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Examining intervention design: lessons from the development of eight related malaria health care intervention studies

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Abstract

Rigorous evidence of 'what works' to improve health care is in demand, but methods for the development of interventions have not been scrutinised in the same ways as methods for evaluation. This paper presents and examines intervention development processes of eight malaria health care interventions in East and West Africa. A case study approach was used to draw out experiences and insights from multidisciplinary teams who undertook to design and evaluate these studies. All found the intervention development process took more time and resources than planned. Four steps appeared necessary: (1) definition of scope, with reference to evaluation possibilities; (2) research to inform design, including evidence and theory reviews and empirical formative research; (3) intervention design, including consideration and selection of approaches and development of activities and materials; (4) refining and finalising the intervention, incorporating piloting and pretesting. Alongside these steps, projects produced theories, explicitly or implicitly, about (i) intended pathways of change and (ii) how their intervention would be implemented.

The work required to design interventions should not be underestimated. Furthermore, the process should be recognised not only as technical, but the result of micro and macro social, political and economic contexts, which should be acknowledged and documented in order to infer generalisability. Reporting of interventions should therefore go beyond descriptions of final components or techniques, to encompass the development process. This transparency will improve the quality of evidence available to decision makers for adopting particular interventions in different contexts as well as for those designing future interventions.

Running title: Intervention design: lessons from 8 malaria studies

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Introduction

In recent decades, demand for evidence of ‘what works’ in health care policy and practice has increased. This has led to intensified efforts to advance and standardise methodologies for the generation of evidence relating to health interventions.¹⁻⁴ Interventions that aim to improve health care have been classified as ‘complex’, reflecting their composition of multiple, often interacting components within dynamic and multifaceted systems.^{5, 6} Significant investment has been made into methodological developments for evaluating such interventions.^{3, 4, 7-10} However, less attention has been paid to the way such interventions are designed and reflecting on how this design process works in practice.

The ACT Consortium joined together 45 leading malaria researchers from 26 institutions around the world who were concerned about increasing access to new first-line Artemisinin Combination Therapy (ACT) antimalarial drugs, targeting the use of ACTs to those with malaria infection, the safety of ACTs when used routinely and the quality of ACTs accessed by malaria-affected communities (www.actconsortium.org). Research had shown that improvement in malaria case management was not amenable to simple interventions and strategies would be required that worked with different components of the health system, including formal public health care facilities, private drug retailers and community health workers.¹¹ In particular, the overdiagnosis of malaria was known to be a deeply embedded social practice that persisted despite WHO policy supporting test-based treatment¹² and availability of rapid diagnostic tests (RDTs).¹³ Interventions would need to go beyond the behaviour of individuals, to shifting social expectations and changing structures, attending to health care as a construct of dynamic social, political and economic processes.

The Medical Research Council's (MRC) guidance on developing and evaluating complex interventions⁴ recommends building on existing evaluations of behavioural interventions to design complex health interventions. However, literature on existing interventions is difficult to learn from and apply to other settings. Even when interventions and their constituent components are clearly described, the processes undertaken and people, agendas and disciplines that have influenced the design of complex health care improvement interventions are often not made explicit, neither internally within the design process nor to external audiences in reporting.¹⁴ This reduces ability to interpret how findings of intervention effects could be inferred from one setting to another, or to a scale-up scenario.

Tools and protocols have been developed in the health promotion field to aid intervention development.^{15, 16} However, the focus of these has been on individual health-related behaviours that may be amenable to psychological or environmental change factors. There is limited guidance on how to develop interventions that attend to the social nature of health care. This paper aims to discuss the process and challenges faced by evaluation projects developing interventions to improve health care for malaria, as an example of a systematic attempt to tackle multiple facets of a problem simultaneously.

We designed eight interventions to improve malaria care in five African countries. The interventions were to be rigorously evaluated, mostly through cluster randomised trials (Table 1). All but one intervention (the Nigerian study) had a measurably positive impact in

one or more outcome. Reflecting calls for multidisciplinary teams for such endeavours,¹⁷ project teams consisted of clinicians, public health practitioners, economists, anthropologists, epidemiologists and statisticians. In this paper, we summarise the intervention design methods and describe challenges faced and lessons learned about the process of health care improvement intervention design from across our projects. We have described lessons learned around evaluation methods elsewhere.¹⁸ The projects had similar aims and overall approaches to intervention design but varied in the detail of objectives, policy related intentions, team knowledge bases and expertise, and budgets allocated to the design process. These similarities and differences enabled us to draw out lessons for intervention design across projects.

