



## Implementation research: new imperatives and opportunities in global health

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*Lancet* 2018; 392: 2214–28

Published Online

October 9, 2018

[http://dx.doi.org/10.1016/S0140-6736\(18\)32205-0](http://dx.doi.org/10.1016/S0140-6736(18)32205-0)

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Implementation research is important in global health because it addresses the challenges of the know–do gap in real-world settings and the practicalities of achieving national and global health goals. Implementation research is an integrated concept that links research and practice to accelerate the development and delivery of public health approaches. Implementation research involves the creation and application of knowledge to improve the implementation of health policies, programmes, and practices. This type of research uses multiple disciplines and methods and emphasises partnerships between community members, implementers, researchers, and policy makers. Implementation research focuses on practical approaches to improve implementation and to enhance equity, efficiency, scale-up, and sustainability, and ultimately to improve people's health. There is growing interest in the principles of implementation research and a range of perspectives on its purposes and appropriate methods. However, limited efforts have been made to systematically document and review learning from the practice of implementation research across different countries and technical areas. Drawing on an expert review process, this Health Policy paper presents purposively selected case studies to illustrate the essential characteristics of implementation research and its application in low-income and middle-income countries. The case studies are organised into four categories related to the purposes of using implementation research, including improving people's health, informing policy design and implementation, strengthening health service delivery, and empowering communities and beneficiaries. Each of the case studies addresses implementation problems, involves partnerships to co-create solutions, uses tacit knowledge and research, and is based on a shared commitment towards improving health outcomes. The case studies reveal the complex adaptive nature of health systems, emphasise the importance of understanding context, and highlight the role of multidisciplinary, rigorous, and adaptive processes that allow for course correction to ensure interventions have an impact. This Health Policy paper is part of a call to action to increase the use of implementation research in global health, build the field of implementation research inclusive of research utilisation efforts, and accelerate efforts to bridge the gap between research, policy, and practice to improve health outcomes.

### Introduction

In global health, many specific interventions can be effective at low cost in relatively controlled environments, in short-term studies, or on small scales.<sup>1</sup> However, building strong and responsive health systems that promote health and wellbeing through sustainable strategies that work on a large scale remains an important challenge, particularly in low-income and middle-income countries (LMICs).

Internationally, the need for implementation research could not be greater or more timely. The Sustainable Development Goals (SDGs) and national commitments for universal health coverage require effective implementation of proven interventions to improve health outcomes and ensure that no communities are left behind and all benefit from improved health and wellbeing. Implementation research provides a set of approaches, methods, tools, and ways of bridging research and practice to address these issues. Implementation research offers a renewed focus on how to accelerate the development and delivery of services that improve and sustain health and wellbeing for all people, including those who are most disadvantaged.

The aim of this Health Policy is to present the characteristics that define implementation research and their application in global health through case studies. We show how evidence can inform practice, and the

potential of implementation research to make a positive impact on health across different contexts and implementation problems using a range of research methods in LMICs. The case studies highlight contexts in which achieving SDGs and universal health coverage presents heightened challenges.

### Defining implementation research

Implementation research builds on several research traditions (panel 1), and each of these research traditions has developed its own set of core disciplines, primary audiences, and typical sets of research questions (table 1).<sup>1–4</sup> In part because of the so-called invisible colleges that have formed from the different traditions, the field of implementation research in health has yielded considerable debate over its scope, theories, methods, terminology, and areas of emphasis (panel 2). Although we recognise the value of these debates, we use a broader and more inclusive definition of implementation research that emphasises the unifying focus of the varied histories and disciplines, such as that defined by Peters and co-workers<sup>4</sup> “the scientific inquiry into questions concerning implementation—the act of carrying an intention into effect, which in health research can be policies, programmes, or individual practices”. Implementation research is about using systematic research methods to improve policies, programme delivery, and knowledge

translation, preferably through real-time application of knowledge gained through real-world programmatic change.<sup>7</sup> Implementation research addresses a range of implementation challenges, including inefficient or inequitable use of resources, inequity in coverage of or supply-and-demand barriers to scaling up interventions, and sustainability challenges.<sup>7</sup> Implementation research is a convergence of approaches better known in high-income countries in the fields of management, education, and social and health services.<sup>4,16,17</sup> Implementation research emphasises attention and dynamic adaptation to local context, stakeholders, local care resources, and end-user engagement in understanding how and why change processes work.<sup>18</sup>

In global health, much effort has been placed on building bridges across knowledge producers, consumers, and beneficiaries, across policy makers, funders, programme implementers, and analysts, and across traditions of research, monitoring, and evaluation.<sup>7</sup> Learning from formally designed research projects, adapting robust research methods for local problem solving and monitoring, and using approaches that systematise tacit knowledge and experience are all used to make more informed decisions and produce consistent results in the real world.<sup>19</sup> Ultimately, implementation research is intended to improve people's health through more informed policies, strengthened service delivery, empowered communities, more capable programme implementers and health providers, and more informed policy makers.

### Methods to synthesise learning on implementation research

We selected and analysed numerous case studies of implementation research projects in differing LMIC contexts within a framework of core characteristics of implementation research. The framework and selection of case studies was informed by a set of five structured and consultative international meetings that were held between 2012 and 2016 (panel 3), bringing together researchers, donors, and policy makers to identify problems and opportunities related to implementation research, build consensus in describing the field, showcase useful examples, and develop priorities for action.

The case studies included here were purposively selected through a process of inclusive debate enabled by these meetings (panel 3). These studies were used to illustrate common characteristics of implementation research (panel 4), and to show its relevance in a range of geographical and political contexts, implementation topics and questions, scales of implementation (continent wide, national, or local), disciplines and methods, and types of impact. Types of impact include improvements in people's health, improvements in policy design and implementation, improvements in health management and service delivery, and supporting and empowering communities and beneficiaries.

### Key messages

- Implementation research offers a way to understand and address implementation challenges and have a positive effect on people's health by contributing to building stronger and more responsive health systems within the realities of specific contexts.
- Implementation research can lead to positive health outcomes, inform policy design, improve health management and service delivery, and support and empower communities and beneficiaries.
- Implementation research uses multidisciplinary approaches and a range of empirical and systematic methods to document, analyse, and address key health problems and test technical health interventions and contextually tailored innovative strategies within the foundations of local context.
- Implementation research can be used to evaluate the feasibility, adoption, and acceptance of interventions and their coverage (particularly in reaching disadvantaged groups), quality, equity, efficiency, scale, and sustainability.
- Implementation research involves an approach to doing research that fosters ownership, collaboration, and influence; policy makers, implementers, communities, and researchers should work together throughout the research and implementation processes to build trusting partnerships and encourage the coproduction of knowledge.
- Implementation research involves some key trade-offs to consider, including rigour versus usefulness of the research, fidelity versus adaptation of an implementation component, embedded versus externally objective approaches, seeking generalisable knowledge versus context-specific problem solving, and incentives versus disincentives for researchers and implementing agencies.

### Panel 1: Differences between researchers and policy makers

Policy makers, funders, implementers, researchers, and community members each view problems differently. Wendy Graham of Aberdeen University famously characterised these differences as "Researchers are from Venus. Policy makers are from Mars."<sup>2</sup> Graham, however, wisely recruited Dr Sam Adjei, a policy maker and researcher, to advise her. Adjei, who died in 2016, had a career bridging these two worlds of research and policy making and was an inspiring champion of the potential of an implementation research vision in Ghana and internationally. Adjei set up the Ghana National Health Research Unit to promote, institutionalise, coordinate, and conduct health systems and operational research focused on the use of research results. Today, this research unit has transformed into a division in the Ghana Health Service with three vibrant internationally recognised field research centres, ensuring that health research is responsive to country needs and priorities.

We have structured the case studies according to this classification to showcase a range of implementation research examples at different levels of the health system and types of research needs (table 2).

