Ethics in innovation in MSF - an initial framework (and three case studies)

This paper sets out guidance on ethics for innovation projects. The first part describes why ethics should be part of the innovation cycle. The second part gives a framework in the form of a checklist that can be used by innovators to weigh up the harms and benefits of their projects. The third part gives some worked case studies using the framework.

Part one: ethics and humanitarian innovation

1. The need for an ethical framework for innovation

The increasing challenges faced by MSF in delivering assistance to people in extreme need mean that innovation is an ethical obligation. The purpose of innovation is to make us more effective and therefore better equipped to achieve our goals. We cannot rely on old solutions for new problems. Innovation can however involve risks. Along with the intended benefits can come harms – either to those individuals or populations we seek to benefit, or to our staff, our processes, our reputation or to the trust placed in us by those in need. In seeking innovative solutions, ethical judgements may need to be made that require potential benefits and harms to be identified and balanced. We have therefore developed a framework to help those looking for innovative solutions to consider the ethical issues that innovation can give rise to.

This framework is not designed to stifle innovation. Its purpose is to enable innovators to identify ethical issues, structure their thinking and adapt their ideas accordingly. It also indicates where external ethical review may be required.

2. Innovation or research?

Medical research involving human beings – or their data – already requires rigorous ethical oversight. A primary purpose of ethical regulation is to protect human subjects. Another vital purpose is to ensure the scientific integrity of the research itself.

Research and innovation are not the same. Research has been usefully and briefly defined as 'the attempt to derive generalizable new knowledge by addressing clearly defined questions with systematic and rigorous methods.' Any research in MSF involving human subjects, including the use of their data, requires approval by the MSF Ethics Review Board. (In the case of retrospective analyses of routinely collected clinical data, the relevant MSF Medical Director can assume responsibility for ethics issues and exempt studies from review).[1]

Innovation is rightly a looser, less-easily defined process. For MSF, it involves the use of new ideas, or the deployment of existing ideas in new contexts, to enable us to change and be more effective in pursuit of our goals. In the majority of cases, a 'light-touch' approach to ethical oversight, proportionate to the reasonably foreseeable harms – and mindful that excessive regulation can stifle innovation – is likely to be appropriate. As with research though, concern for human welfare must be central.

3. The innovation cycle

Innovation is a dynamic process, seldom a one-off event. It involves identifying problems, developing and selecting possible solutions, preliminary implementation and testing and, where effective, widespread adoption.

---

[1]MSF Research Ethics Framework - Guidance Document
http://fieldresearch.msf.org/msf/handle/10144/305288

This framework should not be thought of as an initial ethical hurdle to be jumped at the outset. Its purpose is to promote and inform ethical reflection throughout the innovation cycle.

4. Understanding and identifying harms

As with research, some innovation will involve exposing individuals, or populations, to a risk of harm. The existence of potential harms does not *by itself* invalidate an innovative approach. Where the benefits may be significant and the foreseen harms slight, it may be appropriate to proceed. The important issue is that care is taken to identify potential harms and to see if they may be justified by the anticipated benefits. Where it is decided to proceed with innovation that involves some risk of harm, an obligation arises to mitigate the harms as far as possible, and to communicate the nature and likelihood of the possible harms to those affected by them. Where potential harms are identified as non-trivial, external ethical oversight should be sought.

5. Domains of harm

Harms can arise in a variety of contexts. Health professionals are accustomed to working with interventions that may put people at risk of physical or psychological harm and considerable care must be taken to identify any such risks. But ethically relevant harms can also include, although will not be restricted to:

- Privacy harms: these include inappropriate use, transfer or storage of personal data
- Threats to trust: our interventions cannot succeed without the trust of the individuals and populations we work with. Many things can undermine trust, but they can include:
    - A failure to consider the impact of the innovation on the culture, attitudes or values of the target population
    - A failure appropriately to engage those likely to effected by the innovation. Humanitarian innovation must be rooted in a respect for the dignity of those we work with and for. Parachuting innovations into complex environments without collaborative working with those effected can be perceived as patronizing, undermine trust and result in failure
    - A failure to consider local solutions – humanitarian interventions are often characterized by a significant power differential. A failure to identify, and where appropriate build on, local solutions can undermine trust.
- Reputational harms. These are closely linked to trust. MSF depends on its reputation as a trusted, independent and impartial provider of medical relief in humanitarian emergencies. Factors that can damage our reputation include:
    - Conflicted partnerships. Innovation can include working with non-traditional partners. These can include commercial providers, government or the military. Reputational risks for MSF can arise where partners have agendas that may be, or may perceived to be, antagonistic to our core humanitarian goals.