Materials & Methods

Intervention design steps and lessons learned were developed through a multiple case study approach,¹⁹ with each of our eight intervention projects representing a case. This included all intervention studies undertaken by the ACT Consortium. Initially, an external researcher (LB) undertook reviews of project documents and phone or face-to-face interviews with investigators to learn their perspectives of the most important elements in the design of their interventions and lessons learned in the processes they had undertaken. All study investigators were invited to participate or to nominate relevant team members, and interviews followed a loose topic guide. Additional insights were brought together through a series of face-to-face and email discussions with a team of core scientists who worked across the ACT Consortium projects to support intervention and evaluation designs. A first summary of steps and lessons learned that emerged in common across projects was

produced for review by study teams. Each study team then provided further reflections and insights, forming reflexive accounts of their research processes that could enable learning for others.²⁰ The experiences of our study teams were reviewed together with existing literature on intervention development to characterize a series of key steps and challenges experienced that resonated across studies and were poorly addressed in the literature. This formed an iterative analytical process which continued through the process of writing.²¹ Throughout, we provide empirical examples from our work in the text, 'boxes' and additional files.

Results & Discussion

Each of our projects aimed to produce an evidence-based intervention package tailored for a particular context. Seven were to be delivered and evaluated through cluster randomised trials, one through routine implementation (Table 1). The starting point for our interventions was technical – typically provision of commodities (ACTs and/or RDTs) and some form of training to support a change in practice. The intervention design processes were to yield details of these technical interventions and their delivery into local contexts. Four broad steps in this process were identified from across our projects (Figure 1):

1. Definition of scope
2. Research to inform intervention design
3. Design of the intervention
4. Refining and finalising the intervention

Alongside these activities, projects either explicitly or implicitly developed two sets of theory: programme theory (or a logic model), which depicted the intended pathway for

change from the intervention to study outcomes; and implementation theory, which depicted the intended vehicle for change, consisting of the 'nuts and bolts' of the intervention itself. Each of these sets of theory attended specifically to the local social, political and economic contexts where the interventions would be tested and potentially scaled-up.

In all projects, the time and resources spent in designing interventions exceeded expectations. From the start of formative research to being ready for implementation, the overall process of intervention design took between 6 months and 2 years, requiring project durations to be extended by at least 20%. Projects' expenditure on this phase of work ranged between 10-25% of the overall budget. The variation in investment related to the starting point and goals of each project but also the relative investment compared with evaluations, which in some cases were large-scale and costly. The knock-on effects of unexpected investment required in this phase of work included narrowing of scope of both the intervention and evaluation activities. The highest costs for projects were household surveys used in formative research and the professional development of intervention materials. It was not always possible to predict the length of time intervention design would take, particularly when responding to unexpected local priorities, which made interventions more relevant but less easy to budget time and resources for.

Step 1. Definition of scope

As is often the case, the target 'problem' to be tackled by the ACT Consortium projects had been established prior to the intervention design phase and particular components of the intervention, as well as the study design, had already been proposed as part of securing

research funding. On initiation of funding, decisions were required to define the scale and potential scope of interventions. We found that three key areas needed consideration in defining the scope for interventions: the intended audience for results, the level of control required for the evaluation and intervention and what is possible for evaluation designs.

Consideration of the intended audience for results

ACT Consortium studies aimed to assist health policy makers at the global level and/or programme managers at national and district levels to decide how to maximise health investments in relation to ACTs and RDTs. Keeping this aim and audience in mind was important in articulating the key criteria around which to design our interventions, which included feasibility, replicability, scalability and cost effectiveness. In each study, the intervention design process involved local and/or national stakeholders, who helped define intervention scope. We recognised that our interventions needed to be acceptable to different actors who had power to support the interventions in the future: from those in a position to fund and promote interventions, such as Ministers of Health, to those expected to take up the intervention in their daily practice, such as clinicians. The interventions therefore needed to fit with politically acceptable framings of the ‘target’ problem and potential solutions.²² See table 2 for an example of how this was negotiated with stakeholders in Cameroon.

Consideration of level of control

Unlike in drug trials, which have established phases with different levels of control over the intervention in each, it is often not clear whether health care improvement evaluations are attempting to establish efficacy, effectiveness or both.¹ Our involvement in both the intervention and evaluation designs of our projects meant active decision making around

trade-offs between evaluating pre-defined interventions or interventions-in-action. Consciously defining the level of standardisation for interventions and their constituents therefore emerged as important early on in the studies. Because of the different contexts of our studies, and different gaps in evidence, our studies fell at different points along a spectrum from efficacy to effectiveness²³, which affected intervention design and scope (See table 2 for an example from two community based studies in Uganda). On the whole, we required that interventions would be standardised to some degree, but allowed for varying levels of flexibility in the content of interventions as delivered by implementers. This enabled some adaptation of content to different local contexts, such as different health facilities, provider types or schools, as has been described elsewhere.^{6, 24} In most projects, rather than ensure that all members of the target population had the same experience of the intervention, we opted to encourage adaption and evaluate through process evaluations the fidelity, reach, dose delivered and dose received of intervention components such as training.^{25, 26}

