MAPPING DISASTER RESEARCH ETHICS SCENARIOS: THE CASE STUDIES

Cost Action IS1201

Disaster Bioethics

CASE 1

A team of medical and public health professionals are taking part in humanitarian relief operations in a civil war struck area. They, at the same time, are planning to conduct a public health survey among the refugee population there. The REC learns from their protocol that it only could be carried out if the international team cooperates with local community leaders, professionals, and if they are accompanied by armed insurgents as security guards in order to protect the team of researchers.

Original text: *„W. Courtland Robinson of Johns Hopkins University recalled a situation in which ethnic Karen public health workers crossed the Thai border in Burma accompanied by armed insurgents as security guards in order to conduct public health surveys"*

Holly Reed (2002): Research Ethics in Complex Humanitarian Emergencies

CASE 2

A severe meningitis outbreak takes place in a rural, resource-poor area of Africa, infecting a large population, many of them are children. A big, international pharmaceutical company aims to conduct an RCT to investigate whether their candidate antibiotic is more effective and efficient in treating children infected with meningitis than other existing treatments, including a gold standard treatment. The interventional drug has not been previously tested in children. On the other hand, due to the very poor resources in that area, the gold standard treatment is not available for the target population.

Original text: „*Pfizer, an American multinational pharmaceutical company, conducted a trial of an antibiotic at the site of the outbreak of a meningitis epidemic in the northern state of Kano, where 15.000 people were alleged to have died from these epidemics. Kano is a typical poor area in a developing country, so even the Kano Infectious Diseases Hospital, where the trial took place, was reported to be at the time a poor, dirty hospital with few beds, poor power supply, and no clean water,. Pfizer conducted the clinical trials in Kano to investigate whether to oral form of Trovan was more effective and efficient in treating children infected with meningitis than other existing treatments, including Ceftriaxone, the gold standard treatment. Pfizer's Trovan had not been previously tested in children. However, about 200 infected children participated in the Kano trials. Of these, 100 took Trovan while another 100 were put on Cegtriaxone. Eleven children died in the trials, five of whom were on the experimental drug. There were also other children involved in the trials who suffered seizures, or became paralyzed. While there is no evidence that Trovan was responsible for the deaths and injuries to children, the trials were conducted within a period of two weeks and Pzfizer left immediately thereafter.*"

Yue Wang (2014): Human population Genetic Research in Developing Countries – The Issue of Group Protection

CASE 2 – LONGER VERSION

A severe meningitis outbreak takes place in a rural, resource-poor area of Africa, infecting a large population, many of them are children. A big, international pharmaceutical company aims to conduct an RCT to investigate whether their candidate antibiotic is more effective and efficient in treating children infected with meningitis than other existing treatments, including a gold standard treatment. The interventional drug has not been previously tested in children, yet, the protocol is about involving 200 children. On the other hand, due to the very poor resources in that area, the gold standard treatment is not available for the target population. Having accepted the protocol and started the trial, more than 10 children dies, 4 of them who were in the experimental arm. Though no strong evidence supports the responsibility of the company, the company suddenly leaves the research site.

Original text: „*Pfizer, an American multinational pharmaceutical company, conducted a trial of an antibiotic at the site of the outbreak of a meningitis epidemic in the northern state of Kano, where 15.000 people were alleged to have died from these epidemics. Kano is a typical poor area in a developing country, so even the Kano Infectious Diseases Hospital, where the trial took place, was reported to be at the time a poor, dirty hospital with few beds, poor power supply, and no clean water,. Pfizer conducted the clinical trials in Kano to investigate whether to oral form of Trovan was more effective and efficient in treating children infected with meningitis than other existing treatments, including Ceftriaxone, the gold standard treatment. Pfizer's Trovan had not been previously tested in children. However, about 200 infected children participated in the Kano trials. Of these, 100 took Trovan while another 100 were put on Cegtriaxone. Eleven children died in the trials, five of whom were on the experimental drug. There were also other children involved in the trials who suffered seizures, or became paralyzed. While there is no evidence that Trovan was responsible for the deaths and injuries to children, the trials were conducted within a period of two weeks and Pzfizer left immediately thereafter.*"

Yue Wang (2014): Human population Genetic Research in Developing Countries – The Issue of Group Protection

CASE 3

An international team of health care professionals visit a very poor, rural area in South-Asia, recently struck by a devastating tsunami to take part in the humanitarian relief operations. They decide to conduct a psychological resaerch at the same time, by recruiting the possible participants from the circle of patients seeking medical care in the field hospital. To do so, they attache an additional page to the general IC sheet submitted to these patients by the relief provider physicians.

