



MSF Field
Research

Operational Research Policy Framework

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**OPERATIONAL RESEARCH
DEFINITION, PURPOSE & PROCEDURES
(A POLICY FRAMEWORK)**



Version 2



OPERATIONAL RESEARCH

DEFINITION, PURPOSE & PROCEDURES

(A POLICY FRAMEWORK)

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Document Objectives

This document provides:

- **A clear definition and purpose of operational research from an MSF-Operational Centre Brussels perspective.**
- **Guiding principles to be followed when integrating research into MSF programs.**
- **Information on practical issues linked to research.**

This version replaces the last edition of the OCB Operational Research Policy document of July 2008. Current revisions are based on new experiences, further reflection on experiences and challenges, together with evolving knowledge and expertise in this domain. This document serves to better standardise, guide and facilitate operational research at field and headquarters level.

Comments and suggestions to improve future editions of this document are very welcome and should be sent to:

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Chapter 1

General concepts on operational research in MSF

1.1. Definition: What is operational research?

There are many proposed definitions of operational research¹⁻⁵ but **from a health program perspective** Operational research maybe defined as:

The search for knowledge on interventions, strategies or tools that can enhance the quality, effectiveness or coverage of programs in which the research is being conducted⁶⁻⁷

The key elements of operational research are that the research questions are generated by identifying constraints and challenges of implementing program activities (primarily prevention, care and treatment), and the answers provided to these questions should have direct, practical relevance to solving problems and improving health care delivery. Of course, this may not happen all at once, and often it is an ongoing and iterative process. There is a strong synergy between good monitoring and evaluation of infectious disease programs and operational research. Good quality data on cases and treatment outcomes can be used to conduct operational research, which in turn can help to improve the routine data collected in the field. From a MSF perspective, operational research can often imply "lessons learnt" during the implementation process, often through "targeted evaluations", structured observations, secondary analysis of routinely collected data, or other means of evaluation.

1.2. What sort of research constitutes ‘operational’ research?

Operational research involves three main types of study method:

1. Descriptive (cross-sectional if there is a strong analytical component present); this includes qualitative research
2. Case-control
3. Cohort analysis (retrospective or prospective)

Basic science research and randomized controlled clinical trials (RCTs) should not be included as operational research. While an randomized controlled clinical trial investigates the *efficacy* of an intervention in defined groups of the population, operational research determines the *effectiveness* of an intervention, i.e. how such interventions are translated into benefit, in the heterogeneous setting of routine care.⁶

Although in general terms an RCT is taken to imply “a clinical trial”, this is not always the case as an “RCT design” can be applied to an operational research setting and such research would still be classified as operational research. Specific examples of RCT design used for operational research have been published from various settings⁸⁻¹¹ However such designs are human resource intensive and require specialized resources which often is unable in a sustained manner within MSF

1.3 The importance and relevance of operational research and publications for MSF

If a medical intervention is to serve the patient's best interest, there should be a system of regularly monitoring, recording and reporting the intervention and its effects. The classic example at the bedside are the vital signs, the regular measurements of pulse rate, blood pressure, temperature and respiratory rate. These measurements help to ensure that treatments are appropriate, abnormal parameters kept within normal range and complications minimized.

If disease control or assistance programs are to serve their patients and communities’ best interests, they too need a system of regular monitoring, evaluation and reporting which will ensure a "constant vigil" on how interventions are implemented and their performance over time.⁵ In the simplest terms, running operational research and reporting its findings are geared to fulfilling this goal.

Why is operational research important for MSF (Table 1)?

1. To improve program outcomes in relation to medical care and prevention.
Operational research can be used to identify constraints in intervention strategies, diagnostics and therapeutics or in general control measures which prevent set targets from being achieved. By addressing such constraints, operational research can directly contribute to improving program design and performance, as well as the "quality of MSF assistance". ¹²
2. To assess the feasibility of new strategies or interventions
Operational research can be used to test new tools, strategies, or approaches against existing ones in specific settings or populations.
3. To advocate for policy change
Operational research can be used to advocate for policy change at district, national or international levels. Operational research can also be used to "describe" experiences and methods of implementation for vulnerable populations which could serve as examples for other actors (advocacy and catalyst role).

See Annex 1: for some examples of operational research in each of the above categories¹³⁻²⁸

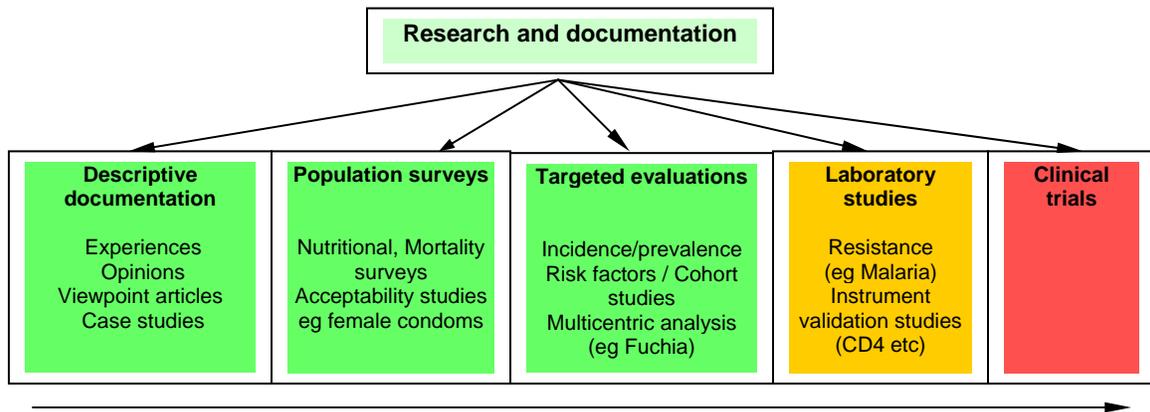
Why is it important to Publish?

- Publishing in peer-reviewed scientific journals is a "quality control standard" in medicine. The credibility of acceptance for publication is important when it comes to presenting the evidence base and discussing policy changes with Ministries of Health or international policy makers.²⁹. Publications thus serve as a *validation process* to enhance advocacy and policy change. *When it comes to science, the pen is mightier than the sword.*
- Publications facilitate international dissemination and access to information. An article which appears on the internet and is referenced electronically in publication databases has the greatest chance of being rapidly accessed by individuals around the world.
- Peer review is an integral part of this process and, although often laborious and time consuming, it is almost always a valuable and beneficial process. Input from good peer reviewers results in a better and stronger paper which eventually becomes "easier to read" and understand. *Experience shows that MSF people read and digest published papers while they tend not to look at heavy internal reports! Publications thus facilitate internal dissemination and memory.*
- Publications are an important form of credibility for the work done by MSF workers and the organization.
- Globally, publications enhance our role and influence in the international community.

- The "process" of documenting experiences and lessons learnt is a valuable process in itself as it forces one to confront/justify ones preconceptions, and is a process of critically reflecting upon a program's impact and orientation.

1.4. Priority research for MSF teams

The figure below depicts a spectrum of documentation and research studies that could be conducted at MSF sites.



The left end of the spectrum (indicated in green) is where most operational research occurs, as these can be annexed to routine operations. The further right one moves along the spectrum, the more complex the studies become with a proportionally increasing likelihood that they will infringe on routine operations.³⁰ These studies are prospective and require considerable additional human and material resources as well as time. Although not exclusive, involvement in clinical trials will likely be an exception for MSF. Academicians and universities are generally much better suited, equipped and "able" to run such studies.

Research that we should be conducting in our field sites needs to primarily focus on "operational" or implementation studies that are likely to have a direct impact on policy and practice and the quality of assistance we render to populations. However, given the proximity of MSF work to unique and vulnerable populations, the results may be important enough to change wider practice.

