Brief Summary – 6th GFBR meeting

17-19 March 2005
BLANTYRE , MALAWI

The theme of this forum was "What Happens When the Research is Over? Post-trial Obligations of Researchers and Sponsors." The theme was highlighted in the plenary session speech followed by report of discussion which occurred during the breakout. During the conference, agreement was achieved on a broad principle regarding the post-trial obligations of researchers and sponsors. Specifically, study populations should benefit from any treatment tested on them. If that is unlikely to happen, then the research should not be carried out, as it is unethical. There were fewer consensuses concerning when to apply the principle into practice. Who should bear the responsibility for providing the treatment, the researcher, the sponsor, the government? For how long? What about those not involved in the study? Even where there was tension between the 'purists' and the 'pragmatists' in real practice, the forum provided a platform to stimulate dialogue that led to more informed opinion on both sides and to influence what actually happens on the ground.

Post-trial access

Regarding this issue, everyone agreed that researchers have a responsibility to trial populations. There was still no consensus achieved in terms of many practical questions which aroused wide debate and argument amongst participants, such as who should bear the obligation of providing treatment, the researchers? the sponsor? the government? For how long? Is it proper to provide trial treatment to patients merely based on one research trial when meta-analysis data on which that healthcare decision usually depends is not available? If so, what about the members of the population who weren't in the study, should they also receive the same intervention?

It might be more pragmatic to provide treatment for a certain period of time after the trial, say five or ten years, but then the concern emerges that is it ethical to take away the treatment for life threatening disease after that period, and who should carry on with the monitoring of potential adverse effects of failing efficacy?

Standards of care

It was the same for standards of medical care offered to trial participants. The embarrassing reality is that the medical services available in the study site in developing countries are almost certain to be inferior to those in developed nations. Based on this, what should the appropriate standards of care in the research context, should they be the developed countries standard? If so, does this constitute an inducement to participate in research? What happens at the end of the study? How would people of the same community outside the trial respond?

Participants agreed that in practice, the benefits of research should be sustainable, and could include indirect benefits. Examples are the training of local healthcare workers, other forms of capacity-building and enhanced infrastructure, such as the introduction of new equipment or technologies.

Consent

In the discussion of consent, consensus was almost achieved through discussion, that is, it was agreed that individual consent is absolutely necessary and could not be replaced by other forms of consent, even in some developing countries, where consent is usually made at the community level. However, there were some difficulties in practice. The concept of "research" might be alien to a culture, that is, if trial participants don't totally understand what "research" means, what does the

consent mean then? Besides, some consent forms are too long and complicated for participants to understand.

Methodology

Study design is another area of discussion in which it was difficult to achieve consensus. Randomised controlled trials have been deemed as the 'gold standard' in scientific design, while participants questioned their appropriateness in resource-poor settings. Is it appropriate to use placebos in control group when there is effective treatment available elsewhere in developed countries? Could observational studies be conducted in life-threatening conditions? Well thought-out trials can both test an intervention systematically and also deliver health gains. Delegates introduced some good examples to solve this issue through extensive consultation with communities involved, such as using Hepatitis C vaccine in the control group for the typhoid vaccine study instead of a blank control.

Consultation

It was consistently agreed that consultation with the community and healthcare authorities are important. This is especially when the research aims to improve conditions for the local population. Close consultation with the local Ministry of Health or similar authorities are even more important, as implementation after the completion of the study depends on the existing healthcare infrastructure and national budgets. This is the case for public-private partnerships as well. Consultation also applies to post-trial access and standards of care, which should be agreed upon before the commencement of a study.

Other Issues

In addition to the issues and concerns listed above, some other issues below emerged as key topics which deserve further discussion:

Governance: The role of the Research Ethics Committees (RECs) becomes increasingly important, but how can we ensure that RECs are carrying out their role satisfactorily? Mechanisms need to be in place. Some delegates introduced national accreditation to RECs, which require REC members to be trained and retrained as necessary.

Communication: Upon the completion of research, researchers hurry in communicating the results to their peers by publishing papers; a more frequently neglected communication is to convey the results to the participants who took part in the research.

"Research fatigue": Some communities are "over-researched", there might be good scientific reasons for using specific communities, but often the main reason may simply be that they are convenient for the researchers. Over-use of one population may introduce scientific bias, people could tire of taking part, and it is unfair to always burden the same group without spreading the research to a wider population.

The Parma legacy: Pharmaceutical companies seem to use clinical trials in developing countries to advance their own interests, instead of improving the health or conditions in the study site. As a result, pharmaceutical companies' activities in developing countries are viewed with deep mistrust.

iIt is acknowledged that pharmaceutical companies devoted considerable efforts and funds to developing countries mainly to serve the interest of the poor, so, constructive cooperation with pharmaceutical companies is a fruitful approach to pursue.