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Using implementation science to enhance global health programmes Complex interventions in global health settings

GLOW Liverpool 2020 Implementing respectful care: the science and the practice

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The implementation challenge

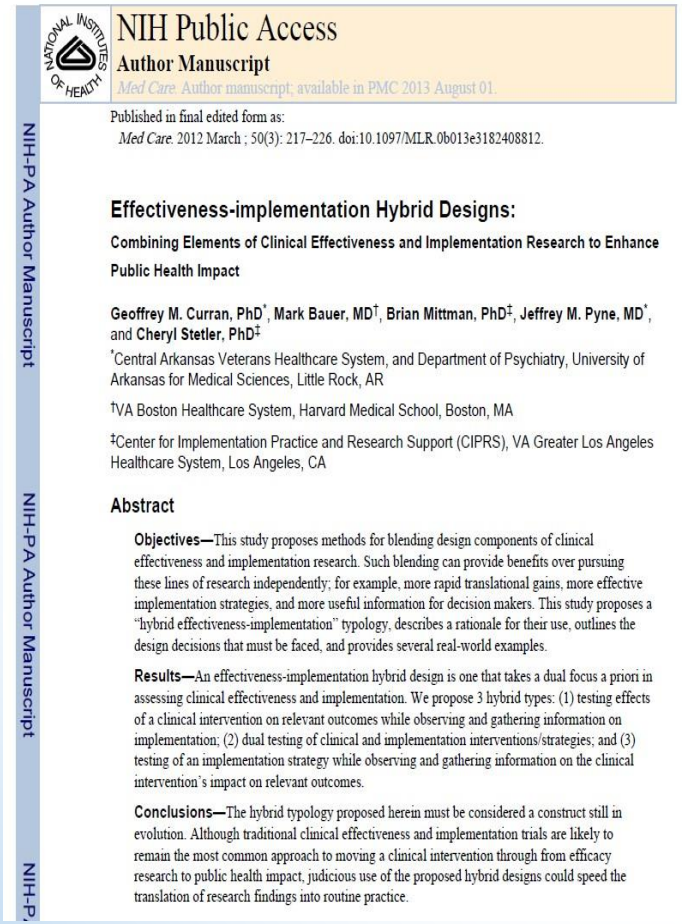
- A key challenge faced by the global health community is how to take proven interventions and implement them in the real world. We spend billions on health innovations, but very little on how best to use them.

- Affordable, life-saving interventions exist to confront many of the health challenges we face, but there is little understanding of how best to deliver those interventions across the full range of existing health systems and in the wide diversity of possible settings.

- Too often interventions that work in small-scale pilot studies fail to live up to expectations when rolled out in national strategies, or fail to transfer from one country to another as a result of contextual differences.

- **How can implementation science combined with complex intervention research inform scale up and real world translation?**

Effectiveness-implementation hybrid designs



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Effectiveness-implementation Hybrid Designs:

Combining Elements of Clinical Effectiveness and Implementation Research to Enhance Public Health Impact

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Abstract

Objectives—This study proposes methods for blending design components of clinical effectiveness and implementation research. Such blending can provide benefits over pursuing these lines of research independently; for example, more rapid translational gains, more effective implementation strategies, and more useful information for decision makers. This study proposes a "hybrid effectiveness-implementation" typology, describes a rationale for their use, outlines the design decisions that must be faced, and provides several real-world examples.

Results—An effectiveness-implementation hybrid design is one that takes a dual focus a priori in assessing clinical effectiveness and implementation. We propose 3 hybrid types: (1) testing effects of a clinical intervention on relevant outcomes while observing and gathering information on implementation; (2) dual testing of clinical and implementation interventions/strategies; and (3) testing of an implementation strategy while observing and gathering information on the clinical intervention's impact on relevant outcomes.

Conclusions—The hybrid typology proposed herein must be considered a construct still in evolution. Although traditional clinical effectiveness and implementation trials are likely to remain the most common approach to moving a clinical intervention through from efficacy research to public health impact, judicious use of the proposed hybrid designs could speed the translation of research findings into routine practice.

