GACD
GLOBAL ALLIANCE FOR CHRONIC DISEASES
AN ALLIANCE OF HEALTH RESEARCH FUNDERS

Study design and measurement (Topic 2)

Vilma Irazola
Institute for Clinical Effectiveness and Health Policy -IECS

Implementation research definition

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

(Eccles/Mittman, 2006)

2

Implementation research definition

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

(Eccles/Mittman, 2006)

3

Implementation Research

KNOW

Interventions are effective in clinical & controlled-research settings

DO

Proven interventions are not implemented in the real world

4

- What is the evidence gap?
- "Question is King"
- Examples of study types/approaches:
  - Pragmatic Trials
  - Effectiveness-Implementation Hybrid Designs
  - Quality Improvement Studies
  - Comparative Effectiveness Research
  - Participatory Action Research

Translational Research

Basic research & Studies in animals

Translation to humans: Case studies (Phase 1 & 2 CTs)

Translation to patients: Efficacy studies

Translation to practice: Effectiveness studies

Translation to population health: Implementation research

- What is the evidence gap?
- “Question is King”
- Examples of study types/approaches:
  - Pragmatic Trials
  - Effectiveness-Implementation Hybrid Designs
  - Quality Improvement Studies
  - Comparative Effectiveness Research
  - Participatory Action Research

Traditional vs pragmatic trials?

Pragmatic trials vs traditional trials

	Pragmatic trials	Traditional trials
Stakeholder involvement	Engaged in all study phases including study design, conducting the study, collecting data, interpreting results, disseminating findings	Limited engagement, often in response to investigator
Research design	Includes internal and external validity, design fidelity, local adaptation, real life settings and populations, contextual assessments	Focus on limiting threats to internal validity, typically uses RCT, participants and settings typically homogenous
Outcomes	Reach, effectiveness, adoption, implementation, comparative effectiveness, sustainability	Efficacy, mechanism identification, component analysis
Measures	Brief, valid, actionable with rapid clinical utility, feasible in real world and low-resource settings	Validated measures that minimize bias, focus on internal consistency and theory rather than clinical relevance
Data Source	May include existing data (health records, admin data) and patient reports	Data generation and collection part of clinical trial
Availability of findings	Rapid learning and implementation	Delay between trial completion and analytic availability

ɔurce: Krist et al, 2013

Pragmatic randomized trials

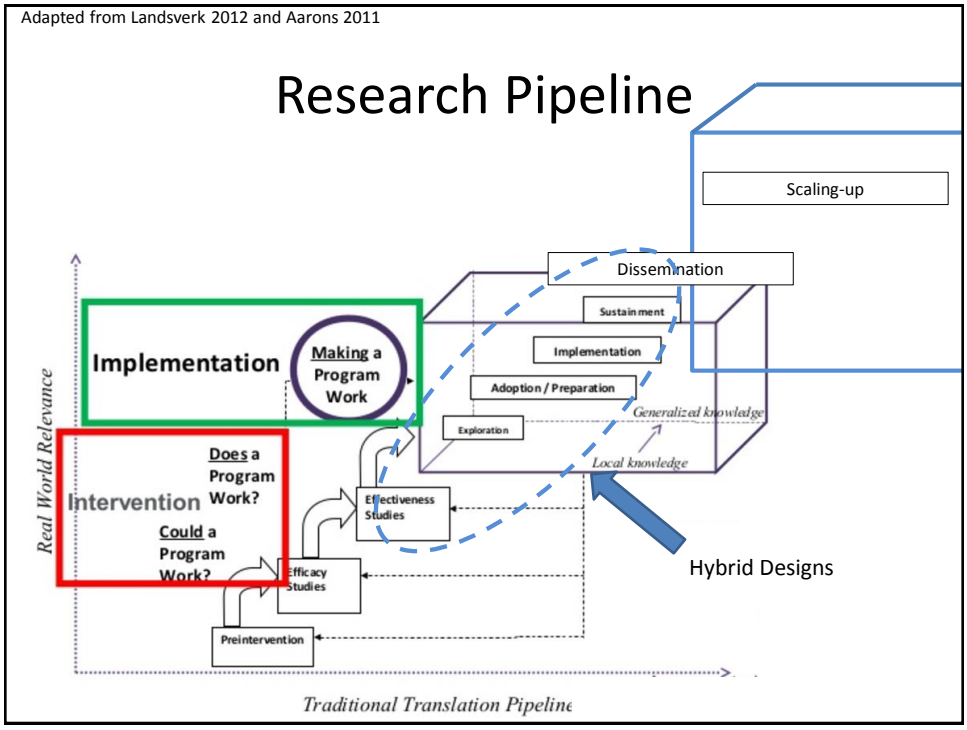
Pragmatic trials	Traditional trials
Few exclusion criteria: higher external validity	More exclusion criteria: low external validity
Wide range of patients, providers and settings	Limited range of patients, providers and settings
Active comparators	Mostly placebo-controlled
Patient-centered outcome measures	Clinical or physiological outcome measures
Longer follow-up with less intensity	Shorter follow-up with more intensity
Often not blinded	Often double-blinded
Often cluster-randomized	Often individual-randomized