### Implementation research that improves people's health

#### Smallpox eradication

The smallpox eradication campaign remains the only successfully completed global health eradication campaign to date. One of the most dramatic and effective uses

	Typical primary audience for research	Typical research questions	Core disciplines at origin
Management improvement	Managers and teams using improvement strategies	How are the right services delivered to the right clients while meeting the right standards for quality?	Engineering and management
Operational research	Executive decision makers (executive bodies and policy makers)	Which solution provides the most rational basis for a decision concerning the optimal performance of a system?	Mathematics, engineering, and management
Policy implementation	Top down, central-level policy makers; bottom up, so-called street-level programme implementers	Top down, how was a policy or programme implemented, and what contributed to its outcomes? Bottom up, which actors are involved in programme delivery in specific locations, how do they understand the problem of implementation, and what influences their behaviour?	Political science, public policy, and public administration
Programme evaluation	Stakeholders of a programme (eg, funders, implementers, or the intended beneficiary)	Is the programme producing the intended effects? How is the programme designed, implemented, used, fit to context and problems, and with what results and programme changes?	Sociology, public policy, economics, social work, and psychology
Dissemination and implementation of evidence-based medicine	Practitioners, health organisation managers, and policy makers who do not use evidence-based interventions	What promotes the integration of research findings and evidence on interventions into health-care practice?	Behaviour change (psychology, sociology, and education) and epidemiology
Participatory action research	Research participants and community members	How can we (community members and research participants) learn and be empowered to act?	Non-disciplinary or transdisciplinary, but largely influenced by social psychology, education, and anthropology

Table 1: Implementation research traditions and their typical research targets, research questions, and initial core disciplines, adapted from Peters and colleagues<sup>4</sup>

of implementation research involved testing a new implementation strategy for smallpox eradication using real-time data. The purposeful application of different research approaches was crucial to the success of the smallpox campaign. These approaches included research on different ways to deliver vaccines, such as the bifurcated needle invented in 1965, which allowed quick and efficient immunisation of large numbers of people. However, when an important shortage of vaccines became apparent, to pursue the long-standing strategy against smallpox (ie, national mass vaccination), field research (as implementation research was known during the smallpox programme) was needed to test a novel implementation strategy. The new approach involved surveillance containment or ring vaccination, whereby response teams rapidly moved into areas where there were newly identified cases, and quickly vaccinated everyone in the affected villages to build rings of resistance around smallpox cases. Implementation research tracked the number of new smallpox cases over time, showing how the new ring strategy led to an immediate decline in the number of transmissions in Nigeria in one high-transmission season and then throughout the year. This finding led to the successful adoption of the ring strategy across west Africa and around the world.<sup>20</sup> More recently, the ring strategy was adapted in an innovative way to test the effectiveness of a new Ebola vaccine during the recent Ebola epidemic in Guinea.<sup>21</sup>

### Neonatal survival

A more recent case involved the testing of locally developed packages of services to improve newborn survival on a large scale in several low-income countries. This case offers a lesson in how implementation research done in real-world conditions using locally available resources can change practices on a large scale and save lives. Sepsis or severe bacterial infection is a leading cause of neonatal death. Severe bacterial infection has a rapid onset and is

difficult to definitively diagnose. Until recently, the WHO recommendation for sepsis was hospitalisation and treatment with injectable antibiotics for 10–14 days. This treatment is not feasible for many families in Africa and Asia.<sup>22,23</sup> Although hospitalisation remains the WHO standard of care, a coordinated set of studies in Africa, Bangladesh, and Pakistan established a new evidence base of implementation strategies for outpatient management when necessary, which have been included in new WHO guidance.<sup>23,24</sup> The simplest of these regimens involves 2 days of injectable antibiotics and 7 days of oral antibiotics with follow-up. Rather than studying these new strategies in better funded settings or under conditions in which research teams could control the quality of care, the studies were designed from the outset to address the realities of severely constrained resources, including shortages of qualified doctors and nurses and unreliable infrastructure, and were tested concurrently in five countries with varying health system contexts.<sup>25,26</sup> In Bangladesh, the government adopted the new WHO guidance as a result of studies that showed that these guidelines could help achieve 20% reduction in neonatal mortality. Following the principles of implementation research in global health, the government of Bangladesh is working with funding agencies, implementation groups, and research partners to evaluate the broader effects of the adoption of the new guidelines, including evaluating the feasibility and safety of the new WHO guidelines in three different regions with different health systems, contexts, and technical support. Reviews every 3 months will allow the refinement of the implementation process and planning for the national scale-up.

### Implementation research that informs policy Ghana

The Community Health and Planning Services (CHPS) is the most local level at which public health services are delivered in Ghana. CHPS started as a family-planning

### Panel 2: Implementation research: what's in a name?

The divergent histories of implementation research and disciplines that have addressed implementation questions continue to stimulate much debate over terminology, theory, and methods. For many people and organisations who are largely interested in effective implementation, distinguishing whether these debates signal any progress in understanding as the science advances or are simply the territorial markings of different research tribes or invisible colleges is often difficult.<sup>2</sup>

Although evidence-based medicine is one of the more recent research traditions, its emergence has spawned a branch of implementation science that now dominates the clinical literature, defining implementation science as the “scientific study of methods to promote the systematic uptake of research findings and other evidence-based practices into routine practice, and, hence, to improve the quality and effectiveness of health services and care.”<sup>3</sup> Within this tradition, an attempt was made to provide consistent definitions for the field, which the authors called dissemination and implementation research.<sup>5</sup> By 2015, a literature review of definitions for implementation science that just focused on HIV and AIDS identified 73 different definitions for the term, mostly from this same tradition.<sup>6</sup> The results prompted the authors to expand the definition of implementation science to a “multidisciplinary specialty that seeks generalisable knowledge about the behaviour of stakeholders, organisations, communities, and individuals in order to understand the scale of, reasons for, and strategies to close the gap between evidence and routine practice for health in real-world contexts”.<sup>6</sup>

A comparison of the different strands of research traditions that study implementation (eg, operational research, scientific management, policy and programme evaluation, participatory action research, and the dissemination of evidence-based practices) suggests that these types of implementation research have much in common with the expanded definition, although some fields have a broader scope (eg, to include policy and programmes beyond practice) or include specific methods, given that evidence has different connotations in different fields.<sup>4</sup> Other research traditions do not focus solely on generalisable knowledge, but also on the use of knowledge or the interface of knowledge and action. Global health discussions have highlighted the importance of multidisciplinary, collaboration, real-world settings, problems of scale and sustainability, and the bidirectional links between practice and evidence,<sup>7</sup> which motivates the use of terms such as delivery science<sup>8</sup> and programme science.<sup>9</sup>

Although the terms science and research are often used interchangeably, research is a crucial part of science and

involves the use of scientific methods to gather and analyse data to answer questions. Yet the term research can also be controversial to some organisations and has practical consequences. For example, some universities might consider activities to be research only when the work is intended for publication (or more broadly to produce generalisable knowledge) or when a specific sponsor for the activity is present. Others may distinguish formal research from problem-solving activities, even when both types of research use the same methods. Similarly, some funded projects are categorised as quality improvement projects or public health practices rather than more traditional human subjects research. The categorisations of these activities as research might result in different types of ethical review of the protocols, depending on how the activity is classified.

Conducting research is also problematic for agencies that do not have a research mandate; in global health, these organisations could include Gavi, the Vaccine Alliance, UNICEF, The Global Fund, and many public health agencies. Because these agencies often need robust information about their programmes and are often expected to use robust monitoring and evaluation, they classify their activities as non-research activities, sometimes as monitoring and evaluation, learning, or occasionally as operations research. These agencies also use different funding mechanisms for these activities. We propose that all these activities can be considered implementation research when robust scientific methods are used to answer questions related to implementation. These different types of classification as implementation research still means there is a need to carefully ask relevant questions and apply appropriate theories and methods to the problem.

Although we do not advocate for a single theory among the many theoretical frameworks in the field, some metaframeworks that bridge theories and help to identify more specific theories and methods that can fit a particular question or context are particularly useful. These metaframeworks include the Consolidated Framework for Implementation Research,<sup>10</sup> the National (US) Implementation Research Network's Active Implementation Frameworks (usable interventions, implementation stages, implementation drivers, implementation teams, and improvement cycles),<sup>11</sup> a synthesis of frameworks on implementation processes,<sup>12</sup> and an analysis of models according to a socioecological framework to help identify and select relevant frameworks.<sup>13</sup> Many handbooks are also helpful, including WHO's introductory implementation research guide,<sup>14</sup> and the Standards for Reporting Implementation Studies statement on how to report implementation research.<sup>15</sup>

research project and then transformed into an initiative aimed at locating primary care services in communities and involving them in the decision making process. The CHPS example shows the practicality of scaling up a successful pilot programme throughout the country, and

what is required to put evidence into action through research, experimentation, multiple validations, and adaptation.

Between 1994 and 2000, country stakeholders went through an interactive and engaging process to pilot,

### Panel 3: Meetings on implementation research that informed the case studies

The approach to case study analysis involved the identification of multiple case studies of implementation research projects in differing low-income and middle-income country (LMIC) contexts and analysing these case studies within a framework of core characteristics of implementation research adapted from the literature.<sup>7,14</sup> The selection of case studies in this Health Policy paper has been informed by a set of structured and consultative international meetings that aimed to bring together different stakeholders with an interest in implementation research in LMICs, to identify problems and opportunities related to implementation research, build consensus in describing the field, showcase useful examples, and develop priorities for action. This series of meetings included the following: a meeting to develop and finalise the guide (*Implementation Research in Health: A Practical Guide*) in Geneva, Switzerland in 2012;<sup>14</sup> consultations on the priorities for a statement on Implementation Research and Delivery Science in Washington DC, USA in April, 2014, and in Accra, Ghana in July, 2014; the launch of the statement on advancing implementation research and delivery science at the Health Systems Global Conference in Cape Town, South Africa in October, 2014; and two paper-writing workshops in Washington in November, 2015 and Montreux, Switzerland in April, 2016. The statement in Cape Town<sup>7</sup> also involved a web statement which different stakeholders (eg, health managers, donors, and researchers) and their institutions signed up to, with actions to take forward the field of implementation research.

experiment, replicate, and scale-up a programme that mobilised local volunteers, resources, and cultural institutions to support community-based primary care.<sup>27</sup> The original CHPS model was piloted through deploying nurses to the community and engaging local leaders, resulting in reductions in child mortality by 50%, maternal mortality by 40%, and fertility by nearly one child per mother in only 5 years, compared with areas relying on existing services alone.<sup>28</sup> The key implementation research lessons to inform scale-up were as follows: the need to place nurses in home districts but not home villages; to adapt to each district context; to mobilise local resources; to develop a shared project vision; to do exchanges, in which staff can observe the model working in another setting; and to pilot the approach locally, and expand based on the lessons learned at that level. Since 2000, the country has continued to gradually scale up the implementation of CHPS with both successes and challenges. A review by Krumholz and co-workers<sup>29</sup> shows that the original scope of CHPS has been expanded, which has increased access to health care, although some implementers are concerned that the original emphasis on community involvement does not have the same prominence as in the original study.

