

Brief Summary – 7th GFBR meeting

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KARACHI , PAKISTAN

The theme of this forum meeting was "Ethical Issues in Research involving Public Health, Health Systems, and Health Services". Although Research on Public Health (PH), Health System (HSys) and Health Services (HServ) share the same ethical principles, and many ethical issues in common with traditional bioethics and existing guidelines, there are additional issues and challenges which aroused interest from the meeting participants in the conceptual ethical frameworks and regulation of research involving population and public health interventions.

The major difference between research in PH, HSys & HServ and clinical research and practice rests within the context, mandate, and range of activities. From an ethical point of view, the latter focuses on the rights and protection of the individual, while the former is more involved with the protection and promotion of the health of the population and the community. Therefore, some of the fundamental research and implementation principles in PH, HSys & HServ may be in conflict with the current guidelines and principles for clinical research.

In order to defend the "common welfare and good", collective power is exercised by health systems to inspect, license, regulate, and impose charges. In addition, large scale interventions are often used in this area. Both of these examples lead to the compromising of individual autonomy. Public health research and activities center on the improvement of the health of the public rather than the advancement of individual rights and liberties. Therefore, the main challenge within public health is an examination exercise of these means, when, and in particular how research in such settings can be ethically regulated.

In the keynote speech "Making a Case for 'Indigenizing' Bioethics", Dr. Farhat Moazam reviewed the history of contemporary bioethics in the US , and introduced the history of contemporary bioethics in Pakistan in which religion played an important role. In bioethics in Pakistan , virtue ethics is important, and is tied to the Islamic value of moral excellence of character. She thus underscored the importance of Western bioethics being indigenized similarly in developing countries.

In the next keynote presentation, Dr Khadija. T. Moalla presented the "Religious Leaders Initiative on HIV/AIDS in the Arab Region". In the presentation, she introduced a program in the Arabic region which involved the interaction of religious leaders with HIV/AIDS patients and the ethical issues involved. The objective of that program was to understand the underlying stigma of HIV in general, to increase commitment and change behaviour at the individual level, and to change cultural norms and values at the collective level, then to focus on model legislation which protects people with HIV from being stigmatized. The main purpose of involving religious leaders was not academic, but was intended to change the response to the program. Religious leaders are the key players in Islamic culture, and they have a great impact upon people's attitude and values. Over one thousand religious leaders were involved, several colloquiums were held and action plans were chalked out. Training courses were held, and the overall outcome was good. Lessons that were learnt from this program is that there was lack of information and misconceptions in Arab States about HIV, and once understanding was achieved and misconceptions resolved, actions of love and compassion towards vulnerable people with HIV could be started.

The first plenary session focused on issues of ethical regulation of health systems research. Dr Jerome Singh stressed that the overall objective of health systems research is to produce evidence-based information for use by policy-makers and managers of health systems to strengthen the health research system overall. The functions and operational components of health systems research are stewardship, financing, creation and sustaining of resources, and the production and use of research.

The components of health systems includes: health research networks, production systems (e.g., agricultural and pharmaceutical systems), social and health delivery systems, regulatory and court systems for decision-making, monitoring and control, groups of end-users, and other relevant stakeholders.

In session two, the themes of PH and HSys Research were discussed more deeply. Professor Jimmy Whitworth firstly introduced the concept of Cluster Randomised Trials, a concept commonly used in PH, HSys & HServ research. He then presented the fundamental ethical considerations for Cluster Randomised Trials: that participant's interests must prevail; research must have the potential to generate scientific understanding; there must be a favourable balance of risk and benefit; there must be individual voluntary informed consent; independent ethical review; and peer review. The key ethical issues for Cluster Randomised Trials are: recruitment bias, community and individual consent, the welfare of participants in the control arm, and the requirement for the scientific basis of the research.

Session three mainly dealt with vaccine research. Dr. John Clemens presented "Ethical Prerequisites for Research on Vi (typhoid vaccine) in Complex Emergencies". He mentioned that currently, policy uncertainties impede the routine use of Vi polysaccharides in populations at risk of typhoid fever during relief efforts for complex emergencies. It is necessary to resolve the problem by carrying out operational research in the context of delivery of Vi vaccine in such settings which require independent ethical review.

Research in PH, HSys and Hservices shares the same ethical principles and many of the same issues as traditional areas of bioethics. In addition, research in PH, HSys and Hservices must negotiate between protecting the rights and welfare of the individual and improving the health of the general community. As a result, additional issues must be addressed. These include recruitment bias, issues between community and individual consent and the welfare of control-arm participants. An additional focus should be 'indigenizing' Western bioethics to adapt to the culture and traditions of host communities.