Engagement with evaluation options

Unlike situations where evaluations are undertaken by researchers external to the intervention, which are intended to be more objective but can suffer from post-hoc interpretations of intervention intentions and procedures,²⁷ our interventions were designed with evaluation options in mind. Our remit, driven by a desire for transferability and scalability, was to identify minimal essential interventions that could stimulate change and be scaled-up in low resource settings. This essentialist agenda fitted well with the experimental paradigm in which randomised controlled trials (RCTs) are a gold standard. Seven of our studies had already planned RCTs to evaluate their interventions, with ancillary

anthropological and economic studies. The use of RCTs affected the potential scope of their interventions. For example, although large-scale interventions have been hypothesised to be effective in changing behaviour,^{28, 29} such interventions would be difficult to evaluate with RCTs due to logistical and budgetary constraints.⁵ Similarly, multi-faceted interventions have been recommended to promote behaviour change,^{30, 31} but because RCTs typically allow for a small number of comparison study arms, a trade-off emerged between potentially more effective multi-component interventions and our ability to evaluate 'what worked' with an RCT. Some trials compared existing practice with 'simple' interventions such as RDTs plus instructions, others tested 'enhanced' intervention packages, such as a series of peer-group workshops. However, the more enhanced interventions that responded to the complex needs of local situations consisted of multiple and interacting components (material, human, theoretical, social or procedural³²), requiring more complex evaluations to attempt to unpick their relative effects. Some projects employed cluster designs³³ due to predicted benefits of group level intervention, and some employed additional evaluation activities to understand the process and mechanisms of change.²⁶ For interventions with a long intended mechanism of effect, these additional evaluation activities became especially important in understanding intervention impact.³⁴

Step 2. Research to inform intervention design

Once the overall goal and broad scope for each intervention were defined, teams were faced with numerous options for the detailed design of interventions. Three domains for research have been recommended for guiding the detail of intervention design,¹⁵ with different emphases from different disciplines: evidence review (most strongly recommended in medicine⁴), incorporation of theory (most strongly recommended in

health psychology³⁵) and formative research (most strongly recommended in anthropology³⁶). All of our projects undertook research in each of these domains, often concurrently, although the lack of clear evidence or theory to guide our interventions, which required engagement with local social constructions of health care, meant our greatest investment was in empirical formative research.

Evidence review

Systematic reviews are advocated for use in complex intervention design, to bring together all evidence of the effectiveness of interventions for a particular outcome.⁴ We faced three major challenges in following this recommendation. First, there were few systematic reviews available related to interventions to improve antimalarial prescribing practice or use of malaria diagnostics. Second, undertaking such reviews ourselves would be methodologically challenging and time-consuming given the number of potential interventions that could be considered to change health care practices, especially if attempting to account for heterogeneity between interventions lumped together and offering mixed results (such as ‘supervision’³⁷ or ‘training’³⁸) that could benefit from being split according to materials, people, theory and procedures.³⁹ Third, the quality of reporting of intervention components was found to be poor, as well as the quality of evaluations, as others have described.^{9, 40} These challenges point to the importance of having readily available systematic reviews of complex interventions and their component parts in the evidence base. In lieu of this, some of our teams undertook scoping reviews ‘to map rapidly the key concepts underpinning a research area and the main sources and types of evidence available.’⁴¹ See Table 2 for an example from a health centre improvement study in Uganda.

These reviews were neither systematic nor comprehensive, but were sufficient to achieve the following:

1. Recognition of the breadth of interventions that have been implemented and evaluated to change a particular practice
2. A sense of the potential effectiveness of particular intervention types in given contexts
3. Specific intervention ideas and components that could be successful in our proposed intervention contexts.

Incorporation of theory

It has been argued that interventions with strong theoretical underpinnings can lead to stronger effects, more refined theories for understanding behaviour change, more replicable interventions and more generalizable results.^{9, 14, 35} However, we could not identify clear guidance for incorporating theory into intervention design beyond the inclusion of individually oriented behaviour change ‘theoretical methods’ from health psychology.^{15, 42} On initiating our attempts to incorporate theory, we entered what appeared as a minefield of competing and conflicting ideas and definitions, whose presentation under the same term, ‘theory’, makes decision making for would-be-designers challenging. Additional difficulty in navigating this field comes with the contradictions and debates between different political perspectives – for example, do cognitive theories and resulting interventions shift responsibility for healthy behaviour to individuals, ignoring broader, structural factors influencing behaviour?⁴³ Some researchers have questioned

whether theories used in complex health interventions to date have offered much beyond 'common sense.'⁴⁴

