

## ABSTRACTS: DAY ONE

### PARALLEL PAPER PRESENTATIONS

#### **GROUP P1: Socio-political and cultural dimensions of research ethics**

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##### **Consent communication and cultural competence: an ethical framework for obtaining informed consent**

*Supriya Subramani, Sreekumar Nellickappilly*

Obtaining informed consent is both an ethical and a legal requirement for conducting biomedical research involving human beings. The value of obtaining consent recognises the status of the subject as an autonomous individual. Hence, obtaining informed consent is to recognise and acknowledge the human worth of a person. It is to concede that people have certain fundamental rights, which cannot be annulled or forfeited. But the process of obtaining consent involves several challenges. It requires not only a strong commitment from researchers to the subject's rights as a person, but also a deep understanding of the challenges involved in pursuing genuine informed consent from subjects. This process thus involves multiple stages, each raising unique demands that have legal and ethical implications. It primarily involves respecting a subject's autonomy which would be incomplete without a proper understanding of his/her cultural values and beliefs, which is a complex enterprise encompassing several challenges. This scenario may invoke serious ethical dilemmas that complicate consent communications and may lead to the unintentional abuse of human rights.

This paper attempts to identify the relevance of cultural competence in the informed consent process in biomedical research, and examines how they affect the outcome. It is based on a pilot study which intends to identify the perspectives of physicians on cultural competence and their relevance in the informed consent process. The paper aims to carry out the study employing in-depth interviews and interactions with professionals involved in biomedical research. Thus the paper examines how an understanding of culture (cultural competence) enables professionals to communicate with their subjects without compromising on their rights as persons and their autonomy as individuals.

##### **Inclusion of the children of minor parents in medical research**

*Angus Dawson*

It is standard practice around the world when enrolling minors in medical research to gain consent from their parents (in addition to the minor's assent in some cases). However,

it is also common for minors to be parents themselves. In the absence of any local laws covering this issue, and where it may be beneficial for the minor's child to be involved in research, what consent requirements are appropriate? This paper explores this question by arguing that in many cases minor parents are no worse at being able to understand (and therefore give informed consent) than adults, and therefore in many cases minor parents' consent for their child ought to be seen as an adequate informed consent. Where there are doubts about the ability of a minor to give consent (e.g. because they cannot comprehend the information, they are too emotionally involved, the design is too complex, etc) then these reasons, where they exist, are also reasons to doubt the adequacy of an adult parent's consent. The fact of being a parent who happens to be a minor, as opposed to being an adult parent, is not ethically relevant.

##### **Collaboration or brokerage? The political economy of local assemblages in global medical research**

*Anuj Kapilashrami, Rekha Khatri, with Biomedical and Health Experimentation in South Asia (BHESA) team*

Clinical and public health research has witnessed an unprecedented growth in trans-national collaborations. In this paper, we take an actor perspective and chart the landscape of such collaborations with a focus on South Asia and explore: how these emerge; what drives research collaborations; and to what extent these redefine local research cultures, institutional practice, and ideas of expertise; and bring about a shift in global economic and political power.

This paper draws on ethnographic fieldwork and interviews conducted between 2010-2011 in India, Nepal and Sri Lanka as part of a multi-country collaborative research on biomedical and health experimentation. We examine how participants in the 'value chain' – sponsors, clinical and contract research organisations, academic collaborators, coordinators and investigators – work through and traverse material, social, technical relations, and institutions to enable trial/ research outcomes. We explore their understanding of collaborations in experimentation and their views on social or intellectual drivers, careers and other motivations; and their positioning (and authority) in these intersecting networks of knowledge, technocratic practices, therapeutic consumption and capital generation. We conclude with a discussion on the ethics of trans-national collaborations, the social and political implications of these practices and how they reconfigure the contours of bioethics in medical experimentation.

## GROUP P2: Empirical bioethics

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### Public attitudes towards clinical research

*Vijayaprasad Gopichandran, Maria Jusler Kalsingh, Geetha Veliah*

**Background:** A good understanding of the ethics of clinical research should be grounded in the needs and perceptions of the public. There is evidence, largely from the developed countries, that the public value the importance of clinical research. Little is known about attitudes of the public towards clinical research in developing countries.