#### Afghanistan

The case of the development and use of a national balanced scorecard for basic health services in Afghanistan shows how implementation research can be used to immediately influence policy, as well as the limitations and potential consequences of close links between research and policy. The balanced scorecard in Afghanistan is part of a monitoring system set up through multistakeholder

engagement to regularly assess the delivery of a basic package of health services across the country. The balanced scorecard was used as a tool for regular renewed planning of activities, reallocation of resources, and problem solving,<sup>30</sup> and also provided a platform to test government and non-governmental organisation (NGO) policy innovations, such as contracting and health financing innovations.<sup>31</sup> A cluster-randomised trial that used the balanced scorecard was done to test different user fee options, and within days of the study being completed, the results were quoted by the Ministry of Public Health (MOPH) as a basis to justify discontinuing user fees at primary care facilities because of the negative effects of these fees on access, while failing to improve quality or raise large amounts of funding.<sup>32</sup> This was a policy the government had wanted to change and the research provided them with confidence to do so. However, more recently, when the same data collection system and revised scorecards were used to evaluate a pay-for-performance scheme that was shown to be ineffective,<sup>33</sup> the MOPH expanded the programme anyway with World Bank support, but has not paid the evaluators for the work.<sup>33</sup> This case shows that close collaboration between policy makers and researchers can result in research that directly leads to policy change, particularly when the results are consistent with government ambitions, but there are also risks to researchers when they work closely with government and the results do not support government expectations about their policies.

#### Nutritional systems

Implementation research has been used effectively to build and sustain multisectoral nutrition systems (MSN) across Ethiopia, Uganda, Burkina Faso, and Mali by identifying important investments that are required in these systems. Malnutrition is a major contributor to the global burden of disease in low-income countries, with more than 2 billion people affected by micronutrient malnutrition and 161 million children suffering from chronic undernutrition.<sup>29</sup> Establishing mutual understanding of the evidence of highly efficacious and cost-effective interventions by policy makers, researchers, and programme managers<sup>34</sup> has been the foundation for the increased importance of nutrition on global and national agendas.<sup>35–39</sup> These communities also coalesced in the creation of Scaling Up Nutrition (SUN), a movement which promotes a multisectoral approach involving delivery of direct interventions and policy reforms in key sectors (eg, health, agriculture, and education), and which aligns policies, programmes, and procedures from the government, donors, and NGOs, consistent with the evidence synthesised in a *Lancet* Series on maternal and child nutrition.<sup>40</sup> However, an evaluation of SUN reported that implementation at country level faces many challenges, including a so-called implementation disconnect.<sup>41</sup> Actors and institutions at national and subnational levels function as a complex adaptive system,

#### Panel 4: The defining characteristics of implementation research applied in global health

##### Context specific

Contextualisation of an intervention in implementation research is important, hence why the detail of context is made explicit, alongside the level of analysis and action (eg, community, district, or national level). Attention is paid to the differences in need for and benefit from interventions depending on gender or other axes of inequity.

##### Relevant and agenda-setting purpose

Identify and address challenges related to any implementation decisions or processes at any level, including identifying and addressing health problems, setting the agenda, setting priorities, and building commitment at all levels.

##### Methods fit for purpose

Research design should be responsive to an implementation problem or question; typically a range of data sources and methods are considered appropriate for the implementation questions, decision context, and community or patient characteristics, while remaining sensitive to gender and other social stratifiers.

##### Demand driven

Research questions are framed or based on needs identified by implementers, intended beneficiaries, policy makers, and research consumers in the health system.

##### Multistakeholder and multidisciplinary

Democratisation of research is important; implementers, policy makers, and researchers (and often communities, including the most marginalised) should coproduce the research, co-create

solutions, and use the results together, drawing on multiple disciplines (eg, management, psychology, sociology, education, epidemiology, anthropology, engineering, political science, and economics). Leadership or partnership of national scientists is important.

##### Real world

Implementation research does not usually take place under controlled trial conditions (but can be part of pragmatic trials with process and context assessments running alongside) and usually takes place within the reality of implementing organisations, communities, and financing systems, and within the context of health systems that are constantly changing and adapting.

##### Real time

Implementation research is designed to provide evidence or solutions through short feedback loops that can be used for real-time improvements, course-correction in implementation, or periodic reflection, and is a dynamic, non-linear, iterative, and evolving process.

##### Focuses on processes and outcomes

Implementation research is focused on processes and engages implementers and documents how interventions are implemented and delivered to assess acceptability, fidelity, adoption, scale-up, and impact. Tacit knowledge is used and acknowledged.

These characteristics were informed by an expert review process and adapted from Peters and co-workers<sup>41</sup> and the Cape Town statement of 2014.<sup>7</sup>

but their implementation logic is based on bureaucratic rational assumptions that ignore this complexity. Consequently, the many stakeholders, including governments, donors, NGOs, civil society, businesses, and researchers still have divergent mandates, incentives, and accountabilities. The nascent formal coordination structures do not have the authority and capacity to coordinate their approaches, and the globally-prescribed monitoring and evaluation systems do not have the contextually relevant, nuanced, and timely information needed during the system-building phase when implementation challenges surface.

Recognising this disconnect, an implementation research effort was undertaken in four countries in the SUN movement to provide real-time and customised information to country stakeholders to better understand implementation challenges based on key principles of strengthening strategic capacity, learning and adapting management, and sharing documented learning. The research identified three crucial investments that are necessary to build and sustain effective MSN systems, including strengthening human resources in the MSN coordinating unit, creating an implementation team to cascade learning and implementation throughout the

country, and ensuring that accurate information on bottlenecks is conveyed and acted upon swiftly by high-level decision makers across the sectors.<sup>42</sup>

### Implementation research to improve health management and service delivery

#### District health systems strengthening

A growing body of implementation research shows that the use of participatory research processes to support learning and district health systems strengthening. In the cases described in this section, the participatory action learning strategies have been assessed using a range of qualitative, participatory, and quantitative methods, and have shown promising results, identifying the probable pathways of effect.

The Improving Health Workforce Performance (PERFORM) project<sup>43</sup> has involved partnerships between researchers and District Health Management Teams (DHMTs) in decentralised contexts (Ghana, Tanzania, and Uganda). Working in three districts in each country, a management strengthening intervention was implemented to identify workforce performance challenges and feasible bundles of interventions to address them.<sup>43</sup> The project uses a systems approach in which people involved

in the health system use data to identify and address workforce problems, within the context of other health system components that are also constraining the DHMTs. Examples of bundles of interventions include linking human resources strategies (eg, attendance monitoring and appraisal) with strategies addressing wider health system problems, for instance by building competence

and ensuring medical supplies are available.<sup>43</sup> This management strengthening intervention is being scaled up across these three African countries, with implementation research guiding this process. The ExpandNet approach to scale-up<sup>44,45</sup> is being used; this approach focuses on key principles, including systems thinking (focusing on the inter-relationships between different