- *When designing, testing or implementing innovation, potential harms must be identified*
- *Where non-trivial harms are identified anywhere in the innovation cycle some form of independent ethical oversight should be sought.*
- *Where there is doubt about whether a harm is non-trivial, innovators should err on the side of caution and seek ethical oversight from the MSF Ethics Review Board or other relevant channel .*

Part two – an ethical framework[2]

In the first part we concentrated on the importance of identifying and mitigating harms. Although essential, it is only one aspect of good innovation. For MSF innovation needs to be governed by principles that are rooted in our core values. Here we set out a number of principles to help MSF innovators structure their ethical deliberation.

Although MSF is committed to these principles, we recognise that they do not, by themselves, provide a 'solution' to all the ethical challenges that innovation can present. Different principles can take priority in different contexts and at times they may need to be balanced against each other. Innovation that seriously conflicts with any of these principles is unlikely to be ethical.

1. Respect for human dignity. This is a primary principle. The focus of concern must be a respect for human beings. It is a broad concept but involves showing due respect for the multiple and overlapping interests of those effected by any innovation. As discussed above, 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 people's data.

2. Involve the end user. 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.

3. Identifying benefits and harms. As discussed above, when considering innovations, a critical first step is the identification, as far as is reasonably possible, of potential harms along with the anticipated benefits. It is also important, as will be picked up in the section on justice below, to identify the spread of those likely harms and benefits.

4. Weighing and balancing benefits and harms. Having identified the likely benefits of harms, and their distribution, the next step involves weighing and balancing them. Where reasonably foreseeable harms outweigh the likely benefits, implementation is unlikely to be ethical. Potential harms include, but must not be restricted to, physical and psychological harms to individuals.

5. Minimising harms. Where innovation involves a favourable balance of benefits and harms, all reasonable steps must be taking to minimise 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.

6. Justice. Innovators need to give careful consideration to the distribution of benefits and harms associated with their projects. Do the risks or benefits fall unfavourably on certain groups? If so, is it appropriate to proceed? If you do proceed, how can these inequalities of distribution be addressed or mitigated?

7. Concern for vulnerable groups. Linked to principles one and six, this principle centres on the idea that justice can entail giving 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.

---

[2] The authors would like to acknowledge their debts to existing work in this area – our sources are listed at the end.

Part three – case studies.

Case 1: unmanned aerial vehicles for tuberculosis sample transport in Gulf Province, Papua New Guinea

The transport of diagnostic sputum samples in Gulf Province, Papua New Guinea, is extremely challenging due to lack of road access. With the agreement of the PNG authorities, the use of unmanned aerial vehicles to transport the samples was trialled in 2014. Although no systematic data collection was carried out, several successful pilot flights were carried out delivering samples from a remote health facility to the capital level laboratory in Port Moresby. However, distance of flight was limited to 28 km due to short battery life; this still needs to be considered a work in progress.

1.	**Respecting human dignity**
•	How respectful of individuals and the community is the intervention?
•	If health data are being transported along with the samples, has thought been given to possible confidentiality issues – particularly an issue where UAVs may be used to gather data.
2.	**Involving the end user**
•	Have relevant communities been involved in decisions regarding deployment, timetabling or flight-lines as appropriate?
•	Have the legal and regulatory issues in relation to the use of UAVs in the proposed area been properly addressed?
3.	**Identifying 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 be given to what would happen if the UAVs were carrying highly infectious material and crashed or were downed?
•	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?
•	Are the UAVs purchased from military suppliers and will this involve reputational risks? Have the risks associated with mechanical failure been addressed?
4.	**Balancing benefits and harms**
5.	**Minimising harms**
6.	**Justice**
•	How would different communities respond to the use of these UAVs?
•	Would the benefits and harms fall on the same populations or be distributed differently?
7.	**Concern for vulnerable groups**
•	Could people, including vulnerable groups such as children, gain access to the material and be infected or otherwise harmed?

