What is effectiveness-implementation hybrid design?

Traditional research sequence

Traditionally, in the research pipeline, there is a sequence of which research takes place. First, it often begins with **efficacy** research of an intervention under ideal and controlled conditions, to then move to **effectiveness** research to better understand the effect of that intervention in real-life conditions. After that, **implementation** research takes place to examine how evidence-based practices (EBPs) get implemented in general practice.

SCHEMA - Efficacy– effectiveness-implementation spectrum

Intervention development ----------> Intervention uptake*
Ideal conditions ----------> Real world conditions

	Efficacy research	Effectiveness research	Implementation research
2	Does "an intervention implemented under controlled conditions have efficacy in specific population"?	Does"the effect remains when implemented in less controlled conditions with broader populations"?	What are "the best methods to introduce the intervention into practice"?**
4	Internal validity	External validity	

* =sustained application in general practice[3]
**"there is clear need to develop specific strategies to promote the uptake of EBPs into general clinical usage. Implementation science has developed to address these needs." [3]

Such a staged approach in research does not help to understand the interactions between the intervention and the implementation strategy.[4] Moreover, it leads to delay before there is an uptake of evidence-based practices in the health system and communities. In order to increase the speed at which research findings are adopted and moved into routine practice, the effectiveness-implementation hybrid design brings a major contribution by proposing to evaluate both the effectiveness of an intervention AND its implementation simultaneously.[1,2]

Emergence of the effectiveness-implementation hybrid design

A group of implementation and clinical trial researchers “codified” the concept of effectiveness-implementation hybrid design, by putting together relevant concepts and methodologies that already existed across diverse scientific fields. Their purpose was to explore the hybrid design framework utility for the needs of researchers and other stakeholders working in real-world conditions. Rapidly, researchers and diverse stakeholders have began to adopt this framework, which testifies that it fills an important gap in research design and methodology.[3]

Gathering both effectiveness and implementation data concurrently brings an important strength of becoming aware of essential contextual factors related to the success of interventions, which helps to make the implementation of EBPs or interventions more effective.[4]

Terminology (adapted from [4])

A distinction between key terms needs to be made to avoid any confusion.

- **Intervention** refers to the (clinical) practice or program of interest
- **Implementation strategy** refers to implementation activities or tools that support the delivery of the intervention of interest

Also, as stated by Landes et al, although we are interested in the effectiveness of both the intervention and the implementation strategy, in effectiveness-implementation hybrid design the term effectiveness refers only to the effectiveness of the intervention.

Three types of effectiveness-implementation hybrid design

There are three types of hybrid design that fall on a continuum between strict effectiveness research and strict implementation research, as described below. The selection of the type of design depends essentially on the primary focus of the research.

Table 1: Distinction between the different types of hybrid design (adapted from [4], [5], [6])

Hybrid design	Research aims	Best suited
Type I	*Primary*: Determine effectiveness of an intervention[4] *Secondary*: Better understand context for implementation[4]	When the clinical effectiveness evidence remains limited and that studying implementation alone is premature[4]
Type II	*Primary*: Determine effectiveness of an intervention[4] *Co-Primary*: Determine feasability and/or (potential) impact/utility of an implementation strategy[4]	When interventions already have evidence of effectiveness in other settings or populations, but not in either the context or population in the current trial resulting in uncertainty that there would be a similar clinical benefit[4]
Type III	*Primary*: Test an implementation strategy at a system or clinic level *Secondary*: Assess patient or clinical outcomes[5] associated with implementation trial	- When different implementation approaches are being tested for an evidence based intervention[6] - When there is a high-level need or call for implementation despite limited evidence base[4]

Question & Answer

1) On which intervention the Uganda team carry out its hybrid design?
2) Is this a problem that it is not a clinical intervention?
3) Why is Uganda's focus not on IFAS?
4) What type of hybrid design does Uganda carry out?
5) Could Uganda carry out a type III hybrid?
6) What types of outcomes will be assessed?
7) Is it normal that these are not clinical outcomes?
8) What tools will be used to collect the data?
9) What is the link between hybrid design and bottleneck inventory?
10) Aren't there several levels of bottlenecks?

1) On which intervention the Uganda team carry out its hybrid design?

With its effectiveness-implementation hybrid design reserach, Uganda is going to study both the implementation and the effectiveness of QI, which is considered the practice of interest. Be careful, the focus of this hybrid design research is neither on IFAS nor on the enhanced support for QI.

The results of such research will help to better understand how QI can be well implemented and whether it helps addressing specific challenges identified in health services.

2) Is this a problem that it is not a clinical intervention?

The hybrid design was initially articulated with the idea of accelerating the uptake of clinical intervention, so the interventions studied are of course clinical. As Uganda will be studying both the implementation and the effectiveness of an intervention, it seems quite legitimate to use this approach. Overall, the concepts do apply.

3) Why is Uganda's focus not on IFAS?

If the focus were on IFAS, the implementation but also the effectiveness of IFAS would have to be investigated. To study the effectiveness of IFAS, a clinical measure of Hb would be needed, which will not be the case.

4) What type of hybrid design does Uganda carry out?

Because the team will actively investigate both the implementation and the effectiveness of the QI intervention, Uganda is carrying out an hybrid design type II.

5) Could Uganda carry out a type III hybrid?

Uganda could decide to do a Type III hybrid design on QI, but in this case the effectiveness of QI would not be actively studied. Instead, it could be carried out on the basis of secondary data.

6) What types of outcomes will be assessed?

- To assess the implementation of QI, Uganda will carry out a process evaluation. This will answer specific questions about context, reach, fidelity, dose delivered and received, and/or recruitment.
- To assess the effectiveness of QI, the team will rely on whether or not specifically identified challenges have been resolved. For Uganda, these challenges relate to stock-out and uncoordinated health education.

7) Is it normal that these are not clinical outcomes?

The majority of the studies using hybrid design appears to have been conducted in clinical settings and thus to influence clinical outcomes. However, the concepts appear to be transferable to interventions that are not necessarily clinical as in the case of Uganda. Thus, Uganda appears to be at the forefront in applying hybrid design concepts outside of clinical interventions.

8) What tools will be used to collect the data?

In its research protocol, Uganda mentions numerous data collection tools. These have been categorized as tools that will be used to collect data on the implementation or effectiveness of the QI intervention and are presented in the table below:

	QI
Primary Aim	**Assessment of the implementation of QI** Implementation assessment tools: - framework for assessing implementation (appendix B) - bottleneck (appendix C) - Team self-evaluation questionnaire to monitor QI process implementation (appendix F) - Survey tool to assess the outcomes of the QI
Co-Primary Aim	**Assessment of the effectiveness of QI** Intervention assessment tools: - Exit Interview questionnaire for pregnant women attending ANC - **regarding bottlenecks** - Interview guide for supply chain/stores personnel – IFA supply interviews - **regarding bottlenecks**

9) What is the link between hybrid design and bottleneck inventory (BI)?

BI is a component of the implementation science approach. IR is another component of IS. As part of an IR and using an hybrid design, Uganda will study QI when applied to IFAS.

A link between these two components is that QI allows solving previously identified bottlenecks. Some of these IFAS-related bottlenecks may have been listed in the BI. Through IR, it would be possible to populate the BI with some bottlenecks already identified.

10) Aren't there several levels of bottlenecks?

There are indeed several levels of bottleneck involved in this research. First of all, there are the bottlenecks related to QI implementation. These will be documented during the study of QI implementation. There are also the already identified bottlenecks related to the implementation of IFAS. These bottlenecks should be addressed through QI implementation so those will be studied during the QI effectiveness study.

References

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