	Context specific	Relevant and agenda-setting purpose	Methods fit for purpose	Demand driven	Multistakeholder and multidisciplinary	Real world	Real time	Focuses on processes and outcomes
<b>Implementation research that has positive health effects</b>								
Smallpox eradication	Nigeria, working specifically with affected villages within the context of a nationwide strategy	Addressed the challenge of smallpox outbreaks when there were not enough vaccines to use the standard national mass vaccination strategy	Field research that involved ring-fenced immunisation and active surveillance in communities in which new cases occurred	Health providers identified the problem	Co-creation with tightly linked implementers and researchers, dependent on and supported by community participation in surveillance	Working with affected Nigerian communities and the health system	Implementation occurred alongside and in response to the smallpox outbreak	Contributed and built the processes for an effective eradication strategy despite resource constraints; similar strategies were adopted later in the Ebola response
Neonatal mortality due to bacterial infection	Urban and peri-urban and rural settings in Bangladesh, Pakistan, DR Congo, Kenya, and Nigeria	Systematic process from validation to introduction of a new approach to increase access and ensure safety of lifesaving antibiotic treatment for sepsis	Range of methods adjusted over time, including clinical assessments of effects of 2 days of injectable antibiotics and 7 days of oral antibiotics and quality improvement	Implementation research process responds to the need for alternative approaches to address bacterial infection, that are acceptable to communities	Implementers, policy makers, and researchers are in an ongoing dialogue on clinical research and evolution to co-create solutions that fit contexts in later stages	A locally developed service package was tested and further adapted in real-world conditions followed by further adaptation in real-world conditions	Initially the research was not in real time, but at later stages efforts were increasingly made to ensure real-time implementation research	Assessment and sharing of learning across contexts to inform country-level and global uptake of learning; Bangladesh has adopted WHO guidelines and an iterative process of assessment is ongoing to inform further adaptations
<b>Implementation research that informs policy design and implementation</b>								
Community-based health services in Ghana	Ghana, a nationwide process to promote scaling up approaches	Identified the importance of supporting and sustaining the scaling up of community-based health services	Original research showed that the intervention was successful and how to achieve success; however, no research was done to inform scaling up in context	In response to policy maker concern over how to effectively implement community-based health services and address the challenges faced in preceding village health-worker programmes	Policy makers, programme implementers, and politicians set the agenda through an interactive and engaging process, followed the progress of the research, and translated the research knowledge into national policies and programmes	Working within programme realities through an ongoing iterative process	Ongoing research to inform processes of scale-up in real time	Shows the process and impact of scaling up the intervention throughout the country, through experimentation, multiple validations, and adaptation
Balanced score card in Afghanistan	Afghanistan, a nationwide approach with pilots in different districts	Responding to the need to provide and assess the provision of a basic package of health services across the country	Serial health facility surveys, a cluster randomised trial, and process evaluation	Linked to both government priorities and government and non-governmental organisation interventions	Involved the government, non-governmental organisations, and researchers	Working within the realities of different districts in a fragile and conflict-affected country	Developing, implementing, and assessing a basic package of health services in real time	Documented process of developing a balanced score card; focuses on outcome and impact, including being part of the evidence base for discontinuing user fees
Multisectoral nutrition approaches to reduce stunting	Working within national processes and collaborations in Ethiopia, Uganda, Burkina Faso, and Mali	Addressed the need for joint approaches between actors and sectors to have an effect on nutrition across different country contexts	Engaged, embedded action research and developmental evaluation of national policy implementation; method deliberately chosen to support commitment building and co-creation of solutions	Actively responding to the need for more linked approaches identified in the country and globally	Researchers, policy makers, and practitioners from different sectors interacting in formal and informal venues to address immediate and longer-term system needs	Led by implementers with support from researchers from a project-led team	Implementation research driving the promotion of multisectoral approaches for joint action on malnutrition and stunting	Addressed numerous bottlenecks in real time and identified three crucial investments that appear necessary in the long term to build and sustain effective multisectoral nutrition systems and to reduce stunting

(Table 2 continues on next page)

	Context specific	Relevant and agenda-setting purpose	Methods fit for purpose	Demand driven	Multistakeholder and multidisciplinary	Real world	Real time	Focuses on processes and outcomes
(Continued from previous page)								
<b>Implementation research that improves the management of programmes and enhances service delivery</b>								
District health systems under constant and changing challenges	South Africa, Tanzania, Ghana, Uganda, and Nepal	All the projects and processes supported the strengthening and building of quality and more responsive health systems at the district level	Action research and processes of co-learning between researchers and implementers to support co-creation of solutions	All implementation research processes responded to the expressed need for health system strengthening at the district and subdistrict level, where health services are arguably realised	Partnerships between district-health management teams, managers, health-facility management committees, and researchers, in some cases including partnerships in sectors other than health; policy makers were involved throughout	Working within the resource constraints at the district level	In Nepal the implementation research approach facilitated an immediate research response following the earthquake, a halt to implementation of the management system, and a refocus on how best to support health workers responding to the crisis	Showed that strengthening approaches can enable impact and action across different contexts and projects even in remote and challenging district contexts; the partnerships required for change were documented
Respect for maternity care	Kenya, Tanzania, and global dialogue	Responding to a problem that has too often been ignored in the health system in LMICs and industrialised countries	Problem scoping followed by identification of multilevel intervention	Responsive to unaddressed problems	Dialogue and evolving partnerships to address complex multidimensional problem	Working in programme realities with co-learning and participation of policy makers, researchers, and implementers	Ongoing with service delivery	Documentation and development of tools for introduction and scale-up for these countries and other settings
Integrated community case management	Sub-Saharan Africa	Delivery of primary care service access barriers for child health in areas where human and financial resources are constrained	Multimethod observational and interventional studies to document and address delivery challenges	Focus on barriers to provision of essential services	Dialogue and engagement	Working in programme realities	In real time in several settings	Extensive documentation for country-specific and cross-country learning
<b>Implementation research empowering communities and beneficiaries</b>								
Ensuring HIV and AIDS target interventions meet the needs of sex workers in India	India, in Andhra Pradesh and Karnataka	Developing targeted interventions to respond to the sexual and reproductive health needs of an isolated and stigmatised group	Qualitative process evaluation of systematic use of a broad range of programme data	Focused on developing context-specific strategies for groups identified as high risk	Involved the National AIDS Control Programme, non-governmental organisations, researchers, and sex workers	The approach took place in an iterative manner	Development of targeted interventions in real time to respond to the needs of sex workers	Ongoing iterative process of change; both the processes and effects on HIV prevalence were documented
Onchocerciasis	District level in Cameroon, in areas where co-endemicity with loiasis indicates new approaches are required	Tested a new approach to addressing the spread and effect of onchocerciasis where traditional approaches need adapting (because of the co-endemicity with loiasis and severe adverse events)	Implementation approach to test an alternative strategy (in partnership with community structures to support adherence over 10 weeks) with embedded qualitative research and community assessments	Responding to the need to identify the possibility of new treatments, particularly in areas where loiasis is highly endemic	Brought together researchers, programme managers, and communities (through community drug distributors selected through community processes), and deployed different disciplines; developed trusting relationships	Working within the realities of the control programmes and in partnership with community resources (community-based drug distributors)	Implementation and qualitative assessments were carried out concurrently with the testing of the new alternative approach	Processes were documented (including community choice), and high adherence leading to a reduction in prevalence and infection rate, enhanced wellbeing, and policy change was documented

Table 2: Applying the defining characteristics of implementation research to the case studies

stakeholders and the wider environment), sustainability (institutionalising the intervention into policies, guidelines, and budgets), enhancing scalability through ongoing monitoring so that implementers are able to adapt the intervention and learn and improve scalability, and respect for human rights, equity, and gender.

In the Ghana PERFORM sites, positive changes in service delivery and workforce performance indicators at the district level include improvements in vaccination and attrition and improvements in quality of HIV clinic services. Research was used to build management capacity in problem analysis and inform the design of integrated

strategies for improving workforce performance and health systems. This strategy resulted in strengthened supportive supervision, more regular feedback meetings, and improved documentation at the district and subdistrict levels.<sup>43</sup> An increase in initiative and risk-taking culture, teamwork and collaboration, and empowerment has also been observed.<sup>43</sup>

In Nepal, an implementation research project used similar participatory processes as PERFORM to enhance health worker performance in three different districts and assessed the processes, effectiveness, and feasibility to scale up.<sup>43</sup> The key components of the intervention included orientating health workers and health-facility operation and management committees to the performance management package, setting benchmarks for key service delivery indicators at the facility level, group monitoring and assessment for staff, individual appraisal, supportive supervision and feedback, development of outcome-focused job aids for health workers, and community assessment. The findings showed improved functionality of health service delivery with increased motivation of health workers, which contributed to a reduction of health workers' absenteeism in several health facilities. Group monitoring and supportive supervision was considered one of the components that helped improve health workers' performance. Health workers' performance was linked to improvements in the quality of health services and has potentially contributed to improved health outcomes, especially in maternal and child health.<sup>46</sup>

The District Innovation and Action Learning for Health Systems Development (DIAHLS) project in Mitchell Plain, South Africa, aims to strengthen leadership and governance within the district health system to support primary health-care improvement and strengthen policy implementation. The approach has involved intervening in the routine processes of decision making—ensuring the cohesion of health systems.<sup>47</sup> The learning is negotiated and constructed among practitioners and researchers<sup>48</sup> to coproduce knowledge on how complex systems function and can be strengthened, and to support further action. The DIAHLS approach includes cycles of action research and learning with engagement of providers at different levels, includes relationship building, mentoring and coaching, and reflection and writing, and is implemented at both the individual and team level.