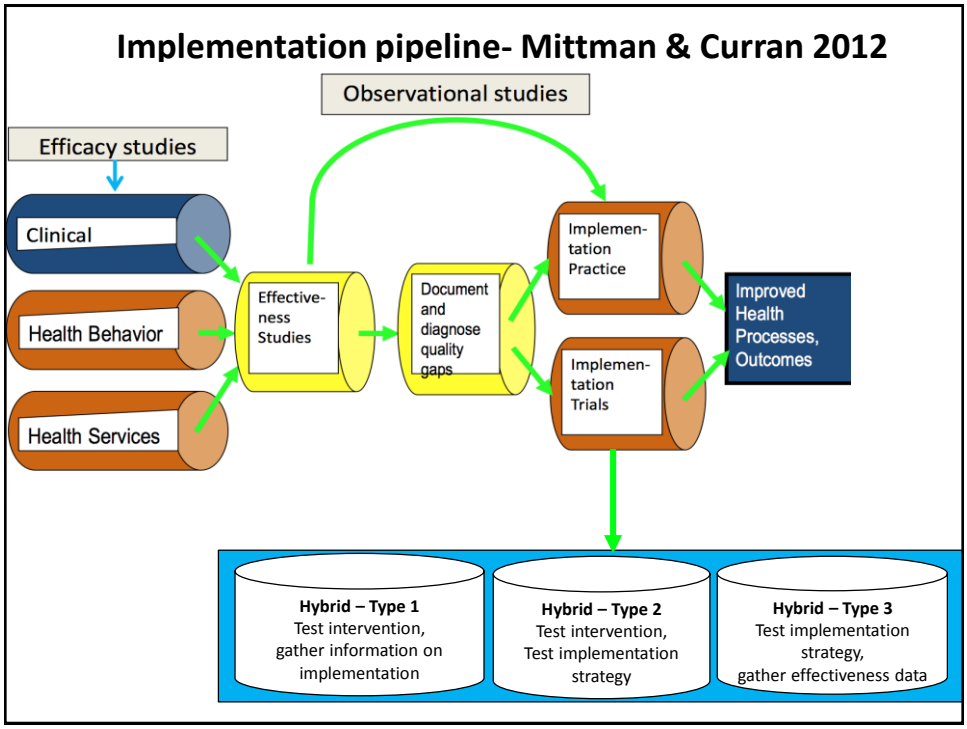
10

Effectiveness vs Implementation Trial?

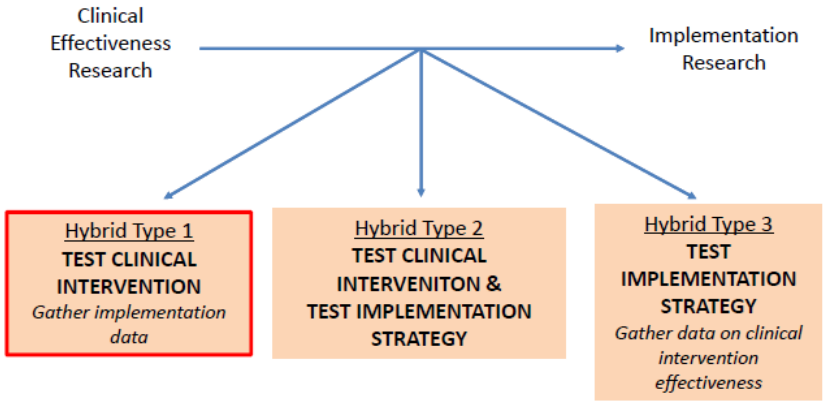
- What is the evidence gap?
- "Question is King"
- Examples of study types/approaches:
  - Pragmatic Trials
  - Effectiveness-Implementation Hybrid Designs
  - Quality Improvement Studies
  - Comparative Effectiveness Research
  - Participatory Action Research

