

WEBINAR:

Improving Iron and Folic Acid Supplementation through Quality Improvement in Uganda: An Effectiveness-implementation Hybrid Study Type III

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International
Initiative for
Impact Evaluation



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FOR IMPLEMENTATION
SCIENCE IN NUTRITION

Plan

- Introduction to the Implementation Science Initiative (ISI)
- Part I: An Introduction to hybrid effectiveness-implementation designs
- Part II: The Programmatic Context
- Part III: The Implementation Research
- Question & Answer

The Implementation Science Initiative (ISI)

1. National Core Team



2. Bottleneck Assessment and Inventory



3. Knowledge Brokering



4. Implementation Research



5. Implementation Science Network



6. Documentation of Experiences



Part I: An Introduction to Hybrid Effectiveness-Implementation Designs

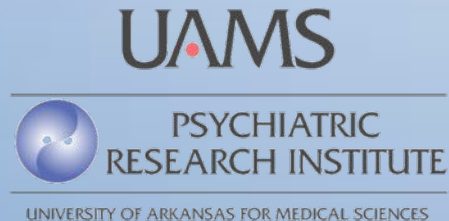
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Director, Center for Implementation Research

Professor, Departments of Pharmacy Practice and Psychiatry

University of Arkansas for Medical Sciences

Research Health Scientist, Central Arkansas Veterans Healthcare System



The next few slides cover material from this paper:



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Author Manuscript
Med Care. Author manuscript; available in PMC 2013 August 01.

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Med Care. 2012 March ; 50(3): 217–226. doi:10.1097/MLR.0b013e3182408812.

**Effectiveness-implementation Hybrid Designs:
Combining Elements of Clinical Effectiveness and Implementation Research to Enhance
Public Health Impact**

**Geoffrey M. Curran, PhD^{*}, Mark Bauer, MD[†], Brian Mittman, PhD[‡], Jeffrey M. Pyne, MD^{*},
and Cheryl Stetler, PhD[‡]**

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What are Hybrid Designs?

- **Blending research questions about the “clinical” effectiveness of some intervention/innovation/program along with research questions about how best to support uptake of that intervention...**
 - Some studies focus more on the effectiveness of the clinical intervention
 - Other focus more testing competing strategies to support uptake of an interventions
 - Others look into both sides more equally

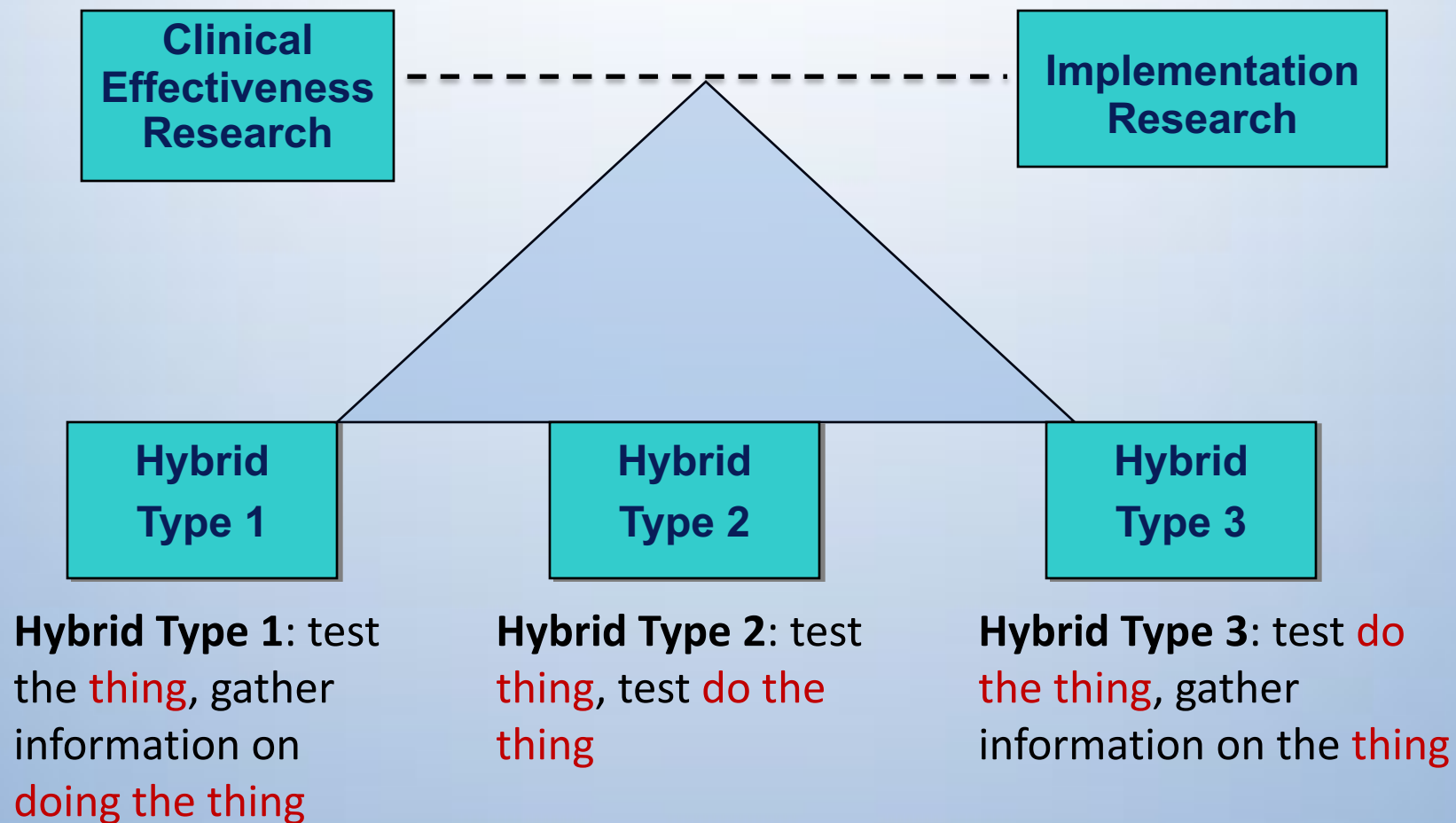
Why Hybrid Designs?