In the Mitchell Plain subdistrict, South Africa, impressive gains have been made. For example, women with antenatal appointments booked before 20 weeks gestational age increased from 114 women in 2011 to 1452 in 2014. The incidence of HIV positivity per year in infants has been significantly reduced, with mother-to-child transmission declining from 1.8% in 2011 (28 infants positive in a cohort of 1570 pregnant women undergoing prevention of mother-to-child transmission of HIV [PMTCT]) to 0.6% in 2014 (nine infants positive in a cohort of 1564 women undergoing PMTCT). Local

system actors agree that the gains in managerial confidence, new managerial styles, positive attitudes, and greater proactiveness in identifying and tackling service challenges at both facility and mid-managerial levels, together with improved relationships across systems and structures, has sustained and enhanced performance.<sup>47,49</sup> There have also been new positive ways of working, including creative approaches to management in different areas, which have led, for example, to innovative work addressing gender issues in a range of projects. This approach won the corporate City of Cape Town awards for its gender programme, action, and leadership.

Knowledge gained from these different projects showed that implementation research used for district strengthening can inform action and produce better results even in remote and challenging district contexts, with no additional financial resources. The effects on improved performance in delivering services is fostered when there is continuity and commitment of leadership and a systems approach that identifies and addresses unintended consequences, engages key stakeholders, and functions across the health system to catalyse wider change. Ultimately, building trusting partnerships between researchers, health workers, managers, and policy makers that facilitate the coproduction of knowledge and action is crucial. Trusting relationships with key stakeholders (including the Ministry of Health) in Nepal ensured collaborative dialogue when the 2014 earthquake caused great damage to one of the implementation research districts, Rasuwa. Following dialogue between the research team and policy makers it was agreed that the originally planned management interventions could no longer be implemented in Rasuwa, but that the team should do quick qualitative assessments to describe changes in service delivery and working environments after the earthquake, and should develop recommendations for policy makers to reinforce coping strategies and supportive systems. The findings highlighted the resilience of health workers in providing services and the need for additional psychosocial support, compassionate leave, and recognition.<sup>50</sup>

### Respectful maternity care

Disrespect, abuse, and neglect of women is a barrier to facility-based birth and a violation of the human rights of pregnant and post-partum women.<sup>51</sup> In Kenya and Tanzania, research studies have documented the prevalence of and factors associated with abuse.<sup>52</sup> Research in Kenya involved a multilevel intervention initiated by a partnership of researchers, Ministry of Health officials, and other implementation agencies with multiple components, including draft legislation and guidelines and training for facility-based supportive counselling for health providers.<sup>53</sup> Through close work with stakeholders, packages of interventions were developed and tested to reduce abuse. The study documented a reduction in

	Training and supervision <sup>47,48,56</sup>	Supplies <sup>49,51,54,55,57,58,59-61</sup>	Quality of services <sup>47,51,53-55,57-60,62</sup>	Deployment <sup>47,63,64</sup>	Use <sup>31,64-67</sup>
Findings that cut across all contexts	The schedule, duration, and approaches to training and supervision varied; some evidence suggests that consistent on-site supervision improves the quality of CHW performance	Well supported, often parallel, systems ensure limited stockouts of supplies, but when these systems are not in place, stockouts are common	CHWs and local drug store attendees are able to provide high-quality diagnosis, treatment, and referrals, but only when they are well supported (ie, when they are trained, supervised, and provided with supplies and job aids)	CHWs might not be deployed where they are most needed (eg, close to public health facilities or private providers)	Generally, these services have been underused and there might be a preference for private or traditional health facilities over iCCMs, although social mobilisation can increase demand
Example of context-specific findings	Supportive supervision (clinical mentoring) visits were effective at improving the consistency of iCCM skills in health extension workers in Ethiopia	A mobile health technology that reported on community stock data in Malawi (cStock) was feasible and acceptable, and resulted in lower stockouts of supplies	In Zambia, CHWs providing iCCM appropriately classified malaria and pneumonia 94–100% of the time, and provided correct treatment in 94–100% of infection cases	In Sudan, global-positioning-system mapping showed that more than 75% of CHWs were deployed within a 5 km radius of a health facility or another CHW, contrary to programme planning and design	In Niger and Mozambique, demand increased for iCCM services following the implementation of comprehensive social mobilisation efforts
Implications	Additional research is needed on the optimal training and supervision approaches and to improve integration into existing health supervision and training systems	Improved logistics of the supply chain for the overall health system, including community distribution	Most well-supported programmes were implemented by non-governmental organisations; sustaining support by Ministries of Health in health-care systems that are in difficulty is unlikely unless correlated with overall improvements in the health-care system	Increased research with geospatial analysis of CHWs and health facilities is needed	Increased research on understanding the uptake of health-care services, increased social mobilisation and demand generation is needed, as is testing their impact on health outcomes

The information in this table is based on our review of the literature and reports from implementers on training and supervision. iCCM=Integrated Community Case Management. CHW=community health worker.

**Table 3: Examples of implementation research in iCCM in predefined priority areas in 2008–16**

overall disrespect and abuse from 20% to 13% after the intervention, despite the introduction of a national policy of free maternity care (presumably leading to higher use of this type of care) and nurses' strikes.<sup>54</sup> On the basis of these results, the government of Kenya is beginning a national scale-up of the strategy. Stimulated by the early findings of this intervention study and a companion study in Tanzania, WHO commissioned a review and released a policy statement on the prevention and elimination of disrespect and abuse during childbirth,<sup>24</sup> and has embarked on a multicountry study to measure global prevalence of this abuse. Concurrent to these efforts and these initial implementation research studies, the White Ribbon Alliance has engaged in policy dialogue at the country level and global level, bringing this topic into the global and country dialogues and stimulating further research efforts.

### Integrated community case management

From 2008 to 2013, there has been strong financial and technical investment across 36 countries in the African region to assess the effects of Integrated Community Case Management (iCCM), a delivery system that makes use of community health workers to deliver treatment for pneumonia, malaria, and diarrhoea to children closer to communities. The findings of these studies, led by a variety of implementers, were mixed, often showing no effects on mortality.<sup>55</sup> Implementation research grounded in local contexts was needed to better understand different practices and outcomes in different contexts, and provide overall learning on how best to adapt the implementation of iCCM. Following in-depth

consultation, recommendations were developed to focus research on a range of implementation issues (table 3).<sup>57,58</sup>

From 2008 to 2013 large increases in supportive policies for iCCM and increased implementation of these policies in the African region have been seen.<sup>58</sup> Delineating the specific effects of these implementation research studies on iCCM implementation in Africa is difficult, because iCCM policy development and implementation is influenced by the prevailing conditions of the health system in each country, their history of primary health care, the role of community health workers, and available funding and local champions and leaders.<sup>59,62</sup> However, evidence from studies in three countries suggests that policy makers greatly valued local implementation research, and international research evidence was used to identify locally relevant policy options.<sup>61</sup> In addition, WHO and UNICEF functioned as knowledge brokers, bringing these implementation research findings from other countries through academic publications, statements, guidance documents, and meetings to the attention of local policy makers.<sup>60</sup>

### Implementation research to empower communities and beneficiaries

#### People at risk for HIV infection and discrimination

The government of India developed the National AIDS Control Programme, which involves the implementation of targeted interventions to reduce HIV for key populations, including female sex workers (FSWs). A qualitative process evaluation was done in two Indian states, Andhra Pradesh and Karnataka, to assess the ways in which targeted interventions are appropriately adapted

to FSW needs and changing contextual and programmatic factors.<sup>68</sup> Establishing outreach activities for FSWs, many of whom were illiterate, was challenging, because these women are stigmatised, face extreme discrimination (including a history of violence at the hands of police and family members), and do not have support groups or associations. The outreach strategy required several refinements, including the hiring of peer educators of different ages, the creation of drop-in centres, the introduction of pictorial materials, and the design and redesign of interventions acceptable to FSWs. Similarly, the condom promotion and distribution strategy and clinical service delivery models evolved. Several models were implemented, adapted, and ultimately differentiated according to the needs of the clients. The most important component of the targeted interventions was the gradual inclusion and integration of FSWs in the provision of services that were more responsive to their needs. The targeted interventions started with needs assessments to better understand the community of FSWs, revealing how addressing threats of violence and harassment are more important than HIV prevention. The regular involvement of peer educators facilitated community-led interventions, eliciting interest in forming community-based organisations and generating greater community participation. These factors contributed to a social movement recognising the rights of sex workers and their social entitlements.