Our endeavours to incorporate behaviour change theories into our intervention designs involved attempting to uncover the theoretical basis of interventions identified as successful through empirical literature reviews (described above). This required some familiarity with different theoretical perspectives commonly used (a useful summary of the evolution of clinician behaviour change approaches can be found in Mann⁴⁵), because most often the theory, model or hypothesis for a programme was not clearly reported. It also involved building on theoretical understandings and implications of formative research (described below). For example, we found Communities of Practice theory⁴⁶ to be a useful framing for several of our intervention designs, highlighting different ways that clinicians may learn and change their practice in groups, given our prescribing contexts where colleague relationships appeared important. We felt that our reviews of the theories behind interventions and incorporation of this into our intervention designs achieved the following:

1. Recognition of the breadth and strength of different approaches that have been applied to behaviour change regarding target problems or behaviours of interest;
2. Identification of specific theories that may be successfully adopted to inform the approach to interventions within the proposed parameters;
3. Familiarity with the use of frameworks to conceptualise the way an intervention is proposed to achieve an effect, to inform project logic models that explicitly outline intended mechanisms of change (as described below).

Formative research

Formative research has been advocated to enable optimal intervention design by understanding the scale of and reasons for the target ‘problem’ in the particular context where the intervention will take place.^{36, 47} Most of our ACT Consortium projects undertook qualitative and quantitative research prior to intervention design, to understand the extent and nature of current practices, including perceptions and enactment of care and treatment seeking, as well as local histories of previous and existing interventions. We had anticipated formative research phases for our ACT Consortium projects to last between 3 and 9 months, but this phase ended up requiring significantly more time and human resources for the fieldwork and analysis. This initial investment was considered valuable because the target behaviour of antimalarial prescribing was known to be difficult to change.^{48, 49} However, in future studies we would hope this period could be condensed. One reason our formative research took a long time from conception to informing intervention design may have been our focus on current behaviour as the ‘problem’. This approach emphasises identification of ‘barriers’ to desired practices, such as physical, economic, cognitive, social or policy ‘factors’, with the assumption that release of such barriers through an intervention would lead to the emergence of desired behaviour.⁵⁰ Important challenges arose for our intervention designs based on this approach (see Table 2).

Our experiences suggest areas of our formative research that were more informative for intervention design, and which might be most productive in future studies. First, the areas of formative research that focused on eliciting stories of past ‘success’ were particularly useful. The qualitative research in some of our projects borrowed from the perspective of appreciative inquiry, which proposes that solutions already exist in organisations, and

analysis of these can allow interventions to amplify ‘what works’ in that context (illustrated in Table 2).⁵¹ Second, understanding the landscape in which practices were embedded helped with understanding the motivations and priorities of the targets of interventions, and to align intervention messages and modes of delivery with these.

Programme theory development

The decisions that emerged from Steps 1 and 2 above fed into explicit or implicit programme theories of our interventions:⁵² the way the intervention was intended to achieve particular outcomes. This has also been described as the intended mechanism of change⁵³ or change theory.⁵⁴ These descriptions of the intended *journey* on which the target of an intervention is hoped to travel can usefully be distinguished from the *vehicle* in which the journey is intended to be taken. The latter has been variously referred to as implementation theory,⁵² an action model⁵⁴ and process theory,⁵⁵ and reflects the ‘nuts and bolts’ of the intervention, discussed after Step 3 (design of the intervention) below. Typically, these theories are developed post-hoc, in relation to evaluation design.⁵⁶ We found it useful to articulate our assumptions and rationales for interventions during intervention design.

A useful method to depict programme theory was logic modelling. Logic models describe the presumed causal linkages from project start to goal attainment.⁵⁷ Building on the work of others,^{58, 59} several of our Consortium projects developed logic models containing some or all of the components listed in Table 3. Additional File 1 provides an example of a logic model from one project.

Our experiences of developing a logic model during intervention design suggest key benefits are:

1. To assist with the choice of intervention by articulating presumed hypotheses linking intervention options to intended outcomes;
2. To ensure that the intervention has internal consistency; that a mechanism of effect is predicted for each intervention component, that supporting components are accounted for in the model and therefore also in the evaluation activities and that there are no important gaps or additional activities that are not justified within the model;
3. To act as a visual aid to communication, enabling the team and wider stakeholders to reach a common and consistent understanding of the components of the intervention;
4. To guide data collection for the intervention evaluation by showing where, when and what information needs to be documented or collected.

Of note, our logic models rarely remained static. They became dynamic tools, being adapted and in turn adapting the design of both intervention and evaluation activities. Crucially, these logic models were developed, and assumptions articulated, with close attention to the specific contexts in which the interventions would take place, particularly the social, political and economic contexts. Although we did not state the findings of formative research explicitly in our logic models, this was implicit in our processes of considering context and mechanisms of effect, and could be included explicitly in future work.