TABLE 2. SOME EXAMPLES OF PUBLISHED DOCUMENTATION & TARGETED EVALUATIONS

Documentation
<ul style="list-style-type: none"> ▪ Antiretroviral therapy in primary health care: Experience of the Khayelitsha program in South Africa case study. WHO case study ³¹ ▪ Involvement of people living with HIV/AIDS in treatment preparedness in Thailand. WHO case study ³² ▪ Understanding health care in the South Caucasus: examples from Armenia. British Medical Journal ³³
Targeted evaluations
<ul style="list-style-type: none"> ▪ High acceptability of voluntary counseling and HIV-testing but unacceptable loss to follow up in a prevention of mother-to-child HIV transmission program in rural Malawi: Scaling up requires a new way of acting ³⁴ Trop Med Inter Health ▪ A drug dosage table is a useful tool to facilitate prescriptions of antiretroviral drugs for children in Thailand ³⁵ Int J STD AIDS ▪ Mortality, Violence and lack of access to health care in the Democratic Republic of Congo ³⁶ Disasters

1.5. Judging the success of operational research

- Research is only useful if it delivers the goods. A research initiative or program can be routinely assessed in relation to its annual work-plan and whether proposed outputs, in terms of studies initiated, studies completed, papers written, published and disseminated, have been met. This requires an ability to move fast with analysis and write-ups of manuscripts.
- Ultimately research must be of benefit to MSF programs. **The ultimate proof of judging the effectiveness of operational research is whether it helped to improve program performance or influenced policy change.**^{5, 7} Influencing policy is a "process" in which publication (or putting evidence in the public domain) might just be the beginning, which often needs to be followed by a coherent dissemination and advocacy strategy.

1.6 Disseminating MSF Research: MSF Field Research Website

- MSF wants to make its research experience available to those who are most able to use it, health workers and policy makers in developing countries and a website has been developed for this purpose: *MSF Field Research*. It is a searchable repository containing all MSF-authored research articles as well as conference abstracts and various research tools that are suitable for operational research. The site is completely **open access**, with all articles in **full text, downloadable for free**. Go to <http://fieldresearch.msf.org>.

Chapter 2

Integrating research and documentation into MSF programs

Considering the spectrum of potential research and documentation studies that could be conducted at MSF sites (section 1.4), programs might, in practice, be faced with two different types of situations:

- The first would involve "classical research" such as determining resistance patterns to a particular drug, field testing a new instrument or running a drug trial.
- The second could simply involve descriptive papers on experiences or "monitoring and evaluation (albeit targeted)" of implementation work within programs.

The principal steps outlined below (section 2.1) apply mainly to the first situation. Section 2.2 (below) will attempt to clarify the second situation further. "Classical research studies" particularly when they are prospective (e.g. clinical trials) should involve the medical director as other considerations such as priority level, relevance, most appropriate setting to conduct the study etc., might come into play.

2.1 Principal steps

The following are the *principal steps* to be followed when embarking on a classical research study, i.e. one that may involve an intervention (treatment, medication, program, survey) using human subjects.

I. A relevant operational research question (or problem) must be identified.

- Research questions should ultimately be generated from within programs and be relevant to program implementation. If research is disconnected from health-service delivery and there is little or no input from program staff, it risks being resented as an additional and often unwanted burden on existing services^{5,7}
- It is useful for all programs to have clearly specified objectives and targets which will permit one to look at the constraints which hinder these objectives and targets from being met. Once constraints are identified, then *research questions* can be asked to better clarify the constraint or find a solution to the problem. Research questions could arise from lack of knowledge on a particular subject, lack of a tool or intervention or inefficient use of a tool (Table 3).
- Often operational research is more about opportunities than constraints – MSF finds itself doing pioneering work in unique contexts where academics do not have access. In these contexts, it is a question of designing a study to document properly the outcomes of what we are doing.

Table 3. Two examples of generating operational research questions from the program level

Example 1. Lack of knowledge about patient defaulting
<p><i>Program objective:</i> Achieve excellent treatment completion or excellent retention rates on therapy (e.g. for tuberculosis or antiretroviral treatment)</p> <p><i>Constraint:</i> High default rates from therapy</p> <p><i>Research question:</i> Why do people default?</p>
Example 2: Inefficient use of a diagnostic tool
<p><i>Program objective:</i> Achieve high quality sputum smear diagnosis using three sputum smears per patient</p> <p><i>Constraint:</i> Three smears per patient are demanding for the laboratory technicians due to human resource shortages and high sputum caseload.</p> <p><i>Research question:</i> Are <i>two smears</i> as efficient as three for diagnosing smear-positive pulmonary TB?</p>

General comment: Defining a clear research question is probably the most difficult part of any research study. It may be useful for you to discuss your ideas with one of the operational research team who are experienced in this process. Having a precise research question undoubtedly focuses the research and write-up and saves a lot of wasted time and energy.

II. *Integration of studies into annual action plans.*

- Once a study question or subject has been identified, it must be discussed with the medical coordinator, the polyvalent and operational research team at headquarters in order to have it included in the annual action plans of the mission. This is necessary to enable budgetary, human resource and time planning both within the field mission, cell and in the respective support unit(s) of the medical department, and to guard against duplication. *Insertion within mission annual action plans also obliges an operational commitment both (from the operational cell and the medical coordinator) and allows progress to be evaluated over time.* Many studies or documentation do not require major budgetary adjustments. However, possibilities to accommodate OR activities, identified in the course of the year (if relevant/valuable etc.), should be considered on a case-by-case basis.

- National partners should be included and, where possible, MSF research studies should be inserted into national research plans.

III. *Insertion into research inventories.*

- The medical department keeps a research inventory which gives a global "yearly" overview of all research studies being conducted by the Brussels Operational Centre. Studies that have been included in the annual action plans appear on this inventory. This inventory forms the basis for coordination, and progress assessments at the headquarters level. The inventory helps to avoid duplication of research studies, optimises the milieu for particular research, and ensures priority questions are not being neglected. The subtext is that, while you may want to do research in your mission, it might not be the best place to ask that question.
- The OCB research inventory is added to an international research inventory that includes research done by all MSF sections.

IV. *Writing a study or research protocol.*

- To be efficient and precise, research needs a "road map" which takes the form of a "*study or research protocol*". A study protocol is required to seek formal approval from national authorities, and for the purposes of ethics review.
- Broadly, a research protocol should include: a study description, ethics considerations, the budget and a description of investigators.
- The *study description* is the main core of the research protocol and should explain the study in terms of answers to the following questions:
 - ⇒ *WHY?* Sets out the study question, the rationale and the relevant background information.
 - ⇒ *HOW?* Describes the study design and the justification for choosing it.
 - ⇒ *WHO?* Defines the study populations and sample size.
 - ⇒ *WHAT?* Identifies the variables to be measured, instruments to use and outcomes to be analysed.
 - ⇒ *SO WHAT?* Comments on the expected significance of results and contribution to knowledge.
- Depending on setting, it may be necessary to translate the protocol and share it with local partners. This should be considered in the planning.
- An example of the typical format of a research protocol is given in annex 2.

V. *Seeking ethics and scientific approval (where relevant)*

- If you plan to publish in a peer-reviewed journal, ethics approval is usually always required. You should plan for this early in the process.
- Ethics approval should be sought both from the appropriate authority in the country of study as well as from the MSF Ethics Review Board (ERB) (See below). Research that involves interventions (medication, treatments) with humans should be conversant with the declaration of Helsinki³⁷. Simple documentation studies and studies that are considered "targeted evaluations" or retrospective audits, based on routine program data, may not require ethics approval and should not be unnecessarily subjected to such a heavy process. However, it is wise to have the Operational Research Unit confirm this. Also, check with your intended journal's requirements.
- The process of ethics review needs to be built into the timeline as it may take 8-12 weeks and, if not planned in advance, may lead to unnecessary delay and frustration. There are practical examples of situations where field teams have sent investigators to the ground, imported drugs etc, and were delayed unnecessarily because they had to wait eight weeks for ethics approval!
- When in doubt about whether a study should or not undergo ethics approval, please contact the Operational Research Unit Please also (see Chapter 3).

VI. *Study authorship.*

- The main *study authors*, their hierarchy, institutions and responsibilities should be clearly defined in the study methodology to avoid potential conflict of interests at a later stage. *National partners* should be involved to foster partnership, a sense of ownership, responsibility, and to facilitate dissemination of research findings and translation of the results into policy and practice.
- The issue of study authorship is described in detail in Chapter 7.

