## Introduction to Implementation Science

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## **Centre for Implementation at Trimbos**

- Knowledge center for implementation and implementation research for programs, policies, and innovations related to mental health, alcohol (mis)use, drug (mis)use, and tobacco use
  - Research support
  - Training
    - Implementation strategies
    - Implementation science models and research methods
    - Research design
  - NIC partner



## Nederlands Implementatie Collectief/ Netherlands Implementation Collaborative

The Netherlands Implementation Collaborative (NIC) is a professional network for implementation scientists and implementation specialists in the Netherlands. By sharing knowledge about how professionals can effectively implement and evaluate evidence-based programs, policies, and guidelines, NIC hopes to improve the health, well-being, and welfare of people in the Netherlands.

#### NIC website

https://nederlandsimplementatiecollectief.nl/





## **Defining implementation science**

- Implementation science is <u>"the scientific study</u> of methods to promote the systematic uptake of research findings and other <u>evidence-based practices into routine practice</u>, and, hence, to improve the quality and effectiveness of health services".
  - 'Health services' can be read broadly as human services, including educational organizations, social welfare, community centers, public sport and fitness organizations, professional societies, prisons, and services for the developmentally disabled

References Eccles, M.P., Mittman, B.S. Welcome to Implementation Science. Implementation Science 1, 1 (2006)



## **Evidence-based practices**

- Interventions shown, through research, to be effective
  - Efficacy and effectiveness studies
- Interventions can include:
  - Internal or external programs
  - Policies
  - Guidelines and practice standards
  - Personal health technologies, medications, and therapies
  - Community-based programs
  - Prevention programs
  - Campaigns and outreach efforts
  - Educational endeavors

#### References

McKibbon, K A. "Evidencebased practice." *Bulletin of the Medical Library Association* vol. 86,3 (1998): 396-401.

Rabin, B.A. et al. "A glossary for dissemination and implementation research in health." *Journal of Public Health Management and Practice* 14.2 (2008): 117-123.



## Implementation

- Defined as "the process of putting to use or integrating evidence-based interventions" into a practice
  - Ideally, implementation is:
    - done in a planned manner through collaboration and **co-design with practices**
    - adapted to the setting
    - guided by an evolving, tailored, and feasible implementation strategy
    - informed by the evidence-based intervention
    - supported by an implementation team
    - routinely evaluated and improved
  - Implementation of evidence-based interventions can be timeconsuming

Reference

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## Implementing and evaluating the implementation of evidence-based interventions

- The development of three plans
  - Intervention
    - The protocol describing the evidence-based intervention
  - Implementation
    - The strategy or methods of putting that intervention into practice
  - Research
    - The plan for researching the implementation of the intervention
- These three plans are interrelated and build off one another



## **Implementation strategies**

- Implementation strategies are the *"methods or techniques used to enhance the adoption, implementation, and sustainability of a clinical program or practice"* 
  - Described in an implementation strategy document
- Implementation strategy templates
  - ERIC
  - RE-AIM Planning Tool
  - ZonMw Implementation Plan

Develop the implementation strategy with – not for – practice partners. Reference Proctor, E.K. et al. "Implementation Strategies: Recommendations for Specifying and Reporting." *Implementation Science*: *IS* 8 (2013): 139.



## The implementation strategy document

- Developed with all stakeholders
- Informed by the intervention and the research question
- Routinely updated
- Strategy document often includes:
  - Description of the goal of the program and of implementation
  - Capacity building plan tools and training needed for implementation
  - Information about the setting and context
  - Overview of key stakeholders and target population
  - Description of the plan for implementation support
  - Timeline
  - Budget



## Understanding the context

- Collaborate with partners at the practices to learn
  - the need for the intervention
  - how the intervention might need to be tailored
  - what capacity building is needed
  - who the key stakeholders and champions might be
  - current ways of working with the practices
- Desk research to gather information about
  - the population served by the context
  - the community
  - existing resources in the area

Existing tools – like the RE-AIM Planning Tool – can guide this context data collection.