Original text: *„In humanitarian crises, researchers are also often the providers of assistance, and particular care must be taken to ensure that consent or refusal to participate is in no way interpreted as being linked to the provision of assistance"*

Ford et. al. (2009): Ethics of conducting research in conflict settings

„Some researchers allegedly harassed survivors (of the South Asian tsunami) with questionnaires and pressurized people to participate in research projects" Sumathipala et al (2010): Ethical Issues in Post-Disaster Clinical Interventions and Research: A Developing World Perspective. Key Findings from a Drafting and Consensus Generation Meeting of the Working Group on Disaster Research and Ethics (WGDRE) 2007

CASE 4

A team of psychologists and sociologists are aiming to conduct a research on domestic violence against women particularly in refugee populations. The protocol they submit contains a design to gather informed consent from the research participant women that allows the possibility to gather the consent first from the community leaders. They believe it to be harmless and necessary at the same time, since a majority of their proposed subjects could only be first reached through them; by means of their patronage and important role within their community. On the other hand, a cultural anthropologist member of the group reminds the others that while these leaders may be prepared to take risks disclosing information, the members of the community might not share their view. This divide is often gendered, with ale leaders speaking on behalf of the entire community.

Original text: *"In refugee and IDP contexts, complex and contested issues of community representation are also often encountered. Community leaders and those familiar with the language, social systems, and culture in these settings may exert tight control through their ability to offer patronage to some researchers (…) While community leaders may be prepared to take risks disclosing information, community members might not share this view. Often this divide is gendered, with male leaders speaking on behalf of the entire community*"

Pittaway et al. (2010): ‚Stop stealing our stories…'

CASE 5

An international medical team was taking in medical relief operations in an undeveloped country struck by a tsunami, which destroyed the local infrastructure. Some members of the group believe that on the one hand it does not require ethical approval, nor does it put extra risk on patients seeking for medical care if they are drawn blood to take neurobiological stress markers from, and take these samples to their home institutions to conducts research on them.

Original text: „*Blood and genetic samples are believed to have been smuggled out of the devastated regions for research on neurobiological stress markers.* (…) *A case study was published by IRD on how a Japanese research team tried to take biological samples out of Sri Lanka in a study to test stress biomarkers without any ethical approval.*"

Sumathipala et al (2010): Ethical Issues in Post-Disaster Clinical Interventions and Research: A Developing World Perspective. Key Findings from a Drafting and Consensus Generation Meeting of the Working Group on Disaster Research and Ethics (WGDRE) 2007

CASE 6

A medical team of professionals researching viral hemorrhagic fevers visit to a rural area of Africa, where local communities are hit by a recent and rapidly escalating outbreak to provide medical care. They are consulting with the local community leaders and are supported by them to provide medical relief. The team asks the leaders, whether they were consent bring some of the blood samples back to their home countries for further investigation, and the leaders grant this consent on the behalf of the whole community. They have received a REC approval by their home institutions to conduct non-invasive, minimal risk researches – e.g. to collect biological samples collected through their relief interventions, like routine blood draws -, therefore they do not think they should counsel with the local REC as well .

Original text: „*Among the 34 definite research interventions, individual consent was sought in 15 cases and consultation with an REC was mentioned in three cases. In these three cases, consulted institutions were described as based in countries of foreign investigators, but approval by local health authorities was granted as well.*"

Calain (2009): Research Ethics and International Epidemic Response: The Case of Ebola and Marburg Hemorrhagic Fevers

Case 7

- After a devastating tsunami has struck a small, south-asian country, psychiatrist students writing their thesis on PTSD are accompanying other health care professionals to take part in the relief operations. They, on the other hand, would like to collect data for their thesis, so they decide to ask very few, simple questions testing their cognitive ability as a part of the routine psychological help provided for those survivers seeking for psychological consultation. They inform them about the fact that their answers – anonymously – will be evaluated as a part of a research and ask all of them whether they consent to it or not. They believe that no REC approval should be seeken for, since this is a non-invasive study that poses no more than minimal risk on the subjects.