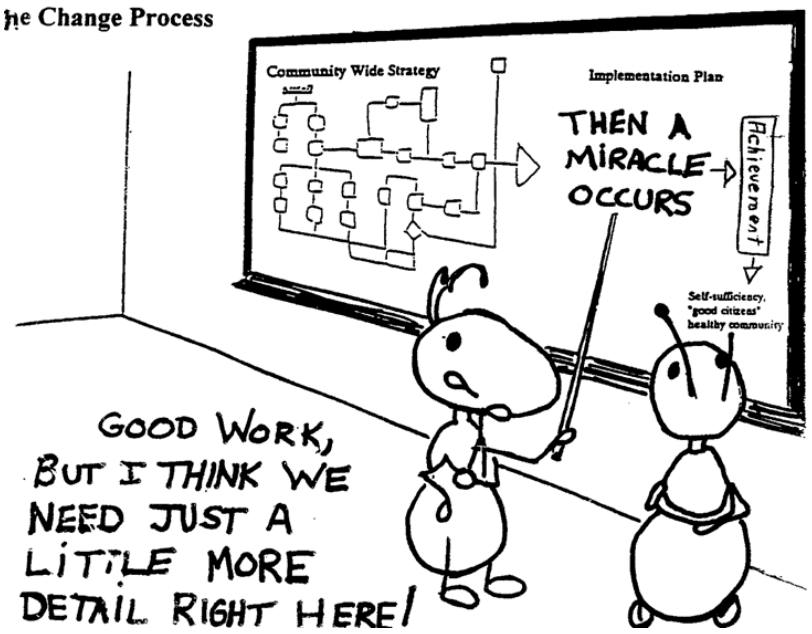
An effectiveness-implementation hybrid design is one that takes a dual focus a priori in assessing clinical effectiveness and implementation.

(1) testing effects of a clinical intervention on relevant outcomes while observing and gathering information on implementation;
(2) dual testing of clinical and implementation interventions/strategies
(3) testing of an implementation strategy while observing and gathering information on the clinical intervention's impact on relevant outcomes.

Why is implementation and process evaluation necessary?

If an intervention is effective in one context, what additional information does the policy-maker need to be confident that:

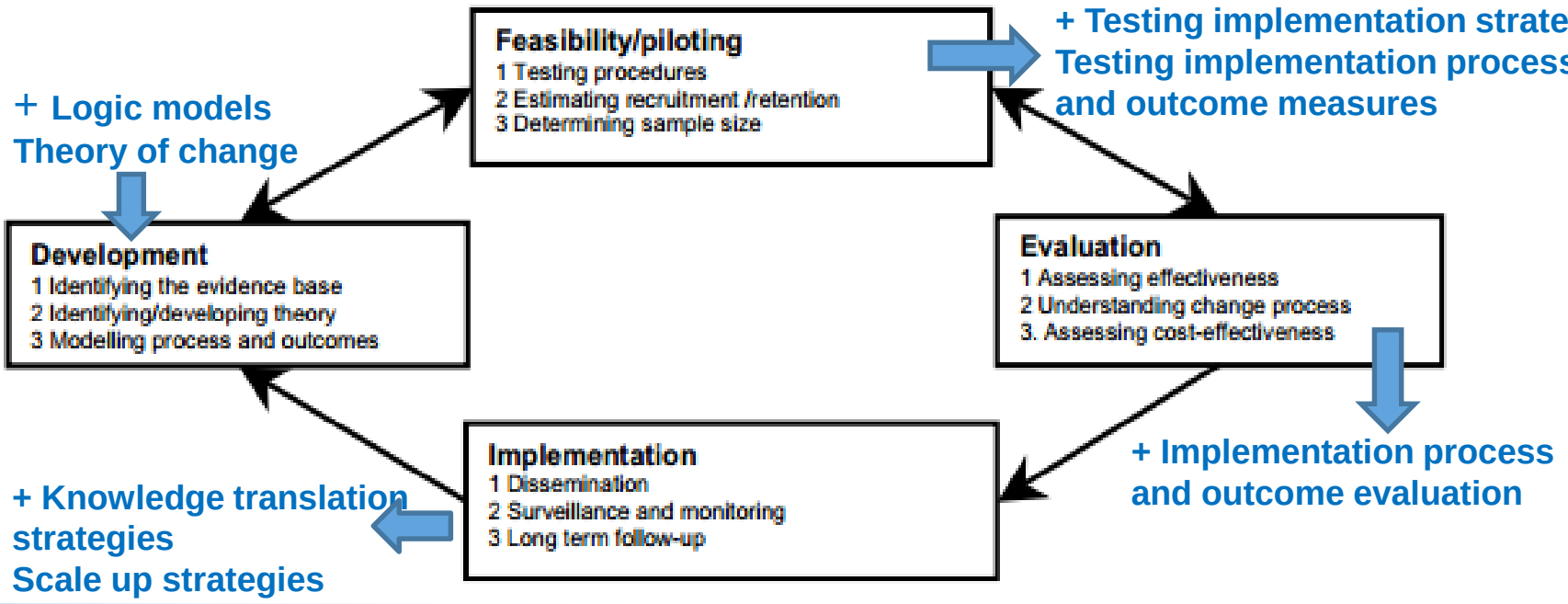
- **Another organisation (or set of professionals) will deliver it in the same way; and if they do, it will produce the same outcomes in new contexts?**
- **Lack of effect is attributable to the intervention itself, rather than to poor implementation;**
- **The intervention benefits the target population;**



