REPORT

Symposium on bioethics: empowerment of research participants/patients

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YRG Centre for AIDS Research and Education (YRG CARE) is a non-governmental organization based in Chennai, India, providing a comprehensive range of services for persons living with HIV/AIDS. It functions in a hospital setting and conducts socio-behavioural research studies and clinical trials on HIV/AIDS.

YRG CARE conducted *The YRG CARE Bioethics Symposium (TYBS)* in collaboration with the National Institute of Epidemiology (NIE), the Indian Council of Medical Research (ICMR), Chennai, through the National Institutes of Health Project "Centrally Coordinated Bioethics Education for India" and the National Institute for Research in Tuberculosis (NIRT), ICMR, Chennai on January 6, 2013. TYBS was co-sponsored by Public Responsibility in Medicine and Research (PRIM&R), Boston, USA, and ICMR, New Delhi. The theme of TYBS 2013 was "Empowerment of research participants/patients."

Seventy-seven delegates attended TYBS, including speakers, clinicians, researchers, persons working in the pharmaceutical sector, non-governmental organisations (NGOs), ethics committee/institutional review board (IRB) members, ethics committee/IRB personnel and students.

The **Welcome Address** was delivered by **Dr Suniti Solomon**, Director of YRG CARE and Chairperson of TYBS 2013. She spoke about how ethics had grown over the years since she was a student.

In her opening remarks, **Dr Soumya Swaminathan**, Scientist 'G' and Director, NIRT, Chennai said that a concerted effort has to be made to ensure that the **participants and patients are empowered**, in line with the theme of the symposium. The challenge is in following ethics in spirit and not just in letter. Most of the time, participants are unable to comprehend the complexity of research. The autonomy of participants cannot be violated. They should be asked for permission and informed about the research, including its uncertainties, in the simplest and best possible way.

Dr Sanjay Mehendale, director, National Institute of Epidemiology, Chennai and principal investigator, NIH Bioethics Project, National Institute of Epidemiology, ICMR, Chennai spoke on "**Community participation in clinical research related to HIV/AIDS: the Pune experience**." He shared his experience as principal investigator (PI) for studies at the National AIDS Research Institute (NARI) in Pune, which required the establishment of a community advisory board (CAB). The composition of the CAB has grown to include doctors, women activists, and educationists, men who have sex with men (MSM), students and sexual minorities. The CAB now participates in carrying out review of protocols and reviews translation and back translation of informed consent documents and questionnaires. It helps in building relationships between NGOs, community-based organisations (CBOs) and researchers, and helps in alleviating rumours regarding clinical trials. In addition, NARI had developed a community involvement plan through NGO partnerships to help volunteer recruitment in phases 2 and 3 of clinical trials. NGO partnership gives a lot of visibility and acceptance of the institution and the project in the community. It is important to specifically inform people about the subtle differences between health literacy and research literacy. Dr Mehendale also spoke about the right way to reach the media for research projects to ensure support for sensitive projects such as HIV vaccine trials. He said that community involvement is a cost-intensive effort that requires careful budgeting, as people's time cannot be taken for granted.

Dr Tal Burt, Scientific Director, Duke Global Proof-of-Concept (POC) Research Network, Duke Clinical Research Unit (DCRU) and Duke Clinical Research Institute (DCRI), Assistant Professor, Department of Psychiatry and Behavioral Sciences, Duke University, Durham, NC, USA, spoke on "**The PARTAKE initiative: public awareness of research for therapeutic advancements through knowledge and empowerment**."

He said that the PARTAKE initiative covers the different stakeholders involved in clinical research in India—academia, clinicians, government, media, industry, public, and patients. There may be communication problems between them as the public, patients, and media are ranged on one side and industry, academia, clinicians and regulatory bodies on the other. He explained the goals, objectives, and components of the PARTAKE initiative

On the media's negative projection of research, and whether organisations should take steps to project positive issues in research, Dr Burt said that research is based on trust, and PARTAKE needs all stakeholders to come together.

Dr Sunil Shroff, Professor and Head, Urology and Transplantation, Sri Ramachandra Medical College and

Hospital, Chennai, spoke on "**Organ transplantation and ethical dilemmas**". He spoke about the types of organ donors; and using examples, elaborated on ethics in organ donation, whether compensation is justified, the ethics of using stem cells in organ donation and policy issues. He said that in India we have no laws in place to embrace the current advancements in science. Most laws are in the form of ICMR guidelines.