## **Capacity building**

- Training and support for relevant parties in both the intervention **and** in implementing the intervention
  - Tailored to the setting and needs
  - Multiple forms of training
    - Online, phone, in-person, email, training manuals
  - Support at many time points
    - Address barriers and changes
    - Motivational messaging
  - Different trainers for different aspects
  - Can be evaluated as independently or as part of a larger research plan



## **Implementation support**

- Use stand-alone tools, videos, and fact-sheets
  - Easy-to-share with little explanation
- Use Motivational Interviewing and messaging
  - During development, implementation, evaluation, and sustaining
- Build tailoring, evaluation, and sustainability into the program
  - Collect *all* the evaluation data that you may need for this project and for grant writing





#### LEARN HOW AMERICAN SANDWICH BREAD

This classic sandwich bread is among the simplest and fastest yeast breads you can make. The milk and butter add richness, while the honey adds a touch of welcome sweetness. Simple steps and two risings deliver bread in 2 hours (plus cooling time). If you don't have a stand mixer, you can mix and knead the bread dough by hand; see pages 590-91.



1. WEIGH THE FLOUR: Measure out 31/2 cups bread flour using a scale.

WHY? Because the ratio of flour to liquids is critical, weighing your flour is advisable because it is more accurate. We use bread flour rather than all-purpose flour because it is higher in protein; the higher the protein, the more gluten in the dough, which produces a taller, sturdier loaf.

5. SHAPE THE LOAF: Press

the dough into a rectangle

about 1 inch thick. With the

long side facing you, roll the

dough into a firm cylinder.

Pinch the seam closed and

place the dough seam side

down in a greased loaf pan.

all four sides of the pan.

Press the dough so it touches

WHY? Rolling the dough into

a cylinder builds structure

and makes a nice, tall loaf.



2. MAKE SURE THE WATER AND MILK ARE 110 DEGREES: Before combining all the wet ingredients, make sure that the milk and water are the

right temperature. WHY? If the liquids are too hot (130 degrees or more), they will kill the yeast; if too cool the yeast won't activate and the bread won't rise. We use instant yeast because it can be added without needing to proof it ahead of time. because it is easier.



3. KNEAD THE DOUGH: 4. LET THE DOUGH RISE: Turn Combine the dry ingredients in a stand mixer fitted with a dough hook, and then slowly add the milk mixture until the dough comes together. Increase the speed to medium and knead until the dough is smooth. WHY? Kneading develops gluten, which is crucial to the texture of the bread. We prefer to use a stand mixer

the dough out onto a floured counter and knead it briefly to form a round, smooth ball. Place the dough in a greased bowl, cover with greased plastic wrap, and let it rise until doubled in size, about 40 minutes.

WHY? After kneading, the dough needs to rest, relax, and rise. During this stage the yeast causes the dough to rise and fosters flavor development.



6. LET THE LOAF RISE: Cover 7. HEAT A BAKING STONE AND CREATE A STEAMY ENVIRONMENT: Place a baking stone on the lowest oven rack and put a loaf pan on the stone. Heat the oven to 350 degrees. Pour boiling water into the hot loaf pan. WHY? A steamy oven prevents

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- AMERICA'S -----**TEST KITCHEN** 

signify a perfectly baked loaf.

#### American Sandwich Bread

MAKES 1 LOAF TOTAL TIME 2 HOURS (PLUS 2 HOURS COOLING TIME)

WHY THIS RECIPE WORKS: Many people who might enjoy making terrific sandwich bread at home don't even try it because they think it takes most of a day. We wanted a good, solid sandwich bread recipe that could be prepared in 2 hours, start to finish, including baking time. We found that sandwich bread improved markedly when kneaded with a stand mixer. This method helped us resist the temptation to add extra flour in an effort to tame the sticky bread dough, as more flour tends to make the dough denser and less flavorful; it also makes it rise less. We were also surprised to find that we preferred instant yeast to active dry yeast for our sandwich bread recipe. Not only did it greatly reduce rising times, but it also made for better-tasting bread. If you don't have a stand mixer, you can mix and knead the bread dough by hand; see pages 590-91. If you don't have a baking stone, bake the bread on an overturned and preheated rimmed baking sheet.