Adapted from Landsverk 2012 and Aarons 2011





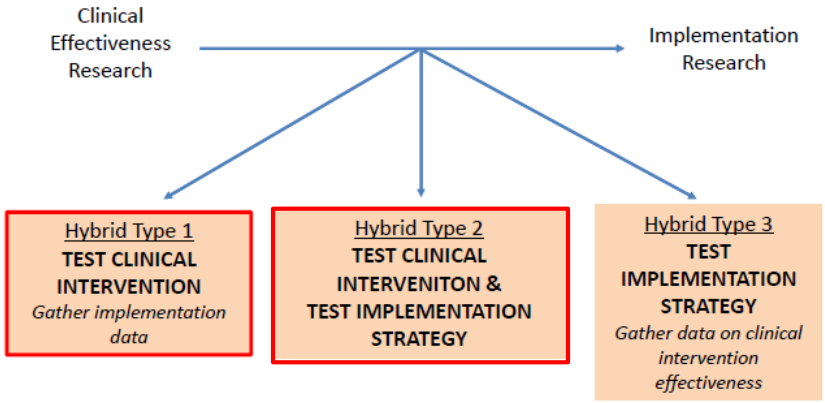
Differences between hybrid designs 1, 2 and 3



Hybrid Trial Type 1

- Research Aim:
  - Primary Aim: Determine effectiveness of a clinical intervention
  - Secondary Aim: Better understand context for implementation
- Sample research question:
  - Primary question: Will a clinical treatment work in this setting/with these patients?
  - Secondary question: What are potential barriers/facilitators to a treatment's widespread implementation?

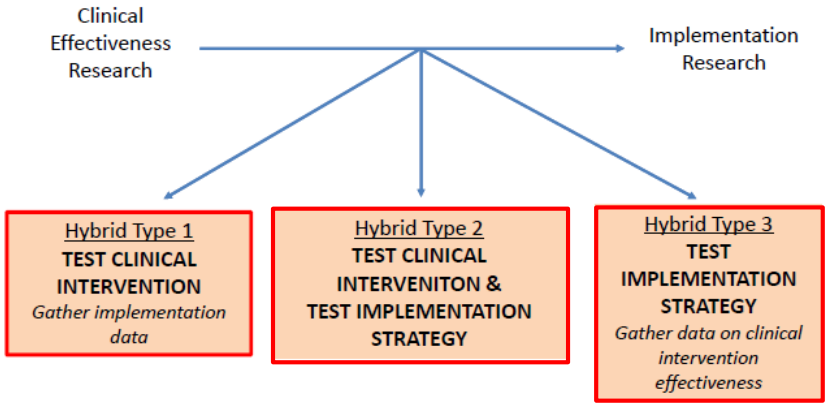
Differences between hybrid designs 1, 2 and 3



Hybrid Trial Type 2

- Research Aims
  1. Determine effectiveness of a clinical intervention
  2. Determine feasibility and potential utility of an implementation intervention/strategy
- Sample research questions:
  1. Will a clinical treatment work in this setting/these patients?
  2. Does the implementation method show promise in facilitating implementation of a clinical treatment?

