Operational research in low-income countries: what, why, and how?

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Operational research is increasingly being discussed at institutional meetings, donor forums, and scientific conferences, but limited published information exists on its role from a disease-control and programme perspective. We suggest a definition of operational research, clarify its relevance to infectious-disease control programmes, and describe some of the enabling factors and challenges for its integration into programme settings. Particularly in areas where the disease burden is high and resources and time are limited, investment in operational research and promotion of a culture of inquiry are needed so that health care can become more efficient. Thus, research capacity needs to be developed, specific resources allocated, and different stakeholders (academic institutions, national programme managers, and non-governmental organisations) brought together in promoting operational research.

Lancet Infect Dis 2009; 9: 711–17

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Introduction

Tukur, an illiterate patient diagnosed with malaria for the second time in a month, receives a prescription from the doctor for chloroquine pills, but he is unhappy and returns to the doctor to seek an alternative therapy, arguing that he has taken chloroquine several times in the past and it does not work. The doctor tells him that chloroquine is what the national malaria programme recommends and that it is the only medicine available.

Tukur is not a health professional, policy maker, or scientist, but he realised that the medicines he was given were not working, and had questioned his doctor. His experience should have prompted the doctor to ask similar questions about the drugs that he was prescribing. Similarly, those responsible for the malaria programme should have been monitoring the results of treatment as a part of routine care. Several months later, operational research done by an international non-governmental organisation (NGO) proved that Tukur's experience was correct—chloroquine treatment had a 91% failure rate[1]—and the drug was not effective in most patients with *Plasmodium falciparum* malaria.

The described example does not lay blame on clinicians in this kind of setting, who often do the best they can with limited resources. However, what was clearly lacking within this malaria control programme was a systematic process of monitoring drug resistance and treatment failure, and the ability to assess the implications on health-care delivery.

The subject of operational research is increasingly being discussed at institutional meetings, donor forums, and scientific conferences, but there is limited published information on its role from a disease-control and programme perspective. We have been involved with operational research in the field of infectious diseases over many years in resource-limited settings, and this article is thus based on our experiences. From a programme perspective, we will suggest a definition of operational research, clarify its relevance to infectious-disease-control programmes, and describe some of the enabling factors and challenges for its integration into programme settings and into changing policy and practice.

What is operational research?

Operational research has its roots in military and industrial modelling, in which it is defined as the discipline of applying advanced analytical methods, including mathematical models, to help make better decisions.[2,3] In the commercial sector, operational research has been widely used, for example, to improve the scheduling of airline crews and in the design of queuing systems at Disney theme parks.[2,3] However, its application to health programming is much less developed.

Many definitions of operational research have been proposed,[4–6] but from a health programme perspective, a pragmatic definition is as follows: the search for knowledge on interventions, strategies, or tools that can enhance the quality, effectiveness, or coverage of programmes in which the research is being done. Operational research involves three main types of method: descriptive (cross-sectional, if a strong analytic component is also present), case–control, and retrospective or prospective cohort analysis. Basic science research and randomised controlled trials should not be included as operational research. The randomised controlled trial determines efficacy of an intervention in a strictly controlled environment with inclusion and exclusion criteria, whereas operational research should assess effectiveness within routine settings. Both types of research play an important part in the generation of new knowledge: the randomised trial provides clear-cut data on the efficacy of an intervention in defined groups of patients, whereas operational research determines how such interventions are translated into benefit in the heterogeneous setting of routine care.

The key elements of operational research are that the research questions are generated by identifying the constraints and challenges encountered during the implementation of programme activities (prevention, care, or treatment), and the answers provided to these

