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The Union and Médecins Sans Frontières approach to operational research

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SUMMARY

Operational research (OR) has become a hot topic at national meetings, international conferences and donor fora. The International Union Against Tuberculosis and Lung Disease (The Union) and Médecins Sans Frontières (MSF) Operational Centre Brussels strongly promote and implement OR with colleagues in low- and middle-income countries. Here we describe how the two organisations define OR, and explain the guiding principles and methodology that underpin the strategy for developing and expanding OR in those countries. We articulate The Union's and MSF's approach to supporting OR, highlighting the main synergies and differences. Then, using the Malawi National Tuberculosis Control Programme as an example, we show how OR can be embedded within tuberculosis control activities, leading to changes in policy and practice at the national level. We discuss the difficult, yet vitally important, issue of capacity building, and share our vision of a new paradigm of product-related training and performance-based OR fellowships as two ways of developing the necessary skills at country level to ensure research is actually performed. Finally, we highlight the need to consider and incorporate into practice the ethical components of OR. This is a key moment to be involved in OR. We are confident that in partnership with interested stakeholders, including the World Health Organization, we can stimulate the implementation of quality, relevant OR as an integral part of health service delivery that in turn will lead to better health for people, particularly for those living in the poorer parts of the world.

KEY WORDS: operational research; tuberculosis; HIV/AIDS; The Union; Médecins Sans Frontières

DEFINING THE TERM 'OPERATIONAL RESEARCH'

If 10 different people are asked to define operational research (OR), there will probably be 10 different answers. 'Operational research', also sometimes known as 'operations research', has been variously defined as an interdisciplinary branch of applied mathematics or formal science that uses advanced analytic methods to make better decisions or research that provides optimal solutions to complex decision-making.[1,2] The term 'implementation research' is also commonly used, and has been defined by some as the scientific study of methods to promote the systematic uptake of clinical research findings and other evidence-based practices into routine practice, and hence to improve the quality (effectiveness, reliability, safety, appropriateness, equity, efficiency) of health care.[3,4] These various definitions have a certain commonality.

At the International Union Against Tuberculosis and Lung Disease (The Union) and the Médecins Sans Frontières (MSF), based on our shared experience, we have developed a more simple and pragmatic understanding of these types of research. We prefer the term 'OR', which we define as research into strategies, interventions, tools or knowledge that can enhance the quality, coverage, effectiveness or performance of the health system or programmes in which the research is being conducted.[5] We see OR as a spectrum of activities that encompasses reviews of registers and treatment cards, minor modifications and

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evaluations of operational practices to field testing new technologies.

GUIDING PRINCIPLES AND RESEARCH METHODOLOGY

We have three guiding principles that underpin our way of conducting OR and help us to set up a research agenda and determine research priorities. The first principle is that a health programme (or health system) should have well-defined goals and objectives. For example, for a tuberculosis (TB) control programme, these goals will often focus around case finding and case holding/treatment, with objectives directed towards better and more equitable diagnosis, improved cure rates, low death rates, uninterrupted drug supplies and reliable monitoring. The second principle is that constraints and obstacles that prevent these objectives from being achieved must be identified, prioritised and articulated. The third principle is that research questions need to be asked to address these constraints. The avenues of enquiry are usually of three main types—is there a lack of knowledge? a lack of a suitable tool or intervention or the possibility of a better tool or intervention being used? or an inefficient use of a tool or intervention? Table 1 provides an example of how these guiding principles might work in a number of different programme settings.

OR is often observational in nature, and involves three main types of methodology: descriptive studies (sometimes called 'cross-sectional research' if it includes a strong analytic component), case-control studies, and retrospective or prospective cohort analysis studies. We do not regard basic science, experimental research or classical randomised controlled clinical trials (RCTs) as OR. Most RCTs determine the efficacy of an intervention in a strictly controlled environment with inclusion and exclusion criteria, while OR assesses effectiveness within the routine programme setting. However, pragmatic randomised controlled designs, such as a cluster-randomised trial of community support for human immunodeficiency virus (HIV) care,[6] carried out within routine programme settings, might be included as OR.

Table 1 An example of the process of developing an operational research study

Type of setting	TB programme HIV treatment programme Smoking cessation intervention
Objective	85% treatment success in TB programme 80% retention on antiretroviral treatment 90% successful completion in smoking cessation cohort
Constraint	High rates of loss to follow-up
Research question	Why are patients lost to follow-up?
Research methodology	Involves identifying and tracing patients lost to follow-up: • Review of clinic and laboratory registers • Active tracing to determine how many of those lost to follow-up are unreported deaths, un-notified transfer outs, patients who have stopped treatment or patients who are still on treatment but from other sources • Qualitative research to determine why patients have stopped treatment—Payment for medication? Cost of transport to clinic?
Answers to the question	The programme seeks to solve the problems and reduce losses to follow-up and ultimately improve treatment outcomes.

TB = tuberculosis; HIV = human immunodeficiency virus.