Step 3. Design of the intervention

Once research was completed to inform design options, we attempted to take an evidence based approach to developing the detail of intervention components and materials. In most ACT Consortium projects, two activities were undertaken: workshops to review research undertaken so far and to select which specific interventions would be implemented; and detailed development of intervention content, activities and materials.

Intervention selection

We found small-scale workshops to be a useful format to bring together findings from steps 1 and 2 with input from across the research team to consider potential interventions and their feasibility and potential effectiveness. Inviting stakeholders to the workshops, or to individual follow-up meetings, was useful in ensuring the interventions fitted with priorities and other previous or current interventions, and ensured that policy makers and those who would be responsible for scaling up interventions felt the interventions were relevant to their concerns. We adapted recommendations of other researchers⁶⁰ to structure these workshops, which had a similar format across the projects. Broadly, these included a discussion and agreement of criteria for the intervention design (e.g. effective, feasible, replicable, sustainable), informed by both the parameters considered in step 1 as well as the values and priorities of stakeholders attending the meeting. The workshops were an opportunity to present and discuss reviews and formative research undertaken by different members of the research team. Following this, a collaborative effort by the researchers, stakeholders and field teams led to a long-list of potential interventions which was refined to a short-list that fitted the criteria set out at the start (see Additional File 2 for an example structure of our intervention design workshops).

A key challenge to note at this stage was the bringing together of disparate evidence from theory, literature and empirical research. In some cases, we had to negotiate conflicts between these different sources or between members of study teams from different disciplinary backgrounds. For example, preferences over one or other model of behaviour change could conflict and were not easy to resolve in a context where evidence was weak. In these cases, the resulting intervention component or mode of delivery represents a compromise across different disciplinary and individual preferences.

Development of content, activities and materials

ACT Consortium projects found that designing the detail of intervention materials took considerable time and resources. Activities and materials used in interventions included facilitated group learning, self-reflection tasks, participatory dramas, peer education, supervisory visits, tools for referral of patients or requisition of supplies and distribution of posters and leaflets. Each required project teams to return to literature, to the field or to seek external expertise to identify evidence, best practice and user perspectives on the implementation of activities. For several projects that used workshops to facilitate change, a six-step learning process was developed, based on literature of theory and best practice in adult learning (see Additional File 3).

Investment in the additional work in developing materials at this stage was considered valuable for the following reasons:

1. To ensure quality of intervention activities and materials and optimise the likelihood of effect;
2. To ensure consistency in intervention delivery in order that components are easily replicable;

3. To enable evaluation of the intended intervention through clear documentation of the activities, materials and procedures to be implemented.

Some ACT Consortium projects attempted a bottom-up approach to the design of some intervention materials, explicitly recognising that target recipients are best placed to identify or refine content, messages, modes of delivery and visual details that are likely to be effective and acceptable to end users.⁶¹⁻⁶³ These projects found participatory research valuable as it enabled them to draft material quickly for further testing and revision in intensive rounds of development (see for example Davies et al.⁶⁴ for a description of the use of participatory research in the pharmacovigilance materials project in Uganda).

To assist with evaluation of interventions and our ability to draw conclusions from results, ACT Consortium projects recognised the need for consistency in the delivery of interventions, from the procedures followed and materials delivered to participants, to detailed manuals for workshop ‘trainers’. Such manuals required careful design of visuals and layout, for example with the use of summary boxes and icons to assist the reader to follow activities during and after the workshop (see Additional File 4: Developing visual aids for learner and trainer workshop manuals, Uganda).

Implementation theory

Step 3 gave rise to our theories and protocols for how the interventions should be delivered, which is sometimes known as ‘implementation theory.’ This was most commonly articulated through process objectives that encompassed both content, for example perceptions that specific workshop objectives were relevant and achieved, and procedures, for example participant attendance at workshops or receipt of specific supplies at a particular time.

These were depicted in manuals, protocols and standard operating procedures for trainers, those delivering resources, supervisors, feedback messengers and others engaged in the implementation process. This implementation theory was tested in process evaluations by assessing the fidelity, reach, dose delivered, dose received, effectiveness and context of implementation.²⁵

Step 4. Refining and finalising the intervention

Once intervention activities, materials and protocols were drafted, most of our projects undertook a period of piloting and pre-testing these components in order to evaluate comprehension, acceptability, relevance and to refine final versions. Our project teams noted the importance of investment in this stage, when a gap was revealed between the materials and procedures developed so far and the reality of delivery to and understanding of these by the target audience in practice. From across the ACT Consortium projects, investment in this stage is reported to have led to the following consequences:

1. Optimisation of materials and activities through pretesting to identify and adapt any components that failed to communicate intended messages, were misunderstood or were not deemed relevant to the target audience⁶⁵ (see Additional File 5: Example of pretesting process for TACT leaflet, Tanzania).
2. Ability to adapt procedures for ease and impact of delivery and receipt of the intervention during implementation, for example decisions on grouping of participants to maximise peer interactions, timing and transport for workshops to ensure timely participation with minimised disruption, feasibility of intervention intensity in practice.