	Country	Study description	Main findings	Implications for policy and practice
Improving medical care and practice				
Zachariah et al[7]	Malawi	Cohort study to assess feasibility and effectiveness of voluntary counselling, HIV testing, and co-trimoxazole in patients with tuberculosis by use of historical controls	Voluntary counselling and testing and adjunctive co-trimoxazole shown to be feasible, safe, and associated with reduced mortality in tuberculosis patients under programme conditions	Provided evidence to support countrywide expansion of HIV testing and co-trimoxazole within tuberculosis programmes
Harries and Salaniponi[8]	Malawi	Cross-sectional survey of patients with tuberculosis to assess classification of recurrent tuberculosis in 43 hospitals	Misclassification of recurrent tuberculosis cases as having new tuberculosis, and incorrect administration of anti-tuberculosis treatment regimens	Improvements in diagnosis, reporting and management of recurrent tuberculosis
Heiden et al[9]	Thailand, Cambodia, South Africa, China	Cross-sectional systematic retinal screening of patients with AIDS by fundoscopy	20% of AIDS patients with CD4-cell counts $<50\times10^6$ cells per L had cytomegalovirus retinitis, and 37% of individual eyes were blinded by cytomegalovirus	Establishment of decentralised diagnostic capacity for cytomegalovirus retinitis in HIV-positive individuals with CD4-cell counts $<50\times10^6$ cells per L
Reid et al[10]	Kenya	Descriptive assessment of intervention strategies in the care of HIV patients	Effective strategies to sustain HIV/AIDS care and antiretroviral therapy	Improved contingency measures for sustaining antiretroviral therapy and tuberculosis drug supplies during slum violence in Nairobi
Rieder and Deun,[11] Katamba et al,[12] Mabaera et al[13]	Moldova, Mongolia, Uganda, Zimbabwe	Retrospective audit of laboratory registers to assess incremental sputum yield in smear-positive pulmonary tuberculosis	Showed that two sputum smears were as good as three smears for diagnosing smear-positive pulmonary tuberculosis	Two-sputum-smear strategy replaced the previously internationally accepted three-sputum-smear strategy as the gold standard for diagnosing smear-positive pulmonary tuberculosis
Reyburn et al[14]	Tanzania	Prospective observational study of children and adults with suspected malaria over 1 year	Malaria commonly overdiagnosed in people presenting with severe febrile illness, leading to a failure to treat alternative causes of severe infection	Consideration of syndromic treatment
Berkley et al[15]	Kenya	Observational study involving a priori definition of a hierarchy of syndromic indications for antibiotic therapy	Simple clinical syndromes effectively target children admitted with invasive bacterial infection and children at risk of death	Led to an understanding that malaria parasitaemia does not justify the withholding of empirical parenteral antibiotics, and that lumbar puncture is critical to the rational use of antibiotics
Assessing feasibility of interventions in specific populations or settings				
Culbert et al[16]	Democratic Republic of Congo	Descriptive study of lessons learnt during 3 years of antiretroviral treatment in a conflict setting	Antiretroviral therapy can be offered in a conflict setting with good outcomes	Provided knowledge and contingency planning for sustaining comprehensive HIV/AIDS care, including antiretroviral therapy in chronic conflict settings
van Griensven et al[17]	Rwanda	Descriptive report of treatment and outcome data for health centres providing antiretroviral therapy	Antiretroviral therapy successfully offered by nurses at health-centre level	Showed feasibility and effectiveness of non-physician-based HIV/AIDS care including antiretroviral therapy for policy makers
Bedelu et al[18]	South Africa	Descriptive report of a rural model of antiretroviral treatment	A decentralised, simplified model of antiretroviral therapy delivery based on nurses was feasible in rural South Africa	Led to policy change in allowing non-physician clinicians to administer antiretroviral therapy
Advocating for policy change				
Guthmann et al[19]	18 countries	Multicentre studies of drug resistance and efficacy in falciparum malaria	High levels of drug resistance in falciparum malaria and ineffective national regimens	Led to a shift in national and international policy on use of more effective antimalarial treatment
O'Brien et al[20]	8 countries	Multicentre analysis of routine programme data for antiretroviral therapy in children	Very satisfactory outcomes in children on split-tablet generic fixed-dose antiretroviral therapy regimens	Showed that split-tablet, fixed-dose combinations of generic antiretroviral drugs were as effective as branded drugs in resource-limited settings
Zachariah et al[21]	Kenya	Retrospective cohort analysis of routine treatment outcomes of patients on antiretroviral therapy who did and did not pay for treatment	58% higher risk of loss to follow-up associated with payment for antiretroviral therapy; antiretroviral therapy dilutions by patients who pay for treatment	Policy change occurred and antiretroviral therapy begun to be offered free of charge to all patients in Mbagathi hospital
Lowrance et al[22]	Malawi	Descriptive report of experience and treatment outcomes of antiretroviral therapy scale up	Rapid countrywide scale-up of antiretroviral therapy is feasible and associated with good outcomes	A successful example of a public-health approach to countrywide scale-up of antiretroviral therapy in resource-limited settings based on simplified clinical decision making, standardised regimens, non-physician-based care, limited laboratory support, and centralised monitoring and evaluation

