A Médecins Sans Frontières ethics framework for humanitarian innovation plus worked case studies

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Introduction

Humanitarian organisations often have to innovate to deliver health care and aid to populations in complex and volatile contexts. Innovation projects can involve ethical risks and have consequences for populations even if human participants are not directly involved. While high-level principles have been developed for humanitarian innovation, there is a lack of guidance for how these should be applied in practice. MSF has well-established research ethics frameworks, but application of such frameworks to innovation projects could stifle innovation by introducing regulation disproportionate to the risks involved. In addition, the dynamic processes of innovation do not fit within conventional ethics frameworks and there is a need for ethics guidance for innovations specific to humanitarian action. Therefore, we developed and piloted an ethics framework for innovation projects. Research involving human participants, including use of their data, requires approval by the MSF Ethics Review Board (ERB) and, similarly, innovation projects that constitute medical research (i.e. involving human participants or their data) should follow the research ethics review process. More information on the derivation and use of the framework has been published.[1]

Framework: *This framework is intended to be used to guide work that does not directly involve human participants and does not lie within the purview of formal research ethics oversight.*

1. Clearly **identify the problem** you are seeking to address, and what benefit you expect the innovation to have. This step may seem obvious, so what is its ethical significance? When identifying the problem, there should be consideration of up-stream solutions that may address the problem in a holistic and sustainable way. For instance, rather than focusing on technocratic fixes, what are the socio-political determinants of the problem and the wider possibilities for solutions? Who has stakes in finding a solution and who may have interests in perpetuating the problem? Is the problem a moving target? Collaboration and cross-fertilization with other disciplines should be considered in order to help to see the problem from various perspectives. In short, do not underestimate the importance of fully identifying the problem.

2. **Ensure that the innovation shows respect for human dignity**. While this is a broad

concept, it has practical implications. The focus of concern is respect for human beings, reminding us that the simplest or most direct solutions may not be ethically appropriate. Innovators must show due respect for the multiple and overlapping interests of those affected by the innovation. It extends beyond a concern for physical wellbeing to include psychological and cultural integrity. It also incorporates a concern for individual privacy and a respect for the confidentiality of individual, family, and community-based data.

3. **Clarify how you will involve the end user** from the start of the process. Innovation should be driven by the requirements of the user. The innovation cycle should be participatory, using methods to involve relevant individuals and communities. Innovators must be sensitive to power dynamics between and within cultures and power imbalances between aid workers and beneficiaries.

4. **Identify and weigh harms and benefits**. When considering innovations, a critical first step is the identification, as far as is reasonably possible, of potential harms along with the anticipated benefits. The next step involves weighing these harms and benefits.
    a. Where reasonably foreseeable harms outweigh the likely benefits, implementation will not be ethical. Potential harms include, but are not limited to, physical and psychological harms to individuals. There is also need to consider potential harm to communities.
    b. Where innovation involves a favourable balance of benefits and harms, all reasonable steps must be taken to minimise (mitigate) the harms as far as possible. Unnecessary harms must be eliminated. Where harms are unavoidable, those affected should be informed of the nature and severity of the risks involved.
    c. Conflicted partnerships or conflicts of interest may result in reputational harm to the organisation. If these are identified then oversight by an existing Ethics Review Board is recommended.
5. **Describe the distribution of harms and benefits, and ensure that the risk of harm is not borne by those who do not stand to benefit**. Innovators need to give careful consideration to the distribution of benefits and harms associated with their projects. Do the risks or benefits fall unequally across groups? If so, is it appropriate to proceed, and how can these inequalities of distribution be addressed or mitigated? Equally, it is important that the innovation takes into account vulnerable groups; it may be ethically warranted to give particular attention to those who have particular needs. Just as we tend to give more health care to the unwell, so particular attention may need to be given to those who are vulnerable or who may not be able to protect their own interests. This is expressed in the humanitarian principle of impartiality. In addition, consider whether anyone is ‘wronged’ by the innovation. A ‘wrong’ is an infringement that is distinct from harm. For example, selecting one group for an innovation project over another may

wrong the other group (as opposed to harming them).

6. **Plan (and carry out) an evaluation that delivers the information needed for subsequent decisions to implement or scale-up the innovation; and then ensure that the beneficiaries have access to the innovation.** Innovation requires an acceptance of the risk of failure – not all innovation projects will achieve their desired outcome. But in all cases, we can learn and apply these lessons in the future. Given the time, energy, and resources that these projects require, rigorous evaluation and sharing of lessons is itself a moral obligation. Therefore, consideration should be given to dissemination of findings, since it may be important to avoid further exposure to potential harm by sharing findings, whether these are positive or negative. Likewise there should be a willingness and strategy for wider implementation of the innovation if found to be successful, and a commitment to ensure beneficiaries - at least in the communities where it was tested and ideally in similar communities affected by humanitarian crises - have access to the innovation subsequently.

Applying the framework

The case studies presented below are based on analysis of abstracts and slides of conference presentations of MSF innovation projects. Project leaders were contacted and gave permission for their project to be analysed and to provide clarification where necessary. Each case study contains: a brief outline of the project; analysis of the project using the innovation ethics framework; and conclusions about the ethical considerations raised and what might have been done differently if the framework had been applied at the start of the project.