Differences between hybrid designs 1, 2 and 3

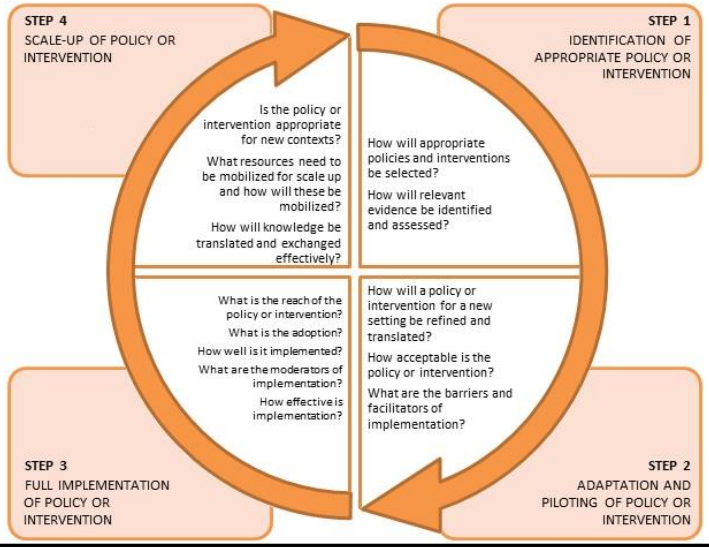


Hybrid Trial Type 3

- Research Aim
  - Primary: Determine utility of an implementation intervention/strategy
  - Secondary: Assess clinical outcomes associated with implementation trial
- Sample research question:
  - Primary question: Which method works better in facilitating implementation of a clinical treatment?
  - Secondary question: Are clinical outcomes acceptable?