**Objectives:** To describe public perspectives and attitudes towards clinical research in India.

**Methods:** A semi structured questionnaire was designed based on available literature on attitudes towards clinical research with responses on a Likert scale. The questionnaire survey was conducted both through the internet survey method and the face to face interview method.

**Results:** A total of 300 internet questionnaires were sent and 88 responses were obtained (response rate 29.3%) and out of a total of 33 individuals approached for personal interviews, 30 responses were obtained (response rate 90.9%). The sample was predominantly urban, educated and younger than 40 years. The mean attitude score was 43.8 (SD 6.8) in a scale of 15 to 75. Factor analysis revealed that a three factor structure explained 47.6% of the overall variance. The three main domains of attitudes were: Clinical research is important, Clinical research is exploitative and Clinical research is harmful and negative. Cluster analysis with the regression factor scores revealed two clusters, those with positive attitudes to clinical research (n=63) and those with negative attitudes (n=55). Those who had positive attitudes were younger than 40 years, had a post graduate degree, were not currently married, had participated or had a family member who participated in clinical research earlier.

**Conclusion:** Public attitudes to clinical research among a sample of predominantly educated, young and urban population were equivocal with about half of them having positive attitudes. Those having positive attitudes were those with prior experience with clinical research.

### Methodological and ethical challenges in studying HIV/AIDS

*Asima Jena*

The social model of health takes a critical stand towards biomedicine. There is much substance in this model, in terms of pinpointing the social constitution of disease, commodification of health services, medicalisation, the loss of the social identity of patients in laboratory medicine, the violation of the rights of patients in clinical trials and so on. However, the social model of health does not scrutinise at greater length nor critically examine its own practice. By critically reflecting on the author's own ethnographic field work experience in East Godavari district, Andhra Pradesh, this paper first describes

the intricacies involved in being a female researcher which turned out to be both risky and beneficial for the research and the researcher whose subject of interest includes sexual relationships and the sex service industry in the broader context of HIV/AIDS. Secondly, it attempts to explain the ways in which the field affects the researcher and research, and vice versa. In this context, the influence of the author's own gendered positioning in exacerbating this tension and further complicating the relationship between the researcher and respondent, as also the ethical dilemmas involved in social science research on HIV/AIDS are discussed. The latter aspect is mostly critical in researching sufferers, especially HIV positive persons, as this process brings more pain to the respondents while unraveling their traumatic illness experiences.

### Ethical issues in recruitment of healthy volunteers: a study in Hyderabad

*Shilpa Krishna, Purendra Prasad N*

The trials registered in the Clinical Trial Registry of India (CTRI) are those conducted on new chemical entities, but not on bioavailability and bioequivalence (BA/BE) studies. BA/BE studies are more prominent and are carried out on healthy volunteers. The Drugs Controller General of India's efforts to make the registration of BA/BE studies mandatory with the CTRI are yet to become a reality. This paper addresses some of the ethical issues involved in the recruitment of volunteers for BA/BE studies through clinical research organisations and their networks. It also explores the reasons for their participation and the manner in which they are managed by the CROs. The data was collected by conducting a case study on a CRO in Hyderabad. The paper dwells on the details of the perceptions of the 50 healthy volunteers participating in the study, their profiles, demands/ problems and their vulnerability. Although informed consent was administered, none of our study participants knew anything about the research study. However, the study participants insisted on knowing the risks involved so that it would help them bargain for a few more incentives for their participation. The study findings also indicated that the very design of the CRO has been structured by surveillance protocols which put the healthy volunteers within strict disciplinary boundaries. The study also analyses the inadequacy of the regulatory bodies.

### Interface between research ethics and socio-cultural specificities of a study setting

*Nilangi Narendra Sardeshpande, Rashmi Padhye*

This paper aims to unravel the interface between research ethics and the socio-cultural context in which a study is conducted, based on the experiences of field researchers during a study conducted by SATHI in ten districts of Maharashtra. The aim of the study was to document gaps in access to healthcare services across social groups based on caste, household asset index, gender and geographical region. The study used the stratified random sampling technique to select over 1650 households from the state.

Given ethnic variations within the state, local dialects differ significantly across geographical regions. Hence, despite explaining the purpose of the study to participants, field researchers were sometimes unsure whether participants had really understood the text of the consent form, leaving them in doubt as to whether the consent was a true 'informed' consent.