Case study 1: New technology for an old disease: unmanned aerial vehicles for tuberculosis sample transport in Papua New Guinea[2]

Unmanned aerial vehicles (UAVs) for tuberculosis sample transport in Gulf Province, Papua New Guinea
The transport of diagnostic sputum samples in Gulf Province, Papua New Guinea (PNG), is extremely challenging due to lack of road access. With the agreement of the PNG authorities, the use of unmanned aerial vehicles to transport such samples was trialled in 2014. Although no systematic data collection was conducted, several successful pilot flights were carried out delivering samples from a remote health facility to the laboratory in Port Moresby. However, the distance of flight was limited to 28 km due to short battery life.
1. Identify the problem
The problem that this innovation project addresses is clearly stated, and expected benefits of UAVs in this context identified.
2. Respecting human dignity
• How respectful of individuals and the community is the intervention? The local community was widely informed about the activity and was supportive. The involvement of the local community is a must in the use of drones for civil use in any area.

- If health data are being transported along with the samples, has thought been given to possible confidentiality issues? In this pilot no real samples were transported. The question of how much risk is allowable will be important if this approach is adapted operationally.

3. Involving the end user

- Have relevant communities been involved in decisions regarding deployment, timetabling, or flight-lines as appropriate? Coordination with the Civil Aviation, local authorities, and all required permissions were obtained. All levels of authorities were supportive.
- Have the legal and regulatory issues in relation to the use of UAVs in the proposed area been properly addressed? Flights were conducted through non-populated areas at low altitude. All authorities approved the flying schedules. No specific regulation for UAVs was in existence in the country.

4. Identifying and balancing benefits and harms

- A successful trial would provide the possibility for rapid scaling and wider implementation.
- The potential benefits include rapid collection and testing of samples which benefits both infected individuals and affected populations and results in increases in efficiency.
- Has thought been given to what would happen if the UAVs were carrying highly infectious material and crashed or were downed? An outer, crash-proof case around the samples was used; no infectious material was carried in this pilot. Further evaluation would be needed before hazardous material was transported.
- In conflict zones, would they be associated with military UAVs and generate suspicion and resistance? Could this entail risks for staff or reputational risks for MSF? In this setting there is no history of military use of drones.
- Are the UAVs purchased from military suppliers and will this involve reputational risks? In this case the supplier is civilian with no military connections.
- Have the risks associated with mechanical failure been addressed? The UAV used was small and flying over unpopulated areas. For operational use, issues around transport of hazardous material would need to be addressed, as noted.

5. Consider the distribution of harms and benefits

- How would different communities respond to the use of these UAVs? The community here has no negative experience of drones and the authorities are supportive.
- Would the benefits and harms fall on the same populations or be distributed differently?
- Could people, including vulnerable groups such as children, gain access to the material and be infected or otherwise harmed? (For instance if UAVs crashed due to power or mechanical failure and were retrieved by children.) This risk would need to be assessed before transport of hazardous material.

6. Evaluation and subsequent implementation plan

- No evaluation or scale-up was mentioned in the abstract. This was an early-stage pilot, and probably did not aim to address all questions relevant to subsequent implementation.

Conclusion: insufficient information was provided to assess whether the relevant ethical issues have been identified and managed appropriately – the authors should address this as a significant shortcoming.

If the framework had been applied from the start of the project: more effort may have been made to address issues of confidentiality and risk mitigation; means of evaluating the innovation may have

been identified.

Case study 2: The Niger REFRESH borehole project: a paradigm change [3]

Refresh **project – regenerating damaged or contaminated water boreholes**
Sustainable access to potable water is a vital aspect of many of our programmes. Frequently, this can be achieved only by drilling boreholes down into the aquifer, often at considerable depth. Boreholes are expensive to drill. Unless properly maintained they can also degrade. They are liable to chemical and biological contamination, physical blockage, and fracture of the casings. They can also be breached by plant and tree roots. The solution has traditionally been to drill a new borehole. This is expensive. Trialling is under way of a cheaper option involving the identification of poorly-performing boreholes, investigation and diagnosis of the problems, and, where appropriate, regeneration of boreholes. This can involve: removing blockages by air-lift pumping; and addressing water quality by chemical treatment, scrubbing, and flushing.
1. Identify the problem
• The problem was clearly identified, and the expected benefits of the intervention were described.
2. Respecting human dignity
• Not applicable.
3. Involving the end user
• The requirements of the end user are integral to the innovation, but there are questions about the extent to which the technology and expertise can be rapidly and effectively transferred to the local population.
4. Identifying benefits and harms
• Financial savings of regeneration make a strong initial case for the project. • The innovation does not directly expose end users to harm – the question is whether the water is safe to drink; this can be scientifically established before use.
5. Consider the distribution of harms and benefits
• Not applicable.
6. Evaluation and subsequent implementation plan
• Some cost analysis was carried out showing that this approach offered significant cost savings relative to digging new wells. • It is not clear that this project addressed all questions necessary to decide on implementation.
Conclusion: this is an example of an innovative approach to a specific problem that raises no significant ethical concerns. Human participants are not directly involved – or obviously at risk – and the potential benefits significantly outweigh the harms.
If the framework had been applied from the start of the project: more thought may have been given as to how this technology and expertise could be transferred to the local community, and what evaluation information would be needed to enable decisions on wider implementation.