Original text: *„In another example, a research testing cognitive ability was conducted on tsunami survivors also without any ethical approval."*

Sumathipala et al (2010): Ethical Issues in Post-Disaster Clinical Interventions and Research: A Developing World Perspective. Key Findings from a Drafting and Consensus Generation Meeting of the Working Group on Disaster Research and Ethics (WGDRE) 2007

Case 8

- After a devastating and sudden terrorist attack carried out against a crowded metropolitan area, a group of psychologists decided to conduct telephone interviews with the survivors and witnesses very shortly after the event. Having evaluated the results, some members of the team decide to conduct an other research aiming to trace whether the former interview could have had a traumatizing effect on the subjects of that research. Their conclusion is that eventually such researches could indeed have a re-traumatizing effect!

Original text: „*One investigation was included as part of three telephone surveys conducted in New York City in the aftermath of the 11 September attacks that had proven this traumatizing effect*”

O’Mathuna (2010): Conducting research in the aftermath of disasters: ethical considerations

Case 9

- A group of anthropologists and medical professionals visit a rural, resource-poor area in South-East Asia to conduct studies on inhabitants of a local refugee camp. Having completed their interviews in the first round, when they visit back again they find that their former subjects no more consent to answer their questions, and evidently they try to avoid their company. After talking to a representative of the community it becomes clear that criminal elements in the camp have made serious threats against the subjects of the research. The study, however, is not finished yet.

Original tetx: „*In one site in Bangladesh, refugees who talked to researchers had very serious threats made against them by criminal elements operating in the camp, necessitating high-level intervention from those in authority (…) In another instance, following a visit by the authors, over 100 families at risk were resettled from a particular refugee camp in an African nation to countries in the West.*"

Pittaway et al. (2010): ‚Stop stealing our stories…'

CASE 3 - VIRTUAL

An international team of health care professionals visit a very poor, rural area in South-Asia, recently struck by a devastating earthquake to take part in the humanitarian relief operations. A group of psychologist – whose main research area is PTSD – are also part of this team. They submit a protocol for approval of their research aiming to study the disaster struck population by means of PTSD questionnaires and personal interviews. They have used their questionnaires and interview-templates several times before – yet, only on subjects coming from "first-world countries". On the other hand, due to the devastation caused by the disaster on the local infrastructure, the interviews and the questionnaires could only conducted in a separate room of the ill-equipped, ad-hoc field hospital, where the medical relief operations take place too. Besides, they also decide to recruit the possible participants from the circle of patients seeking medical care in the field hospital, by attaching an additional page to the general IC sheet submitted to these patients by the relief provider physicians.

Original text: *„In humanitarian crises, researchers are also often the providers of assistance, and particular care must be taken to ensure that consent or refusal to participate is in no way interpreted as being linked to the provision of assistance"*

Ford et. al. (2009): Ethics of conducting research in conflict settings

„Some researchers allegedly harassed survivors (of the South Asian tsunami) with questionnaires and pressurized people to participate in research projects"

Sumathipala et al (2010): Ethical Issues in Post-Disaster Clinical Interventions and Research: A Developing World Perspective. Key Findings from a Drafting and Consensus Generation Meeting of the Working Group on Disaster Research and Ethics (WGDRE) 2007

CASE 5 - VIRTUAL

A team of psychiatrists and mental health professionals visit to a metropolitan area somewhere in California to provide psychological relief for the survivors of a terrorist attack carried out against a shopping mall, resulting in several death and injured people. Someone from the team – who is actually working in a research group investigating the such terrorist attacks' short-term psychological consequences – proposes the following: While providing the relief, the survivors could be asked whether they consent (orally) to have their conversation recorded – anonymously, with any data capable of personal identification anonymized –, for "the sake of a better understanding and future therapeutic means". The same colleague also adds that – given the lack of time, and given that he considers this at such a research that carries "no risk at all" – it should not be submitted for ethical approval.