Table 1: **Examples of operational-research studies and their impact on policy and practice**

questions should have direct, practical relevance to solving problems and improving health-care delivery. Of course, this might not happen all at once, and is often a continuous and iterative process. A strong connection exists between good monitoring and evaluation of infectious-disease programmes and operational research. Good quality data on cases and treatment outcomes can be used to do operational research, which in turn can help to improve the routine data collected in the field. Nothing is more encouraging to health-care workers than to see their work in recording and monitoring data on treatment cards and registers being used to answer important questions, provided that this performance is recognised and applauded.

Why is operational research relevant?

There are at least three reasons why operational research is relevant to health. To improve programme outcomes in relation to medical care or prevention, to assess the feasibility of new strategies or interventions in specific settings or populations, and to advocate for policy change. Table 1 presents some examples of operational research in each category. In all cases, the research questions were generated from the field and answered issues of relevance for particular health programmes. Some studies provided descriptions of programmes with results over time (based on monitoring and evaluation), whereas others were purposefully designed to answer research questions. From a programme perspective, the ultimate relevance of operational research is whether it contributes to an improvement in performance or influences policy change at district, national, or even international levels.[23] Imbedding operational research into a programme setting brings with it intellectual stimuli that are an attractive change to the, at times, routine monotony of planning, logistics, supervision, data management, and dealing with bureaucracy.

Panel: **Factors that enable operational research and its translation into policy and practice**

- Research questions are generated from within programmes
- Research planning, agenda setting, objectives, targets, and budgeting are included within programme plans and as agenda items in programme management meetings
- Research projects use simple designs and are focused to answer implementers' questions
- Close collaboration and partnership has been established between researchers and programme managers
- Research is done within existing systems and not done in parallel
- A competent research officer works alongside the programme manager
- Training, mentorship, and on-the-job supervision is sustained over time
- Sufficient programme capacity exists to host workshops, present, and discuss research findings, and ensure their translation into policy and practice
- Programme staff have access to scientific literature through subscribed journals or the internet
- Sufficient numbers of programme staff are available with the capacity to do operational research, write up manuscripts, and publish relevant research
- Funding for applied research is available and individuals develop a desire to participate in research and are mentored
- Non-governmental organisations and other stakeholders are recognised and have a contributory role in operational research
- Good quality, appropriate, and relevant research gets translated into policy and practice and thereby has a spin-off effect to stimulate more research

Enabling factors and challenges for operational research

We have suggested several factors that we believe can foster programme-related operational research and the translation of its results into policy and practice (panel). We also discuss our failures over the past 10–15 years and their possible solutions (table 2).

Direct relevance to the programme

A research study is only thought relevant to busy and often overburdened programme managers and staff if the study question is of importance to programme implementation. Much of the internationally published research done in Africa has been generated by academic institutions and researchers, predominately reflecting their interests or based around basic science or questions of intervention efficacy.[24] Although these issues might be very useful in their own right, this type of research needs to be balanced by increasing the work done by operational organisations (eg, NGOs) who will have different perspectives. Different actors will naturally have comparative advantages for particular kinds of research and this should be used to the benefit of programmes. For example, an academic institution might be best placed to design and implement a randomised clinical trial or a vaccine study, whereas an implementing organisation might be best suited to take the lead in feasibility and acceptability studies. If research is disconnected from health-service delivery and there is little or no input from programme staff in terms of design, implementation, analysis, and writing, it risks being resented as an additional and often unwanted burden on existing services. One of the challenges is that foreign academic institutions often have the funding, time, and mandate for research and thus the associated power in decisions about what gets done. The way forward is surely to ensure that local institutions are also supported with money and staff for operational research, thus allowing them the necessary independence to make decisions, take responsibility, and establish partnerships that are more equal in resources and decision-making power.