- Can we hurry up please?
 - Get what works into routine practice faster (*we hope*)
- Don't wait for "perfect" effectiveness data before moving to implementation research
- We can "backfill" effectiveness data while we test implementation strategies
- How do clinical outcomes relate to levels of adoption and fidelity?
 - How will we know this without data from "both sides"?

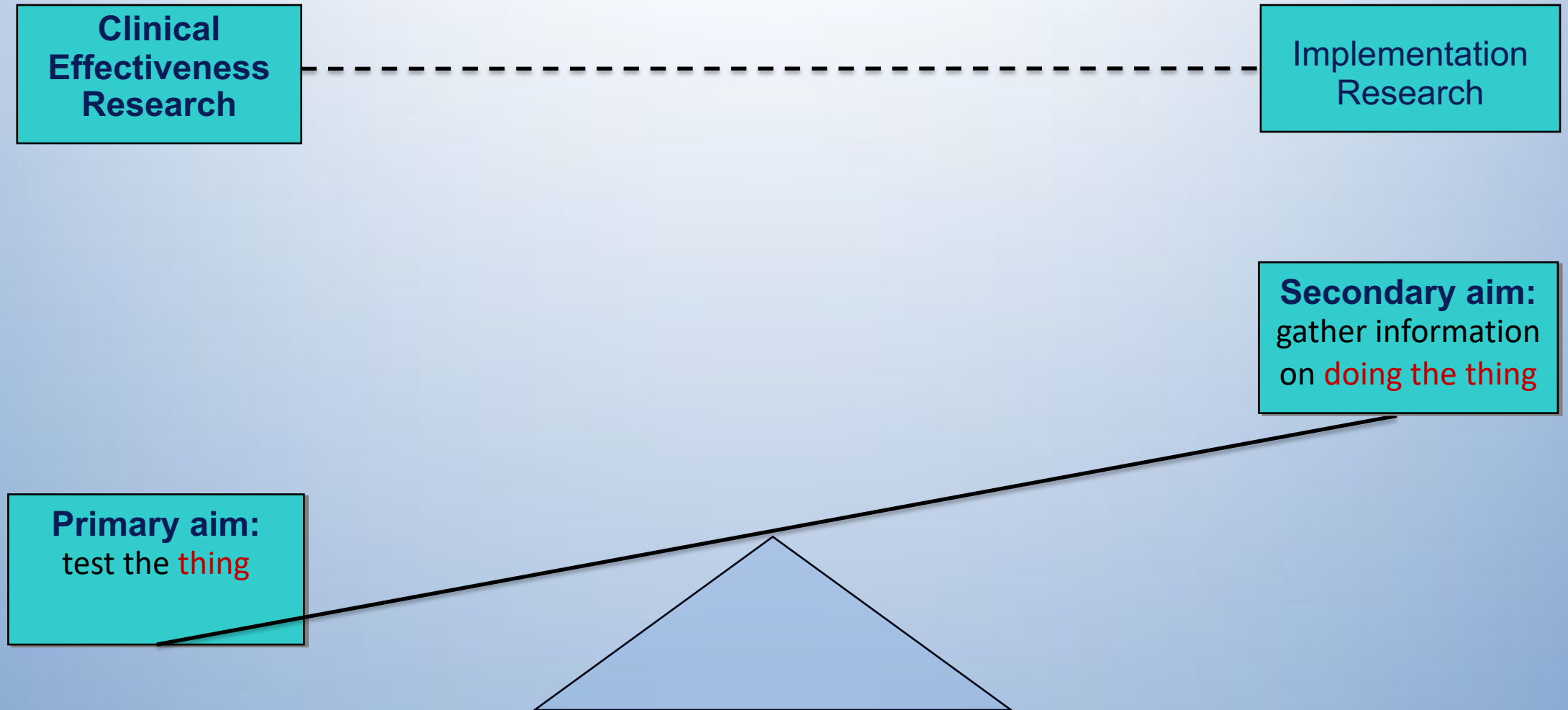
When teaching this stuff, some very non-scientific language can also be helpful...