VII. *Budgets, human resources and time.*

- These issues must be carefully considered and planned, as studies may require additional resources and time and will add additional workload on field teams. Operational research should ideally be annexed to programs and the workload should not lead to a compromise of the program itself. It is important to stress that if research is integrated within a program and there is a clash of interests, program activities will have to take precedence.
- The main reason why research often fails is because it is carelessly added onto the workload of an already busy field team who find it is too time consuming. The research then inevitably loses out to operational priorities.

- The necessary human and other resources should thus be carefully assessed and planned, in order to avoid such a situation.

VIII. *Documentation/writing a scientific paper*

- No study is considered complete until the work has been translated into a manuscript and submitted for publication for reasons elaborated in Chapter 1, section 1.2. Missions embarking on operational research studies should have the capacity to quickly write-up studies into manuscripts and complete this process before embarking on new ones. Studies can be written for international or national peer reviewed publications, or as MSF internal publications. Manuscripts should generally follow the instructions of the International Committee of Medical Journal Editors. For further details, please consult the following article “Uniform Requirements for Manuscripts Submitted to Biomedical Journals”³⁸ (www.icmje.org).
- Chapter 6 broadly covers the subject of "writing a scientific paper".

2.2 Descriptive papers and targeted evaluations.

Often, MSF does pioneering work in different contexts. Writing descriptive papers of experiences can be of a major operational interest. The starting point in such situations might simply be an interesting observation or experience that is considered valuable for reporting. It is important to realise that the steps outlined in 2.1 above, may not be (or may be only partly) applicable to such studies or documentation. A study protocol is, however, necessary to clarify the objectives and methodology as well as to request ethics exemption or clearance for publication.

Some examples:

- The two WHO case studies^{24,25} referred to in section 1.3 were written-up a number of years after the projects were underway and were considered, in "retrospect", as worthwhile case-studies (best practices in implementation). Although embarking on such work requires people and time to produce the paper, the issues of writing "a study protocol" or "seeking ethics approval" do not apply.
- Another example was the reporting of difficulties experienced while trying to offer ART to children and how these were tackled³⁵. Although this constituted a very relevant publication, it actually depicted "lessons learnt" through program implementation.
- The examples from Malawi describing unacceptable losses to follow up in a PMTCT program³⁴. This was in essence an evaluation using routine data. Another classical example is reporting high death rates and associated risk factors³⁹ based on retrospective audits of routine data.

- Another final example is reporting and publication of multi-centric data involving routine implementation of ART in a number of programs. This comprises monitoring and evaluation of routine program implementation. If you plan to write this type of article, check with the Operational Research Unit regarding requirements, especially for ethics.

2.3. Capacity for conducting and following-up operational research.

- Specific funding and resources for operational research need to be built into programs to equip them with the capacity to undertake this research so that it can be planned and implemented within the existing program. While there may be a tendency for local programs to outsource research to academic institutions, this can hinder the development of their own operational research capacity⁶.
- Program staff and researchers need to foster a collaborative partnership in which the entire team is involved in developing the research question, data collection, data analysis and dissemination of results.⁶ Engagement with policy makers is also important in the planning stage, so that they are aware of what is being looked at and may promote ownership of the results. In this way, the likelihood for translating research into policy and practice can be greatly enhanced.
- Writing study protocols, data management, analysis and eventual manuscript-writing, all require considerable skills and experience. The capacity and time required for these activities should not be under-estimated. A *pre-requisite* for embarking on research studies should be that adequate capacity is available at mission level for the duration of the study and a coordinator (or any other person), who is adequately qualified or trained, should be linked to this work.. Capacity for direct support to field missions is being beefed up through the "rotating or full time- epidemiologists" in selected missions, and a gradual increase in capacity at the medical department.
- Once a manuscript has been written and submitted for publication, it often takes between 12 to 24 months (due to extensive peer review and revisions, and production delays) before eventual publication in an international journal. Thus, there is often "a long journey" to be undertaken and thus a reliable *corresponding author* should be designated to ensure continuity in this process.
- Basic training in epidemiology including knowledge of basic software (Epi-Info, Excel), and writing skills are necessary. Individuals wishing to embark on operational research should contact the Operational Research Unit for appropriate support.

Note:

When capacity does not exist for processing data (including writing it up etc) within MSF and the data is of potential "public benefit" then efforts should be made to find the additional resources either in headquarters or outside. Data of public health interest should not be held at ransom by MSF teams if they cannot do anything with it. However, in the event where external support is required,

the selection of an external partner would need to follow a dialogue process with MSF headquarters and no data should be released without approval of the medical director and, where applicable, before a clear declaration of interests.

2.4. Enabling factors for operational research and its translation into policy and practice⁶

Table 4. Enabling factors for operational research and its translation into policy and practice

- Research questions are generated from within programs.
- Research planning, agenda-setting, objectives, targets and budgeting are included within program plans and as agenda items in program management meetings.
- Research projects use simple designs and are focused to answer implementers' questions.
- Close collaboration and partnership is established between researchers and program managers.
- Research is conducted within existing systems and not conducted in parallel.
- A competent research officer(s) works alongside the program manager.
- Training, mentorship and on-the-job supervision is sustained over time.
- Relevant staff have a respected degree of protected time to ensure follow the research process through to completion.
- There is program capacity to host workshops, present and discuss research findings, and ensure their translation into policy and practice.
- Program staff have access to scientific literature through subscribed journals or the internet.
- A critical mass of program staff has the capacity to conduct 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 Organizations and other stake holders are recognized and have a contributory role in operational research.
- Good quality, appropriate and relevant research gets translated into policy and practice and thereby stimulates more research.

2.5 Barriers to operational research in MSF and lessons learnt. (Table 5) ⁷

Barriers to operational research	Possible reasons	Lessons learnt
<i>Perception and awareness about the role of research</i>		
<p>Senior managers fear that operational research will divert resources from aid delivery</p>	<ul style="list-style-type: none"> ▪ Lack of knowledge on the role and relevance of applied research to field operations ▪ No dissemination or knowledge translation strategy for operational research within the organization 	<ul style="list-style-type: none"> ▪ Establishing an institutional policy framework and reference document for operational research reassures operations staff and guides research activity ▪ Research resources are complementary (e.g. a statistician or data clerk can not do the work of a nurse). ▪ The MSF Field Research website (http://fieldresearch.msf.org) brings MSF research activity and its impact into the public domain and makes MSF-authored publications easily accessible.
<i>Time and opportunity</i>		
<p>Field and headquarters staff have no dedicated time or opportunity for research activity related to protocol development, data analysis or writing papers.</p> <p>No-one to manage research activity at headquarters or in the field</p>	<ul style="list-style-type: none"> ▪ Research is added as an additional responsibility on already overworked senior staff. ▪ No dedicated budgets or human resources for research implementation 	<ul style="list-style-type: none"> ▪ Open a post of operational research officer at headquarters and field levels to coordinate research activity ▪ Include budgets and additional human resources needed for research during the annual operational planning exercise ▪ Give staff dedicated time (e.g. two days per week) to conduct research
<i>Lack of human resource capacity</i>		
<p>Very limited outputs of planned research</p>	<ul style="list-style-type: none"> ▪ Individuals in charge of research have limited research or program skills. 	<ul style="list-style-type: none"> ▪ Establish strict criteria for selection of potential candidates for training ▪ Persons involved with

