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

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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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The next few slides cover material from this paper:

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

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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

**Hybrid Type 1**: test the **thing**, gather information on doing the **thing**

**Hybrid Type 2**: test **thing**, test do the **thing**

**Hybrid Type 3**: test do the **thing**, gather information on the **thing**
Types of Hybrids – Hybrid type 1

Primary aim: test the thing

Clinical Effectiveness Research

Secondary aim: gather information on doing the thing

Implementation Research
Types of Hybrids – Hybrid type 2

- Clinical Effectiveness Research
- Implementation Research

Co-primary aim: test the thing

Co-primary aim: test do the thing
Types of Hybrids – Hybrid type 3

Primary aim: test do the thing,

Secondary aim: gather information on the thing

Clinical Effectiveness Research

Implementation Research
Some Type 3 examples

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 II protocol

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

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

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

Use of QI approach to improve IFAS
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
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Part III: The Implementation Research

Dr. Moses Tetui – Co-Principal Investigator, IFAS ISI Uganda
Recall: Hybrid Type 3 design

**Primary aim:**
Test (do the thing)

**Test an implementation strategy**

**Secondary aim:**
Gather information on the thing

Assess effectiveness
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

INTERVENTION ARM

Enhanced-QI for IFAS delivered through health services
arrow down
IFAS + bundle of actions to address bottlenecks
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

**Primary aim:**
Implementation

**INTERVENTION ARM**
- Enhanced-QI for IFAS delivered through health services
  - IFAS + bundle of actions to address bottlenecks

**COMPARISON ARM**
- Standard-QI delivered through health services

**Secondary aim:**
Effectiveness

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
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?
Want to find out more about SISN and the benefits of membership?

- Check out our website: www.implementnutrition.org
- E-mail us at: info@implementnutrition.org
- Follow us: @implementntr

The Society for Implementation Science in Nutrition