The targeted interventions benefited from a broad variety of implementation research, using multiple data sources to inform implementation changes. The programme used three major sources of data, including periodic surveys and assessments, annual sentinel surveillance, and routine programme data. The results were regularly triangulated to ensure their validity before decision making and strategy refinement. A key lesson, however, is for managers to recognise that data will always have limitations, and that they needed to make “decisions based on the best available data rather than wait for the next sample or a more refined analysis”.<sup>63</sup> With a quasi-experimental design that varied the intervention intensity, statistically significant declines in HIV prevalence among young pregnant women were observed between 2007 and 2011 in the districts with the highest intensity of targeted interventions, whereas similar changes were not observed in districts with lower intensities, suggesting that targeted intervention had a role in causing the decline.<sup>64</sup>

#### Community-directed treatment for onchocerciasis

Community-directed treatment with ivermectin (CDTI) is a core factor in the control of onchocerciasis in Africa. The strategy relies on active community participation in the process of ivermectin delivery; the community decides how, when, and by whom ivermectin should be delivered.<sup>69,70</sup> Several studies have shown that ivermectin alone cannot eliminate onchocerciasis, because this drug

is active only on microfilariae, and its use is contraindicated in areas where *Loa loa* is highly endemic because individuals with high microfilarial loads of *L loa* are at risk of serious adverse events.<sup>65,71,72</sup> Antibiotics targeting the endosymbiotic bacteria (*Wolbachia*) of *Onchocerca volvulus* are a promising alternative tool for onchocerciasis control and elimination, particularly in areas of co-endemicity with loiasis, and have the added benefit of also killing adult worms.<sup>66,73</sup> The implementation research process aimed to test the feasibility of a long course of antibiotic treatment (6 weeks). In the intervention arm of the clinical trial, a rigorous process of community engagement was undertaken. First, the team met with the community leaders to explain the treatment process. Communities were then supported to select their own representatives to serve as community drug distributors (CDD). CDDs were trained through an ongoing practical adult learning approach on the importance of adherence through the process of directly observed treatment. CDDs were also supported in record keeping and strategies to ensure consistent supply of drugs through a process of health systems strengthening.

In a CDTI study in Cameroon, the intervention group showed very strong adherence (98%), suggesting that delivering a complex intervention over a sustained period at the community level is feasible and acceptable. Health impact assessments that were done 4 years later showed a 10% reduction in prevalence of the disease and a substantial reduction in the number of parasites in people's skin, and qualitative assessments at the community level revealed a strong sense of enhanced wellbeing. The awareness of onchocerciasis and its socioeconomic effects on the population was a motivating factor for community adherence to treatment. As a result of the research, policy changes in the programmes have been made and have been adopted across Africa. Doxycycline is now used as an alternative to ivermectin in the control of onchocerciasis in areas highly endemic for *L loa*.

#### Limitations of implementation research: a matter of balance

As with any research endeavour, questions about the quality of research that is applicable to the methods chosen can be asked, and these questions are every bit as relevant to the methods used in implementation research. However, the trade-offs between the pursuit of rigorous methods and the timeliness and utility of the research is a major consideration in implementation research. As a simple example, policy makers often do not require a confidence of  $p < 0.05$  to make a decision, and might hesitate to expand a sample size or the duration of a study simply to meet this threshold. Another trade-off to consider in implementation research is whether to do this research in an embedded way within an organisation being studied or to do the research from outside the organisation. The embedded approach

encourages internal problem solving and adoption of findings, whereas an external approach can offer greater objectivity by the researchers, and more scope to produce findings that might be crucial to the organisation's performance.

Another issue is that implementation research is often focused on answering a particular problem in a particular setting, reducing the generalisability or ability to learn in places other than where the study was done. Being explicit about the application of theory<sup>74</sup> and using recently developed standards for reporting implementation studies guidelines should help to improve this issue.<sup>15</sup>

Another common tension is between the need to study and maintain the fidelity (implementation according to its design) of a particular intervention and the need to be able to adapt the intervention and learn lessons in the course of implementation. Adaptations to the intervention often happen as it is being scaled up or as conditions change. Implementation research can provide valuable information to guide these adaptations so that they fit the different contexts and needs, showing the importance of implementation research from the outset of the scale-up of complex interventions. The need to not only test the effectiveness of standardised interventions but also to use implementation research to support the evolution of interventions to fit the organisational and ecological contexts within which they are used is increasingly being recognised. This approach recognises that such adaptation can improve the outcomes of an intervention, rather than lead to an inevitable decrease in effectiveness.<sup>75</sup> Both approaches can be appropriate, but importantly key stakeholders (eg, researchers and authorising and implementing agencies) should be in agreement at the outset, or at least should agree how long they want to pursue a particular approach. One way of dealing with the need to change an intervention over time in pragmatic trials is to have a design phase in which the feasibility of different implementation arrangements or components is tested and agreed, and then fixed for the duration of the trial.<sup>76</sup>

Other tensions arise when balancing stakeholder interests and incentives within implementation research. Researchers need to spend time getting to know policy and practice organisations and need to give up some control over their research. These requirements involve skills and time that researchers might not have, in part because of the challenges of budgeting and knowing how much time is needed while meeting deadlines in conventional research funding proposals. Giving up control in this way requires a greater tolerance for uncertainty, but the pay-off is frequently better engagement, more immediate effects of the research, and sustained engagement. However, if universities do not value research impact in their recognition and promotion criteria, implementation research might be a risky endeavour, especially for junior academics. For implementing agencies and policy makers, implementation research provides opportunities

to improve their programmes and services, but might also attract attention to their work, with real consequences if performance is poor. Despite these organisational tensions, improvements in accountability are likely to benefit patients and populations served by health systems.

## Conclusion

The case studies show the wide range of implementation research processes in terms of scale, topics, methods, and range of impacts in global health. The effects of implementation research do not always fit neatly into the categories we have used to describe them. The same research can affect health outcomes while also informing policy, improving health management and service delivery, and empowering communities and beneficiaries. Many of the case studies illustrate how implementation research can be used to improve health service delivery within specific contexts and discuss the processes that can inform scale-up and efforts in other settings. Some of the case studies focus on vertical or disease-specific interventions (eg, smallpox, HIV, or onchocerciasis), and other case studies focus on broader health systems strengthening (eg, the national balanced scorecard for basic health services in Afghanistan and district level cases). In the case of disease-specific interventions, implementation focus brings in the need to acknowledge and address the broader health system factors that can either enable or inhibit effective action, and raises other areas for important consideration, such as community ownership and adaptation to community needs.

Context is crucial to the implementation research endeavour, and the case studies make context explicit. Many of the case studies include implementation research processes across different county contexts and programmatic objectives. There are strategic opportunities to learn lessons across diverse contexts. The case study examples of national nutrition systems, iCCM, and strengthening health systems at the district level illustrate a cumulative and growing body of knowledge about developing the health system's organisational capacity across multiple contexts and issues. Implementation research allows the documentation of processes to ensure that the depth and detail of what has been done is made explicit, so that adaptation to other contexts can be considered. Earlier work in this area has emphasised the importance of context and local and ongoing adaptation. For example, a systematic review of 150 strategies to strengthen health services in LMICs highlighted much higher implementation outcomes with flexibility and modification through stakeholder feedback, constraints reduction plans, initial and continuous adaptation of the strategy to the local context, broad-based support of stakeholders, and coordination and community organisation.<sup>31</sup>

Implementation research is about how to improve implementation: testing feasibility, adoption, and acceptance of the intervention; addressing quality, equity, efficiency, scale, and sustainability; and ensuring coverage

of all people, even those who are marginalised, with the ultimate goal of strengthening health systems to improve health outcomes. These endeavours involve a range of research methods, shaped according to the questions addressed and further iterative processes linking research, reflection, and action. These processes have important roles in helping policy change to be realised, sustained, and to have an effect.

The case studies also show how implementation research involves partnerships across the research and implementation cycles with coproduction and concurrent use of knowledge. Dissemination alone is not sufficient to support real change. The core characteristics of implementation research (panel 4) include the nurturing of trusting partnerships to do real-world, real-time research that addresses relevant implementation challenges. The case studies illustrate the importance of context and how health systems operate as complex adaptive systems,<sup>71</sup> constantly changing and shaped by the activities of a diverse set of actors who have different types of incentives to engage or not to engage in implementation research. The case studies illustrate approaches to complex issues in health systems strengthening, and how different stakeholders can learn from their efforts. Local leadership to support ownership, flexibility, and responsiveness of research to the realities and challenges posed by changing, complex, and adaptive health systems is important. Fragility and disaster bring into sharp focus the importance of trusting relationships and approaches that are both embedded and iterative to address the needs and realities of changing contexts.

The implementation research and delivery science statement released at the Cape Town Global Symposium on Health Systems Research is a call to action to the global health community (including academia, implementers, national and global health institutions, and donors) to take up the challenge of strengthening implementation through productive partnerships between policy makers, implementers, and researchers.<sup>7</sup> Advancing implementation research will require overcoming some challenges, including the misalignment of incentives in some academic institutions, which discourages young academics from creating a career in this area and sharing experiences through networks and publications. The growing effort to produce guidelines for publishing implementation research reveals the limitation of current approaches and recognises the importance of reporting studies in sufficient detail to permit replication or adaptation.<sup>64</sup> This highlights the need for further dialogue between journals and authors on how to report the implementation process and learning from implementation research and the broader field of health policy and systems research. Implementation research, as outlined in this Health Policy paper, presents an opportunity to bridge the know-do gap for the ultimate shared health impact that we researchers, policy makers, programme implementers, and communities seek to achieve.