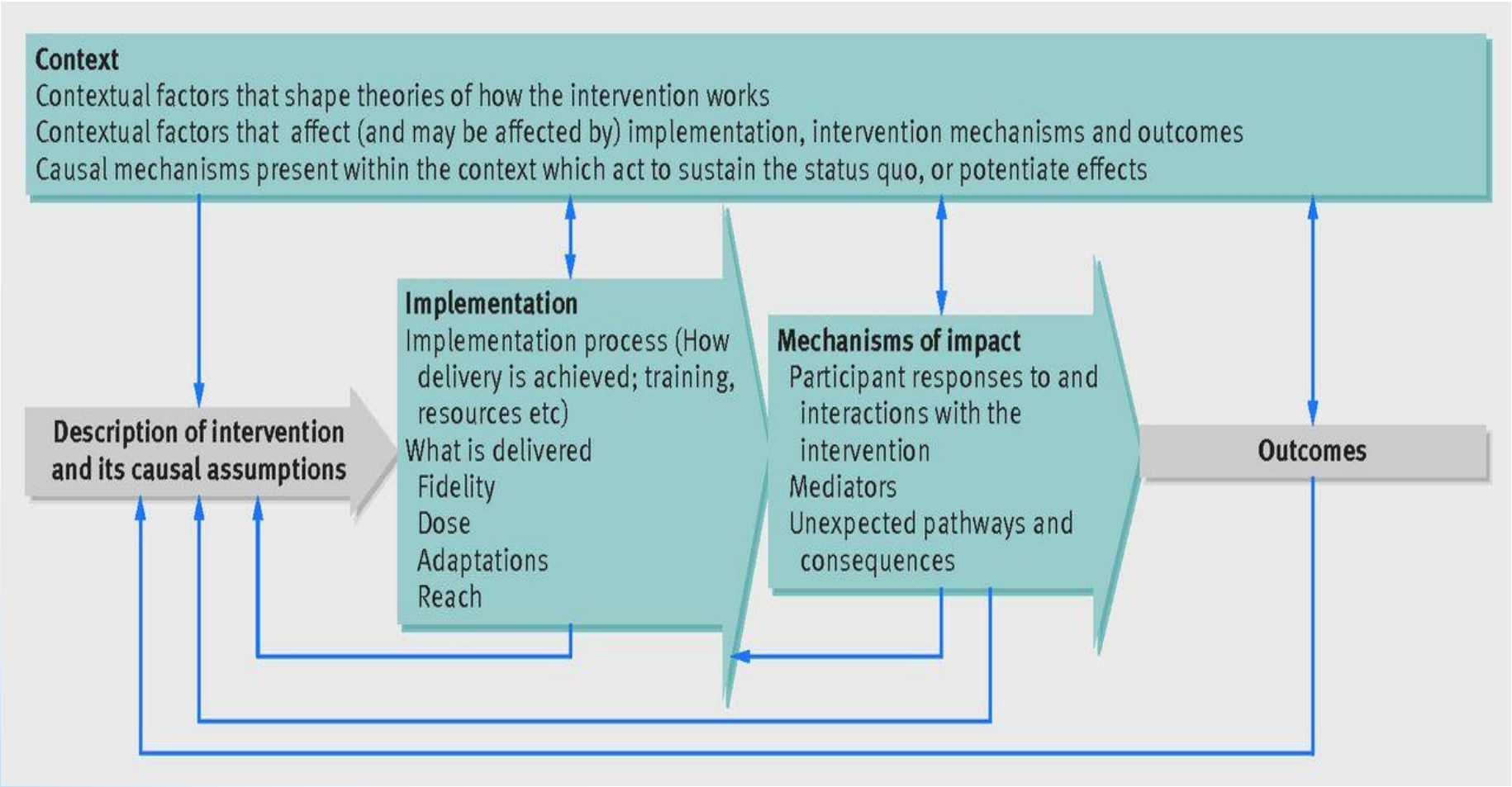
MRC Guidance: Developing and evaluating complex interventions