3. Opportunity to train delivery staff during pilots, with two-way review of the intervention and delivery practices, which could feed into updated protocols for implementation procedures.
4. Opportunity to involve stakeholders in reviewing and revising the content and implementation of the intervention.
5. Opportunity for evaluation teams to pilot tools to document the implementation of the intervention.

Piloting and pre-testing involved presentation of the draft intervention component, such as a training module or leaflet, with various methods to elicit feedback from the target audience, implementers and/or observers. Methods included structured questionnaires, focus groups and informal discussions. Several rounds of revisions to draft materials were often made, with each new draft tested and the feedback used to improve the subsequent draft, until the quality, suitability and comprehension of the final product was deemed sufficient to implement and evaluate formally.

Conclusions

Intervention design is a crucial, yet often neglected and black-boxed, process in the field of health care research. We believe it is time more attention is paid to how it is done. This paper shares methodological experiences from eight ACT Consortium projects, which designed and evaluated a variety of complex health interventions to improve malaria care in five malaria endemic countries in Africa. This paper highlights that this process is not merely a technical one, but attends to social, political and economic priorities. Our insights and

reflections on these processes of intervention design should alert others to the requirements and realities of such endeavours and encourage greater transparency in articulating these processes. The steps outlined here and in the figure provide a framework with which to view processes of intervention design. Routine articulation of such processes would allow for improved internal validity assessments as well as transferability of interventions and inference of their potential effects to other scenarios.

We have added empirical examples to existing guidance on the evidence-based design of health interventions, which thus far have been limited in terms of detail ⁴ or have mostly focused on individual health behaviour change^{15, 16} rather than changes to health services in social, political and economic contexts. We have described four broad steps identifiable across our projects, which in practice were iterative, feeding both backwards and forwards into the other steps of the intervention design process as well as feeding into the development of theories of the intervention and into evaluation design. In our examples, we have shown some of the methods that we found useful, and some of the limitations to our approaches. Our studies took place in varied contexts and with different levels of control therefore like-for-like comparisons of design processes with outcomes of intervention were not possible. The pre-defined RCT nature of our evaluations constrained the types of interventions undertaken. It is likely that successful but more tightly controlled interventions would need further development, and additional evaluation, in scale-up scenarios where mechanisms of change or dimensions of the problem could be different.

The time taken to design interventions using these methods was invariably longer than expected, required multiple rounds of protocols and ethics approvals and crucially, required

a substantial proportion of overall project budgets. Funders and researchers both need to recognise that health care improvement interventions cannot be taken 'off-the-shelf'; they require substantial investment to develop, and this should be planned for accordingly. Without this investment, funders and researchers risk further well-conducted evaluations that describe the lack of impact of poorly-designed interventions. In situations with limited funding, those designing interventions would benefit greatly from learning about the rationales and processes of the design of other similar interventions, emphasising a need for better reporting.

The dearth of methodological and empirical literature on the process of intervention design unnecessarily lengthened our efforts to design robust interventions. We argue strongly that the process of intervention development should be routinely reported, in the same way as trial protocols are now requested to be published. Criteria for reporting interventions have been proposed,⁶⁶ largely from the health psychology field, and through a lens of interventions as 'behaviour change techniques'.⁶⁷ While such taxonomies are useful to understand what finally constituted an intervention, we propose that the process by which such interventions were arrived at are equally crucial for transferability of findings. Reporting of interventions should go beyond their final constituents, to describe the process of development including reflection of the social, political and economic context that led to that particular intervention package. Such reporting could follow the framework of steps and theory outlined in this paper. Specific sections of journals where intervention designs can be published would support and promote both publication and debate over methods. Unless this happens, the publication of evaluations of interventions whose process of development has not been clearly articulated will continue, with a consequent risk of

replicating mistakes and reinventing wheels that could have been avoided with greater and better quality reporting of the process of intervention design.