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.

Case 2: *Refresh* project – regenerating damaged or contaminated water boreholes

Sustainable access to potable water is a vital aspect of many of our missions. Frequently, this can only be achieved 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 involving the identification of poorly-performing boreholes, investigation and diagnosis of the problems and, where appropriate, regeneration. This can involve removing blockages by air-lift pumping, and addressing water quality by chemical treatment and scrubbing and flushing. Regeneration of existing boreholes is by some degree less expensive than drilling a replacement.

1. Respecting human dignity	
2. 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	
3. Identifying benefits and harms	
• The 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 and this can be scientifically established before use	
4. Balancing benefits and harms	
5. Minimising harms	
6. Justice	
• It is not clear that specific questions arise in relation to justice	
7. Concern for vulnerable groups	
• It is not clear that specific questions arise in relation to the needs of vulnerable groups	

Conclusion: this is an example of an innovative approach to a specific problem that raises no significant ethical concerns. Human subjects are not directly involved – or obviously at risk – and the potential benefits significantly outweigh the harms. Our framework suggests however that thought needs to be given to how this technology and expertise can be transferred to the local community.

Case 3: 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. 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 is captured.   - Where identifiable information is being recorded or transferred, appropriate methods for seeking consent need to be explored.
2. 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
3. Identifying benefits and harms
- 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
4. Balancing benefits and harms
5. Minimising harms
These potential harms can be to an extent managed by the use of secure MSF servers
6. Justice
7. Concern for vulnerable groups

Conclusion: this innovation project raises some ethical concerns in relation to confidentiality, consent and data-security, which would need to be addressed. Ultimately though, where these can be appropriately managed, the likely benefits significantly outweigh potential harms.

Sources

Agich GJ. Ethics and Innovation in Medicine. *Journal of Medical Ethics.* 2001.
http://jme.bmj.com/content/27/5/295.full.

Baregheh A et al. Towards a multidisciplinary definition of innovation. *Management Decision.*
2009. http://www.emeraldinsight.com/doi/abs/10.1108/00251740910984578.

Betts A & Bloom L. *Humanitarian Innovation: The State of the Art*. United Nations Office for the
Coordination of Humanitarian Affairs. 2014.
https://docs.unocha.org/sites/dms/Documents/OP9_Understanding%20Innovation_web.pdf.

Fabian C & Fabricant R. The Ethics of Innovation. *Stanford Social Innovation Review*. 2014.
http://ssir.org/articles/entry/the_ethics_of_innovation.

Greene I. *The ethics of innovation and the Development of Innovative Projects*.
http://www.innovation.cc/scholarly-style/greene-ethics.pdf.

International Association of Professionals in Humanitarian Assistance and Protection (PHAP).
Live online consultation: Principles for Ethical Humanitarian Innovation. 2015.
http://www.elrha.org/wp-content/uploads/2015/08/150708-Principles-for-Ethical-
Humanitarian-Innovation-event-report.pdf.

O'Sullivan D. *Applying Innovation*. London: Sage. 2009

United Nations Office for the Co-ordination of Humanitarian Affairs. *Unmanned Aerial Vehicles in
Humanitarian Response*. 2014.
https://docs.unocha.org/sites/dms/Documents/Unmanned%20Aerial%20Vehicles%20in%20Hu
manitarian%20Response%20OCHA%20July%202014.pdf.

Ramalingam B et al. *Strengthening the Humanitarian Innovation Ecosystem – Humanitarian
Innovation Ecosystem Research Project.* 2015.
https://www.brighton.ac.uk/_pdf/research/centrim/humanitarian-innovation-ecosystem-
research-project-final-report-with-recommendations.pdf.