	<ul style="list-style-type: none"> ▪ Capacity building efforts are targeted to the wrong individuals ▪ Rapid turnover of staff 	<p>research have to accept contracts of at least two years.</p>
<p><i>Study design and implementation</i></p> <p>The research question is not relevant to program implementation. Poor adherence to research protocol Poor quality of data or too much data.</p>	<ul style="list-style-type: none"> ▪ The researcher has inadequate understanding or experience working at a program level (program skills). ▪ Inadequate on-the-job training and supervision ▪ Poorly designed data collection tools. 	<ul style="list-style-type: none"> ▪ Provide support in defining the study question, designing method and data tools. ▪ Ensure regular supervision and feedback ▪ Review data on a regular basis
<p><i>Ethics clearance</i></p> <p>No ethics clearance is sought or received</p>	<ul style="list-style-type: none"> ▪ Program staff conclude that no ethics clearance is required ▪ Perception that ethics committees are a burden ▪ No functional ethics board exists in the setting 	<ul style="list-style-type: none"> ▪ Ensuring that all study protocols undergo formal ethics review. ▪ Making ethics an essential part of training to promote the perception that ethics boards are allies and not adversaries. ▪ Establishment of an MSF Ethics Review Board facilitates ethics clearance in conflict settings.
<p><i>Writing skills for publication</i></p> <p>Failure of research to produce manuscripts and publications</p>	<ul style="list-style-type: none"> ▪ Poorly designed studies ▪ Inadequate writing and language skills ▪ No interest in investing efforts for publication in scientific journals 	<ul style="list-style-type: none"> ▪ Writing skills training for publication is vital ▪ Having the support of a medical editor(s) is vital to develop writing skills capacity (through workshops and mentoring) and enhance publication outputs
<p><i>Policy and practice</i></p> <p>Research findings are not translated into policy and</p>	<ul style="list-style-type: none"> ▪ Key decision and policy makers are 	<ul style="list-style-type: none"> ▪ Empower decision makers and local partners to value the

<p>practice at the field, national or international levels</p>	<p>not involved from the start and thus lack ownership</p> <ul style="list-style-type: none"> ▪ Study authorship s not inclusive of key decision makers ▪ MSF workers lack the skills for interacting with national authorities and partners. 	<p>study from the beginning and sense ownership</p> <ul style="list-style-type: none"> ▪ Selected operational research officers should have both research and program management skills and have longer term contracts (e.g. 2 years) ▪ Introduce a clear performance framework with indicators to evaluate the impact of research on policy and practice over time.
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Chapter 3

Ethics review of research

3.1. The importance of ethics review

Ethics review is essential for all biomedical research carried out on human subjects. This is normally undertaken by an Ethics Review Board (ERB) which should have knowledge on the context in which the research is to be conducted. The ethics framework of such a committee is based on four principles of duty – the duty to alleviate suffering, to show respect for human beings, to be sensitive to cultural differences and not to exploit the vulnerable. The main ethics considerations that an ERB will cover within a study protocol will include:

- Whether there was a collaborative partnership with local researchers/staff
- What is the social value of the project?
- What is the scientific validity of the study?
- Was there a fair selection of study population?
- Describe the benefit/harm ratio – it should be favourable
- How was informed consent obtained?
- Was there respect for the recruited participants and the study communities?

MSF has created an independent ERB to which research studies are sent. It is often wrongly termed the "MSF" ERB, but, in fact, it is independent and its members are not employees nor do they have any vested interest in MSF programs or its research activities.

3.2 What studies should undergo ethics review?

One should clearly distinguish between (1) routine monitoring and evaluation, (2) the generation of new general knowledge through hypothesis testing, and (3) clinical research. The last two need ethics review.

- Full ethics review: clinical trials and operational research projects with hypothesis testing.
- Review not necessary: monitoring and evaluation as part of normal implementation of projects.
- Gray area (consider ethics review): Descriptive studies, those involving monitoring and evaluation as a means to test a new approach (“innovative practice or hypothesis testing”) with the intent of eventual publication. There

are two possibilities: (1) request from the ERB an expedited review of a fully developed research proposal, (2) request that the ERB confirms that ethics review is not required. The ERB chair usually quickly indicates if no review, expedited review or full review, is necessary. Note that publication in all peer-reviewed journals, requires ethics clearance. This may come as a formal ethics review from the ERB or an explanation of why formal ethics review was not necessary. To be sure, **all potential studies or articles should be sent to the Operational Research Unit for confirmation of ethics requirements.**

- Post-Hoc Review: Analysing routinely collected data for the purpose of directly improving patient management does not need ethics review. However, if a generalisable research hypothesis is to be tested by a posteriori analysis of routinely collected data, ethics review should be sought. In these cases individual informed consent from patients is usually neither necessary, nor feasible. However, community consent may be necessary if the community can potentially be harmed. Other ethics issues to consider are local partnerships, the social value of the proposed research and what will be the benefits for communities involved.

3.3 Who are the members of the MSF Ethics Review Board?

- The MSF ERB is currently composed of six permanent members of varying professional backgrounds in line with international recommendations, ensuring geographic (Africa, Asia, Europe, North America) as well as professional (medicine, public health, law, anthropology, bioethics) variety.
- The members of this board include a senior lecturer from the Aga Khan University in Karachi, Pakistan, the head of Bioethics and Health Law from the University of Durban, South Africa, a specialist in epidemiology from the Institute of Tropical Medicine, Belgium, a member of the Centre for Studies in Ethics and Rights, India, and the Director of the Joint Centre for Bioethics of the University of Toronto, Canada.
- One chair person, a medical doctor with knowledge on international medical ethics, manages the work of the committee. Members conduct their duties on a voluntary basis.

3.4 Why an independent MSF ERB

- There are many developing countries or settings (e.g. conflict, refugee populations) where ERBs simply do not exist. MSF is still bound to ensure that research conducted in such settings upholds sound ethics principles and duties.
- There are several countries in the developing world where ERBs, although present, may be ineffective or under-resourced. In addition there may not be a

pool of sufficiently trained and independent people to serve on such committees, or the countries may lack regulatory mechanisms and a legal framework for biomedical research. Poverty, poor pay and ignorance may also breed corrupt practices which unfairly influence approval of certain research approvals.

- Independence of ERBs is a critical issue and ethics review needs to be independent of the sponsors, governments, academia or institutions that conduct the research. This is not always the case in practice. For example: in some developing countries "university" based ERBs often approve research studies that are conducted by individuals who may belong to the same institution. Ethics approval in such circumstances could be influenced by vested interests in the "science" rather than the "participants" and cannot be considered independent.

3.5 Justification for review of MSF protocols by an independent MSF-ERB1. *To comply with international standards: For all international collaborative research in the South, the standard procedure in research institutions is that every study must go through the ethics committees of ALL the institutions involved in the study, both ERB's from North and South should be consulted. MSF as a humanitarian organization should respect international standards on ethics.*

2. Civil liability and support: MSF ERB review implies a certain legal responsibility in case of litigation against the organization and/or its investigators. Particularly in civil suits, ensuring international standards of ethics and having an MSF ERB adds increased protection against prosecution. *By not having an MSF ERB review, MSF compromises its position of legal support/defense and leaves itself in the hands of the other national ethics boards (an academic institution or other) who may have no interest nor mandate to protect it.*

3. Vulnerability and equity: The MSF ERB provides very comprehensive reviews, and often has a different perspective from that of an academic institution. In particular, MSF ERB is more oriented to programmatic relevance (feasibility issues) and is particularly sensitive to *vulnerable populations* and *equity*. It is also likely to be better aware of other similar studies within MSF, helping to avoid duplication.

4. Fairness and transparency: This policy should apply to all MSF OCB missions, regardless of their location and access to local ERBs. This will ensure harmonized standards of care in different protocols. *This is only fair and transparent.*

3.6. Ethics framework for medical research as proposed by the MSF ERB

The ethics framework for medical research of the MSF ERB is included in Annex 3.

3.7. Procedure for requesting ethics review

- Before submission to the ERB, all study protocols **must** to be reviewed by the Operational Research Unit staff who act as agents for the medical director.
- Protocols should have been discussed with the polyvalent and referent and be approved by the relevant authority or ethics board in the country of research.
- Once cleared by the OR Unit, protocols are then forwarded to the chairperson of the ERB. The ERB will respond with either approval or a request for further clarification through the OR Unit contact. The protocols should **not** be sent directly to ERB by the researcher.
- Revisions and clarifications are often necessary, and once these are addressed satisfactorily, a formal letter of approval is issued by the board.