"It is important to begin thinking about implementation at an early stage in developing an intervention"

Figure 1 Key elements of the development and evaluation process



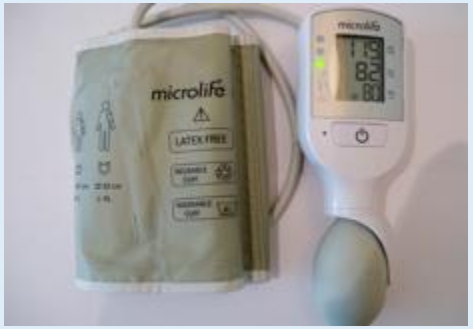
Key functions of process evaluation and relations among them (blue boxes are the key components of a process evaluation.

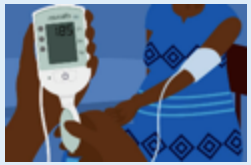


Graham F Moore et al. BMJ 2015;350:bmj.h1258

Lessons learnt during the implementation of a novel vital sign device and training package across three low-resource settings: a mixed method feasibility study for the CRADLE 3 trial

Intervention

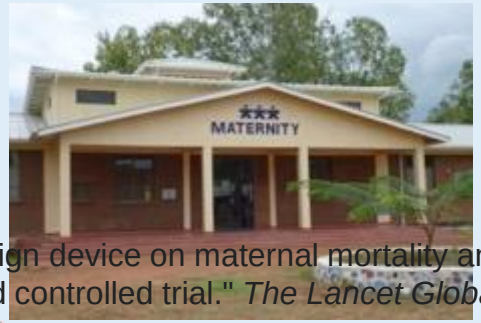




Community

Clinics

Hospitals



Implementation strategies

- Engage local opinion leaders
- Educational sessions with interactive training package
- Standardised key content but delivery adapted to local context
- Identification of CRADLE Champions in each site
- Ongoing facilitation and technical assistance to champions and HCP by implementation team

Vousden, Nicola, et al. "Effect of a novel vital sign device on maternal mortality and morbidity in low-resource settings: a pragmatic, stepped-wedge, cluster-randomised controlled trial." *The Lancet Global Health* 7.3 (2019): e347-e356.

Implementation process evaluation aim

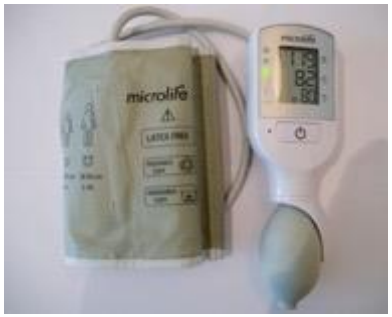
1. To describe implementation and local context in the trial through mixed-method evaluation

2. Integrate implementation outcomes with effectiveness outcomes to determine whether differences in the effect of the intervention between sites could be explained

Vousden, Nicola, et al. "Exploring the effect of implementation and context on a stepped-wedge randomised controlled trial of a vital sign triage device in routine maternity care in low-resource settings." *Implementation Science* 14.1 (2019): 38.

Implementation Outcomes

Intervention



Implementation

- Was the intervention delivered as planned?
- What is the reach?
- How much is delivered?
- Was it adapted?
- Can it be maintained?