- The intervention/practice/innovation is **THE THING**
- Effectiveness research looks at whether **THE THING** works
- Implementation research looks at how best to help people/places **DO THE THING**
- *Implementation strategies* are the stuff we do to try to help people/places **DO THE THING**
- Main implementation outcomes are **HOW MUCH** and **HOW WELL** they **DO THE THING**

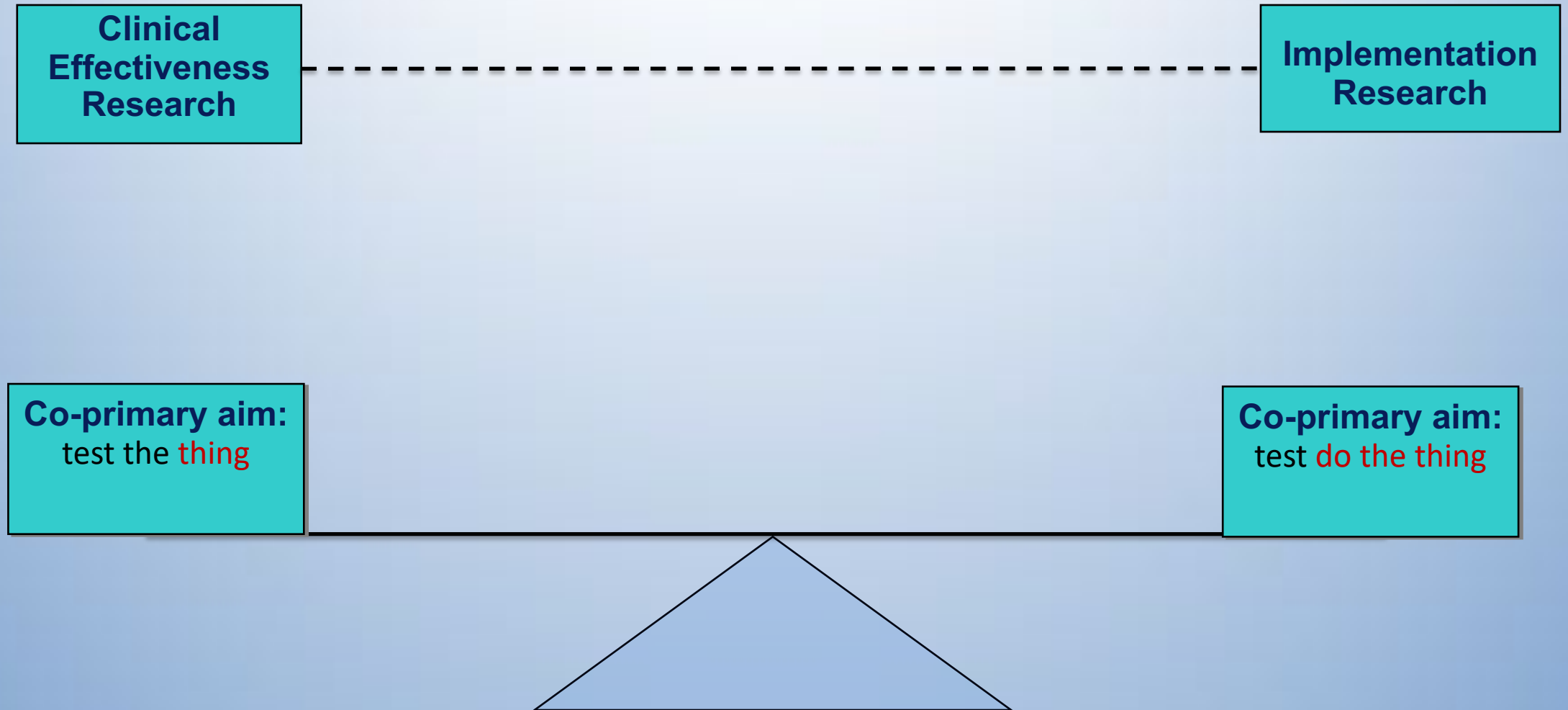
Types of Hybrids



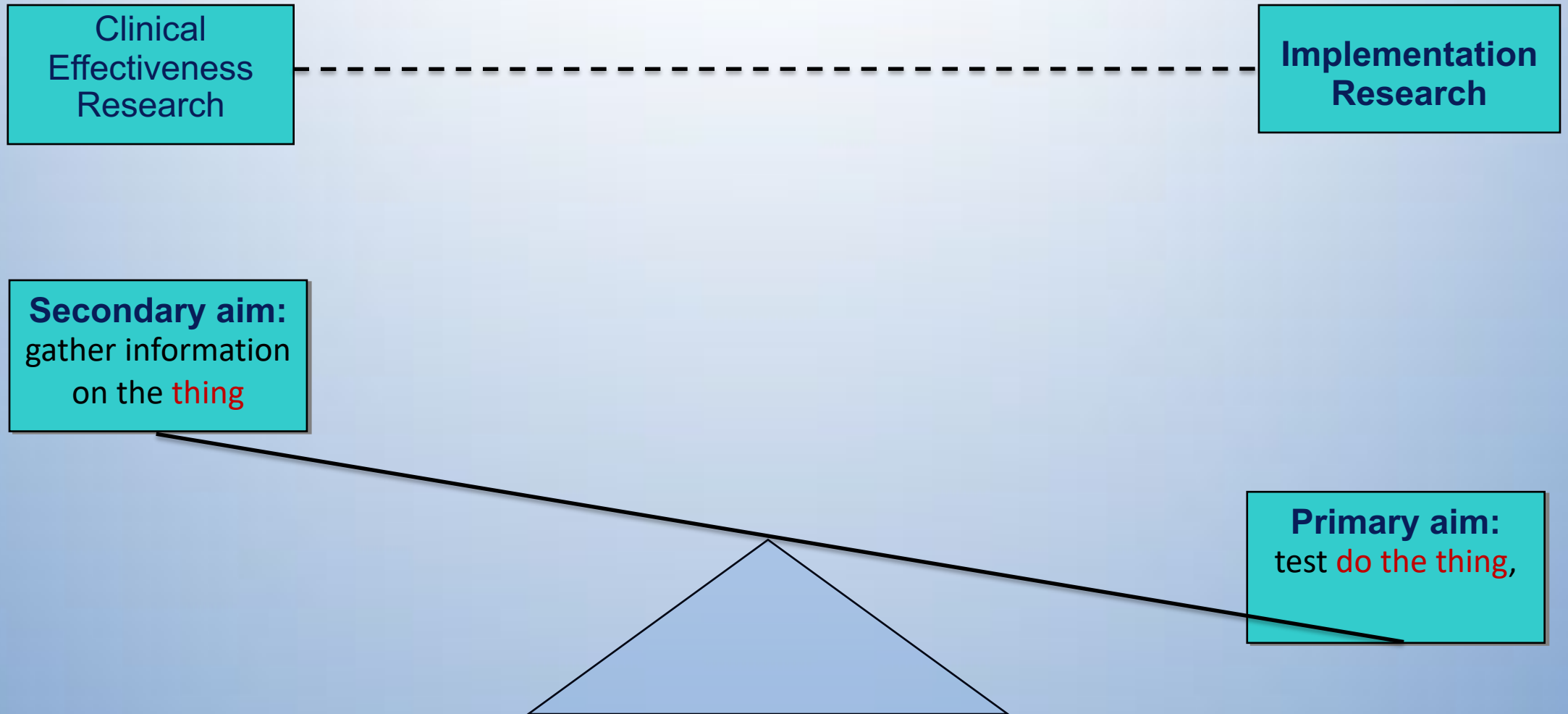
Types of Hybrids – Hybrid type 1



Types of Hybrids – Hybrid type 2



Types of Hybrids – Hybrid type 3



Some Type 3 examples


Spoolstra et al. *Implementation Science* (2019) 14:60
<https://doi.org/10.1186/s13012-019-0907-1>

Implementation Science

STUDY PROTOCOL Open Access

Testing an implementation strategy bundle on adoption and sustainability of evidence to optimize physical function in community-dwelling disabled and older adults in a Medicaid waiver: a multi-site pragmatic hybrid type III protocol

Sandra L. Spoolstra^{1*}, Monica Schueller¹ and Alla Sikorski²



Swindle et al. *Implementation Science* (2017) 12:90
DOI 10.1186/s13012-017-0624-6