In the patriarchal culture, husbands acted as gatekeepers restricting women from taking decisions regarding participation in the study. Within the limited period of interaction, the field researchers were unable to overcome this constraint and ask women about their choice.

Maintaining privacy during interviews is another important ethical requirement of any study. However, in rural settings it is often not possible to interview women alone, as the family members then get suspicious. Similarly, to circumvent language problems, sometimes interpreters were involved. Hence, these practical solutions in a way compromised privacy during interviews.

The conflict between their roles as researchers and as responsible citizens was another ethical issue. For example, when the researchers came across information regarding sex selective abortions, they were prevented by the principle of confidentiality from disclosing that information.

Through this paper, the authors share these ethical dilemmas faced by field researchers in a specific socio-cultural setting.

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### **GROUP P3: Public health ethics**

#### **Growing violence towards healthcare professionals: a public health issue**

*Nausheen Saeed*

**Background:** Violence towards healthcare professionals (HCPs) by patients and their attendants is rising at the global level. It is becoming a pandemic in some countries like Pakistan. HCPs working in ICUs are commonly subjected to violence by the patients' attendants. HCPs who work in emergencies report being threatened by political workers. They also encounter intense pressure from religious fundamentalist groups when there is a terrorist incident.

**Purpose:** The purpose of this paper is to explain why violence towards HCPs ought to be recognised as an emerging ethical and public health issue as it has negative consequences on the community at large. It argues that all healthcare organisations (HCOs) should have robust policies in place to address this unique ethical challenge.

**Discussion:** Violence towards HCPs reflects the general attitude of intolerance in a society. It ranges from verbal abuse to physical assault. HCPs also experience a wide range of psychological trauma. Such experiences lead to a negative impact on their professional and personal lives. Hostile patients and families also target other patients, equipment, and property of the

hospital. As a result, public hospitals face unnecessary cost and economic instability. The unsafe working conditions have led many qualified professionals to leave the country.

Unfortunately, violence towards HCPs is grossly underreported. It has not been recognised as a crucial ethical and public health issue in Pakistan as yet. The majority of hospitals and public health facilities, in particular, do not have effective systems in place to combat violence. There is also a vacuum of research in this particular area.

To conclude, violence has a deleterious effect on public health. All HCOs ought to develop, implement and maintain effective violence prevention programs. In addition, HCOs need to collaborate with professional medical associations, state, media and community to combat violence towards HCPs.

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#### **National Vaccination Policy, India: ethical and equity issues**

*Jayakrishnan T*

**Back ground:** Vaccines have been among the most successful health interventions, bringing about significant reductions in infectious disease. The ministry of health and family welfare published a National Vaccination Policy in April 2011, which listed certain criteria for the introduction of new vaccines under the Universal Immunisation Programme (UIP) as follows: disease burden in the country, safety, efficacy, programme capacity to introduce new vaccine, cost effectiveness, alternatives other than vaccination, and financial sustainability even if the initial introduction is supported by an external funding agency. The policy paper also supported certain vaccines-- Haemophilus B influenza (Hib), Pneumococcal conjugate, Rota virus, HPV vaccine-- for inclusion in the UIP. This was criticised by some public health scientists as being contrary to the above criteria.

**Methods:** A literature review was done by searching the web on articles published on the National Vaccine Policy and the above mentioned vaccines.

**Results and discussion:** The stated rationale in the policy for introducing new vaccines is not based on indigenous surveillance data or on specific local needs, but either on their long time existence in the market or on availability in the private sector. Their efficacy and cost effectiveness have not been considered. The policy of recommending a vaccine only needed for selective immunisation for the universal programme, and vice versa, is also unethical. The draft vaccine policy is silent on the reopening of public sector vaccine manufacturing units which have been closed since 2008. The proposed model for the financing and pricing of the vaccines to be introduced seems to favour the interests of the private vaccine industry and could result in an ill-advised vaccine trap.

To ensure the selection of appropriate vaccines on scientific grounds for the UIP, the universal, well-defined criteria of cost efficacy and appropriateness must be applied, based on the science of public health.