Both OR and the classical RCT play an important part in the generation of new knowledge: the RCT provides clear-cut data on efficacy in identified groups of patients, while OR determines the effectiveness of interventions in the real world of routine patient care. OR is often regarded as second best to the RCT, but each contributes to better patient care in its own way; in fact, they are complementary. Recent guidelines for the reporting of observational studies (the Strengthening the Reporting of Observational Studies in Epidemiology [STROBE] statement) will help towards improving the scientific credibility and value of this type of research.[7]

Well-performing TB control or antiretroviral treatment (ART) delivery programmes are well adapted for OR because of their strong, inherent standardised monitoring and evaluation systems. These systems routinely track the number of patients enrolled for treatment over defined periods, key demographic and clinical characteristics, types of treatment and treatment outcomes. Such data, documented in treatment cards and facility-based registers and sometimes within electronic data systems, are ideally suited for OR. Furthermore, conducting OR using programme data invariably has a beneficial effect on data collection and quality. Linking monitoring and evaluation data to OR is thus a win-win situation, which should lead to better quality monitoring and research and ultimately to improved programme performance.

THE UNION'S APPROACH TO OPERATIONAL RESEARCH SUPPORT IN TB CONTROL

In the last 10–15 years, there have been impressive gains in global TB control, with gradual increases in case detection and treatment success rates.[8] However, many challenges remain, including access to early diagnosis, implementing programmatic management of multidrug-resistant TB (MDR-TB) and HIV-associated TB and the efficient and informed introduction of new diagnostic tools into routine programme settings. These are all priority issues that could benefit from timely and pragmatic OR studies. While OR has been included in the most recent Global Plan to Stop TB (2006–2015),[9] actual implementation of research activities in the field for various reasons, such as lack of capacity and difficulty in formulating research

questions, has not been systematically developed in many of the high-burden countries most in need of these efforts.

The Union is currently trying to address these deficiencies through two independent, yet interlinked, research initiatives. In September 2008, through resources awarded by the United States Agency for International Development (USAID), The Union launched the TREAT TB (Technology, Research, Education and Technical Assistance for TB) Initiative. This initiative aims to address specific research gaps globally in the area of diagnosis and treatment of TB, and build OR and programme assessment capacity at country level among ministries of health and their National TB Programmes (NTPs) in USAID-priority countries. Through this five-year initiative, The Union is engaging with numerous technical partners working at international, regional and national levels to achieve a number of objectives. One of these is to define and address priority needs for OR among NTPs and their local partners. In January 2009, through generous philanthropy, The Union was able to found the Centre for Operational Research, which aims to strengthen OR capacity and the collection and use of strategic information in low- and middle-income countries. Its focus is on TB and HIV/AIDS (acquired immune-deficiency syndrome), key non-communicable diseases such as diabetes and hypertension, and monitoring methods that include the use of electronic medical records to track chronic disease and village-level vital registration.

OR is not new to The Union, however. Founded in its present form in 1920, The Union has had a long history of engagement in OR.[10] The Union's Board of Directors in 1987 approved the prioritisation of three main activities: education, research and technical assistance. OR features in each of these priority activities. Consultants, with their colleagues in country programmes, currently publish about 50 OR articles per year. The Union also provides a platform for exchanges about OR through its international and regional conferences and through the scientific journal, the *International Journal of Tuberculosis and Lung Disease* (IJTLD).

Country-level needs have always been paramount in The Union's thinking, and a comprehensive approach to support OR has been the predominant strategy. Figure 1 illustrates the comprehensive support package articulated by the TREAT TB Initiative. A necessary starting point is a situational analysis that provides a clear understanding of the existence or not of a research agenda; past and present OR activities, including the identification of key national and international partners involved in OR; linkages between national academic institutions and government programmes; human and financial resource capacity to undertake OR; and past publications and policy changes related to national research efforts.

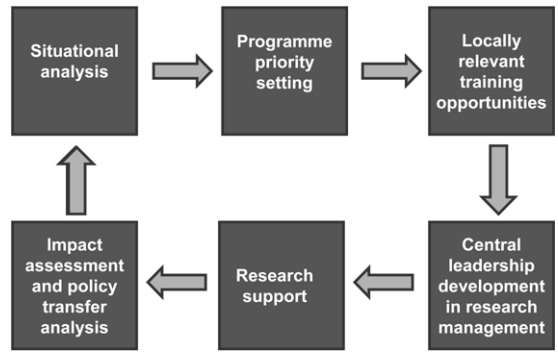

Figure 1 The Union's operational research support package.

Countries and programmes vary in their OR achievements at the time that this analysis is undertaken, with some programmes having virtually no OR capacity while others may be fairly experienced. This analysis also serves as a baseline against which annual evaluations and assessments of OR activities can be conducted, and it also allows for the development of a coordinated plan for OR.

The next important step is the clarification of programme objectives and the development of clearly defined priorities, which often require a broad consultation process with local and international partners. Where a priority setting exercise has already taken place, updates may be necessary at regular intervals to ensure the greatest relevance of OR activities on an ongoing basis. Situational analyses, clarification of programme objectives and priority setting activities are helpful steps to identify OR agendas and training plans that are tailored to national needs. Related to, yet distinct from the broad training requirements for successful OR at country level, is the need for leadership in the management of research programmes. This capacity can be developed through a variety of international training and mentoring opportunities, including support and training for OR fellows.