Implementation Science

STUDY PROTOCOL Open Access

A mixed methods protocol for developing and testing implementation strategies for evidence-based obesity prevention in childcare: a cluster randomized hybrid type III trial

Taren Swindle^{1*}, Susan L. Johnson², Leanne Whiteside-Mansell³ and Geoffrey M. Curran³



Kilbourne et al. *Implementation Science* 2014, 9:132
<http://www.implementationscience.com/content/9/1/132>

IMPLEMENTATION SCIENCE

STUDY PROTOCOL Open Access

Protocol: Adaptive Implementation of Effective Programs Trial (ADEPT): cluster randomized SMART trial comparing a standard versus enhanced implementation strategy to improve outcomes of a mood disorders program

Amy M Kilbourne^{1,2*}, Daniel Almirall³, Daniel Eisenberg⁴, Jeanette Waxmonsky^{5,6}, David E Goodrich^{1,2}, John C Fortney⁷, JoAnn E Kirchner^{8,9}, Leif I Solberg¹⁰, Deborah Main¹¹, Mark S Bauer¹², Julia Kyle^{1,2}, Susan A Murphy^{3,3}, Kristina M Nord^{1,2} and Marshall R Thomas^{5,6}

Bauer et al. *Implementation Science* (2016) 11:22
DOI 10.1186/s13012-016-0385-7

Implementation Science

STUDY PROTOCOL Open Access

Partnering with health system operations leadership to develop a controlled implementation trial

Mark S. Bauer^{1*}, Christopher Miller¹, Bo Kim¹, Robert Lew², Kendra Weaver³, Craig Coldwell⁴, Kathy Henderson⁵, Sally Holmes⁶, Marjorie Nealon Seibert⁶, Kelly Stolzmann⁶, A. Rani Elwy⁶ and JoAnn Kirchner⁵



Hybrid Type 3 Designs

Definition: Test do the thing, gather info on the thing (80%-20%...?)

Description:

- Largely focused on trial of implementation strategies
- Randomization usually at level of provider, clinic, or system
- Clinical outcomes are “secondary”

Indications (circa 2012):

- We sometimes proceed with implementation studies without completing a “full portfolio” of effectiveness studies (e.g. mandates)
 - Strong momentum in a system, e.g., “We are rolling this out!”
- Interested in exploring how clinical effectiveness might vary by level/quality of implementation?
- More feasible and attractive when clinical outcomes data are more widely available

Additional Thoughts on Type 3 designs

- Don't need to do randomized designs
- Important to consider how much of a “need” there is for the collection of the “clinical” effectiveness data
 - Is the intervention being adapted for this study?
 - Is it being delivered in a new context?
 - Behavioral outcomes or “physical”?
- For nutrition field in general, for what kinds of interventions do hybrid 3 designs make sense, and for others not so much?
- Try to study “mechanisms of action” of the implementation strategies
 - Why do they work/not work? Use theory to guide hypotheses...
 - E.g., need to change attitudes and beliefs before behavior?



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Part II: The Programmatic Context

Dr. Nathan Tumwesigye – Principal Investigator, IFAS ISI Uganda



Overview of Anemia in Uganda



Uganda is located in Eastern region of Africa



32% of women of reproductive age are anemic (UDHS 2016)



The prevalence among women aged 15 - 49 years increased from 23% in 2011 to 32% in 2016



URC is working through the health system to implement the Regional Health Integration to Enhance services in East Central Region (RHITES- EC) program

Overview of RHITES-EC

Project Goal

To increase access to and sustained utilization of health services by strengthening district health systems, improving quality of health services, and increasing demand for services.

Five key results

1. Increased availability and accessibility of health services (malaria, HIV, TB, MNCH, family planning, laboratory services, nutrition and WASH)
2. Improved quality of health services
3. Increased availability of resources for public sector services
4. Improved organization and management of service delivery
5. Increased adoption of health behaviors and positive child development practices in focus areas and target population groups.



RHITES-EC Approach



Quality Improvement



Health Systems Strengthening



Social and Behaviour Change

Focus on Iron Folic Acid Supplementation (IFAS) ISI



Intake of IFAS during pregnancy improves maternal health and pregnancy outcomes – WHO recommendation



Iron requirements in pregnancy are rarely met by dietary food intake alone.



Only 23% of pregnant women take 90+ tablets and only 12% of pregnant women **in Busoga** region get the dosage as recommended



The Implementation Science Initiative (ISI) aims to address priority barriers and improve IFAS using existing knowledge first and generating additional evidence through IR.

