care intervention. *BMC Med Res Methodol 22*, 175. https://doi.org/10.1186/s12874-022-01655-0

Find out More About NPT

- They have a website!
  - https://normalization-process-theory.northumbria.ac.uk/

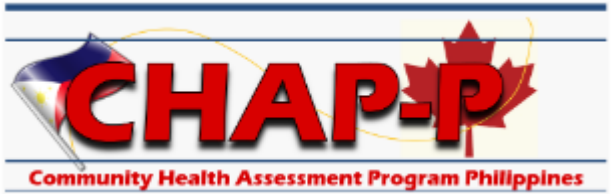
- Key reference:
  - Murray, E., Treweek, S., Pope, C. et al. Normalisation process theory: a framework for developing, evaluating and implementing complex interventions. *BMC Med 8*, 63 (2010). https://doi.org/10.1186/1741-7015-8-63

Proctor et al. Implementation Science Framework

Implementation Outcome	Definition[a]
Acceptability	Perception that the intervention is agreeable, satisfactory, or confers relative advantage
Adoption	Early uptake or intent to try
Appropriateness	Pre-adoption perception of practicability, fit, or relevance
Cost	Marginal cost, cost-effectiveness, cost-benefit
Feasibility	Whether the intervention is suitable for everyday use, practicable, or fits with provider workflow
Fidelity	Whether the core components of an intervention were implemented as intended
Penetration	Spread within an eligible population or level of institutionalization
Sustainability	Extent to which an intervention can be maintained, routinized, or institutionalized by a provider or facility

[a]As defined by Proctor et al. (2011) [24]

Example: CHAP-P Program



- The **C**ommunity **H**ealth **A**ssessment **P**rogram in the **P**hilippines
- **Aim:** To adapt the Canadian intervention to an LMIC setting and determine the effect of CHAP-P on the HbA1c of residents from selected communities of the Zamboanga Peninsula, Philippines
- Volunteer-led, walk-in "CHAP-P sessions" for **diabetes and cardiovascular health** with:
  - Risk assessments
  - Health education
  - Referrals
- **Scale-up target:** 30 municipalities across 3 provinces

Applying the Framework to CHAP-P

Outcome	Method of Evaluation	Data Source	Timing
Acceptability	Interviews Self-administered survey	Community residents who have participated in CHAP-P (n=30/community) BHWs* (n=20/community), Public Health workers involved in CHAP (n=10/community)	Month 1 to 2
Adoption	Observation/Research data analysis (Number of communities who started implementing CHAP-P)	Community reports CHAP-P database analysis	Month 1 to 2

**Barangay Health Workers - lay community volunteers*

Applying the Framework to CHAP-P

Outcome	Method of Evaluation	Data Source	Timing
Appropriateness	Self-administered survey	BHWs* (n=20/community), Public Health workers involved in CHAP (n=10/community)	Month 1 to 2
Fidelity	Observational checklist Research data analysis	Research data collection, Community reports CHAP-P database validation/ analysis	Months 1 to 3
Implementation cost	Economic analysis	Finance data from research and stakeholders	Months 6 and 12

**Barangay Health Workers - lay community volunteers*

Applying the Framework to CHAP-P

Outcome	Method of Evaluation	Data Source	Timing
Penetration	Numbers of attendees/participants; Numbers of referrals made for newly diagnosed and poorly controlled cases with HTN and DM (intervention vs. non-intervention communities)	Community reports, CHAP-P database analysis (built in analytics)	Monthly
Sustainability	Number of municipality who maintained CHAP-P implementation 6 months post research funding period	Research data collection, Community reports	Months 6-12

Important Takeaways

Implementation Outcomes	Evaluation
Acceptability and Appropriateness	Qualitative interviews with policy makers, implementers, and potential participants showed that CHAP-P was acceptable and appropriate to the community setting
Adoption	Already implementing the program rural communities
Feasibility	Feasible, but there are challenges in sending offline data to the server due to weak internet signals
Fidelity	• Fidelity checks were conducted on regular intervals • In some sites, retraining was required to improve implementation fidelity. • Overall, the BHWs* followed the program implementation protocol
Implementation Costs	To be completed

**Barangay Health Workers - lay community volunteers*

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Thank you!