## **Ethical issues in the delivery of prevention of mother-to-child transmission of HIV interventions in Mysore, South India**

*Purnima Madhivanan, Karl Krupp, Reshma Shaheen, Suvarna HC, Sean Philpott, Celia Fischer*

**Background and purpose:** The Indian government recently changed HIV testing guidelines from 'opt-out' to routine HIV testing of all pregnant women receiving antenatal care (ANC). NACO guidelines state that clients must be informed of the purpose of the test, give informed consent, and have the right to opt-out of testing if they desire.

**Methods:** This qualitative study examined experiences of delivered women undergoing HIV testing during ANC, and healthcare workers who conduct HIV counseling testing in hospitals in Mysore. Three focus group discussions (FGD) among recently delivered HIV-ve women, and eight in-depth interviews with HIV+ women were conducted to explore experiences with HIV counseling testing during ANC. Two FGDs with healthcare workers were conducted to assess knowledge, practices and attitudes around HIV testing of pregnant women.

**Results:** In the FGD, only six women recalled being informed the purpose of HIV testing. The majority of women reported their doctor being the only person who suggested they get tested for HIV if they wished to deliver at the hospital. Only three women recalled signing consent forms for testing; but a majority said they were given forms and told to sign. A majority of women said their husbands/relatives were informed of results either before or at the time they learned about their results. Healthcare workers had sufficient knowledge about HIV testing and maintained confidentiality. Many admitted that other hospital employees occasionally find out about a women's HIV status. Several expressed derogatory stigmatising remarks about 'uneducated rural women' who don't comprehend HIV counseling or reasons for giving consent.

**Conclusions:** Women are poorly informed about the risks and reasons for routine HIV testing. The level of information given during post-test counseling varies depending on the HIV status. HIV negative women get minimal to no information during post-test counseling. Healthcare workers should be further trained on confidentiality and informed consent in addition to sensitising them about the need for non-stigmatising HIV testing.

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## **Shared risks, shared privacy: research among young men using tobacco in Tamilnadu.**

*M Santhosh Kumar*

**Background:** The Declaration of Helsinki has assigned protection of privacy as a duty of the physician conducting medical research. It also emphasises that every precaution should be taken to respect the privacy of the research participants.

**Description of the ethical issue:** Research involving community-based group counseling approaches faces peculiar problems in

the maintenance of privacy. In this study, group counseling is used as a strategy for tobacco cessation among young men in rural Tamilnadu.

**Results:** In the rural context, young men learn to use tobacco products together and share tobacco products, particularly during situations of shortage. When notions of male bonding include the sharing of risks, almost all members of the group share information about each other's consumption patterns and can report accurately about each other. Attempts to separate such individuals from their groups, in the interests of the requirement of privacy, carry with them the problems of sudden isolation from the peer group. Forcing isolation could be detrimental to the research and to the shared sense of camaraderie which has the potential to facilitate cessation efforts. The relative benefits of enforcing privacy for the research process must be weighed against the potential harms of breaking the bonds of such camaraderie.

**Discussion:** This scenario highlights the need for greater debate on acceptable compromises to privacy guidelines that would facilitate community-based intervention research that depend on group solidarity for results. In public health, one has to weigh the concerns of both the individual and the community. There is no ethical principle which can provide a solution to this perennial tension in public health. Though community is the primary interest of public health, we still need to pay attention to the rights of individuals.

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## **PARALLEL WORKSHOPS: W1- 4**

### **Community involvement in public health intervention research**

*Facilitators: Angus Dawson, Neha Madhiwala*

The workshop will focus on the issue of community involvement in health research, and explore various aspects of the researcher-community relationship, such as accountability, standard of care, sharing of benefits and post-trial access. Researchers approach communities through a series of intermediaries, such as voluntary organisations and local democratic institutions. Each of these also has long-standing complex relationships with the community. Thus, the research participant relationship is multi-layered and multi-dimensional. This workshop will bring together a panel of diverse resource persons, including bioethicists, researchers and non-governmental organisations. The audience will consist of individuals who are involved in research in different capacities as community advisory board members, researchers, service providers, activists and policy makers. The objective of the meeting would be to arrive at a draft document which outlines various ethical issues surrounding community-based research in different contexts and can provide guidance to groups who are planning or collaborating in such research.