- 1 cup whole milk, heated to 110 degrees
- 1/3 cup warm water (110 degrees)
- 3 tablespoons honey
- 2 tablespoons unsalted butter, melted
- 31/2 cups (191/4 ounces) bread flour
- 2¼ teaspoons instant or rapid-rise yeast
- 2 teaspoons salt

1. Whisk milk, water, honey, and butter together in 4-cup liquid measuring cup. Using stand mixer fitted with dough hook, combine flour, yeast, and salt on low speed. Slowly add milk mixture and let dough come together, about 2 minutes. Increase speed to medium and knead until dough is smooth and slightly tacky, about 10 minutes.

2. Transfer dough to lightly floured counter and knead by hand to form smooth, round ball, about 15 seconds. Place dough in large, lightly greased bowl, cover tightly with greased plastic wrap, and let rise until doubled in size, 40 to 50 minutes.

3. Grease 9 by 5-inch loaf pan. Transfer dough to lightly floured counter and press into rectangle about 1 inch thick and no longer than 9 inches, with long side facing you. Roll dough toward you into firm cylinder, keeping roll taut by tucking it under itself as you go. Pinch seam closed and place seam side down in prepared pan, pressing gently into corners. Cover with plastic and let rise until nearly doubled in size. 20 to 30 minutes.



Even beginning bakers can make our sandwich bread, which takes only 2 hours from start to finish.

4. One hour before baking, place baking stone on lowest rack and place empty loaf pan (or other heatproof pan) on stone. Heat oven to 350 degrees. Bring 2 cups water to boil. Working quickly, pour boiling water into hot pan and place pan with loaf on baking stone. Bake until loaf is golden brown and registers 195 degrees, 40 to 50 minutes, rotating pan halfway through baking.

5. Let bread cool in pan for 5 minutes, then transfer to wire rack and let cool to room temperature, about 2 hours, before serving.

#### VARIATIONS

#### Wheat Sandwich Bread

For extra wheat flavor, we add toasted wheat germ to the dough. Toast ¼ cup wheat germ in dry skillet until fragrant, about 5 minutes. Reduce amount of bread flour to 2 cups and combine with 1¼ cups whole-wheat flour and toasted wheat germ.

#### **Oatmeal-Raisin Sandwich Bread**

Omit warm water from milk mixture. Bring 34 cup water to boil in small saucepan. Stir in 3/4 cup old-fashioned rolled oats or quick oats (do not use instant oats) and cook until

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3. Grease 9 by 5-inch loaf pan. Transfer dough to lightly floured counter and press into rectangle about 1 inch thick and no longer than 9 inches, with long side facing you. Roll dough toward you into firm cylinder, keeping roll taut by tucking it under itself as you go. Pinch seam closed and place seam side down in prepared pan, pressing gently into corners. Cover with plastic and let rise until nearly doubled in size, 20 to 30 minutes.



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4. One hour before baking, place baking stone on lowest rack and place empty loaf pan (or other heatproof pan) on stone. Heat oven to 350 degrees. Bring 2 cups water to boil. Working quickly, pour boiling water into hot pan and place pan with loaf on baking stone. Bake until loaf is golden brown and registers 195 degrees, 40 to 50 minutes, rotating pan halfway through baking.

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Oatmeal-Raisin Sandwich Bread

Omit warm water from milk mixture. Bring ¼ cup water to boil in small saucepan. Stir in ¼ cup old-fashioned rolled oats or quick oats (do not use instant oats) and cook until

An evidence-based 'program': Tested before implemented in your local setting



5. SHAPE THE LOAF: Press the dough into a rectangle about 1 inch thick. With the long side facing you, roll the dough into a firm cylinder. Pinch the seam closed and place the dough seam side down in a greased loaf pan. Press the dough so it touches all four sides of the pan. WHY? Rolling the dough into a cylinder builds structure and makes a nice, tall loaf.



6. LET THE LOAF RISE: Cover the loaf pan with plastic and let the dough rise until doubled in size, 20 to 30 minutes.

WHY? This second rise, called proofing, allows the dough to regain some airiness lost during shaping, and the gluten to relax. To test if the dough is properly proofed, press on it gently with your fingertip: it should leave an indentation that slowly fills in.