These issues are being addressed internationally by organisations such as the Global Fund to Fight AIDS, Tuberculosis and Malaria, US Agency for International Development, WHO, UN Joint Programme on HIV/AIDS, and World Bank Global HIV/AIDS Program.[5] Nationally, at which level we have the most experience, we suggest building a research agenda into district and national programmes, based on local needs, but primarily reflecting the research priorities of the country. Within a country, it is important to have a coordination mechanism to provide a clear strategy of who sets research priorities and how choices are made at national level. This is particularly important because research resources for addressing health problems in low-income countries remain disproportionately scarce compared with their massive disease burdens. A bibliometric analysis of tuberculosis research done globally between 1997 and 2006 showed that Africa, which has the highest tuberculosis case rate burden in the world, contributed only 7% of global research output.[25] The focusing of resources in a concerted manner has been shown to optimise direct health benefits at the levels of programmes and patients.[26,27]

	Possible reasons	Lessons learned
Training and capacity building		
Capacity building efforts are targeted to the wrong individuals; trained staff, with MPH and PhD degrees, do not engage in research and are not retained in research activities when returning to their countries	Individuals who are selected for training do not have an interest in operational research; qualified researchers end up in senior management positions or have no opportunity or time for research	Establish strict criteria for selection of potential candidates for training; establish an operational research position within the programme; ensure that dedicated time to do research and a conducive infrastructure are provided; introduce a research bonus for completed research studies
Study design and publications		
Poor adherence to study protocol and poor quality of data	Inadequate on-the-job training and supervision	Ensure scheduled regular supervision and feedback, invest in in-service training
Failure of research to produce manuscripts and publications	Wrong choice of research question; poorly designed studies; inadequate writing and language skills; no ethics clearance or exemption	Provide mentoring in defining the study question and designing studies; writing-skills training for publication is vital; ensure that ethics is an essential part of training and attention paid to timely ethical submission
A competent researcher is available in the programme but does not do relevant research	The researcher has inadequate understanding or experience working at a programme level (programme skills); the proposed research is too academic	Invest in individuals who have programme experience to develop research skills; introduce the concept of research fellows who will be imbedded within programmes and who will be mentored
Ineffective research partnerships		
A research partnership starts but fails with time	The partner (academic institution, UN or technical agencies, or NGOs) has the money and staff for research and holds the power of decision; a lack of joint ownership of research by programme staff; programme managers sideline research	A partnership model needs to be built with active involvement of programme staff during all stages of the research; money and staff should be integrated within annual programme planning and budgeting; the research question should be relevant to the programme
Policy and practice		
Research findings are not translated into policy and practice	Key decision and policy makers were not involved right from the beginning (lack of ownership); the researcher invests until the publication stage and goes no further; authorship is not inclusive of key decision makers	Empower decision makers to value the study right from the beginning and sense ownership; recognise that publication enhances credibility of research findings and is only the beginning of a process for translation of findings into policy and practice; introduce a clear performance framework to evaluate the impact of research on programme performance over time

Table 2: **Failures of operational research, possible reasons, and lessons learned**

Partnering with local programmes

Local programmes have a tendency to outsource research to academic institutions, which then set up parallel research systems or affiliated sites.[23] Although this might be a highly efficient means to produce quality research and scientific publications, if there is no satisfactory mechanism for integration, collaboration, and communication with the programme, then such an approach might hinder the development of operational-research capacity by drawing national researchers away from national programmes. Furthermore, because research institutions and technical agencies (either international or national) normally have no mandate or responsibility for implementing research findings after their studies are completed, the results often end up being sent or presented to busy programme managers, who have no ownership of the research and who are therefore unlikely to direct the effort needed to translate the research into policy and practice.

What is needed is a change to a partnership model that counteracts this tendency through greater involvement, co-ownership, and responsibility of programme staff along with researchers.[28] For example, the research question should be developed by the entire team, including those involved with questionnaire development, collection and analysis of data, and dissemination of the results. Planning at this stage also requires a clear engagement with the people who make decisions on policy (eg, directors of preventive or clinical services in the Ministry of Health, or the Chief Commissioner of Prisons if the research is directed towards health issues of prisoners), so that they are aware of what is being asked, supportive of the research, and interested to learn about the findings. Specific funding and resources for operational research should thus be built into the programme.[23] Encouraging examples of co-ownership and partnership include institutions that are part of the INDEPTH network, an international non-profit organisation that is involved with demographic and health research in low-income countries in Africa and Asia. In addition, the literature on getting research into practice and policy provides guidance on how to tackle some of the challenges of translating research findings.[29] Other commendable initiatives include the Consortium for Research on Educational Access, Transitions, and Equity and the partnership between Liverpool School of Tropical Medicine, Malawi College of Medicine, and the Wellcome Trust.

