Operational Research Framework

January 2019
SAMU-supported OR projects

- Approximately 80 OR projects on HIV/TB/HCV
- Across missions; heterogeneity in recourses, “productivity”, measurable impact
  - 50% in South Africa
  - UKR one OR project
- Across studies; heterogeneity in design, size, complexity, partnerships
  - RCTs, qual & mixed-methods, retro
  - In-house, Epicentre, Academia
Existing Framework and Tools

- OCB Policy Framework 2013
- South Africa OR Policy 2017
- Data Sharing & Data Protection Policies
- MSF ERB SOPs and documentation
- Intersectional (field research repository, Sci Days, Remit)
Machete or just pruning?
What kind of support does SAMU provide?

Support in:

1. asking the right research questions, prioritizing and deciding
2. implementing research
3. disseminating research findings
4. evaluating impact
5. building research & M&E capacity
6. monitoring OR and providing a framework
The OR process

1. Research Question
   - PICOT

2. Concept Note

3. Research Protocol
   - STOP/GO at any stage

4. Research Outputs
   - REPORT(s)

5. Research Implementation

6. Prioritization & Decision
   - CONCEPT

7. Research Questions
   - PICOT

8. MSF Operations
Asking research questions?
Who – When – How

WHO
• Anyone from field to HQ and back
• Partner proposals

WHEN
• Any time in the project cycle
• Fixed workshops and meetings, “OR exercise”
• AROs

HOW
• PICOT → Concept Note
• Qualitative Inquiry

• PI(C)OT
  o Population/Patient/Problem
  o Intervention/Indicator
  o (Comparison)
  o Outcome
  o Time/Type of Study
What the others do?

- **OCA Research Committee Structure**
  1. Head of Research, Deputy MedDir
  2. Deputy MedDir— chair of Health Advisor
  3. Research Technical and Training Advisor
  4. Research Coordinator

- Fortnightly/30 mins /longer
Deciding, prioritizing? Who – When - How

WHO

- **SAMU CFP**
  - Cell
  - SAMU Tech Ref (OR, Lab, PCS etc.)
  - Med Dept
  - Mission/Project
  - External experts

- WHEN
  - AROs
  - Any time in the project cycle
  - Fixed workshops and meetings

- HOW
  - Using OCB OR Framework
  - Scientific oversight?

[Diagram showing the flow of Research Question (PICOT), Concept, Note, Research Protocol, and Research Implementation with decision points at 1st Screening/stop/go/hold, 2nd Screening/stop/go, and STOP/GO at any stage.]
“What?” Criteria to check relevance

<table>
<thead>
<tr>
<th>Feature</th>
<th>Questions to Ask</th>
</tr>
</thead>
<tbody>
<tr>
<td>Problem base</td>
<td>Is there a health problem that is big/important enough to fix?</td>
</tr>
<tr>
<td>Context placement</td>
<td>Has prior evidence been systematically assessed to inform (the need for) new</td>
</tr>
<tr>
<td></td>
<td>studies?</td>
</tr>
<tr>
<td>Information gain</td>
<td>Is the proposed study large and long enough to be sufficiently informative?</td>
</tr>
<tr>
<td>Pragmatism</td>
<td>Does the research reflect real life? If it deviates, does this matter?</td>
</tr>
<tr>
<td>Patient centeredness</td>
<td>Does the research reflect top patient priorities?</td>
</tr>
<tr>
<td>Value for money</td>
<td>Is the research worth the money?</td>
</tr>
<tr>
<td>Feasibility</td>
<td>Can this research be done?</td>
</tr>
<tr>
<td>Transparency</td>
<td>Are methods, data, and analyses verifiable and unbiased?</td>
</tr>
</tbody>
</table>

doi:10.1371/journal.pmed.1002049.t001
Checklist for OCA Research Committee in Concept Paper review

1) Is the study purpose (intended impacts) useful for MSF?
2) Are the objectives achievable?
3) Is it a priority topic/necessary for operations/part of a topical research agenda? Is there a timeliness reason to do this now?
4) Is research the best way to answer this question?
5) Does it meet the ‘why MSF?’ question?
6) Has the question been/being answered before – inside or outside MSF?
7) Are the methods appropriate and described in sufficient detail?
8) Do the resources and time for each stage seem feasible?
9) What support might the PI need? Does the PI/or their team have the necessary skills to conduct the research including data analysis, writing, responding to reviewer comments (if intended for publication)? What skill gaps are there?
10) If ERB exemption has been requested, has the template been completed and does the study qualify for exemption?
11) For studies not seeking ethics exemption -are the benefits/harms proportionate? Are consent and confidentiality arrangements suitable? And has local ERB approval been/will be sought?
12) Are the Study Coordinator (usually topic specialist or epi advisor) and Primary Investigator appropriate?
13) Has the topic specialist/topic holder been informed/involved?
14) Have the responsibilities of the research team been appropriately described?
15) Has the field been involved, and if not, should they be?
16) Has the Health Advisor given support on behalf of the Mission?
17) Are external partners appropriate, are Moh/national partners involved, has the community been involved?
18) Are there conflicts of interest that need to be addressed?
19) Is the data management and sharing plan in compliance with OCA/MSF policies?
20) Is the dissemination plan appropriate- does it include field/national partners/participants/community as appropriate?
21) Has consideration been given to how this will feed into change in/outside MSF?
22) Is the Study Coordinator likely to be able to deliver the impacts specified?
“What?” Criteria to decide priorities

1. Operational Priority
2. Demand/buy-in by MSF and/or the stakeholders
3. Timeliness
4. Innovative models of delivery
5. Advocacy
6. Resources

Any study assessed as fulfilling 4 or more of the above could be considered a priority
What kind of support does SAMU provide?

Support in:

1. asking the right research questions, prioritizing and deciding
2. **implementing research**
3. disseminating research findings
4. evaluating impact
5. building research & M&E capacity
6. monitoring OR and providing a framework
“Who” is implementing and supporting OR?

- The WHOLE TEAM, not just the epis
- PI
- Co-PI/Study Coordinator

Where
- Field
- Coordination
- Epicentre
- Other partners
- SAMU-based
What kind of support does SAMU provide?

Support in:

1. asking the right research questions, prioritizing and deciding
2. implementing research
3. disseminating research findings
4. evaluating impact
5. building research & M&E capacity
6. monitoring OR and providing a framework
Some tools; experience from the field

● OR exercise
  ○ Khayelitsha DR-TB
  ○ India
  ○ Malawi
  ○ Mozambique
  ○ Guinea, KZN

● “Retreats”/ workshops
  ○ Kinshasa Protocol workshop
  ○ Zimbabwe Writing Retreat
  ○ SA Writing Retreats
  ○ Malawi mini-retreats
Monitoring OR: Inventory/Repository

- (Crowd-sourced) Excel sheet manually & slowly updated
- ERB inventory
- Thematic OR up-dates
- Remit
  - [https://remit.oca.msf.org/](https://remit.oca.msf.org/)
- Field Research
  - [http://fieldresearch.msf.org/](http://fieldresearch.msf.org/)
Future plans

- **SAMU OR ↔ M&E Frameworks**
- OCB “circle” for OCB OR Framework
- Intersectional collaboration /ReMlT
A success story

The contribution of MSF data on the WHO Rapid Communication: Key changes to treatment of multidrug- and rifampicin-resistant tuberculosis (MDR/RR-TB)
Maybe an organic olive grove?