Bioethics In Public Health Research
Seventh Global Forum On Bioethics In Research

Arshi Farooqui & Zulfiqar A. Bhutta
Aga Khan University, Karachi, Pakistan

The seventh Global Forum on Bioethics in Research took place at the Aga Khan University in Karachi from February 17–19, 2006. The meeting focused on ethical issues pertaining to health systems research, public health research, and health services, through the presentation and discussion of case studies. There were over 150 participants, including 67 overseas delegates representing more than 20 countries.

Professor Farhat Moazam (Center of Biomedical Ethics and Culture, SIUT, Pakistan) delivered a keynote lecture on "Making a Case for 'Indigenizing' Bioethics". She sketched the history of bioethics in the USA and the circumstances that led to its defining characteristics. Moazam described this "Western Bioethics" as insensitive to the cultural norms of developing nations and ignorant of the fact that most people in the developing world turn to religion for moral guidance. Further, in contrast to the West, in the majority of the developing societies the family, rather than the individual, forms the primary social unit. Moazam stressed the importance of an indigenous bioethics that is sensitive to the social, cultural and religious practices of local communities.

In a second presentation, Dr. Khadija. T. Moalla (UNDP/HARPAS) discussed the "Religious Leaders Initiative on HIV/AIDS in the Arab Region." The initiative involved educating religious leaders about HIV/AIDS and its associated stigma. Moalla's findings indicated that the intervention resulted in increased awareness of the issues in the minds of religious leaders, illustrated by their call for love and compassion in action toward vulnerable groups and people living with HIV/AIDS.

The first plenary session focused on the ethical regulation of health systems research. Dr. Jerome Singh (Centre for the AIDS Programme of Research in South Africa) gave a background presentation entitled "Ethics and Health Systems Research". Dr Singh stated that the overall

objective of health systems research was to contribute to the generation of evidence-based information for use by policy makers and managers at all levels of the health system. He highlighted the functions and operational components of health research systems, and described health research networks that contribute to technological innovation, production systems (e.g., agricultural and pharmaceutical systems), and regulatory systems that influence and oversee nutrition and health.

This introduction was followed by a case study on the effectiveness of alternative models of care for HIV/AIDS. This cluster randomized trial (CRT) compared facility-based care with home-based care, which relied less on the expertise of professional facility based staff, burdened existing health services less, and did not require patients to travel long distances. The discussion revolved around the process of acquiring informed consent. It was suggested that for such research investigators should follow a community participatory approach from the outset to control the issue of stigma, and that they should develop a dialogue with the community before approaching individual prospective research participants. Deliberate efforts should be made to release only essential information in order to minimize the risk of participants in particular treatment arms being identified. Discussants agreed that post-trial benefits should be negotiated with the research community at the time of pre-trial exploration along with the options for scientifically and ethically sound trial designs. Regarding the design, some discussants would be comfortable with cluster randomized trials if the risks associated with the intervention were low, but if the intervention was associated with significant risk, it could be problematic. In this case the general opinion was that: given that the research is important for the community, there had been consultation with the community beforehand regarding the risk, and that the risk was none to minimal, methodological and logistical issues should take precedence over autonomy.

The Forum returned to CRTs in the second plenary session. Professor Jimmy Whitworth (Wellcome Trust) presented an overview of “Ethical considerations for Cluster Randomised Trials”. Interventions in CRTs can be divided into two broad categories: interventions received by the whole cluster (e.g., fluoridation of the water supply); and interventions that individuals can themselves decide to receive (e.g. watching a video on HIV prevention). The key ethical issues involved in cluster randomized trial include recruitment bias, community and individual

consent, and the limited options available to participants in the control arm. These issues are more difficult to address because the research is based on community blocks rather than individuals.

The opening presentation set the stage for a case study of a cluster-randomized controlled trial on the effectiveness of an educational intervention delivered through health services to improve nutrition in young children in Peru. The study took place in urban shanty towns which are characterized by poor housing, the lack of one or more essential services (e.g., piped water, reliable electrical supply, sewage disposal), and low income inhabitants. Although most families have access to various nutritious foods, feeding patterns and food choices vary, and both anemia and growth-faltering are common. The health facility-based nutrition education intervention was implemented in specific clusters by health system staff.

Among the ethical issues raised was whether individual informed consent was necessary in such situations? Most discussants agreed that while informed consent to trial participation from the mothers was necessary, given that there were two trial arm clusters, telling participants specific trial arm allocations would jeopardize scientific results. Most also agreed that researchers should get community assent but that formal consent from community members was not mandatory. Rather than opting out, the main worry for the researchers was contamination due to opting-in because participants could feel that health system functioning was better in the intervention arm. Some discussants were concerned about issues of fairness. These concerns are compounded when viable alternatives are not available. The discussion also focused on uncertainties about how such study designs related to existing ethical guidelines, and the limited capacity of ethics review committees to review public health research proposals. This was considered an area for further empirical work.

The final plenary session considered the ethics of research in complex emergencies. Dr. John Clemens (Director General, International Vaccine Institute, South Korea) presented a paper on “Ethical Prerequisites for Research on Vi (typhoid vaccine) in Complex Emergencies”. Currently, policy uncertainties impede the routine use of Vi polysaccharide in populations at risk of typhoid fever, particularly during relief efforts for complex emergencies. Clemens argued that

randomized controlled trials were not a prerequisite for scientific credibility of research in emergency settings; alternative operational research was a feasible option. However, this research would require particularly thorough ethical review because of the vulnerability of the population following natural or man-made disasters.

The third case study was on proposed research accompanying typhoid vaccination in an emergency situation. The cataclysmic earthquake of October 2005 in Northern Pakistan killed over 70,000 people and displaced 3 million more. Most were moved to makeshift camps where poor hygiene conditions increased the risk of infectious disease outbreaks, especially typhoid and other water-borne illnesses. An NGO providing health care in the Mansehra district, one of the worst effected areas, arranged 1-million typhoid vaccine doses with the support of a donor agency. The donor agency made it a condition of supplying the vaccine that there would be formal evaluation (case control or alternative design) of its effectiveness in this situation. This would be critical in generating evidence for the future use of the vaccine in similar emergencies. The majority of the discussants agreed that a CRT was not ethically defensible in this situation, since half of the population at risk would not receive any vaccine. There were issues also with a case control study as the unvaccinated controls might represent a different population with different risk levels. Most discussants thought that in the circumstances the NGO should conduct the vaccination without being tied down to an evaluation and that it was unethical for the donor agency to place the precondition. An inbuilt monitoring strategy through an alternative design might also work. Some people thought that there ought to be specific guidelines for research interventions in emergency situations.

The meeting highlighted several neglected issues in research ethics. These included the appropriate way to treat cultural differences in moral norms, the special problems of cluster randomized trials, and the ethics of research in emergencies. It provided the opportunity for discussion of the ethics of public health research, and the sharing of viewpoints and knowledge about it from different parts of the world.

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