CASE STUDIES

CASE STUDY 3

BACKGROUND

RESEARCH ON VACCINATION IN EMERGENCY SITUATIONS

The recent cataclysmic earthquake in the North West Frontier Province (NWFP) of Pakistan dislodged nearly 2 million people from their homes. Most are now living in temporary camps where hygiene conditions are far from ideal; they are very likely to develop infectious diseases, especially typhoid and other water-borne illnesses. Various organizations are providing services to restore and protect the health of the earthquake victims, but financial and operational problems keep the basic health units within most of the compounds from working optimally.

The Government of Pakistan recognizes the potential for a typhoid outbreak, but it unable to afford any preventive measures such as vaccination for those at risk. An NGO that is providing health care in the Mansehra district, one the worst effected areas in the NWFP, proposes to give typhoid vaccinations to children living in the camps as well as in some high-risk hamlets. The NGO approached various donor agencies about providing the vaccine, and one agreed to provide 1 million doses if the vaccine were administered in a way that allowed formal evaluation of its effectiveness under such condition. This study would be critical in generating evidence for the future use of this vaccine in similar situations. The Government and the NGO willingly agree.

As the million doses of the donated vaccine begin to arrive, critical decisions remain to be made about the vaccination campaign as well as how to integrate the required evaluation. Two suggestions are floated:

- To use a case-control design, matching people in camps and villages in the affected area with those in control villages from unaffected areas, or
- To allocate villages in the earthquake zone on a cluster-randomized basis either to have a vaccination campaign or no intervention.

Both designs have proponents and detractors. In the first alternative, the local governments in the unaffected areas are only willing to participate if assured that their residents will get the vaccine in due course; in the second, the manner in which the clusters are chosen is regarded as problematic. A final decision is urgently needed, given the limited vaccine supply and the pressure of time before an epidemic of typhoid strikes.

QUESTIONS

1. Is the position that not allowing research in such situations wrongly loses an opportunity that is needed for better management of natural disasters in future ethically justifiable?

2. If research is allowed in such a disaster, does that amount to exploiting the vulnerabilities of the victims?

3. If research is allowed, which means of selecting intervention and control groups is best, and why?

4. If research is allowed, which post-trial benefits should be "assured" to whom?

DISCUSSION

The discussion was generated on whether cluster randomized trial is ethically justifiable in such situations; majority of the discussants agreed that this is not an ethically defendable design because it would mean that half of the population will not receive any vaccine or any benefit perhaps. Under emergency situations when standard of care is not available, conducting cluster randomized trial will be difficult to stand the ethics challenge. Similarly, if case control study design is chosen then perhaps control will be in disadvantageous group. If the controls are selected from different region then there is a chance that result of the research is not defendable on the scientific ground.

There was nearly a consensus that under the given circumstances investigators should not conduct research and carry on with the vaccination. If it is necessary to carry out research then perhaps a better approach could be to built-in evaluation strategy for the intervention. Similarly, providing choice to the research participants in the form of opting-in or opting-out of vaccine trial could also be a feasible alternative. Likewise, it was also discussed that the vaccine could be provided to both the disaster and nondisaster areas and then evaluation should be done for the effectiveness of the vaccine in both areas as a follow-up. In case if the cluster randomized trial is allowed then an established standard of care should be available to the both populations.

There was also discussion on the issue that this vaccine is already tested and has been found to be effective thus there is no reason to go for efficacy trial once again. This brought in the issue of resource prioritization because there were other equally competing issues such as provision of sanitation and emergency health care provision that needed the resource allocation on priority basis. By providing resources for sanitation, the incidence of typhoid could also have been controlled or impact could be improved many fold if both the sanitation and typhoid vaccine could have been provided rather than diverting resources to research in such situations. By doing research, resource prioritization was not considered appropriately. It was also discussed that perhaps a good monitoring and evaluation strategy will be useful exercise rather than conducting a separate research and thus wasting the potential resources.

Similarly, discussants criticized the stance of the donor agency to tie the vaccination supply grant with a ‘research study’. Most of the participants hold the view that this is equivalent to using the vulnerable population who already victim of the natural disaster.

Participants discussed that there are scientific ways and means available for predicting the natural disasters (earthquake belts) and we should plan proactively to prevent and control the harm of such disasters rather than waiting for such events to occur and then act. We should plan such research studies a head of time and in that way it could be carried out in a much organized way as compared to a research which is done in an emergency situation with involved deficiencies and difficult ethical issues to handle. Another important discussion was generated on the concern that this research was planned on the vulnerable population. The NGO which was conducting research was also providing healthcare to the same population and this may lead to therapeutic misconception and participants could find it difficult to say ‘no’ to research because that organziation (NGO) is the only source of health care.