Impact

- What impact did it have?
- What are the mediators?
- Were there unexpected pathways?
- How acceptable was the intervention?

Outcomes

- Maternal Death
- Hysterectomy
- Eclampsia
- Secondary Outcomes

Context

Methods - Measures

Context

Measure	Data Collection
Availability of MgSO4, blood transfusion and ICU beds	Facilities surveyed at trial start and minimum three subsequent points.
Maternity staff per 1000 deliveries	Facilities surveyed at trial start and minimum three subsequent points.
Proportion of deliveries by caesarean section	Monthly reporting by facilities
External environmental or political influences	Monthly review with international research team

Measure	Data Collection
Geographical spread of site	Mean distance (km) from peripheral to tertiary facilities measured at trial start
Physical and cultural environment around measurement of vital signs, management of pregnancy complications, escalation of care and referral systems.	Semi-structured interviews and focus group discussions; 3 months after implementation and focus group discussions; 6 to 9 months after implementation.

Implementation Fidelity

Measure	Data Collection
Number of days implementation	Structured observation of implementation
***Proportion of HCP trained (Doctors, nurses, midwives, clinical officers, community HCP)**	Training registers compared to staff working in maternity
***Proportion of core components delivered in central training**	Structured observation of implementation
Adaptations to the intervention	Structured observation of implementation

Reach

Measure	Data Collection
Proportion of maternity visits with BP documented	Four-week sample immediately prior to and three months after implementation
***Proportion of facilities with access to working BP device**	Review pre- and post-implementation
***Change in availability of BP devices per maternity staff**	Review pre- and post-implementation
Review of VSA use and reach	Semi-structured interviews and focus group discussions, 3 months after implementation

Adoption

Measure	Data Collection
Engagement and uptake of VSA	Semi-structured interviews; 3 months after implementation, focus group discussions; 6 to 9 months after implementation.
***Proportion of clinical areas using the CRADLE VSA**	Review up to 6- and 12-months post implementation

Results - Fidelity

- 2747 health care providers were trained
- 61.1% of maternity workforce (range 16.5% in Kampala, Uganda to 89.2% in Zomba, Malawi)
- Key content delivered in 9/10 sites
- Majority of participants reported training adequate and champion training acceptable



Results - Adoption

- Rapid use of the device on all pregnant women
- 73.1% of clinical areas were using solely the CRADLE VSA device at 6 months (range 33.3% in Addis Ababa, Ethiopia to 90.2% in Ndola, Zambia).