The presence of clearly established research priorities and adequate human resources at all levels are necessary, but not sufficient, components for successful OR implementation. Funding is required, and The Union supports countries and programmes in identifying and securing the necessary financial resources to address national research priorities. Moreover, The Union provides comprehensive guidance for all aspects of OR, including protocol development, ethics review processes through to peer-reviewed publications and presentations and knowledge translation.

A unique aspect of The Union's OR package is the inclusion of two new frameworks in its training and OR initiatives. The impact analysis framework (IAF) developed by the Liverpool School of Tropical Medicine and partners, and being tested, in part, through The Union-led TREAT TB Initiative, examines new tools and approaches through a broad lens.[11] It moves

beyond simply an analysis of efficacy, adding further analyses related to equity, health systems, scale-up and policy. It is accompanied by a policy transfer analysis framework developed by The Union. Policy transfer analysis adds a further dimension to OR by assessing the factors that affect uptake into policy and practice and the impact of OR on national policy.

MÉDECINS SANS FRONTIÈRE'S APPROACH TO OPERATIONAL RESEARCH

MSF is an international medical non-governmental organisation (NGO) that works in many countries and provides medical assistance to vulnerable populations living in difficult and resource-limited settings. Over the past 10 years, the organisation has become increasingly involved in disease control programmes such as HIV/AIDS, TB and malaria. Unlike at The Union, OR in MSF is rather new. There was a time when research was considered taboo by senior managers, who felt it to be in conflict with the core 'implementation' mandate of the organisation and a possible diversion of operational resources. However, this attitude has changed with the realisation that research can be complementary to project goals and can support the mandate of the organisation.

The three main reasons why MSF now embraces OR are 1) to assess the effectiveness of treatment or prevention interventions in projects, thereby leading to improvements in the quality of the assistance; 2) to assess the feasibility of implementing new models of care; and 3) to gather evidence to support advocacy for health policy change.[12] Although the basic principles upon which The Union and MSF have built their research foundations are synergistic, there are some differences related to the mandates of the two organisations that are worthy of note.

First, as an implementing organisation, MSF directly implements research on the ground. The project medical coordinator is held responsible, enhancing ownership and helping to make research an integral part of routine operational activity.

Second, programme officers help to define the research questions based on monitoring and evaluation data. Studies are therefore often descriptive or cohort in nature, and involve routine programme data.[12] Eight of 10 studies conducted by MSF fall into this category, with prospective studies and clinical trials constituting a minority of 6%.[12] MSF rarely conducts clinical trials, as it is not resourced to do so and has no comparative advantages over academic or other research institutions in this regard. Previous experience with RCTs within MSF has also shown that these can become a parallel activity with routine operations, and this risks a conflict with the core implementation mandate of the organisation.

Third, research studies generated from programme data are incorporated into annual project planning exercises where funding is an integral component. This facilitates administrative aspects, and means that researchers do not have to worry about securing external funding.

Fourth, MSF's research agenda is more diverse than that of The Union, as it is driven by changing operational projects. Until now, the focus at The Union has been centred on TB and respiratory disease, although this is changing. While a dynamic OR agenda in MSF keeps the focus congruent with operations, the downside is that research activities in specific domains might not be sustained, and the expertise needed might not necessarily be available within the organisation. Fifth, operational activity and capacity building are primarily focused at the district or project level, rather than at the national level as with The Union. However, it is through such decentralised modus operandi that technical and advocacy links are made to the central level and beyond.

Finally, The Union hosts the IJTLD and disseminates knowledge on TB, lung health, HIV and tobacco control in this and a number of other journals. MSF also disseminates knowledge through publications in a variety of journals, but it also hosts the *MSF Field Research Repository*[13] and conducts annual scientific days.[14,15] The *Field Research Repository* makes all MSF-authored, peer-reviewed publications available free-of-charge online thanks to permission granted by over 100 journals. A recent analysis of the repository showed that close to 130 peer-reviewed publications are downloaded each day from different countries around the world, indicating the relevance and public demand for these publications. Table 2 highlights a number of examples of research conducted by MSF, their main findings and implications for policy and practice.[12,16–22] Table 3 highlights some key enabling factors that have permitted the development of research in MSF. However, it is important to note that this has not always been smooth sailing, and several barriers have been encountered along the way. Table 4 highlights some of these barriers, the possible reasons and lessons learnt.[12] It is only by addressing such challenges and persevering that one can continue to 'learn by doing', and in this way find solutions.

AN EXAMPLE OF INVESTING IN OPERATIONAL RESEARCH: THE MALAWI NATIONAL TB PROGRAMME

Between 1996 and 2004, the Malawi NTP, with support from the international donor community, invested in OR as an integral part of its activities. A partnership was set up whereby research ideas from within the NTP, from local institutions (such as the Malawi Medical School, NGOs such as MSF and the National AIDS Programme) and from international organisations (such as the World Health Organization

Table 2 Examples of operational research studies published by Médecins Sans Frontières and their contributions to policy and practice. Adapted from Zachariah et al.[12]

