

CONTENTS

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FROM THE ORGANISERS

**Achievements and opportunities** ..... S-3  
 GEORGE THOMAS

**Conference in the making** ..... S-4  
 NEHA MADHIWALLA

**Conference objectives and structure** ..... S-5  
 AMAR JESANI

**Concept note** ..... S-7  
 ORGANISING COMMITTEE

KEY-NOTE ADDRESSES

**Biomedical ethics** ..... S-10  
 P N TANDON

**Ethical issues in HIV/AIDS care provision in India** ..... S-12  
 SUNITI SOLOMON

**Ethical responsibilities of researchers involved in clinical trials** ..... S-13  
 M D GUPTA

**Violence as a public health and human rights issue** ..... S-15  
 MANISHA GUPTA

PROGRAMME AND ABSTRACTS

**Conference programme outline** ..... S-18

**Conference programme day I** ..... S-19

**Conference abstracts day I** ..... S-21

**Conference programme day II** ..... S-29

**Conference abstracts day II** ..... S-32

**Conference programme day III** ..... S-46

**Conference abstracts day III** ..... S-48

**WHO satellite workshop programme** ..... S-53

|   |           |
|---|-----------|
| MAP   | S-54      |
| BIONOTES  | S-55      |
| COLLABORATING INSTITUTIONS, COMMITTEES AND FINANCIAL ACKNOWLEDGEMENTS | Back page |

INDIAN JOURNAL OF MEDICAL ETHICS

# 1st NATIONAL BIOETHICS CONFERENCE

November 25-27, 2005

## CONFERENCE THEME:

**Ethical challenges in health care: global context, Indian reality**

## CONFERENCE FOCUS SUBTHEMES:

Ethical challenges in HIV/AIDS

Ethics of life and death in the era of high-tech health care

Ethical responsibilities in violence, conflict and religious strife

Ethics and equity in clinical trials

## VENUES:

### ***For plenary sessions:***

Rail Nikunj Hall/Auditorium  
near Mumbai Central (East) Station,  
Mumbai Central, Mumbai 400 008.

### ***For paper presentations and workshops:***

YMCA International House and Methodist Centre  
YMCA Road, Mumbai Central, Mumbai 400 008.

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## FROM THE ORGANISERS

### Achievements and opportunities

GEORGE THOMAS

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The first national bioethics conference, organised by the *Indian Journal of Medical Ethics*, signals a new milestone in the journal's development.

*IJME* is the journal of the Forum for Medical Ethics Society, Mumbai. It was started in 1993, in response to perceived problems in the ethical practice of medicine and was, initially, a newsletter representing the aspirations of a small group of committed medical professionals. It has grown to become a peer-reviewed journal, which reaches out and links health care professionals, researchers, students, policy makers and the lay public. In these years, there have been a total of 50 issues in 13 volumes of the journal. They contain the contributions of many people, both in India and abroad, and provide a rich collection of material on ethics – on clinical practice, professional behaviour, research, public health, and so on. Thus, *IJME* has grown to provide a forum to discuss and to debate, and – we hope – contribute positively to resolving ethical questions in health care.

The growth of *IJME* over the past decade coincides with the emergence of health care ethics as a discipline in India. The journal has contributed to, as well as benefited from, these developments. Indeed, the increasing support enjoyed by *IJME* is made possible by the growing awareness and concern for ethics in the health professions, in academic institutions and elsewhere.

We are, of course, aware that ethics is not static but that it changes in the social and historical context in society. In this new millennium, we are confronted with many new problems while many past ones are still unresolved. An example of a new problem is the ethical dilemmas associated with assisted reproduction. An example of an old problem that is still very much with us is the question of the egalitarian distribution of health care resources. Both these issues have been addressed in the pages of the journal.

Other issues that did not exist a few years ago – when the journal was in its early years, for instance – is that of clinical

trials being outsourced to India and of medical tourism. Both, it appears, have been welcomed by the government and policy makers because of the obvious economic benefits as well as other perceived and real benefits. However, there are many ethical issues which arise out of these new trends. These have been commented on in previous issues while some of them are topics that will be discussed during the conference.

This is where we feel that a journal from the developing world can be especially relevant and important. Some of the ethical problems that we face in India and in countries with limited resources are unique to our cultures and to our state of social and economic development. It is necessary to develop an ethical consensus on the resolution of these problems. This can best come from discussion.

This conference is a statement and an opportunity. It is a statement that such questions are being discussed by many individuals and organisations from all over the country as well as from abroad. As the programme indicates, discussions will range from issues in medical ethics more familiar to practitioners to subjects such as gender-based violence and disaster relief, subjects that we rarely discuss but which are very much within the purview of health care ethics. It is also a statement that medical ethics is of interest not just to physicians but also to philosophers, social scientists and, yes, even the "common person," who, as a patient, is affected the most by ethical issues in medicine. Thus, many participants here are neither physicians nor philosophers.