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APPENDIX

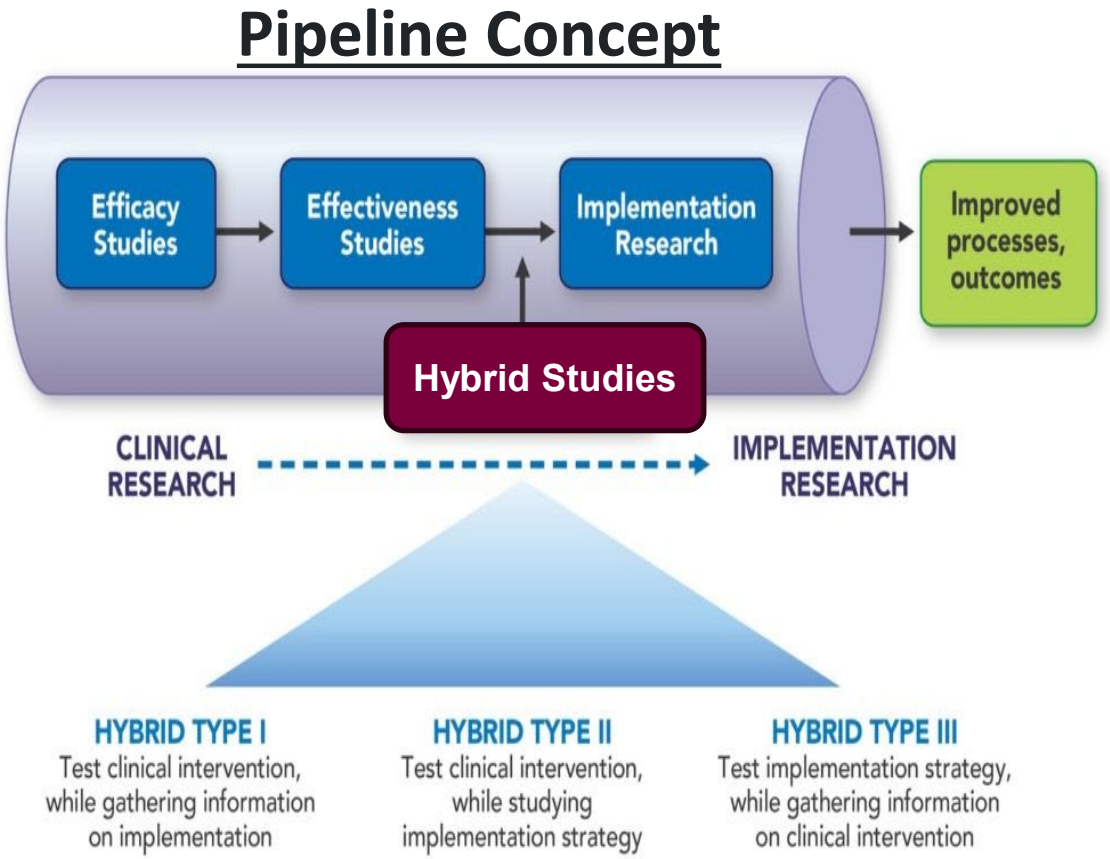
Definitions

- Theory: set of analytical principles or statements designed to structure our observation, understanding and explanation of the world. Provides a clear explanation of how and why specific relationships lead to specific events. Descriptive or explanatory.
- Model: a deliberate simplification of a phenomenon or a specific aspect of a phenomenon. Descriptive.
- Framework: denotes a structure, overview, outline, system or plan consisting of various descriptive categories e.g., concepts, constructs or variables, and the relations between them that are presumed to account for the phenomenon. Descriptive.

Hybrid Studies

Intersection

- *Clinical Effectiveness Research*
  - Clinical interventions to improve health outcomes
- *Implementation Research*
  - How and under what circumstances interventions work in practice



Curran, GM. Effectiveness-Implementation Hybrid Studies: An Overview and Reflection on 10 Years Since Their Introduction. May 25, 2023. Available: https://youtu.be/E9mXQvwsMUc?si=93z6Y6xJafUgS2RY (KT Canada).