Case study 3: Mobilisation of local people and technology in mapping for the Sierra Leone Ebola epidemic response [4]

Mobilisation of local people and technology in mapping for the Sierra Leone Ebola epidemic response
During the Ebola epidemic in Sierra Leone, MSF encountered difficulties in rapidly locating villages in

which Ebola cases, and contacts, had been identified. There were villages with similar names in different chiefdoms, and villages with alternate names. New villages, and some satellite villages, were missing from maps completely. In Tonkolili District, Sierra Leone, MSF trialled an innovative method of gaining accurate information about the location and identity of villages, and the availability of local health facilities. Using local 'okada' motorbike drivers, and local people with GPS-enabled mobile phones, information was gathered across the district about the name, GPS location, chiefdom, ward, and constituency of individual villages. Alternate names, the name and contact number of the village chief or head, and the number of houses in the village were also recorded. Information about the nature and location of any available local health services, and the contact details of the local health-care worker were also recorded. This information was processed using open-source mapping software to develop accurate and up-to-date maps of the district.

1. Identify the problem

The problem was clearly identified, and the expected benefits of the intervention were described.

2. Respecting human dignity

- Enrolment of local populations not only in gathering information, but also agreeing to its collection and use is important.
- Among the potential questions the project raises are the security of the data, and the consent of any individuals whose identifying data are captured.
- Where identifiable information is being recorded or transferred, appropriate methods for seeking consent need to be explored.

3. Involving the end user

- One of the great strengths of the project was its ability to use locally-appropriate technology in genuine partnership with local people.

4. Identifying benefits and harms

- Volunteers were asked to travel to areas affected by the Ebola epidemic, thus increasing their exposure. This potential harm was mitigated by daily health education briefings that included information on: no-touch policy, no contact with objects or surfaces that might have been in contact with sick people, self-assessment (report any headaches or other symptoms), drinking adequate MSF-supplied bottled water, hand-washing, etc.
- Increased risk of infection to the community. Mitigated by the approach described above and weighed as similar risk to that of outreach workers.
- The teams were at risk of being exposed to violence as a result of fear of travellers, particularly those associated with Ebola treatment. This potential harm was mitigated by mappers being instructed to politely ask permission of all village authorities to conduct their surveys, and to never argue if asked to stay away or to leave.
- Reputational risk to MSF or backlash against the EMC if the behaviour of mappers was not in line with MSF policy. Mitigated by the approach described above.
- The benefits to the overall Ebola epidemic response of accurate mapping were significant. The financial cost of the project was modest in relation to the utility of the information.
- If this technology were used in conflict zones, for example, it might create anxiety about the data falling into the wrong hands. This potential harm can be to an extent managed by the use of secure MSF servers.

5. Consider the distribution of harms and benefits
• There might be some concern that harms were concentrated on the recruited drivers.
6. Evaluation and subsequent implementation plan
• No formal evaluation, but good analysis of lessons learnt and quality of data collected. • It is not clear what the ultimate implementation plan was (in case of a successful pilot).
Conclusion: this innovation project raises some ethical concerns in relation to confidentiality, consent, and data-security, which would need to be addressed. However, it should be acknowledged that this is not clinical data, and is thus less sensitive an issue. Ultimately the likely benefits of this innovation significantly outweigh potential harms.
If the framework had been applied from the start of the project: more effort may have been made to address issues of confidentiality, consent, and data security; and more attention paid to evaluating the innovation to decide on wider implementation possibilities.

[1] Sheather J, Jobanputra K, Schopper D, Pringle J, Venis S, Wong S, et al. (2016) A Médecins Sans Frontières Ethics Framework for Humanitarian Innovation. PLoS Med 13(9): e1002111. doi:10.1371/journal.pmed.1002111

[2] Chikwanha I, Pujo E. New technology for an old disease: unmanned aerial vehicles for tuberculosis sample transport in Papua New Guinea. MSF Scientific Day, London, UK; May 7, 2015. Available: http://www.msf.org.uk/sites/uk/files/1._2_chikwanha_new_operational_models_ocp_sv_final_0.pdf.

[3] Nuttinck J-Y, Zongo M, Faure G, Madondo H, Van den Bergh R, Maes P. The Niger REFRESH borehole project: a paradigm change. MSF Scientific Day, London, UK; May 7, 2015. Available: http://www.msf.org.uk/sites/uk/files/2_30_maes_new_models_ocb_sv_final.pdf.

[4] Gayton I, Lochlainn LN, Theocharopoulos G, Bockarie S, Caleo G. Mobilisation of local people and technology in mapping for the Sierra Leone Ebola epidemic response. MSF Scientific Day, London, UK; May 7, 2015. Available: http://www.msf.org.uk/sites/uk/files/3_26_lochlainn_gayton_e-health_oca_sv_final_1.pdf.