It is also an opportunity. It is an opportunity for us, in the journal, to strengthen our links with individuals and organisations, to network with as many people as possible who are concerned about these issues. It is axiomatic that in unity there is strength. We hope that working together, we can achieve more than the sum of our parts.

## FROM THE ORGANISERS

### Secretariat's report

NEHA MADHIWALLA

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The process of organising the first national bioethics conference began nearly 10 months ago. Once the national organising committee was set up there has been a continuous process of dialogue. While the secretariat can do little more than ensure that people are kept informed, it is only due to the close involvement of organising committee members that the democratic process could be sustained.

One of the most difficult tasks confronting the secretariat was the selection of abstracts. After a lukewarm response between April and June, we were flooded with abstracts in the month of July. We received nearly 120 abstracts, from which we had the unenviable task of selecting only half. To make our work harder, Mumbai was brought to a complete halt by the floods in the last week of July, which was the deadline for receiving abstracts. We received frantic calls from authors who were worried that their abstracts would not reach before the deadline with phone lines down, the Internet dead and the postal services in complete disarray.

Nonetheless, we managed to put together all the abstracts, blind them for author and author details, and circulate them to the entire organising committee and the editorial board of the *Indian Journal of Medical Ethics*. Within a week, we had reviews from 13 people. Their comments were summarised and the ratings were tabulated. Each abstract was rated as 0 (reject), 1 (accept with revision) and 2 (accept). Those which received at least one rating for 'accept' were short-listed, but we still had more than 90 abstracts to select from.

The programme committee met for a full-day meeting in Mumbai to make the final selection. It was unanimously decided that those abstracts that had not received any 'reject' rating should be included automatically. Of the remaining, 15 more were selected by consensus. It was vital to have a participatory and transparent process for deciding on the programme and the papers to give each author a fair chance to be selected on the merit of the abstract. Hence, to our own surprise, when the abstracts were un-blinded, we found that some abstracts submitted by younger and less-known authors were selected, while some from more established authors were not. However, these decisions were quite sportingly accepted and many whose abstracts were rejected are also participating in the conference.

Work at the secretariat has been very hectic but also quite rewarding, especially due to the enthusiastic response from those who wanted to present papers, but even from those who simply wanted to be a part of the proceedings. One of the most pleasant experiences of the conference has been the increasing familiarity and warmth which frequent correspondence helped

to build. I started with the awkward "Dear Sir/Madam/Dr" but eventually was writing friendly, informal notes to everyone and receiving similar notes in turn.

The secretariat was run voluntarily for the large part, and paid staff were engaged only in the last three months. The main responsibility for the organisation of the conference has been on the core group which comprises the secretariat and the Mumbai-based members of the organising committee. It was a struggle for these people to extricate themselves from their other lives as surgeons, researchers and editors, to devote time to conference work. However, we maintained the discipline of meeting once a week in the late evening. Large doses of good humour and several double shifts have seen us through. One cannot have hoped for a better group than this motley bunch, who have brought their varied experiences and a willingness to try their hand at everything.

Finally, we were lucky indeed to find the most helpful and dedicated assistants at short notice. Without Anirban and Ann, we could not have coped with the heavy workload that the unanticipated response to the conference has created. Within a few days, they familiarised themselves with the work, blended effortlessly with the team and did their best to make this conference a success. Together with the others, they were in the office late at night, drinking the nth cup of tea, determined to meet yet another deadline.

We would also like to thank the entire administration of the Centre for Studies in Ethics and Rights, where the secretariat was housed, and the volunteers from the different collaborating organisations for their enthusiastic support. Bishakha Dutta stepped in to help us plan the cultural events. Our thanks to the YMCA International Centre, Methodist Centre and the Railway Officers' Club for the facilities that they made available to us. Our thanks to Parkar Arts, VPrint, and Omega Press for bringing out the background material in record time. The name tags were prepared by students and staff of Sahyog Sangharsh Special School, in their maiden attempt at income generation. Finally, Prayas, the field action project of Tata Institute of Social Sciences supplied the conference bags.

On behalf of the secretariat, I would like to extend a warm welcome to all the participants of the conference, whose enthusiasm kept us motivated to work harder.

## FROM THE ORGANISERS

### Conference objectives and structure

AMAR JESANI

In September 2004, a discussion was initiated on the possibility of organising the National Bioethics Conference. A preliminary announcement on this was made in the October-December 2004 issue of *IJME*. In consultation with like-minded individuals and institutions, the first draft of the concept note was developed. It was decided that such an event would be a collaborative effort of many institutions and organisations. It would be conducted under the guidance of an organising committee (OC) made up of representatives of institutions who agreed to be collaborating organisers.