For more on the **INDEPTH network** see http://www.indepth-network.net/

For more on the **Consortium for Research on Educational Access, Transitions, and Equity** see http://www.create-rpc.org/

For more on **the partnership between Liverpool School of Tropical Medicine, Malawi College of Medicine, and the Wellcome Trust** see http://www.mlw.medcol.mw/

Building local research capacity

Writing up study protocols, seeking funding, collecting and analysing data, writing manuscripts, dealing with peer review, and revision of papers are all essential components of taking a research project from conception to completion, but capacity and time for such activities within most programme settings are often lacking. However, if they are planned as an essential part of the programme, they can be accomplished. The experience of integrating operational

research within the Malawi National Tuberculosis Control (NTP) programme is an example of how these aspects can be successfully built into a national programme, and be of great value in shaping policy and practice.[4] Between 1996 and 2004, many studies were designed, planned, and budgeted within the NTP.[30] The programme invested in a full-time operational-research officer and a data-management officer who worked alongside the programme manager and provided on-the-job training and supervision of research. Planned and continuing programmatic research was always an agenda item at the regular 6-weekly programme management group meetings. The NTP held an annual scientific review and dissemination meeting, and operational-research findings were presented by local and international investigators to all stakeholders. A medical editor was recruited to give an annual workshop on paper writing skills and on how to get the research published. All publications in national and international journals were collated each year, and the resulting booklet was distributed to health-care workers around the country at national meetings and during supervision so that everyone had potential access to the results of locally generated research. All these components were built into the NTP plans with explicit budget streams, and these helped to develop the capacity to ask pertinent questions and to carry them through to publication for dissemination.

Inevitably, however, there were failures. Several research projects that were started and implemented with funding through the Malawi NTP never reached completion because of inaccurate data collection, poor adherence to study protocols, and inadequate supervision. A phased training and operational-research capacity-building exercise involving 25 district tuberculosis officers with close mentorship throughout resulted in only 11 (44%) officers taking the directed research through to completion and paper writing.[31] The failure to publish research is not just confined to the low-income countries: a recent report found that only 53% of 79 research studies reported in conference abstracts were published in peer-reviewed journals after 9 years.[32] Common reasons for so-called research waste include the wrong choice of research question, poorly designed studies, and failure to publish relevant research promptly or at all.[33]

Developing trained researchers

There is a perceived need to create a so-called critical mass of trained researchers within health programmes to ensure that sufficient numbers of researchers continue in post to sustain future research. The Japanese Research Institute of Tuberculosis, the Japanese Foundation for AIDS Prevention, the International Union Against Tuberculosis and Lung Disease, and the US Centers for Disease Control and Prevention are among some of the institutions that support international training on operational research. Although these initiatives need to be encouraged, there is also a need to assess whether current capacity-building initiatives are having an effect. Do we know, for example, how many health workers who have been trained through these initiatives actually complete their research studies and publish papers? How many became researchers? We suspect that the answer to both questions is "very few", but we should be tracking personnel after training (eg, through databases) to document the outcomes, explore any barriers, and capture suggestions for reversing this trend. Many researchers from low-income countries, even after obtaining PhDs, do not take up research when working back in disease-control programmes. This might be because they end up in senior-level management posts, the infrastructure to plan or do research is lacking, or there are simply no opportunities. Talented local individuals need to be encouraged to participate in research at programme level.

There are various ways in which these opportunities could be created. First, small grants could be offered to pursue locally applied research. Second, junior and senior operational research fellowships could be created for colleagues in low-income countries with active mentoring by international researchers, institutions, or NGOs. The International Union Against Tuberculosis and Lung disease is planning such an initiative in 2009. Bureaucracy should be kept to a minimum with the main focus on deliverable outcomes that would include publications with specific benefits to programmes and communities.[34] Targets for research output should be set (eg, one or two research papers each year submitted to a peer-reviewed journal), with financial and technical support continued when targets have been met and termination of support if targets have been missed. With international funding from the Global Fund now available for AIDS, tuberculosis, and malaria, and a stated intention that a sizable proportion of funds should go towards operational research, funding for local and national research fellowships could become reality. Third, young national researchers should have the opportunity to present scientific abstracts and participate at regional and international conferences, and more attention should be paid to teaching the principles of how to write scientific papers and to mentoring. Fourth, attention must be paid to the problem of poor access to up-to-date scientific literature, and despite laudable initiatives (ie, the Health InterNetwork Access to Research Initiative),[35] this remains a barrier in low-income countries. Many research studies done in Africa are published in high-impact-factor journals in high-income countries, and these are often unavailable because of cost or lack of internet capacity. Free and open access for all articles of interest to low-income countries is thus urgently needed. For example, Médecins Sans Frontières (MSF) has negotiated with publishers to allow free access to all articles written by its staff.