#### Contributors

ST and NB drafted the paper with guidance from DHP. ST and DHP managed revisions of subsequent drafts. ST, NB, DHP, SE-S, and MG worked collectively to develop the conceptual underpinnings of the paper, the core characteristics of implementation research, and the approach to developing and interrogating the case studies. TD, SW, SE, JR, HE, SB, DP, MG, NB, DHP, and SE-S developed the case studies. EP provided input with respect to the literature search and application of implementation research in different contexts. All authors contributed to the analysis of case studies and elucidating key lessons for the application of implementation research, and all approved the final version of the manuscript.

#### Declaration of interests

We declare no competing interests. The views expressed in this Health Policy are our own, and do not necessarily represent those of USAID, the World Bank, or WHO.

#### Acknowledgments

Funding was obtained from the Funding Alliance for Health Policy and Systems Research, the World Bank, and USAID, through the Health Research Challenge for Impact Project with a Leader with Associates Cooperative Agreement (GHS-A-00-09-00004-00) to John Hopkins University, and the Translating Research into Action project funded under cooperative agreement (GHS-A-00-09-00015-00) with University Research Corporation. We thank Mark Taylor, Irene Ageypong, Lucy Gilson, Daniela Rodriguez, Laura Reichenbach, and Supriya Madhavan for their review and input, and Susie Crossman and Faye Moody for their support with references.

#### References

- 1 World Bank Group. Disease control priorities: improving health and reducing poverty. In: Jamison DT, Gelband H, Horton S, et al, eds. Disease control priorities, 3rd ed. Washington DC: World Bank Group, 2018.
- 2 Zuccala A. Modeling the invisible college. *J Assoc Inf Sci Technol* 2006; 57: 152–68.
- 3 Eccles MP, Mittman BS. Welcome to implementation science. *Implement Sci* 2006; 1: 1.
- 4 Peters DH, Adam T, Alonge O, Ageypong IA, Tran N. Implementation research: what it is and how to do it. *BMJ* 2013; 347: f6753.
- 5 Rabin BA, Brownson RC, Haire-Joshu D, Kreuter MW, Weaver NL. A glossary for dissemination and implementation research in health. *J Public Health Manag Pract* 2008; 14: 117–23.
- 6 Odeny TA, Padian N, Doherty MC, et al. Definitions of implementation science in HIV/AIDS. *Lancet HIV* 2015; 2: e178–80.
- 7 Health Systems Global. Statement on advancing implementation research and delivery science. Sept 30, 2014. <http://www.healthsystemsglobal.org/the-irds-statement/> (accessed Aug 8, 2018).
- 8 Kim JY, Farmer P, Porter ME. Redefining global health-care delivery. *Lancet* 2013; 382: 1060–69.
- 9 Blanchard JF, Aral SO. Program science: an initiative to improve the planning, implementation and evaluation of HIV/sexually transmitted infection prevention programmes. *Sex Transm Infect* 2011; 87: 2–3.
- 10 Damschroder LJ, Aron DC, Keith RE, Kirsh SR, Alexander JA, Lowery JC. Fostering implementation of health services research findings into practice: a consolidated framework for advancing implementation science. *Implement Sci* 2009; 4: 50.
- 11 Network NIR. Active implementation frameworks. <https://implementation.fpg.unc.edu/> (accessed June 24, 2018).
- 12 Meyers DC, Durlak JA, Wandersman A. The quality implementation framework: a synthesis of critical steps in the implementation process. *Am J Community Psychol* 2012; 50: 462–80.
- 13 Tabak RG, Khoong EC, Chambers DA, Brownson RC. Bridging research and practice: models for dissemination and implementation research. *Am J Prev Med* 2012; 43: 337–50.
- 14 Peters DH, Noor AA, Singh LP, Kakar FK, Hansen PM, Burnham G. A balanced scorecard for health services in Afghanistan. *Bull World Health Organ* 2007; 85: 146–51.
- 15 Pinnock H, Barwick M, Carpenter CR, et al. Standards for Reporting Implementation Studi es (StaRI) statement. *BMJ* 2017; 356: i6795.

- 16 Fixsen DL, Naoom SF, Blase KA, Friedman RM, Wallace F. Implementation research: a synthesis of the literature. Tampa: University of South Florida, 2005.
- 17 Kim JY. Within our grasp: a world free of poverty. <http://www.worldbank.org/en/news/speech/2013/04/02/world-bank-group-president-jim-yong-kims-speech-at-georgetown-university> (accessed Oct 3, 2018).
- 18 Glasgow RE, Chambers D. Developing robust, sustainable, implementation systems using rigorous, rapid and relevant science. *Clin Transl Sci* 2012; 5: 48–55.
- 19 Peters D, Tran NT, Adam T. Implementation research in health: a practical guide. Geneva: World Health Organization, 2013.
- 20 Foege WH, Millar JD, Lane JM. Selective epidemiologic control in smallpox eradication. *Am J Epidemiol* 1971; 94: 311–15.
- 21 Henao-Restrepo AM, Longini IM, Egger M, et al. Efficacy and effectiveness of an rVSV-vectored vaccine expressing Ebola surface glycoprotein: interim results from the Guinea ring vaccination cluster-randomised trial. *Lancet* 2015; 386: 857–66.
- 22 Baqui AH, Saha SK, Ahmed AS, et al. Safety and efficacy of alternative antibiotic regimens compared with 7 day injectable procaine benzylpenicillin and gentamicin for outpatient treatment of neonates and young infants with clinical signs of severe infection when referral is not possible: a randomised, open-label, equivalence trial. *Lancet Glob Health* 2015; 3: e279–87.
- 23 African Neonatal Sepsis Trial (AFRINEST) group, Tshefu A, Lokangaka A, et al. Simplified antibiotic regimens compared with injectable procaine benzylpenicillin plus gentamicin for treatment of neonates and young infants with clinical signs of possible serious bacterial infection when referral is not possible: a randomised, open-label, equivalence trial. *Lancet* 2015; 385: 1767–76.
- 24 WHO. Guideline: Managing possible serious bacterial infection in young infants when referral is not feasible. Geneva: World Health Organization, 2015.
- 25 Esamai F, Tshefu AK, Ayede AI, et al. Ongoing trials of simplified antibiotic regimens for the treatment of serious infections in young infants in South Asia and sub-Saharan Africa: implications for policy. *Pediatr Infect Dis J* 2013; 32 (suppl 1): S46–49.
- 26 Qazi SA, Wall S, Brandes N, Engmann C, Darmstadt GL, Bahl R. An innovative multipartner research program to address detection, assessment and treatment of neonatal infections in low-resource settings. *Pediatr Infect Dis J* 2013; 32 (suppl 1): S3–S6.
- 27 Adjei S, Gyapong J. Evolution of health research essential for development in Ghana. Geneva: Council on Health Research for Development, 1999.
- 28 Awoonor-Williams JK, Bawah AA, Nyongator FK, et al. The Ghana essential health interventions program: a plausibility trial of the impact of health systems strengthening on maternal & child survival. *BMC Health Serv Res* 2013; 13 (suppl 2): S3.
- 29 Krumholz AR, Stone AE, Dalaba MA, Phillips JF, Adongo PB. Factors facilitating and constraining the scaling up of an evidence-based strategy of community-based primary care: management perspectives from northern Ghana. *Glob Public Health* 2015; 10: 366–78.
- 30 Hansen PM, Peters DH, Niayesh H, Singh LP, Dwivedi V, Burnham G. Measuring and managing progress in the establishment of basic health services: the Afghanistan health sector balanced scorecard. *Int J Health Plann Manage* 2008; 23: 107–17.
- 31 Peters DH, El-Saharty S, Siadat B, Janovsky K, Marko V. Improving health service delivery in developing countries from evidence to action. Washington, DC: The World Bank, 2009.
- 32 Steinhart LC, Aman I, Pakzad I, Kumar B, Singh LP, Peters DH. Removing user fees for basic health services: a pilot study and national roll-out in Afghanistan. *Health Policy Plan* 2011; 26 (suppl 2): ii92–103.
- 33 Engineer CY, Dale E, Agarwal A, et al. Effectiveness of a pay-for-performance intervention to improve maternal and child health services in Afghanistan: a cluster-randomized trial. *Int J Epidemiol* 2016; 45: 451–59.
- 34 Black RE, Victora CG, Walker SP, et al. Maternal and child undernutrition and overweight in low-income and middle-income countries. *Lancet* 2013; 382: 427–51.
- 35 WHO. Fifty fourth World Health Assembly: infant and child nutrition. Geneva: World Health Organization, 2001.
- 36 UN. Zero Hunger Challenge. 2016. <http://www.un.org/en/zerohunger/pdfs/ZHC%20-%20Pathways%20to%20Zero%20Hunger.pdf> (accessed Oct 3, 2018).
- 37 UN. General assembly adopts resolution on SDGs report. 2014. <http://www.un.org/en/development/desa/news/sustainable/sdgs-post2015.html> (accessed Aug 8, 2018).
- 38 UK Government. Nutrition for growth: beating hunger through business and science. <https://www.gov.uk/government/news/nutrition-for-growth-beating-hunger-through-business-and-science> (accessed Aug 8, 2018).
- 39 Sun Movement Scaling up nutrition. Annual Progress Report. 2015. [http://docs.scalingupnutrition.org/wp-content/uploads/2015/10/SUN\\_AnnualReport2015\\_EN.pdf](http://docs.scalingupnutrition.org/wp-content/uploads/2015/10/SUN_AnnualReport2015_EN.pdf) (accessed Oct 1, 2018).
- 40 Gillespie S, Haddad L, Mannar V, et al. The politics of reducing malnutrition: building commitment and accelerating progress. *Lancet* 2013; 382: 552–69.
- 41 Mokoro. Independent comprehensive evaluation of the scaling up nutrition movement: final report, main report and annexes. Oxford: Mokoro Ltd, 2015.
- 42 Pelletier D, Gervais S, Hafeez-Ur-Rehman H, Sanou D, Tumwine J. Boundary-spanning actors in complex adaptive governance systems: the case of multisectoral nutrition. *Int J Health Plann Manage* 2018; 33: e293–319.
- 43 Martineau T, Raven J, Aikins M, et al. Strengthening health district management competencies in Ghana, Tanzania and Uganda: lessons from using action research to improve health workforce performance. *BMJ Global Health* 2018; 3: e000619.
- 44 WHO, Expandnet. Practical guidance for scaling up health service innovations. Geneva: World Health Organization, 2009.
- 45 WHO, Expandnet. Nine steps for developing a scaling-up strategy. Geneva: World Health Organization, 2010.
- 46 HERD. Supporting district health managers in Nepal to improve health workers' performance. 2016. <https://www.herd.org.np/projects/6/publications> (accessed Oct 3, 2018).
- 47 Gilson L, Elloker S, Olckers P, Lehmann U. Advancing the application of systems thinking in health: South African examples of a leadership of sensemaking for primary health care. *Health Res Policy Syst* 2014; 12: 30.
- 48 Kernick D. Facilitating resource decision making in public organizations drawing upon insights from complexity theory. *Emerg Complex Org* 2005; published online March 31. DOI:10.1002/emerg.10.1735796c1fa0e90aebd04245c1839de3d157f (preprint).
- 49 Cleary S, Schaay N, Botes E, Figlan N, Lehmann U, Gilson L. Re-imagining community participation at the district level: lessons from the DIALHS collaboration. In: Padarath A, King J, English R, eds. South African Health Review 2014/15. Durban: Health Systems Trust, 2015: 151–62.
- 50 Raven J, Baral S, Wurie H, et al. What adaptation to research is needed following crises: a comparative, qualitative study of the health workforce in Sierra Leone and Nepal. *Health Res Policy Syst* 2018; 16: 6.
- 51 Bohren MA, Vogel JP, Hunter EC, et al. The mistreatment of women during childbirth in health facilities globally: a mixed-methods systematic review. *PLoS Med* 2015; 12: e1001847.
- 52 McMahon SA, George AS, Chebet JJ, Moshia IH, Mpembeni RN, Winch PJ. Experiences of and responses to disrespectful maternity care and abuse during childbirth: a qualitative study with women and men in Morogoro Region, Tanzania. *BMC Pregnancy Childbirth* 2014; 14: 268.
- 53 Warren C, Njuki R, Abuya T, et al. Study protocol for promoting respectful maternity care initiative to assess, measure and design interventions to reduce disrespect and abuse during childbirth in Kenya. *BMC Pregnancy Childbirth* 2013; 13: 21.
- 54 Abuya T, Ndwiwa C, Ritter J, et al. The effect of a multi-component intervention on disrespect and abuse during childbirth in Kenya. *BMC Pregnancy Childbirth* 2015; 15: 224.
- 55 Amouzou A, Morris S, Moulton LH, Mukanga D. Assessing the impact of integrated community case management (iCCM) programs on child mortality: review of early results and lessons learned in sub-Saharan Africa. *J Glob Health* 2014; 4: 020411.
- 56 Marchal B, Denerville E, Dedzo M, De Brouwere V, Kegels G. Decentralisation, decision spaces and human resource management at hospital level. High commitment human resource management approaches used by the management team of Ghana's Cape Coast Central Regional Hospital. Antwerp: Institute of Tropical Medicine, 2005.