Original text: *„There are data to support the notion that some potential research participants post disaster will have impaired decision- making capacity as a result of their traumatic experience*"

Collogan (2004): Ethical issues pertaining to research in the aftermath of disaster.

(Not actual case)

„Some researchers allegedly harassed survivors (of the South Asian tsunami) with questionnaires and pressurized people to participate in research projects"

Sumathipala et al (2010): Ethical Issues in Post-Disaster Clinical Interventions and Research: A Developing World Perspective. Key Findings from a Drafting and Consensus Generation Meeting of the Working Group on Disaster Research and Ethics (WGDRE) 2007

CASE 5/b - VIRTUAL

A team of medical professionals are planning to visit to a poor African country to provide humanitarian relief. Right before their planned departure, a series of terrorist attacks hit the local community. The psychiatrists in the team believe that this is an important opportunity to conduct a research on the effects of such traumatic experiences on people living in nomadic conditions (they have conducted several studies on how terrorist attacks affect people coming from developed countries, and they believe that it would be crucial to widen the scope of their research by involving people coming from so different living conditions to compare the traumatizing effects). However, on the one hand, there is no local REC's at the target destination, on the other, there would be no time to get approval from their home REC's. Yet, they decide to carry out their research without ethical approval, because they regard it as important enough from the future victims relief of such terrorist attacks; also are they convinced about the no-more than minimal-risk nature of their study – they will use community leaders to ask some "simple and surely not re-traumatizing" questions from the victims of the attack.

Original text: „*Past studies have revealed several characteristics of participants and types of studies in which disaster research has increased the subjects' potential for experiencing harms. 'These characteristics include pre-existing distress or mental illness, age (both young and old), history of multiple trauma exposures, social vulnerability, and physical injury. Furthermore, evidence suggests that repetitive research involving the same participants carries a potential for risk*"

Collogan (2004): Ethical issues pertaining to research in the aftermath of disaster.

CASE 5 - VIRTUAL

An international medical team was taking in medical relief operations in an undeveloped country struck by a tsunami, which destroyed the local infrastructure, and led to a sever cholera outbreak. As a part of the routine clinical care, several blood draws were taken for diagnostic and prophylactic purposes. Some members of the team believe that since these biological samples are "already taken" and they would not be used for "other purposes" anyways, why should they "waste" them, and decide to bring some of them back to their country of origin for further – yet unspecified – research purposes. They, therefore, do not feel they should seek for REC approval, not even to ask consent from those the samples were taken from (in fact, some of them have died by the meantime).

Original text: „*Blood and genetic samples are believed to have been smuggled out of the devastated regions for research on neurobiological stress markers.* (…) *A case study was published by IRD on how a Japanese research team tried to take biological samples out of Sri Lanka in a study to test stress biomarkers without any ethical approval.*"

Sumathipala et al (2010): Ethical Issues in Post-Disaster Clinical Interventions and Research: A Developing World Perspective. Key Findings from a Drafting and Consensus Generation Meeting of the Working Group on Disaster Research and Ethics (WGDRE) 2007

CASE 6 - VIRTUAL

A medical team travels to a resource poor, South Asian country, recently struck by a devastating earthquake. They take part in the relief operations – providing basic medical care in the ad-hoc built field hospital. A psychologist, who is part of the team, believes, that it would on the one hand would cause no harm, if patients coming for medical care would be asked whether they agree to answer some "simple and quick questions" while or after receiving medical care. On the other hand, since they are convinced that such questionnaires pose no harm at all, no REC approval should be seek for (not to mention, that under such conditions, it would take too long to seek for this approval, given that in the region they are at there is no local REC that could give such approval). Some other psychologist in the group, on the other hand, raise their concerns about the possible re-traumatizing effects of such "innocent seeming" questionnaires.

Original text: *„Among the 34 definite research interventions, individual consent was sought in 15 cases and consultation with an REC was mentioned in three cases. In these three cases, consulted institutions were described as based in countries of foreign investigators, but approval by local health authorities was granted as well."*

Calain (2009): Research Ethics and International Epidemic Response: The Case of Ebola and Marburg Hemorrhagic Fevers

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