Some of the issues that will be discussed at the workshop are as follows:

- The definition of 'participant' in community based research. This can be quite complex and is important for both conceptual and practical reasons.
- The differing perceptions about a project among the various players involved in an intervention research project.
- The need to assess whether the research was designed to provide a feasible solution. Along with issues of design, scientific rigour and multiple stakeholder interests, the context of the community and its interests should also be highlighted.

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### **Making the voices count: participants' rights and regulation of clinical trials in India**

Facilitators: *Sarojini N, Anjali Shenoi, Patrick Durisch*

Dynamic shifts in the areas of drug development and global pharmaceutical sales have led to an exponential increase in the recruitment of human participants in middle and low-income countries, thus rendering India an attractive destination with an unprecedented growth in its drug trial markets. The market in India has grown from Rs 423 crore in 2005 to Rs 1,611 crore in 2010, while it is expected to cross Rs 2,721 crore by 2012.

However, several controversies surround this unprecedented economic turnover. The recent past has seen many examples of clinical trials taking place in disregard of ethical principles and participant rights. At the levels of planning, design and implementation, there exists a striking lack of transparency. This jeopardises the reliability and validity of medical research itself, in the absence of adequate regulatory jurisdiction and systematic review of the industry.

This knowledge gap is particularly striking with respect to factors related to and surrounding human participation in these trials. Despite the huge increase in enrolment of Indian participants in clinical trials, very little is known regarding their experiences and motivations, with limited narratives on participants' perspectives of recruitment patterns, protocols followed with regard to informed consent, compensation, adverse event reporting, monitoring systems, follow up, post-trial treatment access, etc.

In this context, the Workshop will draw from an ongoing *Action Research* project focusing on the larger socio-economic processes of participation and their interplay with a range of social indicators to explore the various factors and barriers that determine such participation. The speakers will also highlight international chains of conduct of drug trials, particularly with regard to participant rights and universal compliance with ethical norms and guidelines. In this way, the workshop will attempt to further critically examine and inform current debates surrounding the ethics and regulation of clinical trials in India, from a bottom – up, rights based perspective; where the participants' voices and interests are paramount.

### **Playing the ethics monitors: the role of ethics committees in providing continuous oversight of ongoing research studies**

Facilitators: *S Swarnalakshmi, Anant Bhan, Prabha Desikan, Medha Joshi*

Background and purpose: This workshop is part of a continuing series of workshops organised at NBCs 2 and 3 by the facilitators on setting up of ethics committees and related issues. This workshop will be supported and promoted by 'IEC-Exchange' (IEC-Exchange@googlegroups.com), India's first e-forum for ethics committees.

Research stakeholders depend on ethics committees (ECs) to oversee the ethical aspects of research: this involves not only granting initial approval, but also providing ongoing monitoring of study conduct to ensure protection of the interests of participants, a fair risk-benefit ratio throughout the study, review of any emerging scientific updates which might influence equipoise, and checking for the relevance /futility of continuing the research.

The practical mechanisms for, and challenges faced by, the ECs in monitoring ongoing health research include limited training in bioethics, inadequate administrative support, insufficient time due to heavy workload, space, ambiguity regarding their roles and responsibilities, and limited scope for self evaluation. Lack of infrastructure, manpower, funds and time can be a major hurdle for conducting effective site monitoring.

The purpose of this workshop is to discuss the constraints and challenges for EC monitoring of research studies, and to identify solutions and best practices.

Key learning objectives: (1) to enable EC members to understand what criteria should be adopted for monitoring of ongoing research by ECs; (2) evolving a shared understanding of how to ensure quality ethical review of research and ongoing monitoring in light of the time/resource constraints within which the ethics committees function; (3) identifying best practices in monitoring by ethics committees

Proposed methods: Presentations, case studies and group discussions.

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### **Training in public health ethics: views from key stakeholders**

Facilitators: *Raman Kutty V, Mala Ramanathan, Sreejini J, Praveen Pai*

Training in public health cannot be divorced from the ethics of public health practice. This is particularly important because the practice of public health often conflicts with human rights requirements and individual autonomy. However public health is itself much misunderstood and conflated with community medicine or social medicine. Ethics in public health is, therefore, seen either as 'doing good for the community' or the practice of medicine taking into account the socio-economic variations within society. In such circumstances, ethics is seen as a set of rules to be followed to achieve goals.