Major bottlenecks identified

SERVICE DELIVERY SYSTEM

1. Uncoordinated
health education

SUPPLY CHAIN SYSTEM

2. Regular stock-
outs of IFA



USER SYSTEM

3. Lack of male involvement in supporting
pregnant women to seek ANC services

Quality Improvement Approach (PDSA cycle)

- **Iterative process:** PDSA cycles on improving delivery of IFAS at ANC clinic
- **Target:** QI team at health facilities and Work Improvement teams at the service delivery point (e.g. ANC clinic)
- **IFAS priority bottlenecks:** Gaps in health education and recurrent stock out of IFAS tablets





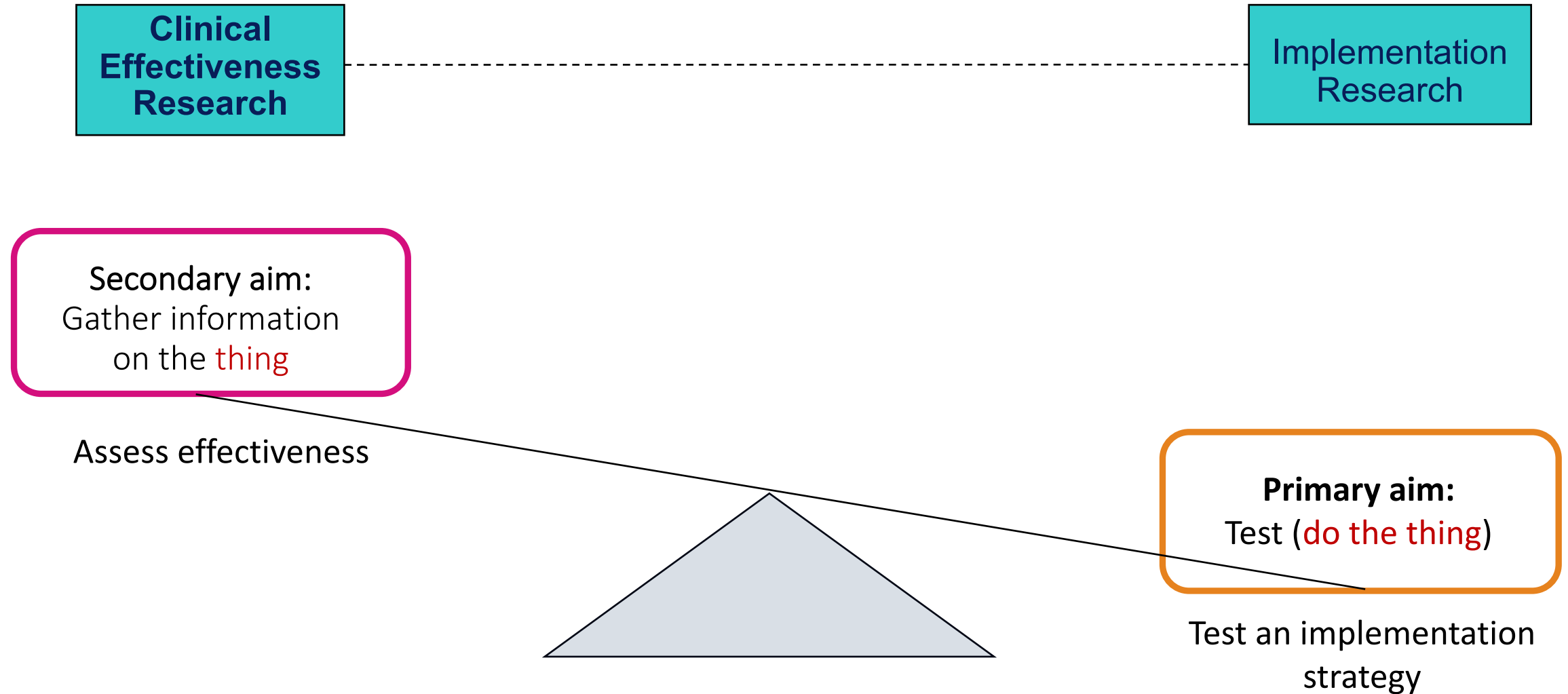
Improving Iron And Folic Acid Supplementation Through Quality Improvement In Uganda: An Effectiveness-implementation Hybrid Study Type III