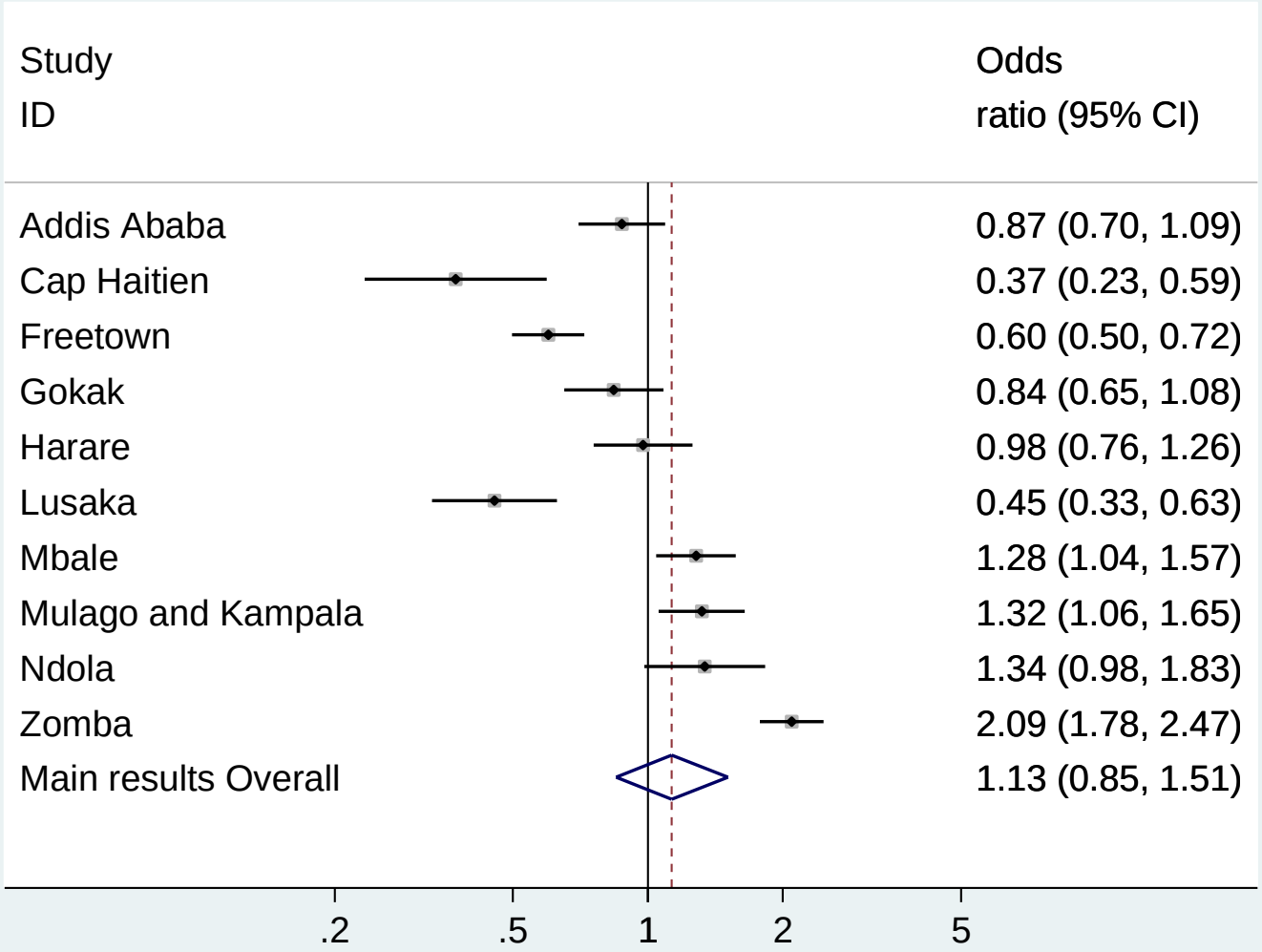
- Barriers to adoption: sensitivity of the VSA to movement, leading to mistrust of the accuracy of results.
- Reported more frequently in sites with low fidelity.
- Active support from the champions or research team resolved this

Results - Reach

- 3868 Cradle VSA delivered across 286 facilities
- Significant increase in women receiving BP measurements after the intervention (79.2% (*n* = 6093/7693) vs. 97.6% (*n* = 7800/7992); OR 1.30, 95% CI 1.29–1.31)
- Better availability of BP equipment in all clusters.
- Availability and ease of use, meant that more vital signs measurements could be done and faster
- Students, junior staff and volunteers took more vital signs measurements due to greater confidence

Medical Officer, India: "Earlier, because of overload of work our *nurses were not checking the BP. Now, after introduction of this machine …they are happy with what they are doing. And they are doing more checks than they were doing earlier.

Results – Effectiveness by Site



Conclusion

- Hybrid effectiveness type 2 implementation study to integrate results with effectiveness outcome with aim of understanding differences in multiple low-resource sites.
- Evaluation of process measures alongside large-scale pragmatic trial is feasible and useful
- Choice of pragmatic process measures suitable for LMIC
- Challenging to describe context and mechanisms in multiple sites in a pragmatic trial
- Insufficient guidance for this methodology

Aligning research with need and ensuring quality

Is there a clear description of what is being implemented (e.g. details of the practice, programme, or policy)?

Does the research involve an implementation strategy? If so, is it described and examined appropriately?

Is the research conducted in a real-world setting? If so, are these conditions described in sufficient detail?

- Does the research appropriately consider implementation outcome variables?
- Does the research appropriately consider context and other factors that influence implementation?
- Does the research appropriately consider secular changes over time, and the level of complexity of the system?
- Does the research clearly identify the target audience for the research and how it can be used?

Acknowledgements

CRADLE team:
Chief Investigator: Andrew Shennan
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