Chapter 4

MSF and "ownership" of research

4.1. Improving MSF internal capacity and ownership

Over the last six years, MSF has built up good experience and expertise and there is now a growing desire for increased "ownership" of research and publications within MSF for a number of reasons:

- An increasing availability of individuals with epidemiological and writing skills both on the field and within the medical department has boosted internal capacity for scientific analysis, abstract writing, and presentations at international conferences. The production of an average of 35 scientific peer reviewed publications per year by MSF-OCB is evidence of a growing sense that "we can do a good part of it ourselves".
- A realization that a strategy of systematically "outsourcing" research over the past years had actually handicapped the development of any internal capacity in analysis, writing and publishing.
- Many institutional research organizations are well designed to do interventional epidemiology (e.g. go in for a specified period and do specific studies) but not to support a mission in a sustained manner over time.
- Successful advocacy requires more "visible ownership" and responsibility for data and publications; this is not only about dissemination-strategies and related credibility, but also about the responsibility MSF needs to take in translating findings into policy and practice for the benefit of communities included in the studies.
- In the past, outsourced research conducted at MSF sites was done in relative "isolation" with respect to national teams and programs. This often led to conflicts between the program and the researchers and the results, if at all, seldom had any influence on policy and practice. Questions on the relevance of such research, coupled with the lack of a "sense of partnership", were real problems.
- The way forward is that MSF should have a strong say in setting its research agenda and priorities⁴⁰. Integrating research into the framework of an MSF operational program(s) is one way of ensuring that programs can start developing a small-scale, research program which can be used as a stepping stone for developing internal research capacity. In this situation, MSF will progressively gain confidence in developing its own research priorities and capacity, and if international institutions or partners join in, they would do so as "equal partners" rather than as dominant partners. The end products of such research are more likely to be to the direct benefit of the MSF program and the local population it serves. ⁴¹⁻⁴²

4.2. Collaborative partnership with "international" institutions and universities

A truly cooperative research partnership between MSF implementation sites and any international institution should rest on four *broad principles*:

- Mutual trust and shared decision-making in all aspects of the study.
- A sense of ownership by the MSF program, field teams and national partners.
- Emphasis on getting research findings into policy and practice.
- Development of research capacity within MSF programs.

Past experience shows that it is often simply the personality and attitude of the lead individuals in institutions (and equally, or perhaps even more so, in MSF) that determine how successful (or unsuccessful) a collaborative partnership eventually becomes.

4.3. Involvement of MSF programs in collaborative research studies

The involvement of MSF programs in independent collaborative research or for recruitment of patients implies a number of *considerations*.

Considerations:

- Formal acceptance of an MSF program as a "study site" even if this only implies "recruitment of patients" does impart "responsibility" in the Results of the study and any ethics considerations during or after the process of implementation.
- MSF has primarily "operational interests" in research which has more often than not, been in direct contrast/conflict with academic research interests.

Thus, a specific request and eventual acceptance/involvement of an MSF site would imply respecting the following general *conditions*.

- a) There should be at least one designated MSF person at the field level integrated into the study. This person(s) should be considered as a co-investigator(s) and eventually a co-author(s) on any related publication(s). The human resource capacity for such participation (from MSF) would need to be assured for the entire period of the study.
- b) There should be at least one reference person(s) at head-quarters who is kept informed of progress on a continuing basis and is able support the field work.
- c) The workload linked to research management is an issue that the field team will have to deal with and this may be an important operational consideration.

All collaborative research must be part of the annual operational plan and not allowed to "disrupt" routine operations.

- d) The involvement of national partners in research conducted at our site(s) is an essential requirement for MSF and our ERB. This in view of fostering partnership, ownership, responsibility, the eventual dissemination of research findings and its translation into policy and practice. If a choice exists between collaboration with a national or international academic institution, the national one is preferred.
- e) Since research studies should be integrated into the annual action plans funding issues will have to be covered by the operations department.
- f) Collaborative research protocols) must be submitted to the MSF ERB even if they have received ethics approval elsewhere.

4.4. Isolated studies approved by MOH and considered to be independent of MSF

In certain circumstances where MSF might be working within an MOH structure, the MOH could give approval for an isolated study to be conducted by another partner at the same site. In such cases it must be made clear to patients, staff and authorities that the study is being run independently of MSF and all the necessary staff, resources, organizational issues and ethics considerations are to remain the entire responsibility of the researchers. The research should also not interfere with routine operations that MSF at the facility.

4.5 Students linked to MSF programs and using MSF data

MSF often receives requests for permission to write "theses" from masters or PhD students. It is important to understand that these requests may add considerable workload to the field team. While masters students may help MSF analyze data that would otherwise not be addressed, the following guidelines should be followed to avoid conflicts.

4.5.1 Implications for the medical department.

Accepting masters students implies the following specific responsibilities for the medical department:

- a) The subject is of "operational relevance" and one that is considered "suitable" to both the student and his/her supervisor and an MSF Mission.
- b) Discussion must take place with the cell (operations) on the practical issues (Lodging, transport, security, etc)

- c) Approval may be required from the respective Ministries of Health or appropriate authorities in the country where the study would be done (and this might include ethics clearance).

4.5.2 Specific selection criteria:

Specific criteria for selection of candidates would include:

- The subject or analysis is of relevance to MSF and preferably part of the operational research inventory. A student might also propose a subject that is of interest to MSF in the form of a "concept paper" and if this is deemed to be of interest, it could be integrated into the operational research inventory. A "concept paper" should be 2-4 pages and should include the a) the main "subject title", b) why it is relevant to MSF or for the general public c) the objectives and d) how the thesis would be of possible benefit e.g. in terms of policy and practice, advocacy, or dissemination of knowledge.
- The results of the study/thesis should eventually be of benefit to the MSF program and the population it serves through its possible translation into policy and practice, or seen relevant for reasons of documentation for dissemination.
- The person must have sufficient supervision from the university/institution of study so that the research supervisory workload for MSF is limited.
- Person(s) that were supported for post-graduate studies by MSF would take priority over external candidates.

4.5.3 Other specific considerations.

- A study proposal or protocol is written and agreed upon.
- Where relevant, Ministry of Health or the local partner(s) approve the study in question.
- Where "data bases" from routine program activity constitute the basis of the study, they will be used only for the study in question and no further exploitation is to be made without due authorization from MSF, that will retain data ownership.
- In case there are scientific publications that stem from the work, study authorship should be inclusive and representative of the main MSF implementers and the local partners on site. MSF should have a leading role in the writing of conclusions drawn from such work.
- Ethics approval or exemption would be required from the MSF-ERB.
- In principle, MSF does not provide funding (tickets, per diems,) to students. Exceptions to this will be considered on a case-by-case basis at the operations level.

Chapter 5

Involvement in national and international conferences

5.1. General considerations

- MSF generally encourages its staff working in projects to submit abstracts to national and international conferences as they serve as important platforms for dissemination of experiences and for advocacy.
- However, there are hundreds of conferences each year and participation needs to be selective as submission implies considerable investment in terms of abstract writing, preparation of presentations, overhead costs and time away from program activity.
- Thus, MSF staff should only attend relevant conferences with specific objectives.
- There are a number of conferences that MSF attends each year and involvement is coordinated through the OR Unit and specific MSF international working groups.
- Abstracts written by individuals in the field who do not have adequate experience should benefit from inputs involving the medical coordinator, and operational research reference persons.

5.2. Abstract writing

- Where required, guidance and support for abstract writing and editing is available from the OR Unit.
- An abstract is a condensed version of a study manuscript, and included the objectives, main methods, results and key conclusions. It must be concise (usually between 200-300 words) and easy to read. Most conferences have their own format for abstract writing and this should be followed to maximize chances of acceptance. In general two options for abstract formats are accepted in most conferences.

Option 1

The first option is for scientific studies and should contain concise statements of the:

Background: the study objectives, hypothesis to be tested, or a description of the problem

Methods: method(s) used

Results: specific results in summarized form (with appropriate statistical

analysis)

Conclusions: description of the main outcome(s) of the study. All abstracts should disclose primary findings and avoid vague statements such as, ‘experiments are in progress or ‘results will be discussed’.