Dr MS Jawahar, Scientist 'F', National Institute for Research in Tuberculosis, Chennai and Member, Ethics Committee spoke on "**Ethical issues in clinical trials**." He discussed the registration of clinical trials with the Clinical Trials Registry of India, and proceeded to talk about the different types of study designs. He elaborated on the different phases of clinical trials and what is tested during a clinical trial, the milestones in research ethics development, the different international and national ethical guidelines, and the international conference on harmonisation of technical requirements for registration of pharmaceuticals for human use – good clinical practice (ICH-GCP) guidelines. He spoke on the different dimensions of vulnerability, special considerations and issues in drug trials. He concluded that there should be stringent regulations governing clinical trials, so that the rights and welfare of the human participants are protected.

Dr Saradha Suresh, HOD and Professor of Paediatrics, Madras Medical College, Chennai and Member, YRG CARE Institutional Review Board spoke on "**Ethical aspects in paediatric clinical trials**."

Paediatric research covers the age group from newborn to 18 years, and has to consider aspects such as physical growth and neurological, emotional and social development. Paediatric research involves the vulnerable population with diminished autonomy. She said that there should be inbuilt monitoring of paediatric research projects by the ethics committee. Children cannot be treated as a commodity and traded away for research by parents. Assent form should be made mandatory after seven years of age.

On whether there are any legal or ethical guidelines for paediatric research in India, Dr Suresh said that in India sociocultural behaviour is different in different places, and is not uniformly applicable.

Dr Shailesh Mehta, Vice President, Clinical R&D, Medical Affairs Biologicals South Asia, GlaxoSmithKline Pharmaceuticals Ltd., Mumbai spoke on "**Ethical dilemmas faced by the pharmaceutical industry in clinical trials.**"

He spoke about patent rights versus patients' rights. Drugs are unaffordable for the patients in whose country the research is conducted. It is essential to strengthen the regulatory framework in the country. The issue of conflict of interest is essential and requires transparency. He discussed the importance of making the trial data public. It is very important to publish the scientific findings, even if the results are not favorable. Dr Mehta spoke about the scientific engagement policy introduced by GSK which completely segregates sponsorship from research and marketing.

Dr Nandini Kumar, Co-Investigator, NIH Bioethics Project, National Institute of Epidemiology, ICMR, Chennai & Organizing Co-Chair, TYBS spoke on "**The ethics of care and related gender issues**" Ethics of care includes both "caring of" and "caring for." She discussed the general and specific aspects of health issues pertaining to women, to include gender disparities, feminism, feminist bioethics and contemporary feminism.

There was a panel discussion on "Compensation for participation in research projects." The panel was moderated by **Mr SS Narayanan**, member, Ethics Committee, National Institute of Epidemiology, ICMR, Chennai. Panelists were Dr Nandini Kumar, Mr B Ramesh, Member, YRG CARE Community Advisory Board and Dr Shailesh Mehta. The **legal aspects of compensation** and how it is perceived in the West and in India were discussed. Mr Sankaranarayanan stated it is necessary to have a specific policy for compensation in clinical trials. Dr Nandini said that the US should also have policies on compensation as in India. Dr Shailesh Mehta said that in GSK, for all new studies, a death clause is inserted along with details on the compensation. Mr Ramesh said that in his work with injecting drug users (IDUs) in the community, the IDUs fear to join any clinical trial as the antiretroviral therapy (ART) drugs prescribed affects their liver.

Dr S Swarnalakshmi, IRB Manager, YRG CARE and Organizing Secretary, TYBS 2013, spoke on PRIM&R which had co-sponsored the symposium through the regional connections programme. She gave an overview on **PRIM&R and opportunities for professional development** offered by PRIM&R. She spoke about PRIM&R's online training course for IRB members – *Ethical Oversight of Human Subjects Research* and the certifications provided by PRIM&R.

The closing remarks were delivered by Dr Nandini Kumar. Dr S Swarnalakshmi proposed a vote of thanks.

The audience and the speakers networked during the tea breaks and lunch. The audience gathered along with the speakers and the symposium organisers for the photo session.