7. HEAT A BAKING STONE AND CREATE A STEAMY ENVIRONMENT: Place a baking stone on the lowest oven rack and put a loaf pan on the stone. Heat the oven to 350 degrees. Pour boiling water into the hot loaf pan. WHY? A steamy oven prevents the crust from setting and allows the maximum rise when the bread enters the oven. A baking stone ensures a wellbrowned bottom crust. 8. BAKE THE LOAF AND CHECK FOR DONENESS: F

the loaf pan on the baking stone and bake until the bread is golden brown and registers 195 degrees, 40 to 50 minutes, rotating the pan halfway through baking. WHY? The use of an instantread thermometer is recommended, but you should also follow the visual cues, as temperature alone doesn't always signify a perfectly baked loaf.





### The protocol for the 'program':

- Background on the program
- A description of the resources, tools, and time needed to do the program
- Program-specific instructions
- Acceptable variations

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- Step-by-step guidance on how to make the 'program' work in your setting
- Advice on how to tailor to your setting
- Guidance on how to know if you've successfully implemented the program

tucking it under itself as you go. Pinch seam closed and place seam side down in prepared pan, pressing gently into corners. Cover with plastic and let rise until nearly doubled in size, 20 to 30 minutes. bine with 1¼ cups whole-wheat flour and toasted wheat germ.

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## **Implementation science**

- Implementation science studies explore and evaluate the implementation of evidence-based interventions in real-world settings
  - How a program works in the real world, not whether a program works
- Implementation science studies are often
  - Pragmatic real-word settings, real-world problems, and real-world solutions
  - Collaborative conducted by multidisciplinary study teams with local stakeholder involvement
  - Guided research is often guided by a model or framework
  - Extensive aimed at comprehensively exploring implementation over time







## **Implementation science studies**

- Implementation science research can be part of **hybrid** effectiveness/implementation studies
- Often longer studies
  - Research on sustaining an intervention frequently has data collection at 6, 12, and 18 months
- Implementation science studies can be intensive
  - Lots of data from multiple sources
  - Deep data



## **Implementation science research questions**

- In general, implementation science research questions are often...
  - **not** about program/project efficacy
  - "how" questions
  - tied to an implementation science theoretical framework
  - include (brief) information about how data will be collected and analyzed
    - Often using data collection instruments tied to the implementation science framework
    - Often mixed methods data collection



## **Implementation science methods**

- Multiple data collection methods can be used to explore implementation research questions
  - Mixed methods and qualitative methods are common
  - Data in the wild
- Multiple populations can be studied
  - Patients
  - Providers
  - Managers and administrators
- Methods selected and used depend on the research question, implementation framework, and resources available



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# Development of an implementation science research protocol

- The study protocol should be comprehensive, concrete, and should include information about:
  - the knowledge/practice gap
  - the evidence-based intervention of interest
  - the research question
  - the ethical review process
  - the implementation science framework
  - research methods
  - an analysis plan
  - a data management plan
  - a timeline



# Ingredients of an implementation science research proposal

| Proposal ingredient   | Key question  |
|---|---|
| 1. The care gap or quality gap  | The proposal has clear evidence that a gap in quality exists?   |
| 2. The evidence-based treatment to be implemented                         | Is the evidence for the program, treatment, or set of services to be implemented demonstrated?  |
| 3. Conceptual model and theoretical justification                         | The proposal delineates a clear conceptual framework/theory/model that informs the design and variables being tested?   |
| <ol> <li>Stakeholder priorities, engagement in change</li> </ol>          | Is there a clear engagement process of the stakeholders in place?   |
| 5. Setting's readiness to adopt new services/treatments/programs          | Is there clear information that reflects the setting's readiness, capacity, or appetite for change, specifically around adoptionof the proposed evidence-based treatment? |
| 5. Implementation strategy/process  | Are the strategies to implement the intervention clearly defined, and justified conceptually?   |
| 7. Team experience with the setting, treatment, implementation process    | Does the proposal detail the team's experience with the study setting,<br>the treatment whose implementation is being studied, and<br>implementation processes?           |
| 3. Feasibility of proposed research design and methods                    | Does the methods section contain as much detail as possible, as well as<br>lay out possible choice junctures and contingencies, should methods not<br>work as planned?    |
| 9. Measurement and analysis section                                       | Does the proposal clarify the key constructs to be measured, corresponding to the overarching conceptual model or theory?   |
|   | Is a measurement plan clear for each construct?   |
|   | Does the analysis section demonstrate how relationships between constructs will be tested?  |
| 10. Policy/funding environment; leverage or support for sustaining change | Does the proposal address how the implementation initiative aligns with policy trends?  |