Option 2

This is most suited for presenting experimental information about studies and observations, policies, program and interventions using alternative research methods and styles. They may include community-based activities, as well as work in the area of prevention, care and social services, human rights programs and policy development. They should contain:

Issues: a short summary of the issue(s) addressed by the abstract

Description: a brief description of the project, experience, service, research and/or advocacy

Lessons learned: a brief description of the results of the project

Recommendations: a brief statement of next steps

Chapter 6

Writing a scientific paper

Research is not complete until the study is written up into a manuscript that is submitted for publication in the peer-reviewed scientific literature. Research that is not reported is research that has no meaning.⁴³ The following gives an overview of usual requirements for publishing but **it is not a substitute for the specific Instructions for each journal.**

6.1 Presentation of manuscripts

General

- First you should identify the journal(s) most appropriate for publication of your study and **review the Instructions for Authors** which are normally found on the journal's website. This will give you precise instructions on how to write the article. Ideally, read these **before** you start your write up. Many people write up a draft and then choose a journal. But this will likely involve revising the draft to accommodate the style requirements of the journal. Why not do it right the first time? Save time and hassles. Identification of a journal should be based on the message you are conveying and the audience you are trying to reach. Consideration should be given to the aims and scope of the journal as each journal has a particular scope of interest. E.g. There is no point going to the Lancet if the subject of your paper (e.g. clinical TB practice, or maternal care) is not part of their scope of interest.
- A very common problem - and annoying because it is so easily avoidable - is that word count limits are not respected. No matter how good your 3,000 word, 50 reference "letter" submission to the BMJ or Lancet is, it will get rejected on the simple basis that letters cannot be longer than 400 words.
- Write your text in good English. A number of studies have indicated that a badly written abstract or paper with poor use of English, even with good science, has less chance of being accepted or published. MSF OCB has native English-speaking editors who can smooth out your paper. Use them.

Format

- A manuscript will generally take the following structure:
 1. Title page
 2. Abstract and Key Words
 3. Introduction
 4. Methods

- a. Designs
 - b. Setting
 - c. Sample
 - d. Interventions
 - e. Outcome measures
 - f. Analysis (including sample size calculation)
 - g. Ethics approval
5. Results
 6. Discussion (including limitations)
 7. Conclusion (may be part of Discussion – check the journal’s usual policy)
 8. Acknowledgements
 9. Conflicts of interest statement
 10. References
 11. Tables and figures

Title page: Provide the following data on the title page

- The *title* should be concise and should catch the readers’ interest in the paper (e.g. by using a question). Avoid abbreviations and formulae where possible.
- *Author names* and *affiliations*. Present the authors' affiliation addresses (where the actual work was done) below the names.
- *Corresponding author*. Clearly indicate who is willing to handle correspondence at all stages of refereeing and publication, also post-publication. Ensure that telephone and fax numbers (with country and area code) are provided in addition to the e-mail address and the complete postal address.

Abstract.

- A concise and factual abstract is required (maximum length usually 200-250 words). The abstract should state briefly the purpose of the research, methods, principal results and major conclusions. An abstract is often presented separately from the article, so it must be able to stand alone.
- It is often best written after you have finished the rest of the paper. Editors often use the content of the abstract to decide whether to send the paper to reviewers. Thus, it must be carefully written.

Keywords. Immediately after the abstract, provide a maximum of 6 keywords. These keywords will be used for indexing purposes.

Abbreviations. Define abbreviations that are not standard in this field at their first occurrence in the article: in the abstract but also in the main text. Ensure consistency of abbreviations throughout the article.

Introduction. Give a brief background, state the study hypothesis and then the objectives of the study. Avoid a detailed literature survey or a summary of the results. Normally this section should be about one to two pages double-spaced.

Materials and methods. This section describes, among others, the study setting, population, (inclusion and exclusion criteria) study procedures, data collection and statistical analysis (including sample size calculation and ethics approval. Provide sufficient detail to allow the work to be reproduced. Methods already published can be referenced.

Results. The text should include the characteristics of the study population, and then describe the most important results. The text should highlight data presented in table or figure form and not duplicate it. All results should be linked to the objectives of the study.

Discussion. This section could start with a paragraph summarizing the main findings in line with the objectives. Then, state the strengths of the study followed by the implications for care, the program or wider policy Explain how your results are similar to or different from other work and include suggestions for further research There should be a section on limitations, usually at the end of the Discussion

Conclusion. Finally, the conclusions of the study are presented. It is important that these accord with the objective of the study as stated in the introduction. And that they are supported by the data presented in the study

Acknowledgements. Place acknowledgements, including information on funding, before the references, in a specific section.

References. Follow the format recommended by the journal's "Instructions for Authors". Most prefer 20-50 references at most.

Tables and Figures . Number tables and figures consecutively in accordance with their appearance in the text. Place footnotes to tables below the table body and indicate them with superscript lowercase letters. Avoid vertical lines. Be sparing in the use of tables and ensure that the data presented in tables is clear so that they “stand alone”.

6.2. Submissions and revisions

- Generally most journals now accept manuscripts through their internet site where they can be uploaded according to specific instructions.
- Once submitted, the manuscript is generally sent by the editor to two or more peer reviewers. When your paper has been returned by the editor, (usually after 3

months or more) you must carefully consider the comments by the reviewers and respond in a "point by point" letter to each comment. The manuscript should be amended accordingly and changes high-lighted in red font to facilitate further review. Rebuttal of suggestions is possible but should be justified. If the paper was rejected for publication, you should rewrite the paper, taking into account the critical comments made by the reviewers, and submit it to another journal.

- Sometimes it takes submission to two or three journals before one finally accepts. Often there is a "long journey" to publication. Adhering to the above is one way of making this journey as short as possible.

For further specific details refer to instructions for submission of manuscripts to biomedical journals (www.icjme.org).³¹

Chapter 7

Study authorship

Deciding on who should or should not be included as a study author is sometimes difficult. Such decisions are often sensitive and can generate conflict and contribute to bad feelings and bruised egos. They should thus be handled in a *clear, transparent* and *fair* manner, right at the start of a project. While the actual contributions of individuals may change over time, and this might affect study authorship hierarchy, there should be general agreement on who will be the principal author and what the contributions and responsibilities of individual authors will be.

In terms of “study authorship” there are ***four practical questions*** that need to be addressed considering the current mode of functioning between the field, headquarters and other partners (Epicentre, academic institutions etc):

- 1. Who should be a study author and how do you determine the order of study authors?***
- 2. Who should be a study author from the national counter-parts/MOH or an international partner?***
- 3. How do you determine study author hierarchy when headquarters or other partners (Epicentre, academic institutions etc) have been “principal contributors”?***
- 4. How do you determine study authorship for manuscripts that are fundamentally considered as “discussion documents” or descriptive papers on policy?***

These four questions are addressed separately. What is proposed below is in line with current international guidelines on study authorship as per the International Committee of Medical Journal Editors (ICJME), (www.icmje.org) that are given here:

Condition 1: *An author should have made a “substantial” contribution to the:*

Conception, study design/method (Conceived the research question, drafted the study protocol, critically reviewed and improved the methods) *or* Implementation of the study and acquisition of relevant data (Implemented key aspects of the study (coordination, training, follow-up, supervision), designed data collection formats, conducted/supervised data acquisition) *or* Analysis and interpretation of data

Condition 2: *Should have*

Drafted the article *or* Revised it critically for important intellectual content

Condition 3: Has agreed on the contents of the final version

These guidelines have been interpreted to the specific question of operational research as applicable to the MSF context.

1. Who should be a study author and how do you determine the order of study authors?

To be a study author, an author must fulfill the above conditions, It is the “quantity” and “quality” of contribution that qualify for “authorship” as against contributorship which qualifies for “acknowledgement” (see 1.3 below).

What does not justify/constitute study-authorship?