Part III: The Implementation Research

Dr. Moses Tetui – Co-Principal Investigator, IFAS ISI Uganda



Recall: Hybrid Type 3 design



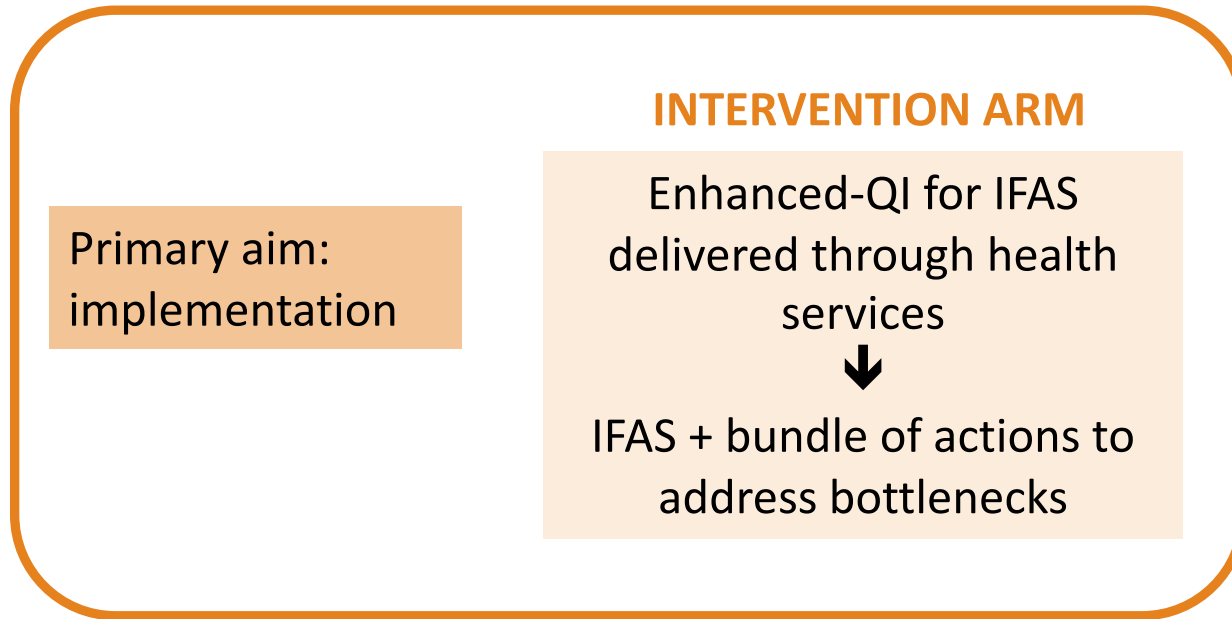
The implementation strategy: enhanced-QI for IFAS

Activities include:

- Bi-monthly mentorship and coaching sessions
- Monthly health facility performance review and QI work planning meetings
- Quarterly Collaborative learning networks
- Bi-weekly data management and reporting
- IFA stock monitoring and re-distribution



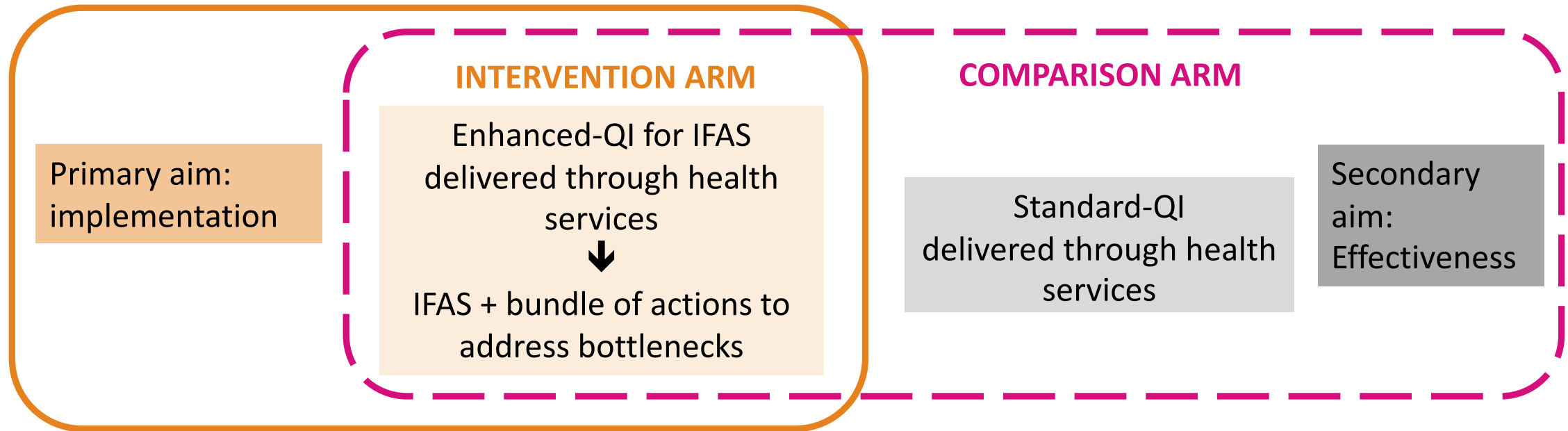
Hybrid Type 3 design



Primary aim: implementation processes

- to examine the state of a) the health education about IFAS during antenatal visits and b) the supply system
- to investigate the implementation of a QI-enhanced process for IFAS intervention to address the bottlenecks identified regarding a) health education and b) essential drugs quantification

