





Methods for designing and evaluating complex interventions in health services in low-resource settings: options for bringing together lessons learned from ACT Consortium studies

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Answering key questions on malaria drug delivery

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Outline

1. The need for guidance for complex interventions in health services in low resource settings
2. ACT Consortium trials and their approaches
3. Examples of methodological lessons learned

Feedback and suggestions welcome!

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What is a complex intervention?

Box 1 | What makes an intervention complex?

- Number of interacting components within the experimental and control interventions
- Number and difficulty of behaviours required by those delivering or receiving the intervention
- Number of groups or organisational levels targeted by the intervention
- Number and variability of outcomes
- Degree of flexibility or tailoring of the intervention permitted

Key issues for us:

- Intervention is complex
- Introduction of a technology ≠ simple
- Intervention is a package = complex

Setting is complex

- Health services environment
- Low-resource countries

Programme orientation

- requirements for assessment of effectiveness with low level of control, but for generalisable results

Peter Craig, Paul Driessens, Sally MacIntyre, Susan Maithe, Irwin Nazareth, Mark Petterson
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Need for more complex interventions guidance?

Expertise in the design and evaluation of complex interventions exists


But foci are often patient practices and developed countries

We argue that complexity is magnified in a health services setting, and in low-resource countries



Developing and evaluating complex interventions:
new guidance

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Complexity of working in health services

Interventions to change health provider practices face new challenges


- Theories of change from patient-oriented studies may not be relevant
- Policy changes affecting implementation environment
- Level of control is hard to define: contextual factors may interact with interventions, and may be a target of change

Proof of principle Effectiveness

More control but less realistic Less control but more realistic

- Evaluation of this complexity can interact with the intended intervention

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Complexity of low-resource settings


Health services trials complexity is exaggerated when resources are scarce:

- Factors such as stockouts, few staff, provide a difficult context to design interventions to change 'one' aspect of services
- Replicability/sustainability of interventions needs to be considered in light of unstable funding
- Trial complexity is enhanced when both study populations and trial staff are low on resources and on skill-sets
- Level of previous exposure to research may affect participation and interact with study outcomes

We found that existing guidance for intervention/trial design and implementation didn't extend to health services in low resource settings

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ACT Consortium – what we do



Access: potential strategies for ACT delivery

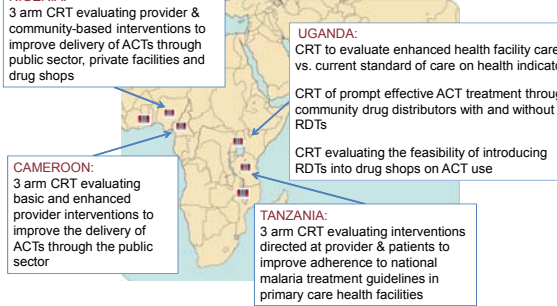
Targeting: under what circumstances rapid diagnostic tests may be effective and cost-effective for directing treatment?

Safety: collecting and collating data on antimalarial adverse events including safety among those co-infected with HIV

Drug Quality: methods of testing for fake & substandard drugs and methods of sampling ACTs to increase chances of detection

16 main projects in 9 countries around 4 research themes

ACT Consortium – project examples



NIGERIA: 3 arm CRT evaluating provider & community-based interventions to improve delivery of ACTs through public sector, private facilities and drug shops

UGANDA: CRT to evaluate enhanced health facility care vs. current standard of care on health indicators

CRT of prompt effective ACT treatment through community drug distributors with and without RDts

CRT evaluating the feasibility of introducing RDts into drug shops on ACT use

CAMEROON: 3 arm CRT evaluating basic and enhanced provider interventions to improve the delivery of ACTs through the public sector

TANZANIA: 3 arm CRT evaluating interventions directed at provider & patients to improve adherence to national malaria treatment guidelines in primary care health facilities

ACT Consortium – trials & approaches

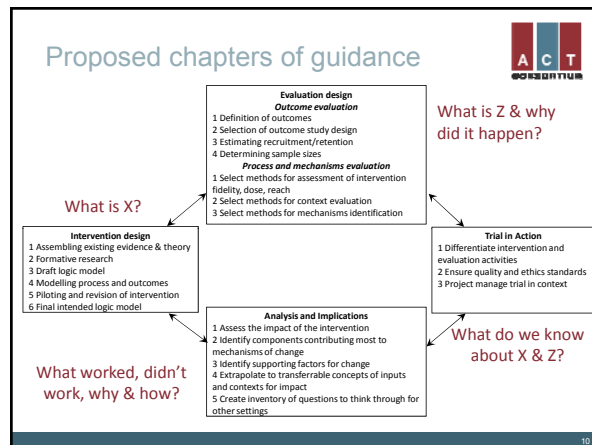
RCTs are widely accepted as the 'gold standard' experimental design to evaluate treatment effect