Operational research studies, author, reference, title	Main finding(s)	Contribution(s) to policy and practice
Improving effectiveness of medical interventions		
Zachariah et al.[16] Payment for antiretroviral drugs is associated with a higher rate of patients lost to follow-up than those offered free-of-charge therapy in Nairobi, Kenya	58% higher risk of loss to follow-up associated with payment for ART; ART dose dilutions by patients who had to pay for ART	Policy makers accepted the detrimental effect of ART payment on outcomes and the service began to be offered free-of-charge to all patients in Mbagathi Hospital Led to policy changes in the Kibera ART programme design and implementation to enhance ART uptake
Massaquoi et al.[17] Patient retention and attrition on antiretroviral treatment at district level in rural Malawi	Relatively high levels of loss to follow-up at district hospital level and mortality at primary health centres while scaling up ART for universal access	Provided policy recommendations to reduce attrition rates
Assessing feasibility in specific populations or settings		
O'Brien et al.[18] Universal access: the benefits and challenges in bringing integrated HIV care to isolated and conflict-affected populations in the Republic of Congo	Integrated ART can be offered in a conflict setting with good outcomes	Provided knowledge on how to implement an integrated HIV/AIDS programme in a rural conflict-affected setting to achieve universal access
Zachariah et al.[19] VCT and adjunctive cotrimoxazole reduces mortality in TB patients in Thyolo, Malawi	VCT and adjunctive cotrimoxazole shown to be feasible, safe and associated with reduced mortality in TB patients under programme conditions	Provided evidence on feasibility and effectiveness to support countrywide expansion of HIV testing and cotrimoxazole for TB patients in Malawi
Wilson et al.[20] HIV prevention, care and treatment in two prisons in Thailand	Describes the experience of offering HIV/AIDS care in two prisons in Thailand	Provided knowledge on how to implement HIV/AIDS care in prison settings
Advocating for policy change		
Van Griensven et al.[21] High prevalence of lipoatrophy among patients on stavudine-containing first-line ART in Rwanda	Showed that lipoatrophy was an important complication of WHO recommended first-line ART regimens	Highlighted the urgent need for access to more affordable and less toxic ART regimens in Africa
Grais et al.[22] Unacceptably high mortality related to measles epidemics in Niger, Nigeria and Chad	Demonstrated unacceptably high measles-related case fatality in the three countries	Provided evidence to advocate for improving measles vaccination programmes in the affected countries.

ART = antiretroviral treatment; HIV = human immunodeficiency virus; AIDS = acquired immune-deficiency syndrome; VCT = voluntary counselling and HIV testing; TB = tuberculosis; WHO = World Health Organization.

Table 3 Enabling factors for building operational research into an implementing organisation such as Médecins Sans Frontières

- A critical mass of experienced and dedicated operational research staff who have programme skills and are available at headquarters and in the field
- Headquarters staff includes a research officer, a data manager and a medical editor, while in the field operational research staff includes a research officer or epidemiologist, a data manager and data entry clerks
- A clear institutional policy framework has been written clarifying the 'what, why and how' of operational research
- Research planning, agenda setting, objectives, targets and budgeting are included in annual country project planning exercises
- Research questions are generated from the programmes, and research is conducted within the framework of field operations and not run in parallel
- Training, strong mentorship and on-the-job supervision is provided to national staff, and close collaboration is established with local authorities and national partners
- Prompt feedback of research results is given to the programmes and disseminated through publications in peer-reviewed journals, booklets and the on-line MSF Field Research Repository
- An institutional ethics review board facilitates ethical review
- Outputs are evaluated on a 6-monthly basis to assess performance and monitor results of research activity.

MSF = Médecins Sans Frontières.

[WHO], The Union and the Liverpool School of Tropical Medicine) were discussed and endorsed at the six-weekly meetings of the Malawi TB Programme Management Group. After priorities were established, research activities were then implemented by the various stakeholders (Figure 2). Many were planned, initiated, completed and published within the Malawi NTP itself; the enabling factors that contributed to this achievement are listed in Table 5.[23] At the end of every year, a report was written on research undertaken, studies completed, studies published and the effect that these studies had on influencing policy and practice.[24,25]

The success of OR was judged in various ways: 1) whether proposed annual targets in terms of projects initiated, projects completed, papers written and papers published were met; 2) whether the research findings influenced policy and practice; and 3) whether the research helped to improve programme performance. The OR led to key changes in national policy and practice, examples of which included the creation of a prison tuberculosis control programme, which continues to this day,[26,27] improved recording and reporting of patients with previously treated TB,[28]

Table 4 Barriers to operational research in Médecins Sans Frontières, possible reasons and lessons learnt. Adapted from Zachariah et al.[12]