- *Data collection.* Data collection and/or data entry alone does not in itself constitute study authorship. Data alone without having gone through the different steps of “refining” is but a “set of numbers” and its value is restricted to just that. MSF and many health surveillance units around the world have tons of such data but they remain of limited value as long as they are not analyzed further.
- *Acquisition of funding, general supervision* of implementation, limited technical help, providing care for study patients, by themselves, do not justify study authorship. The contributions of these individuals should be highlighted in the “Acknowledgements” section of a manuscript (see 1.2 below).

Specific issues regarding authorship hierarchy (order of study authors)

1.1 Order of study authors on a manuscript.

The *first author* on a manuscript is the one who does most of the work for that particular article. It may or may not be the principal investigator-” of the overall research project. If a project results in several papers, the group may decide to have a first author for each paper. Where a manuscript involves mainly an “audit” of routine data, the main criteria for determining study authorship should be relative contributions to intellectual analysis and particularly the write-up of a manuscript. The *second author* is the one making the next largest contribution to the manuscript.

- After the first two authors **there is no universally accepted protocol for order.** Generally, the rest of the authors are listed in decreasing order of contribution. However, in some journals the *last author* position is kept for the most senior member of the team. But there is not hard and fast rule. Check the journal's guidelines.
- Each author must be willing to take public responsibility for the appropriate sections of the manuscript to which they have contributed and are responsible for the accuracy of their contribution(s).

When the number of authors on a particular manuscript is high (e.g. > 8), the first author should pay extra attention to verify that all have satisfied authorship criteria.

1.2 *Acknowledgment of contributions.*

- Individuals who do not qualify as authors but who have contributed to the article should be listed in the acknowledgments section of the manuscript. They should also be informed that they are being acknowledged. Examples of those who might be acknowledged include a person who provided pure technical help, a department chair who provided general support, individuals who were involved with routine care of patients under study etc.
- Financial and material support should also be acknowledged.

1.3 *Declaration of contributions of study authors.*

- Most journals now insist on a “declaration” of the specific contributions of each author and this could be legally binding. It is the responsibility of the first author finalize this issue.

2. Who should be a study author from the national level (MOH or other) or an international level?

There are two main issues that should be considered in this regard.

a) *Is involving a national partner a pre-requisite?* In many countries one of the pre-conditions for conducting any research is that a national partner must be involved. In order to fulfill this condition, researchers are often obliged to include at least one or more national partners as co-authors. Often this might be an individual(s) from the MOH from the district or national level or both. Where there true collaboration at local and national level authorship will contribute to building/improving local research capacity. Formal appearance of national partners on a manuscript is an advantage as this “ratifies” the study and facilitates the MOH accepting eventual “ownership ”of the contents.

b) *Translation of operational research findings into “policy and practice”.* Operational research should be judged primarily by how the findings eventually contribute to policy and practice. In this respect, involving key national partners and sometimes

international partners in a research study right from the conception stage and as co-authors facilitates “diffusion” of the results and eventual translation into policy and practice. *There is really no operational advantage in running a study that ends up getting published but eventually does nothing to improve policies in the field.* Efforts should thus be made right from the start to ensure (as much as possible) that partners participate actively, and feel a real sense of “ownership”, partnership, and responsibility. As a result of these considerations, it may be necessary to include national contributor(s) as authors even if they did not strictly fulfill ICMJE’s criteria as listed above. This just needs to be acknowledged as a necessary condition for publication of research based in a developing country.

3. Author hierarchy when the role of Brussels, Epicentre or an academic institution or other partners has been one of a “first author”

The hierarchy of authors should remain the same in these circumstances.

- If the *major contributions have been made in design, interpretation of data and write-up* by an individual outside the MSF field team then that person should be the first author. The decisions on who comes second and third should be based on relative contributions of the other members of the team, whether in the field, headquarters or an outside institution.

8. Reference documents for further reading

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ANNEX 1: Examples of operational research studies and their impact on policy & practice

Examples of operational research studies (Main author, Title, Country)	Main finding(s)	Implications for policy and practice
<i>Improving medical care and practice</i>		
Zachariah R. Voluntary Counselling, HIV-testing (VCT) and adjunctive Cotrimoxazole reduces mortality in tuberculosis patients in Thyolo - Malawi ¹³	<ul style="list-style-type: none"> ▪ VCT and adjunctive cotrimoxazole shown to be feasible, safe and associated with reduced mortality in TB patients under program conditions 	<ul style="list-style-type: none"> ▪ Provided evidence to support country-wide expansion of HIV testing and cotrimoxazole within TB programs in Malawi.
Harries AD. Recurrent tuberculosis in Malawi: Improved diagnosis and management following operational research – Malawi ¹⁴	<ul style="list-style-type: none"> ▪ Misclassification of recurrent TB cases as having new TB, and incorrect administration of anti-TB treatment regimens. 	<ul style="list-style-type: none"> ▪ Led to improvements in diagnosis, reporting and management of recurrent tuberculosis in Malawi (TB).
Heiden D. Cytomegalovirus retinitis: the neglected disease of the AIDS pandemic.- Thailand, Cambodia, South Africa, China ¹⁵ ,	<ul style="list-style-type: none"> ▪ 20% of patients with CD4 counts < 50 cells/mm³ had CMV retinitis, and 37% of individual eyes were blinded by CMV 	<ul style="list-style-type: none"> ▪ Led to establishment of decentralized diagnostic capacity for CMV retinitis in HIV-positive individuals with CD4 counts <50 cells/ul in four developing countries.
Reid T. Providing HIV care in the aftermath of Kenya's post-election violence Medecins Sans Frontieres' lessons learned January - March 2008 – Kenya ¹⁶	<ul style="list-style-type: none"> ▪ Effective strategies to sustain HIV/AIDS care and ART 	<ul style="list-style-type: none"> ▪ Led to improved contingency measures for sustaining ART and TB drug supplies during slum violence in Nairobi, Kenya.
Rieder H. Proposal for a revision of the case definition of sputum smear positive tuberculosis – Moldova, Mongolia, Uganda, Zimbabwe ¹⁷⁻¹⁹ .	<ul style="list-style-type: none"> ▪ Showed that two sputum smears were as good as three smears for diagnosing smear positive pulmonary TB 	<ul style="list-style-type: none"> ▪ Led to a two sputum smear strategy replacing the previously internationally accepted three sputum smear strategy as the gold standard for diagnosing smear-positive pulmonary TB

<p>Reyburn H. Overdiagnosis of malaria in patients with severe febrile illness in Tanzania: a prospective study ²⁰.</p>	<ul style="list-style-type: none"> ▪ Malaria commonly over-diagnosed in people presenting with severe febrile illness, leading to a failure to treat alternative causes of severe infection 	<ul style="list-style-type: none"> ▪ Led to consideration of syndromic treatment.
<p>Berkley JA. Use of clinical syndromes to target antibiotic prescribing in seriously ill children in malaria endemic area: observational study. ²¹</p>	<ul style="list-style-type: none"> ▪ Simple clinical syndromes effectively target children admitted with invasive bacterial infection and children at risk of death 	<ul style="list-style-type: none"> ▪ 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

<p>Culbert H. HIV treatment in a conflict setting: outcomes and experiences from Bukavu, Democratic Republic of the Congo - RDC²²</p>	<ul style="list-style-type: none"> ▪ ART can be offered in a conflict setting with good outcomes. 	<ul style="list-style-type: none"> ▪ Provided knowledge and contingency planning for sustaining comprehensive HIV/AIDS care, including ART in chronic conflict settings.
<p>van Griensven J. Success with antiretroviral treatment for children in Kigali, Rwanda: experience with health center / nurse-based care-Rwanda ²³</p>	<ul style="list-style-type: none"> ▪ ART successfully offered by nurses at health centre level. 	<ul style="list-style-type: none"> ▪ Demonstrated feasibility and effectiveness of non-physician based HIV/AIDS care including ART for policy makers
<p>Bedelu M. Implementing antiretroviral therapy in rural communities: the Lusikisiki model of decentralized HIV/AIDS care- South Africa²⁴</p>	<ul style="list-style-type: none"> ▪ A decentralized, simplified model of ART delivery based on nurses was feasible in rural South Africa. 	<ul style="list-style-type: none"> ▪ Led to policy change in allowing non-physician clinicians to administer ART in the province.