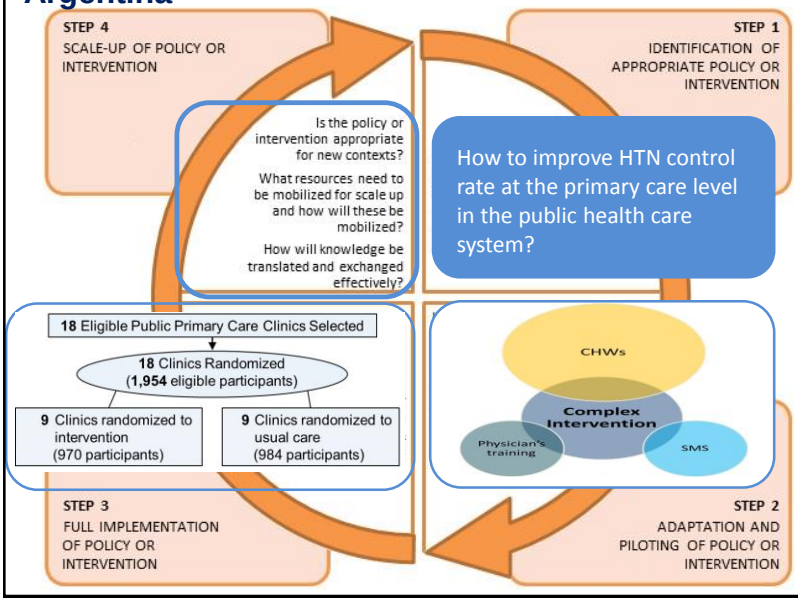
WHO Guide – Framework Model

Relationship between implementation and the implementation research cycle



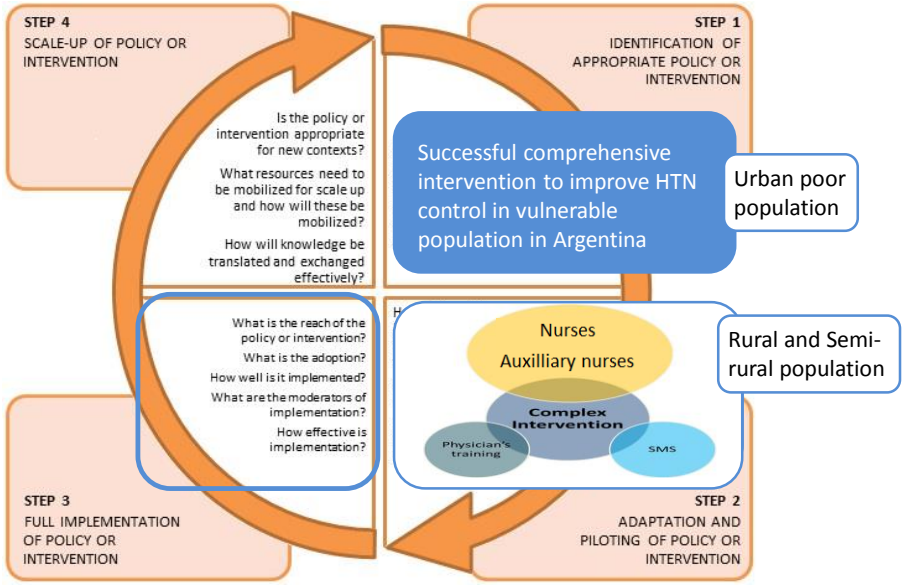
WHO Guide – Framework Model

Example 1: Comprehensive intervention for HTN control in Argentina



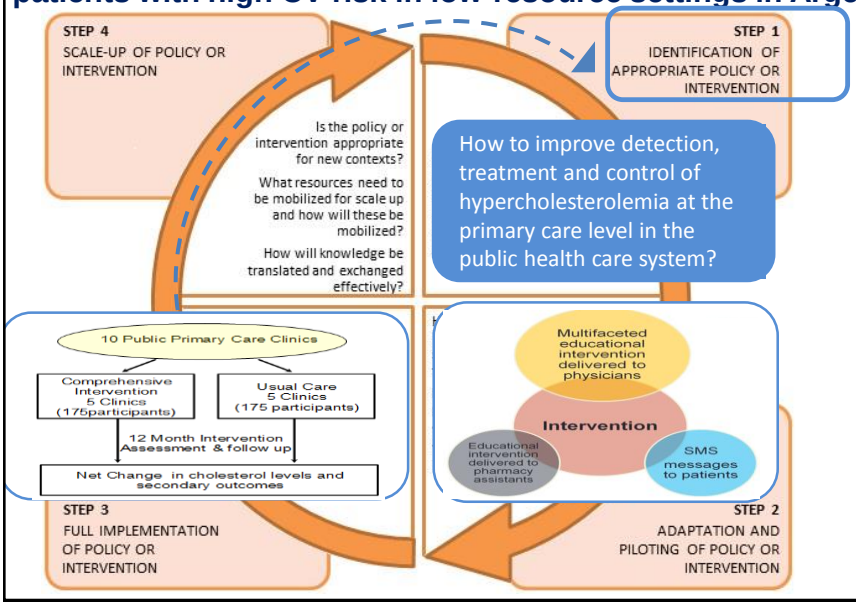
WHO Guide – Framework Model

Example 2: Comprehensive intervention for HTN control in Guatemala

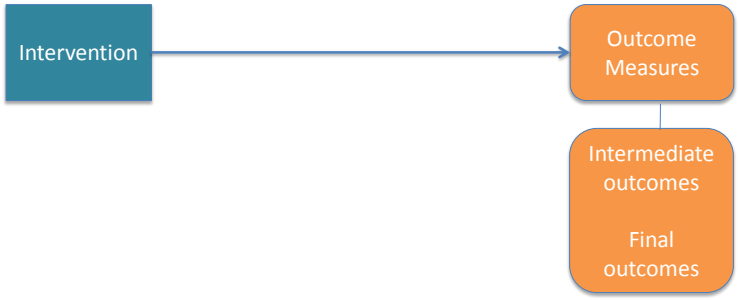


WHO Guide – Framework Model

Example 3: Educational Intervention to reduce LDL-chol in patients with high CV risk in low-resource settings in Argentina

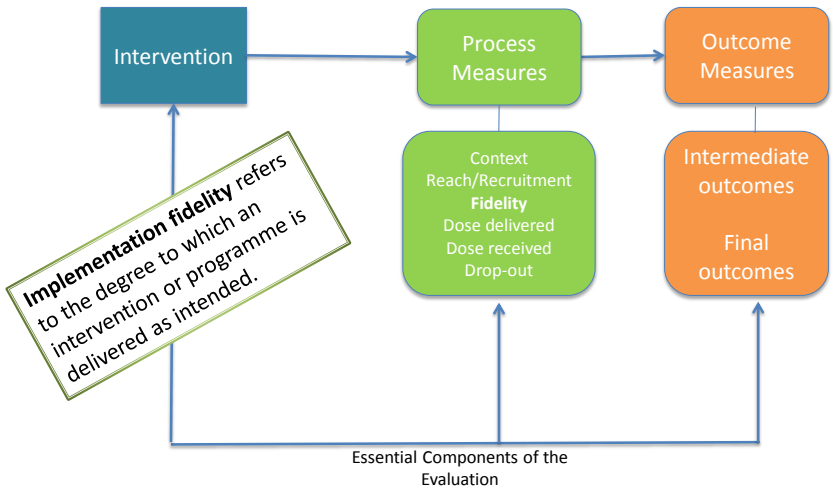


Outcome and Process Indicators



25

Outcome and Process Indicators



26

Process evaluation

thebmj Research Education News & Views Campaigns

Research Methods & Reporting

Process evaluation of complex interventions: Medical Research Council guidance

BMJ 2015 ; 350 doi: https://doi.org/10.1136/bmj.h1258 (Published 19 March 2015)
Cite this as: *BMJ* 2015;350:h1258