Barriers to operational research	Possible reasons	Lessons learnt
Perceptions and lack of awareness about the role of research		
Senior managers fear that operational research will divert resources from aid delivery	Lack of knowledge about the role and relevance of applied research to field operations Weak knowledge translation strategy for operational research within the organisation	Establishing an institutional policy framework and reference document for operational research reassures operations staff and guides research activities Research resources are complementary (e.g., a statistician or data clerk cannot do the work of a nurse) The MSF Field Research Repository (http://fieldresearch.msf.org) raises awareness about research activity and its impact on country health policies
Time and opportunity		
Operations field and headquarters staff have no dedicated time or opportunity for research activity, especially related to protocol development, data analysis or writing papers. No one to manage research activity at headquarters or in the field	Research is an additional responsibility for already overworked senior staff No dedicated budget or human resources for research implementation	Provide dedicated human resources for operational research at headquarters and in the field to support research activities Include budgets and additional human resources needed for research during the annual operational planning exercise Give staff dedicated time (e.g., 2 days per week) to conduct research
Lack of human resource capacity		
Inadequate research capacity among MSF staff	Individuals in charge of research have limited research or programme skills Capacity building efforts are targeted at the wrong people Rapid turnover of staff	Establish strict criteria for selection of potential candidates for training Persons involved with research have to accept contracts of at least 3 years Introduce the concept of research fellows
Study design and implementation		
The research question is not relevant to programme implementation Poor adherence to research protocol Poor quality of data or too much data	The researcher has inadequate understanding or experience working at programme level (programme skills) Inadequate on-the-job training and supervision Poorly designed data collection tools	Regularly provide ongoing mentoring and improved supervision in defining the study question, the studies themselves and data tools Review data on a regular basis
Ethics clearance		
No ethics clearance is sought or received	Programme staff conclude that no ethics clearance is required Perception that ethics committees are a burden No functional ethics review board exists in the setting	Establishment of an MSF Ethics Review Board facilitates ethical clearance Make ethics an essential part of training to promote the perception that ethical boards are allies and not adversaries
Writing skills for publication		
Failure of research to lead to publication	Poorly designed studies Inadequate writing and language skills No ethics clearance or exemption No interest in investing efforts for publication in scientific journals	Development of writing skills training for publication with the support of a medical editor(s) through workshops and mentoring Emphasis at senior level on the importance of research publications
Policy and practice		
Research findings are not translated into policy and practice at the field level	Key decision and policy makers are not involved from the start and thus lack ownership Study authorship is not inclusive of key decision makers MSF workers lack the skills to interact with national authorities and partners	Involve decision makers and local partners in developing studies from the beginning to encourage ownership of the results Selected operational research officers should have both research and programme management skills and have longer term contracts (e.g., 3 years) Introduce a clear performance framework with indicators to evaluate the impact of research on policy and practice over time

MSF = Médecins Sans Frontières.

a change of treatment regimens from hospital-based, 2-month intensive phase therapy centred around daily injections of streptomycin to oral, ambulatory treatment given from health facilities or from family-based guardians;[29] and a policy of routine HIV testing and counselling for all TB patients with provision of cotrimoxazole preventive treatment to those found to be HIV-positive.[30–33]

Despite the achievements, not all the OR was successful. Several projects started and implemented with the NTP funding were never completed because of poor study design or poor, unreliable data collection,

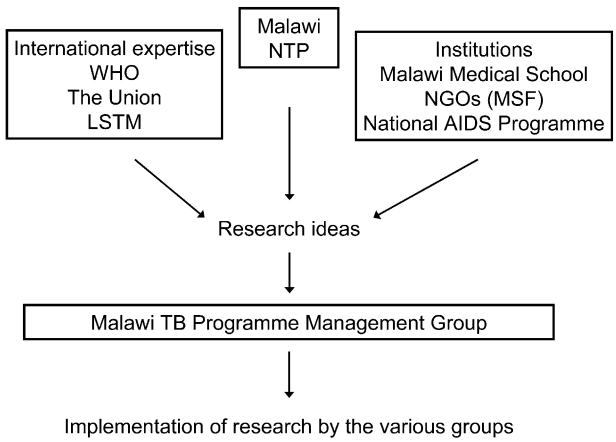

Figure 2 Research planning in the Malawi NTP. NTP = National Tuberculosis Programme; WHO = World Health Organization; LSTM = Liverpool School of Tropical Medicine; NGO = non-governmental organisation; MSF = Médecins Sans Frontières; AIDS = acquired immune-deficiency syndrome; TB = tuberculosis.

and there was sometimes a failure to translate completed but complex projects into understandable and readable papers. Sometimes the research was completed and published showing that an intervention was feasible and useful,[34] yet for various reasons, policy and practice remained unchanged. Failures are inevitable in any endeavour, but because these involve funds, human resource time and energy, it is important to learn from mistakes.

Table 5 Key factors that enabled operational research within the Malawi NTP

- There was a well-functioning TB programme with countrywide, standardised case finding, treatment and monitoring systems
- Research studies addressed constraints in TB control, and used established TB systems
- An annual research programme and research activities were planned within the NTP, included in the annual workplan and approved each year by the NTP Steering Group
- A good relationship was established with the Malawi National Health Science Research Committee that received and approved the annual research plan and programme before the start of the forthcoming year, and in turn expected an end-of-year report
- There was a Central Unit Officer responsible for operational research
- There was a dedicated budget line for research
- Resources were allocated to training that included an annual research training workshop, an annual writing skills workshop and an annual review meeting to disseminate research findings to national and international stakeholders
- Once research studies were completed, they were quickly translated into reports and papers, many of which were subsequently published in international peer reviewed journals
- Research publications from the Malawi NTP were collated each year into an annual report that was printed and disseminated to all districts in the country.

NTP = National TB Control Programme; TB = tuberculosis.