Advocating for policy change

Guthmann JP. Assessing antimalarial efficacy in a time of change to artemisinin-based combination therapies: the role of Médecins Sans Frontières. – Multicentre studies in 18 countries²⁵

- High levels of drug resistance in falciparum malaria and ineffective national regimens in 18 countries
- Led to a shift in national and international policy on use of more effective anti-malarial treatment.

O'Brien DP. In resource poor settings, good early outcomes can be achieved in children using adult fixed-dose combination antiretroviral therapy - Multicentre studies in 8 countries²⁶

- Very satisfactory ART outcomes in children on split-tablet generic fixed dose ART regimens
- Demonstrated that split-tablet, fixed dose combinations of generic antiretroviral drugs were as effective as branded drugs in resource-limited settings.

Zachariah R. 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.²⁷

- 58% higher risk of loss to follow up associated with payment for ART
- ART dilutions by patients who pay for ART
- Policy change occurred and ART in Mbagathi hospital, begun to be offered free-of-charge to all patients.

Lowrance DW. A public health approach to rapid scale-up of antiretroviral treatment in Malawi during 2004-2006 – Malawi ²⁸

- Rapid country-wide scale up of ART is feasible and associated with good outcomes.
- Provided a successful example of a public health approach to country-wide scale-up of ART in resource-limited settings based on simplified clinical decision making, standardized ART regimens, non-physician care, limited laboratory support, and centralized monitoring and evaluation in Malawi.

ANNEX 2: TYPICAL FORMAT AND ELEMENTS OF A RESEARCH PROTOCOL

1. Abstract
2. Study description
 - a. General information
 - Country and study site
 - Study title
 - Collaborating institutions, individuals and affiliations
 - Study background
 - Rationale, hypothesis and aims
 - b. Study questions
 - c. Study Objectives
 - d. Methods
 - Design
 - Setting and sites
 - Study period
 - n
 - Study population
 - Inclusion and exclusion criteria
 - Study procedures
 - Data collection and recording
 - Primary outcome measures
 - Secondary outcome measures
 - Statistical analysis
 - Sample size calculation
 - e. Ethics considerations
 - See Annex 2, below
 - f. Significance or expected impact
 - Implications of the research for national policy and practice
 - Feedback and dissemination of findings.
 - g. References
3. Budgets and funding
4. Chronogram or time-line
5. Investigators. Role and responsibilities.

ANNEX 3: Ethics Framework for Medical Research

Médecins Sans Frontières, March 2005

Principles	Initial benchmarks
Collaborative Partnership	<ol style="list-style-type: none"> 1) Engage in partnership with national and/or international research institutions as relevant and appropriate. 2) Collaborate with local and national researchers and health policymakers to share responsibilities for determining the importance of health problem, assessing the value of the research, planning, conducting, and overseeing the research, and integrating the research into the health system. 3) Respect the community's values, culture, traditions, and social practices. 4) Involve the community in which the study takes place (hereinafter referred to as "study community") through a consultative process in designing the research, in its implementation (advice on problems occurring during study, feed back of intermediate results) and in assessing how research results may be made beneficial. 5) Contribute to developing the capacity for researchers and health policymakers to become full and equal partners in the research enterprise. 6) Share fairly the financial and other rewards of the research.
<u>Social Value</u>	<ol style="list-style-type: none"> 1) Specify the beneficiaries of the research. 2) Assess the importance of the health problems being investigated and the prospect of value of the research for each of the beneficiaries. 3) Devise and implement mechanisms to enhance the social value of the research by: <ul style="list-style-type: none"> ▪ Disseminating knowledge gained locally, nationally, regionally and internationally; ▪ Making drugs or interventions tested and found to be effective available to the study community through advocacy, by involving policy makers from the start, by staying long enough after research ends to ensure its application. 4) Prevent supplanting the extant health system infrastructure and services.
Scientific Validity	<ol style="list-style-type: none"> 1) Ensure the scientific design of the research realizes social value for the primary beneficiaries of the research. 2) Ensure the scientific design realizes the scientific objectives while guaranteeing research participants the health care interventions they are entitled to (this includes a sample size sufficient to reach objectives). <p>Ensure the research study is feasible given the social, political, and cultural environment and with sustainable improvements in the local health care and physical infrastructure.</p>

Principles	Initial benchmarks
Fair Selection of Study Population	<ol style="list-style-type: none"> 1) Select the study population to ensure scientific validity of the research. 2) Select the study population to minimize the risks of the research. 3) Formulate clear inclusion and exclusion criteria. 4) Identify and protect vulnerable populations.
Favorable Harm-Benefit Ratio	<ol style="list-style-type: none"> 1) Assess the potential harms and benefits of the research to the study participants. 2) Assess the harm-benefit ratio for the community 3) Involve the community in assessing potential harms and benefits to study participants and the community at large.
Informed Consent	<ol style="list-style-type: none"> 1) Involve the study community in establishing appropriate recruitment procedures and incentives for the participants. 2) Ensure that consent procedures are acceptable within the study community (may include supplementary community and familial consent procedures). 3) Disclose information in culturally and linguistically appropriate formats. This implies that <ul style="list-style-type: none"> ▪ any information given during the informed consent process must be pretested with people of a similar cultural and educational background as potential study participants; ▪ the information provided on the consent form must be in simple language, avoiding technical terms; ▪ the consent form must be translated into the local language and then back-translated into the “international” language used to get a sense of the accuracy of the translation and correct mistakes; 4) Ensure that participants fully comprehend the research objectives and procedures: <ul style="list-style-type: none"> ▪ if needed, the person should get time to discuss the information received with members of the community or family before deciding on consent; ▪ in addition, community information or “schooling” on the research to be done and on the purpose and process of seeking informed consent will raise pre-enrolment awareness and thus help people to decide if they want to participate in the study. 5) Obtain consent in culturally and linguistically appropriate formatsⁱⁱ. 6) Ensure that potential participants are free to refuse or withdraw from the research at any stage without penalty.

Principles	Initial benchmarks
Respect for Recruited Participants and Study Communities	<ol style="list-style-type: none"> 1) Develop and implement procedures to protect the confidentiality of recruited and enrolled participants (including samples of body fluids/tissues). 2) Provide enrolled participants with relevant new information that arises in the course of the research. 3) Monitor medical conditions, including research related injuries, of enrolled participants and provide care at least as good as existing local norms. 4) Inform participants and the study community of the results of the research. 5) Minimize the risk of exploiting research participants by assessing potential wrongs (i.e. body fluids sent outside the country could be used for commercial purposes) and clearly informing study participants about destruction of samples or possible future use.
Independent Review	<ol style="list-style-type: none"> 1) Ensure public accountability through scientific and ethics review according to international standards. 2) Ensure public accountability through transparency and reviews by a local ERB or other relevant body. 3) Ensure independence and competence of the MSF ethics review.

i. **‘Community’** can be described in many different ways. Most commonly, community is described as a geographic, functional or socio-cultural entity with characteristics such as shared interests and experiences, values, common fate or cultural affinity. Sometimes a community is already organized, for example in the form of village committees. However, one needs to be careful with their real capacity to represent the community. In addition, official community groups can be part of government, be repressive and coercive and deny human rights, thus severely interfering with the voluntaries of participation. In some conflict-ridden environments where MSF works, the social structure has been destroyed. In these contexts it must be carefully explored who would best represent the interests of the population. If it is not possible to have a well functioning community body throughout the research process, at a minimum the community must be consulted during the planning stage of the research, should be consulted on an ad-hoc basis while the research is being done, and should be informed in a structured manner at the end of the research about the results. It is not enough to do this dialogue by consulting local staff, as they may not really represent the community. One option would be to add a few current or past patients to the group planning the study to make sure the objectives, approach, etc. are adequate and adapted to the local context.

ii. In some settings participants have refused to sign a consent form. In fact, signing a consent form is not mandatory, but serves as a back-up proof for the principal investigator. If a person refuses to sign, but gives oral consent, the researcher should keep a written record that the patient has been informed, understood and accepted to participate, but refused to sign.