- 57 Hamer DH, Marsh DR, Peterson S, Pagnoni F. Integrated community case management: next steps in addressing the implementation research agenda. *Am J Trop Med Hyg* 2012; **87** (suppl 5): 151–53.
- 58 Rasanathan K, Muniz M, Bakshi S, et al. Community case management of childhood illness in sub-Saharan Africa—findings from a cross-sectional survey on policy and implementation. *J Glob Health* 2014; **4**: 020401.
- 59 George A, Rodriguez DC, Rasanathan K, Brandes N, Bennett S. iCCM policy analysis: strategic contributions to understanding its character, design and scale up in sub-Saharan Africa. *Health Policy Plan* 2015; **30** (suppl 2): ii3–11.
- 60 Bennett S, Dalglish SL, Juma PA, Rodriguez DC. Altogether now... understanding the role of international organizations in iCCM policy transfer. *Health Policy Plan* 2015; **30** (suppl 2): ii26–35.
- 61 Rodriguez DC, Shearer J, Mariano AR, Juma PA, Dalglish SL, Bennett S. Evidence-informed policymaking in practice: country-level examples of use of evidence for iCCM policy. *Health Policy Plan* 2015; **30** (suppl 2): ii36–45.
- 62 Rasanathan K. Policy analysis—important for improving iCCM implementation; essential for success of global health efforts. *Health Policy Plan* 2015; **30** (suppl 2): ii1–ii2.
- 63 Rau B. The Avahan-India AIDS Initiative: promising approaches to combination HIV prevention programming in concentrated epidemics. Arlington: USAID, 2011.
- 64 Kumar R, Mehendale SM, Panda S, et al. Impact of targeted interventions on heterosexual transmission of HIV in India. *BMC Public Health* 2011; **11**: 549.
- 65 Boussinesq M, Gardon J, Gardon-Wendel N, Chippaux JP. Clinical picture, epidemiology and outcome of Loa-associated serious adverse events related to mass ivermectin treatment of onchocerciasis in Cameroon. *Filaria J* 2003; **2** (suppl 1): S4.
- 66 Turner JD, Tendongfor N, Esum M, et al. Macrofilariocidal activity after doxycycline only treatment of *Onchocerca volvulus* in an area of Loa loa co-endemicity: a randomized controlled trial. *PLoS Negl Trop Dis* 2010; **4**: e660.
- 67 Begum J, Zimmerman B, Dooley K. Health care organizations as complex adaptive systems. In: Mick SN, Wyttenbach M, eds. *Advances in health care organization theory*. San Francisco: Jossey-Bass, 2003: 253–88.
- 68 El-Saharty S, Nagaraj BA. Reducing the risk of HIV/AIDS among female sex workers in India. Washington, DC: The World Bank, 2015.
- 69 Brieger WR, Sommerfeld JU, Amazigo UV, Network CDI. The potential for community-directed interventions: reaching underserved populations in Africa. *Int Q Community Health Educ* 2015; **35**: 295–316.
- 70 Katarbarwa MN, Habomugisha P, Eyamba A, et al. Community-directed interventions are practical and effective in low-resource communities: experience of ivermectin treatment for onchocerciasis control in Cameroon and Uganda, 2004–2010. *Int Health* 2016; **8**: 116–23.
- 71 Alley WS, van Oortmarssen GJ, Boatman BA, et al. Macrofilariocides and onchocerciasis control, mathematical modelling of the prospects for elimination. *BMC Public Health* 2001; **1**: 12.
- 72 Winnen M, Plaisier AP, Alley ES, et al. Can ivermectin mass treatments eliminate onchocerciasis in Africa? *Bull World Health Organ* 2002; **80**: 384–91.
- 73 Hoerauf A, Specht S, Marfo-Debrekyei Y, et al. Efficacy of 5-week doxycycline treatment on adult *Onchocerca volvulus*. *Parasitol Res* 2009; **104**: 437–47.
- 74 Grol RP, Bosch MC, Hulscher ME, Eccles MP, Wensing M. Planning and studying improvement in patient care: the use of theoretical perspectives. *Milbank Q* 2007; **85**: 93–138.
- 75 Chambers DA, Glasgow RE, Stange KC. The dynamic sustainability framework: addressing the paradox of sustainment amid ongoing change. *Implement Sci* 2013; **8**: 117.
- 76 Zwarenstein M, Treweek S, Gagnier JJ, et al. Improving the reporting of pragmatic trials: an extension of the CONSORT statement. *BMJ* 2008; **337**: a2390.

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