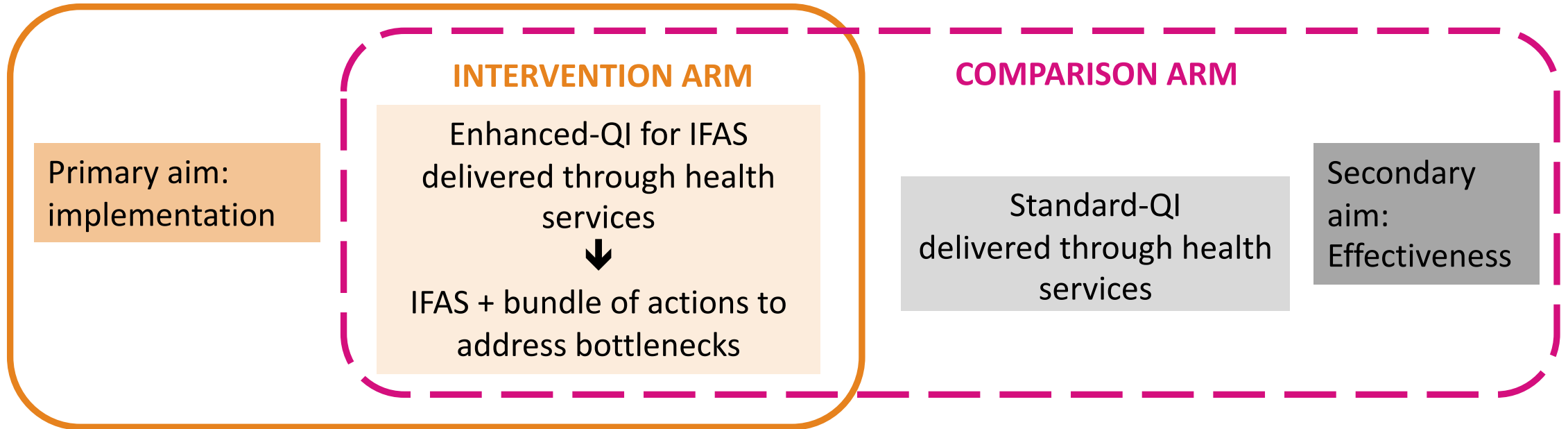
Hybrid Type 3 design



Secondary aim: effectiveness of the intervention

- to assess the effectiveness of the QI-enhanced process for IFAS intervention on:
 - a) the quality of health education
 - b) women' knowledge and motivation to use IFA tablets
 - c) the tracking procedures and availability of IFA tablets at health facilities providing ANC

Hybrid Type 3 design



Evaluate both the effectiveness of the enhanced-QI for IFAS AND its implementation simultaneously

Challenges

1. Characteristics of the implementation strategy (enhanced-QI for IFAS)

- Not a fixed process - differs among health facilities (e.g. intensity, actors, problems, etc...)
- Enhancement has two variables
 - QI process
 - Focus on IFAS

2. Complexity - three levels at play:

- i) IFAS (the technical intervention)
- ii) QI-enhanced for IFAS (the implementation strategy)
- iii) Strengthened QI-enhanced ANC (a bundle of actions based on the use of #ii)

A comprehensive documentation process is taking place to document the various activities carried out at various levels in the system.

Question & Answer

Q&A



#SISNFramework
#InvestinIR

What advice would you give to people to get started with using a hybrid design?

What IFA tablet and packaging is used in Uganda? How is it procured and how does the supply chain reach the health posts? Is there a monitoring system for forecasting and addressing stock-outs?

Have you figured out a way to assess effects of the QI-enhanced IFAS on the other components of ANC (ie does the focus on IFAS potentially have a negative effect on other aspects of ANC), if so how will that be included?

Can we conduct a hybrid II-III evaluation of a traditional RCT? I did not consider a hybrid design during initial design and implementation of a pilot study, however I would like to evaluate implementation outcomes. Can I conduct a hybrid post hoc?

How is hybrid design different from a process evaluation + impact evaluation combination that have been carried out to test effectiveness of several nutrition programs e.g. Alive and Thrive?

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- Check out our website: www.implementnutrition.org
- E-mail us at: info@implementnutrition.org
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The Society for Implementation Science in Nutrition