Recognition of complexity of the delivery and mechanisms involved in interventions intended to change health-related behaviour

The MRC's guidance is valuable for framing a process for the development, piloting, evaluation and implementation of complex interventions

NICE guidance on behaviour change that can be used for planning, delivering and evaluating public health activities aimed at changing health-related behaviours


What Impact did X Intervention have on Z, Why, and Will it Work Elsewhere?



Lessons learned: intervention design

1. Next time, the protocol should include methods, time and expertise for:
 - Formative research AND analysis of qualitative data for intervention ideas

There is little guidance on how to move from a local situation analysis and traditional qualitative research to being creative in methods and messages. We held workshops – field teams were very helpful in identifying what was needed and what might work (or not) and it was important to link findings with those from reviews of evidence and theory



Lessons learned: intervention design

2. Next time, the protocol should explicitly include methods, time and expertise for:
 - Reviewing existing evidence AND theory

Many areas to review. Identification of areas based on formative research findings

e.g. To improve quality of health care Review of empirical evidence

 - Resource-based interventions
 - Knowledge-based interventions
 - Communication-based interventions
 - Supervision interventions
 - Management-based interventions
 - Patient-centred interventions

Review of behaviour change theory

 - Trans-theoretical model
 - Social Cognitive Theory
 - Communities of Practice etc.

Review of methods for training

 - Training facilitation methods
 - Material design methods
 - Training of Trainer methods

Challenges include relating findings to this to low-resource setting

Lessons learned: intervention design



3. Next time, the protocol should explicitly include methods, time and expertise for:

- **Drafting, piloting AND finalising intervention manuals**

Attempting to make intervention materials, e.g. training manuals, evidence-based required close attention to phrasing, terminology, picture development.



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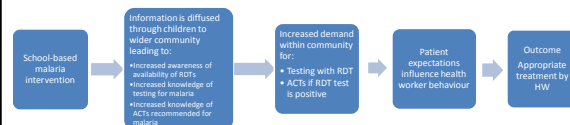
Lessons learned: evaluation design



1. Next time, I would allow more time for understanding the change process (logic model) and defining outcomes

Outcomes have generally been defined based on key indicators but we need to think through the change process and detailing what outcomes are expected on different distal and proximal levels, for example health outcomes, service delivery outcomes and cost-effectiveness outcomes.

Capacity to measure such outcomes



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Lessons learned: evaluation design



2. Next time, I would allow more time for thinking through how the study findings are to be used

How the study findings are to be used influences the key questions of interest and hence the study design, sample size calculations and analysis.

Sample size considerations: Superiority
Non-inferiority
Equivalence

Non-inferiority trials generally require a larger sample size which may have implications for low-resource settings but may be more informative for policy

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Lessons learned: evaluation design



3. Next time, I would allow more time for incorporating monitoring and documentation of the context, process and outcome evaluations

Focus on data collection for primary and secondary outcomes

More formalised approach to documenting information on:

- How the intervention was delivered
- Recruitment process
- Sources of contamination
- Sources of bias

Consideration to the quality of the documentation

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Considerations in analysis



(How) can we answer the question of What Impact Did X Intervention Have, and Why?

- IMPACT, WHY

Methods for integrating qualitative and quantitative data - integration of context, process and outcome data

How to indicate what worked /didn't work (distinguish between components of the intervention) and the implications of this for scale-up and/or applicability elsewhere

Different clusters, different contexts; different individual responses

- Will it work ELSEWHERE?

Generalisability – extraction of generalisable components for use elsewhere

Modelling - future versions of the intervention

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Moving forward



ACT Consortium has a working group to pull together our lessons learned from across sites, planning to:

- Create a **guidance document** targeted at other researchers carrying out implementation research in complex health services in low resource settings
- Publish a **series of manuscripts** targeted at different phases of such studies, exploring challenges and drawing on lessons learned

We are keen to hear inputs from you:

- Will these outputs be useful to you/other research areas?
- Would you like to collaborate?
- Any other ideas for how we can enter dialogue with others facing similar challenges?

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