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Figures, Tables & boxes

Figure 1. Phases in the development of complex interventions

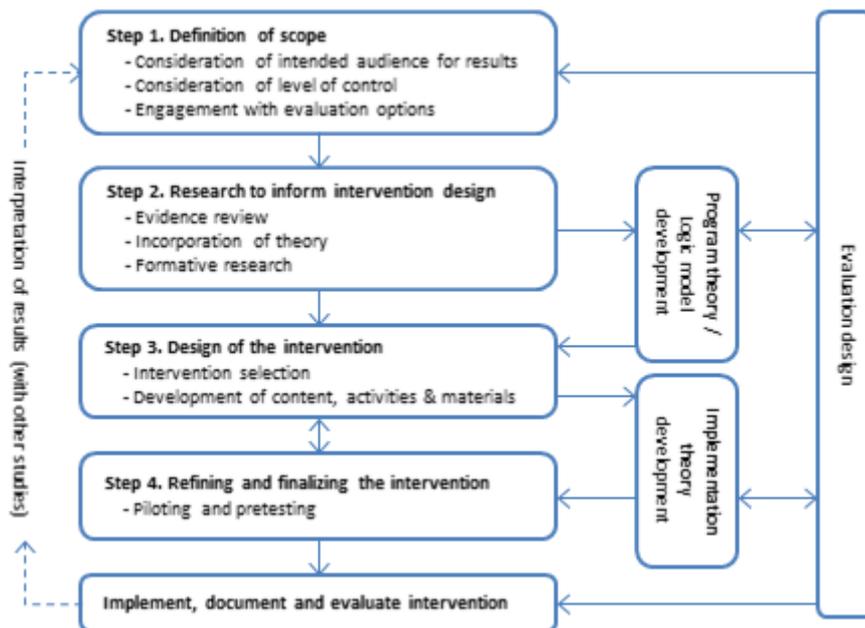


Table 1. Summary of ACT projects and interventions discussed in this article

Study Title ¹	Study Design	Setting and dates of implementation	Intervention	Publications on intervention and trial design, formative research	Publications of intervention effect (including forthcoming)
The PRIME study	2-arm cluster randomised trial	Uganda Public health facilities 2011-2013	Enhanced health facility-based care for malaria and febrile illnesses in children.	22, 68-70	34, 71-73
The REACT project, Cameroon (Research on the Economics of ACTs)	3-arm cluster randomised trial	Cameroon Public and mission health facilities 2010-2011	Basic and enhanced provider interventions to improve malaria diagnosis and appropriate use of ACTs in public and mission health facilities.	74-77	78, 79
The REACT project, Nigeria (Research on the Economics of ACTs)	3-arm cluster randomised trial	Nigeria Public primary health facilities and private medicine retailers 2010-2011	Provider & community interventions to improve malaria diagnosis using RDTs and appropriate use of ACTs in public health facilities and private sector medicine retailers.	80-82	83
The TACT trial (Targeting ACTs)	3-arm cluster-randomised trial	Tanzania Public health facilities 2011-2012	Health worker and patient-oriented interventions to improve uptake of malaria RDTs and adherence to results in primary health facilities.	84	85, 86
ACT Pharmacovigilance project	Participatory research design	Uganda Health facilities and community drug distributors 2010-2012	Development of adverse event reporting forms for use by non-clinical workers to collect data on the effects of ACTs.	64	87
RDTs for home-management of malaria	2-arm cluster randomised trial	Uganda Community drug distributors	Introduction of rapid diagnostic tests (RDTs) for the home-management of		88

RDTs for Drug Shop management of malaria	2-arm cluster randomised trial	2010-2012 Uganda Drug shop vendors	2010-2012 Introduction of RDTs to drug shops to encourage the rational drug use for case management of malaria.	93
Effect of test-based versus presumptive diagnosis in the management of fever in under-5 children	2-arm cluster randomised trial	2010-2012 Ghana Public primary health facilities 2011-2012	Test-based diagnosis of malaria with RDT with restricting ACT to children who test positive ⁹⁴	95, 96

¹ See the ACT Consortium website, www.actconsortium.org, for more information on each of these studies.

Table 2. Examples from case studies of lessons learned for intervention design

<p>Defining scope: consideration of intended audience for results</p>	<p>In the Cameroon REACT project, the initial focus of the intervention, defined in 2008, reflected concerns about appropriate use of first line antimalarial drugs after recent policy changes to ACTs. In 2010, the project’s focus was changed to appropriate diagnosis and treatment of malaria, incorporating the use of malaria rapid diagnostic tests (RDTs). This responded to the upcoming roll-out of RDTs by the government and questions raised by them as stakeholders and the malaria community more broadly around how this could best be supported, given findings elsewhere that basic training was insufficient to support uptake of RDT results and adherence to test results. The trial therefore set out to answer specific concerns of Cameroonian policy makers by providing information about the cost-effectiveness of introducing RDTs alongside either basic training or an enhanced training intervention, compared with existing practice without RDTs. Furthermore, the initial inclusion of private sector providers was removed after feedback from the Ministry of Health that they preferred the tests first to be introduced at public and mission facilities.</p>
<p>Defining scope: consideration of level of control</p>	<p>For example, in the two Ugandan trials which introduced RDTs among community medicine distributors and drug shops, the objective was to learn the effect of the intervention if all providers allocated to the intervention received the full intervention. Training and follow-up supervision was delivered by members of the research team. The intention was not to produce an off-the-shelf intervention directly applicable for scale-up. By contrast, in the Nigerian trial, which introduced RDTs at public health facilities and private pharmacies and patent medicine dealers, the objective was to learn the effect of an intervention under routine conditions. Providers were invited to training sessions but were not followed-up if they did not attend, and for a school-based intervention, school teachers and students were provided with intervention ideas and materials but were encouraged to undertake whatever activities they considered feasible. The intention was to produce interventions and results that would be directly applicable in practice. The latter study was closer to an ‘effectiveness’ design than the former two.</p>
<p>Evidence review: Scoping to identify potential intervention components in Uganda</p>	<p>The Ugandan PRIME project aimed to improve the quality of health care at health facilities in order to improve health outcomes and uptake of services. The ‘target’ problem was identified as multi-faceted, with several components of quality of care identified as targets for improvement in the project’s formative research with health workers and community members. The targets were used as a focus for reviewing evidence of previous interventions:</p> <ul style="list-style-type: none"> • Interventions to improve communication of health workers with patients • Interventions to improve working relationships amongst health workers • Interventions to improve facility-based supervision or coaching of health workers • Interventions to improve the way patients are received and offered services equitably • Interventions to improve the management of primary health facilities <p>For each scoping review, which were conducted in parallel over a period of about three months, the team compiled a document to detail the search</p>