CAPACITY BUILDING

Translating an important research question into a published paper and using the findings to influence policy and practice is a long, hard journey that requires time, capacity and perseverance (Figure 3). In many programme settings this capacity and time are often lacking, but if they are included as an essential part of the programme they can be accomplished.

The Union has for many years modelled its OR training programmes on its successful guide 'Research Methods for Lung Health'.[35] Union training programmes have ranged from 3-day refresher training programmes on OR methods to 2-week protocol development workshops. These are similar in design to OR courses run by the US Centers for Disease Control and Prevention, where over the course of 10 years large numbers of TB programme and laboratory staff have been trained in OR methods.[36] However, questions are rightly being asked about whether these training methods lead to the creation of sustainable, research leadership in programmatic OR with publication of completed studies in peer-reviewed journals. For example, at the International TB Training Course in Japan, with the assistance of external facilitators 28 participants developed OR projects over a 7-year period between 2001 and 2007, none of which resulted in the publication of a scientific paper.[37] New paradigms are clearly needed, and The Union has previously experimented, and is currently experimenting, with several different approaches.

First, The Union used to run a junior consultant programme that included training on how to perform technical assistance, training and OR. Three physicians from low-income countries attended a Union-sponsored OR methods course, and were then linked to their NTP and tasked with developing an OR project that addressed country-relevant issues. However, given that they were not formally employed by the government, it was difficult to obtain country 'buy-in',

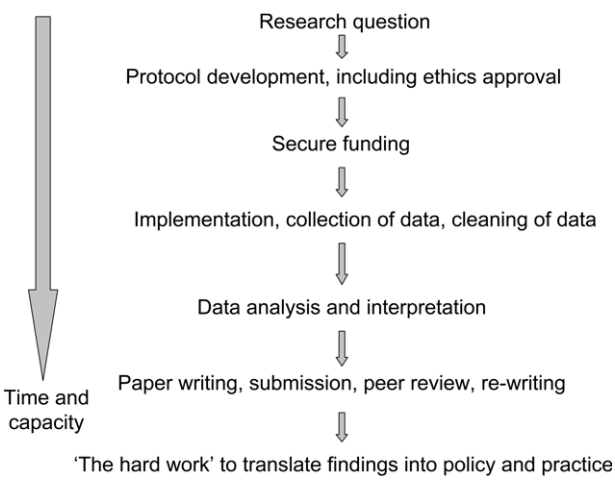

Figure 3 The steps from research question to scientific paper.

cooperation and ownership of the process. In another, similar initiative, after the presentation of a situational analysis of why HIV testing uptake was suboptimal among TB patients, participants at a Union-sponsored OR course in Uganda developed a research protocol to address the issue in five of the country's districts. After the course, a Union-sponsored consultant was mentored and tasked with refining the protocol, obtaining country and Union institutional board approval, developing the questionnaire, training staff, collecting and analysing data with country colleagues, submitting abstracts and writing papers. Two of these were accepted in peer-reviewed journals and helped to change country practice.

Second, The Union has received funding to engage OR fellows, appointed using strict selection criteria, who work within disease control programmes in their countries. They work full- or part-time for The Union and are given support and time from the programmes to carry out relevant OR. By June 2010, eight OR fellows had been placed in six countries (Viet Nam, India, Malawi, Zimbabwe, South Africa and Brazil). They receive training and mentorship from researchers at The Union in collaboration with their country colleagues, and are expected to initiate, complete and write up OR. One of the key milestones of these fellowships is the submission of two papers to peer-reviewed journals by the end of a 12-month period, failure to achieve this resulting in termination of the contract. Four of the fellows had completed their first 12-month contracts by the beginning of June 2010, and each had submitted two or more papers to earn a second 12-month contract.

Third, a new training course has been developed in partnership with MSF-Luxembourg that consists of three modules of 1 week each, spread over 9 months, with clearly defined outputs for each module.[10] The success or otherwise of this course is judged by a measurable product: completed projects that are submitted to and published in peer-reviewed journals, demonstrating that the participants can take a research question through to research protocol, research implementation, data analysis and writing up and publication of a scientific paper.

Fourth, the TREAT TB efforts focus on country-based OR training linked to programme priority research questions with both mentoring support and necessary financial resources to undertake research activities. The training includes the development of research protocols, along with the basic methodological skills necessary to carry out the research. The duration of the training has been limited to 5 days (Table 6) to ensure the most efficient use of programme staff time and resources. Once a workshop is completed, clear timelines and expectations for study implementation are created. Technical support is provided for activities ranging from ethics reviews, study implementation and statistical analysis to peer-reviewed publication. Finally, tracking the impact of the country research efforts in terms of national, regional and global policy change is an essential component of TREAT TB.