For more on **Médecins Sans Frontières** see http://fieldresearch.msf.org/

The role of NGOs

The distinct role for NGOs in operational research should be recognised for two main reasons. First, NGOs such as

MSF often work in conflict settings, with marginalised and vulnerable populations, or with neglected diseases. Academics rarely have access to such settings, and national programmes might decide they do not have sufficient resources to study them. Research in these areas is, nevertheless, needed to better understand how to manage questions such as mental health issues in war zones,[36] treatment and diagnosis of neglected diseases,[37] or offering of HIV/AIDS care in slum settings. For example, when the Sphere Project guidelines recommended against HIV therapy in conflict settings,[38] an MSF study by Culbert and colleagues[16] proceeded anyway and showed good outcomes. The importance of contributing to sustainable and evidence-based change is being recognised within MSF, as shown by its rapidly growing scientific output. Second, NGOs are, by mandate, implementers and can thus be involved in the translation of research findings into policy and practice. If they have skills in research and advocacy as well as sufficient financial and human resources, then they probably have the potential to actively engage in operational research and help change practice.

For more on the **2009 International AIDS Society's Conference** see http://www.ias2009.org/

However, NGOs are sometimes not the appropriate entities for designing or implementing research. They might lack the institutional support, culture, and skills for interacting with national programmes and decision makers; their focus might be on solving localised, short-term problems and they might have had little exposure to systems thinking; they might lack the training and capacity to do rigorous research; and they might have a rapid turnover of staff, which hinders the sustainability of research and the ability to build up trust and understanding with country partners. These points might explain why NGOs rarely undertake research, are rarely asked by country programmes to do so, and why the research they do undertake is sometimes badly done, with little or no programme impact.

Where do we go from here?

Despite the demonstrated value of operational research, there seems to be a real gap between the call for more research and action. For instance, although the Sydney Declaration that "good research drives good policy and programming" in 2007 suggested allocating 10% of all resources to HIV programming for operational research,[39] this has not been taken up and has had a very limited impact. The Global Fund allows 5–10% of each grant to be allocated for monitoring, evaluation, and operations research, but this provision is rarely used.[40] We need to determine the reasons for such poor uptake, which might be linked to the lack of participation of research groups or individuals with research capacity in the country's coordination mechanisms.

Conclusion

We have made the case for the importance of operational research as a necessary component of health programming in low-income countries. What is needed now is further development of operational-research capacity, allocation of specific resources, and the need for different participants such as international and national academic institutions, national programme managers, and NGOs to work together in promoting operational research.

There are some encouraging signs. Strengthening research capacity in Africa has risen up the international agenda, and in July, 2009, the Wellcome Trust announced the formation of seven new international consortia, each led by an African institution, geared to building sustainable research capacity across Africa.[41] The development of functional research platforms is essential to the improvement of health in Africa, and the Initiative to Strengthen Health Research Capacity in Africa and the Wellcome Trust initiative are promising new approaches to help improve the research environment and to support individuals and institutions. Although these initiatives might support the more technologically centred components, they should encourage other funders to invest in sustainable research, including operational research that is built into the framework of programmes. The 2009 International AIDS Society's Conference in Cape Town, South Africa, has had, for the first time, a track dedicated to operational research. Particularly in areas where the disease burden is high and resources and time are limited, we need to invest in operational research and to promote a culture of inquiry so that health care can become more efficient.

Contributors

RZ and ADH wrote the first draft and handled the revisions, which were critically reviewed by all authors. All authors contributed to the different drafts and the final version of the paper.

Conflicts of interest

We declare that we have no conflicts of interest.

Acknowledgments

We are grateful to individuals and donors in several countries who either work or support operational research. In particular, we thank an anonymous donor for his previous and continuing support of operational research in low-income countries. The contents of this document are the sole responsibility of the authors and do not necessarily reflect the positions of the International Union Against Tuberculosis and Lung Disease or other quoted institutions.

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