Formative research: utility	<p>strategy, including search terms, inclusion and exclusion criteria, specific aspects of the intervention, including a taxonomy of potential intervention types that followed Abraham & Michie ⁹⁷, and how to assess outcomes of evaluations, whether qualitative or quantitative. For each paper identified, the team documented details of the intervention and evaluation as well as their perceptions of whether the intervention might be effective and feasible in the project's setting, and whether any intervention materials already existed that could be drawn on. This process enabled the team to narrow down their search to interventions that were found to be effective at changing the target problem of interest and that were potentially transferable to the project's setting. This shortlist of evidence was then reviewed in conjunction with a review of behaviour change theory, review of the findings of formative research and discussion with local stakeholders. Formative research prior to the Ugandan trial with Community Medicine Distributors (CMDs) involved 29 in-depth interviews with CMDs, health workers and district health officials and 13 focus group discussions with mothers, fathers and community leaders. The research aimed to understand existing CMDs' motivation, practices and experiences and to explore the potential for introducing RDTs into the work and profile of these voluntary workers. The findings suggested that specific liaison personnel would be required to provide support to CMDs, and that acknowledgement of their work through provision of commodities to support their roles would be required to sustain motivation.</p>
Formative research: challenges with 'barriers' approach	<p>First, many of the barriers identified in our research were not amenable to change within the pre-defined scope of the intervention. For example, where wider policy dictated that certain providers were not allowed to sell or distribute certain drugs, such as antibiotics, we were unable to meet demand for training on treatment of non-malarial febrile illnesses. Second, even when a 'barrier' might be amenable to change, the research focus on barriers and problems provided little to inform positive action through intervention. For example, the finding in the Cameroon formative research that clinicians considered treatment with antimalarials to be a 'psychological treatment' suggested a need for a change in expectations of consultation outcomes, but did not in itself indicate what might be effective in achieving this. Third, the focus on barriers diverted attention from the motivation and agency of those enacting the 'problem' behaviours; the practices desired by the intervention may not be in line with their priorities and motivations. For example, the Cameroonian clinicians' motivation for prescribing antimalarial drugs was to treat the whole patient, rather than the laboratory result, or the malaria parasite. This represented a fundamental conflict between the focus of the malaria policy and of the study clinicians.⁷⁷</p>
Formative research: value of appreciative enquiry	<p>In one of our studies in Uganda, identifying the aspirations of health workers for strengthening the quality of health care they provided, gave us a framework for designing the PRIME intervention, based on their desires to strengthen technical, interpersonal and management capacities.⁶⁸</p>

Table 3. Example components of a logic model of an intervention

Inputs (resources)	Human, financial and material resources needed for the intervention.
Inputs (activities of the intervention)	Specific activities in which the target audience(s) participate, such as training activities, workshops, events, requisition of supplies.
Conditions	Factors amongst recipients and in their environment that are expected to affect the mechanism of effect of an intervention, for example presence of supporting resources or leaders.
Outputs	Measurable proximal outputs of intervention activities, for example knowledge or motivation of a direct or indirect target audience.
Outcomes	Changes that occur in the target audience(s), which can be either proximal, for example drug use behaviour, patient satisfaction, or distal, for example community health indicators.

Supplemental Material

Additional file 1. Example of a logic model: PRIME Uganda

Additional file 2. Example workshop structure for intervention design

Additional file 3. Review of theory and best practice to inform the structure of facilitated group learning workshops: multiple projects

Additional file 4. Developing visual aids for learner and trainer workshop manuals, Uganda

Additional file 5. Example of pretesting process for TACT leaflet: Tanzania