Table 6 Workshop agenda of the TREAT TB course run in India in 2009

Day 1	By the end of the day, the participants will have: • Identified and recorded the research question • Written a rationale for why this is important
09:30–10:15	Inaugural session: Introductions
10:45–11:45	Lecture: Introduction to protocol development
11:45–12:30	Lecture: The research question
12:30–13:15	Lecture: Justifying the need for research
14:00–16:00	Protocol: Setting the framework and defining the null hypothesis
16:15–17:30	Protocol: Preparing the rationale of the study
Day 2	By the end of the day, the participants will have: • Recorded the study design selected • Described the population to be studied
09:30–11:00	Lecture: Using epidemiology and designing the research
11:30–13:00	Lecture: Identifying the population for study
14:00–15:45	Protocol: Selecting the study design
16:15–17:30	Protocol: Describing the population
Day 3	By the end of the day, the participants will have: • Defined the variables to be measured • Outlined how information is going to be collected
09:30–11:00	Lecture: Variables and their definition
11:30–13:00	Lecture: Measuring and recording
14:00–15:30	Protocol: Defining the variables
16:00–17:30	Protocol: Methods and measurements
Day 4	By the end of the day, the participants will have: • Explained how information will be analysed • Indicated errors and how to avoid them • Defined the ethical issues to be addressed • Specified how the research will be conducted
09:30–11:00	Lecture: Comparing, analysing and defining error and bias
11:30–13:00	Lecture: Ethical and practical issues
14:00–15:30	Protocol: Comparing groups, avoiding error and bias
16:00–17:30	Protocol: Finalising workplan and budget
Day 5	By the end of the day, the participants will have: • Presented the protocol for critical review by peers
09:30–10:30	Lecture: Managing the research
11:00–13:30	Protocol: Presentation of research protocol
14:30–15:45	Protocol: Presentation of research protocol
16:00–17:30	Protocol: Presentation of research protocol
17:30–18:00	Concluding session

TB = tuberculosis.

MSF has three key approaches to OR training. First, there is 'on-the-job' training at project level. Senior-level researchers with doctorates hardly ever work with MSF, due to the rather modest conditions of service and employment settings. The emphasis has thus been to try and develop capacity in either expatriate or national field staff. Promising individuals are sponsored for courses on public health, medical statistics and data management. They are then taken through the practical process of defining research questions, writing protocols, managing and analysing

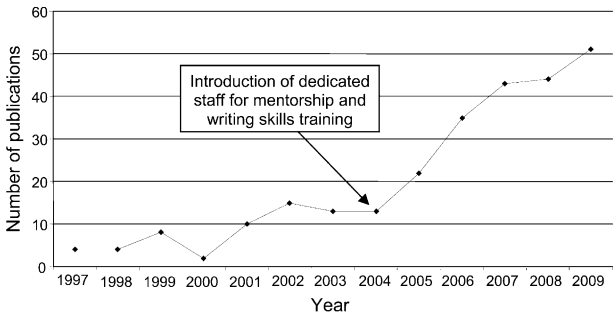

Figure 4 Trend in peer-reviewed scientific publications in Médecins Sans Frontières Operational Centre Brussels (1997–2009) and the impact of dedicated staff providing mentorship and writing skills training.

data and writing manuscripts for publication. The pillar of this approach is strong and sustained mentorship by the OR unit, which is staffed by experienced researchers, epidemiologists and medical editors. There has recently been increased emphasis on training national staff due to rapid turnover of expatriates. This model of training has been successfully conducted in five countries, namely Malawi, Kenya, Cambodia, Thailand and India.

Second, MSF invests in 'writing skills for publication' through workshops led by an experienced medical editor. Most individuals with Master of Public Health degrees or basic statistical training can collect, manage and analyse programme data. The real challenge lies in translating the findings into a manuscript that is accepted for publication. Specific writing skills workshops coupled with mentoring support have been instrumental at enhancing publication capacity both at headquarters and in the field. Figure 4 shows the trend over time in peer-reviewed scientific publications in the MSF Operational Centre, Brussels, and the impact of having a critical mass of headquarter staff providing mentorship support.

The third, rather novel, approach is the joint training course developed with The Union, described earlier. MSF also plans to introduce the concept of OR fellowships for its own staff, as this is likely to enhance retention and provide better career prospects. If partnered with a university, such a fellowship programme might lead to enhanced degree status and increase MSF's own research capacity.

ETHICS

Ethics has always been an important component of research promoted by both The Union and MSF. Both organisations have ethics review boards with terms of reference and policy and operational guidelines.[13,38] MSF has recently published its experience of research ethics reviews in humanitarian contexts.[39] Both ethics committees follow the principles set out in the Declaration of Helsinki, adopted by the World Medical Association (WMA) in 1964 and last revised at the 59th WMA General Assembly in October 2008.[40] In addition to ensuring ethical standards in research, the ethics committees foster discussion and reflection on ethical issues in all areas of work in which their respective organisations are involved. The Union's Ethics Advisory Group (EAG) has recently updated its own standard operating procedures on research protocol reviews and the promotion of ethical standards and issues in lung health services and international development (see http://www.theunion.org/ethics-advisory-group-eag.html).

Protocols developed by the OR Fellows and from the OR Course participants are subjected to review by The Union EAG, as are research protocols supported under the TREAT TB Initiative. Formal ethics review of OR proposals emphasises the need for informed consent to prevent risks to participants, data confidentiality, the need to submit for local ethics committee approval and the need to provide study results to local communities in accessible formats. Proposals for studies on existing data focus on the latter three items.