Proctor, E.K., Powell, B.J., Baumann, A.A. et al. Writing implementation research grant proposals: ten key ingredients. Implementation Sci 7, 96 (2012)

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## **Theories in implementation science**





## **Process models to research implementation**

- Process models are used to gain in-depth understanding of the process of translating an evidence-based intervention into a practice setting
  - Data collected on:
    - All steps taken to implement the intervention
    - Changes or variations from how implementation was originally planned to happen
    - Who was involved in implementation when

Adapted from: Nilsen P. Making sense of implementation theories, models and frameworks. *Implement Sci.* 2015;10(1):1-13.



## Practical, Robust Implementation and Sustainability Model (PRISM)

- PRISM explores "how the health care program or intervention interacts with the recipients to influence program adoption, implementation, maintenance, reach, and effectiveness"
- Constructs and perspectives include:
  - Intervention
    - Organizational perspective
    - Patient perspective
  - Implementation and sustainability infrastructure
  - Recipients
    - Organizational characteristics
    - Patient characteristics
  - External environment
  - RE-AIM evaluation tools and methods

Bethany Hipple Walters bhipplewalters@trimbos.nl Reference

Feldstein, A. C., & Glasgow, R. E. (2008). A practical, robust implementation and sustainability model (PRISM) for integrating research findings into practice. *The Joint Commission Journal on Quality and Patient Safety*, *34*(4), 228-243



## Influences on the design of PRISM

- Chronic Care Model
  - supports the need to leverage support from the community, health system leadership, delivery system design, clinical information and clinician decision systems, and patient self-management to maximize outcomes
- Model for Improvement
  - focuses on evidence, context, and facilitation
- RE-AIM framework
  - RE-AIM outcome measures and evaluation tools

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## Use of PRISM

- Developing and tailoring programs, based on the organizational perspective and the patient perspective
- Supporting implementation of the program with and for the recipients while keeping external influencing factors in mind
- Evaluation, using the RE-AIM tools
- PRISM is often used as a framework for health information systems, technology programs, digital health data initiatives, monitoring systems, and data-informed decision-making





## Factors models to research implementation

- Determinant or factors-based approaches are used to gather data on factors that can influence the implementation of an intervention
  - Inside and outside of the practice
  - Related to the contents of the program
  - Target population
  - Structure of the practice
  - Characteristics of implementers
  - Tools used for implementation

Adapted from: Nilsen P. Making sense of implementation theories, models and frameworks. *Implement Sci.* 2015;10(1):1-13.





"The CFIR provides a menu of constructs that can be used in a range of applications – as a practical guide for systematically assessing potential barriers and facilitators in preparation for implementing an innovation, to providing theory-based constructs for developing context-specific logic models or generalizable middle-range theories." CFIR website



## **CFIR constructs**

- Intervention Characteristics
- Outer Setting
- Inner Setting
- Characteristics of Individuals
- Process

Each construct has several sub-constructs.



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- Evaluation design and data collection tools
  - Qualitative Data
    - Observation template
    - Interview guide
      - Can be tailored to your project
      - Can select the constructs most relevant to your desired outcome
  - Quantitative Data
    - No complete set
    - A few constructs have measures see the CFIR website



## **Evaluation models to research implementation**

- Evaluation approaches are used to evaluate the outcomes of implementing the program
  - Reach
  - Short and long-term impact
  - Feasibility
  - Acceptability
  - Sustainability

Adapted from: Nilsen P. Making sense of implementation theories, models and frameworks. *Implement Sci.* 2015;10(1):1-13.



### **RE-AIM**

"The goal of RE-AIM is 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 website





Reach the target population

Effectiveness or efficacy

Adoption by target staff, settings, or institutions

Implementation consistency, costs and adaptions made during delivery

Maintenance of intervention effects in individuals and settings over time

**RE-AIM** website



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## **RE-AIM tools**

- RE-AIM Planning Tool
- Dissemination Planning Tool
- Checklist for Study or Intervention Planning
- Questions to Ask about RE-AIM Dimensions When Evaluating Health Promotion Programs and Policies

**RE-AIM** website