CONCLUSION

We strongly believe that OR should be an integral part of routine programme activities in low- and middle-income countries. If it is linked to routine programme monitoring and evaluation, OR can strengthen programme activities and lead to improved performance and better health prevention and care for patients. What is needed is further development of OR capacity, allocation of specific resources and collaboration between different actors such as international and national academic institutions, national programme managers and NGOs who should work together in promoting OR.[5]

There are encouraging signs of progress. The Global Fund to Fight AIDS, Tuberculosis and Malaria requests that countries include up to 10% of their funding for monitoring, evaluation and OR,[41] and this should be a major source of the funding needs for field activities. In July 2009, the Wellcome Trust announced the formation of seven new international consortia, each led by an African institution, as a step forward in strengthening research capacity on the African continent.[42] OR needs to be embedded in the research platforms that are being developed. In December 2009, the WHO organised a Stop TB Symposium at the 40th Union World Conference on Lung Health in Cancun, Mexico, a large portion of which was devoted to the role of OR in addressing TB and poverty. In late 2009 and early 2010, the United States government, through its new Global Health Initiative that will serve as the guiding framework for all of the government's health-related efforts, highlighted the role and importance of OR and the use of findings to

'identify critical problems and improvements'.[43] The WHO convened an international meeting in May 2010 of interested stakeholders and donors to discuss the priorities for OR in TB control and the steps needed to develop the necessary capacity to move the agenda forward. In all these efforts, The Union and MSF are committed to playing their full part in working together with stake holders, including the WHO, to turn the vision of better OR into reality on the ground.

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RÉSUMÉ

La recherche opérationnelle est devenue un sujet d'actualité dans les réunions nationales, les conférences internationales et les forums de donateurs. L'Union Internationale contre la Tuberculose et les Maladies Respiratoires (L'Union) ainsi que le Centre Opérationnel de Médecins Sans Frontières (MSF) à Bruxelles suscitent énergiquement et mettent en œuvre la recherche opérationnelle (OR) avec des collègues des pays à revenus faibles ou moyens. Dans cet article, nous décrivons comment les deux organisations définissent l'OR et nous expliquons les principes de guidance et la méthodologie qui étayent la stratégie du développement et de l'expansion des OR dans ces pays. Nous articulons les approches de L'Union et de MSF dans leur soutien à l'OR, en insistant sur les principales synergies et différences. Dès lors, en utilisant comme exemple le Programme National de lutte contre la Tuberculose du Malawi, nous montrons comment l'OR peut être intriquée avec les activités de lutte contre la tuberculose, entraînant des modifications de la politique et des pratiques au niveau national. Nous discutons du problème difficile et pourtant d'une importance vitale du développement des aptitudes et nous partageons nos visions sur le nouveau paradigme d'une formation liée au produit et de la solidarité dans une OR basée sur les performances comme deux moyens de développement des compétences nécessaires au niveau national pour garantir qu'une recherche soit effectivement pratiquée. Finalement, nous mettons en évidence la nécessité de considérer les composantes éthiques de l'OR et de les incorporer dans la pratique. Il s'agit d'un élément-clé à impliquer dans l'OR. Nous sommes confiants que lors du partenariat avec les responsables intéressés, y compris l'Organisation Mondiale de la Santé, nous pourrons stimuler la mise en œuvre d'une OR pertinente et de bonne qualité comme élément intégral de la fourniture de services de santé, qui à son tour contribuera à une amélioration de la santé des populations, particulièrement celles vivant dans les parties les plus pauvres du monde.

RESUMEN

La investigación operativa (OR) se ha convertido en un tema de mucha actualidad en las reuniones nacionales, las conferencias internacionales y los foros de donantes. La Unión Contra el Tuberculosis y Enfermedades Respiratorias (La Unión) y el centro operativo de Médecins Sans Frontières (MSF) en Bruselas fomentan en forma decidida y ponen en práctica l'OR con profesionales de países de medianos y bajos ingresos. En el presente artículo se describe la forma como ambas organizaciones definen la OR y se explican los principios conductores y los métodos que respaldan la estrategia de establecimiento y ampliación de este tipo de investigación en esos países. Se aclara el enfoque de respaldo a la OR de La Unión y de MSF y se ponen en evidencia los principales sinergismos y las diferencias. Luego, se toma como ejemplo el Programa Nacional contra la Tuberculosis en Malawi y se destaca el mecanismo de integración de la OR a las actividades de control de la tuberculosis, con el fin de alcanzar cambios en las políticas y las prácticas a escala nacional. Se analiza el aspecto delicado y al mismo tiempo primordial de la creación de capacidad de acción y se comunica un punto de vista sobre el nuevo paradigma de las becas de capacitación basada en los productos y la OR basada en el rendimiento, como mecanismos de desarrollo de las competencias nacionales necesarias, con el fin de verificar la ejecución real de la investigación en el terreno. Por último, se pone en relieve la importancia de considerar e incorporar en la práctica los componentes éticos de la OR. Este es un momento crucial para participar en la OR. Se espera que la vinculación de interesados directos como la Organización Mundial de la Salud logre fomentar la realización de una OR pertinente y de excelente calidad, como parte integrante de la prestación de servicios de salud. Esto redundará a su vez en una mejor salud para los pueblos, sobre todo en las regiones más pobres del mundo.