Over 60 institutions were contacted with a request to join in the collective as collaborating organisers. The minimum criterion for joining was providing sponsorship to five individuals, from the institution or elsewhere. Organisations were given the option of nominating one person on the OC. They could also contribute in any other way possible. After three months of interaction with a number of institutions (a process that at one stage looked unending), by April 2005, 17 institutions made a firm commitment to be collaborating organisers and nominated one individual each on the OC. Two more institutions joined in June 2005. Finally, one institution chose not to give its name as collaborating organiser but allowed one person from the organisation to be a member of the OC. Besides, it not only accepted the minimum commitment of sponsoring delegates but also provided additional financial support. Thus, for all practical purposes, we have 20 institutions and 20 persons on the OC.

The composition of collaborating organisers and, therefore, of the conference OC provides an interesting insight into the way the bioethics movement is evolving in India. First, the platform of the conference, *Indian Journal of Medical Ethics* and its owner and publisher, the Forum for Medical Ethics Society, are fiercely independent, multi-disciplinary and multi-ideology. They have evolved in the campaign to re-establish ethics in health care. Second, the OC has representation from formal government institutions and private institutions (11) as well as from non-government organisations (nine of them). This alliance between public, private and NGO institutions shows that concerns for bioethics in India have diverse origins. Also, the need to strengthen ethics is so strong that various players are ready to overcome their traditional hostility to each other and work jointly to supplement each other's strength and overcome each other's weaknesses. Above all, it shows that bioethics is not going to be the sectarian domain of a few people and organisations; it has the potential to be disseminated in all kinds of organisations and systems. The third important message emanating from this alliance is that ethics are not the concern only of biomedical and

health systems. Social scientists and legal professionals are also opening up to this movement. That is why we have three major national social science institutions represented on the OC, and the chairperson of the Indian Council of Social Science Research is going to deliver the valedictory address. The fourth important message is implicit in the participation of medical colleges and hospitals in this collaboration. Indeed, if the bioethics movement remains confined to biomedical research institutions, if it does not find its roots in hospitals and health centres where patient care takes place and in medical and nursing colleges where health professionals get trained, it will remain an elitist pastime. It may get condemned as a mere effort to fulfil regulatory and global requirements for ethics review of research projects. As hospitals, health centres, medical schools and working medical professionals join efforts to create a platform to strengthen bioethics, we can have greater hope of making a difference in reorienting and improving health care.

Collaboration among institutions at the national level – particularly those involving a high level of voluntarism as the organisation of this conference has demanded – is not so easy in India. It is even more difficult to sustain such a collaboration. So it is heartening to see that organisations from various backgrounds are working together for a common goal – to create a platform for bioethics in India.

#### Goal and objectives

There are at least three ingredients essential to the development of bioethics as a major health care concern and a discipline:

- There must be an increased awareness and sensitivity in the research and practice of bioethics.
- There must be an increase in debates, discussion, interaction and publications in the field, combined with emergence of bio-ethicists and their networks. Bioethics is a multi-disciplinary activity and must sensitise and bring together individuals from health, social sciences, humanities, and so on.
- Platforms – meeting places and journals – must be nurtured to popularise the discipline and provide impetus to its growth.

The long-term goal of the conference will combine these elements. Since the NBC is organised under the umbrella of a journal devoted to bioethics, it will combine twin purposes – providing a platform for and sharing work and also developing a high quality, nationally and internationally linked journal.

The specific objectives of the first National Bioethics Conference

of November 2005 are as follows:

1. To understand and debate the emergence of bioethics as linked to biomedical and social science disciplines in India – in relation to the globalising world and in terms of the pressures exerted by that process on the developing countries.
2. The focal sub-themes of the conference will provide scope to express Indian concerns on cross-cultural health care practices and issues in public health and research, to present perspectives and work in bioethics on those sub-themes. The conference will also provide space to present work in bioethics not related to the main theme and focal sub-themes.
3. To provide an opportunity to organise workshops, panel discussions, demonstrations, lectures, etc, on issues and programmes that various institutions and groups in various parts of the country have worked on, or are working on.
4. To provide an opportunity to discuss the direction that the bioethics movement in India should take, how it should organise its networks and what should be the periodicity of the National Bioethics Conferences. If possible, this is the time to create the organisational structure for a regular conference.

### **Conference programme**

The conference programme is designed to provide participants an opportunity to learn from eminent experts in the field. It also provides space for presentations of work done by individuals and groups. In all sessions we have also tried to keep sufficient

time for discussion from the floor.

Broadly, the conference programme is divided in four major sessions. They include five plenary sessions (opening inaugural, closing valedictory and three sessions for keynote addresses on the sub-themes of the conference); four parallel paper presentation sessions; two parallel sessions of workshops and sessions on bioethics films shows.

The plenary sessions are scheduled to have 22 presentations, of which 11 will be keynote addresses. 81 paper presentations, including 18 poster presentations, are scheduled in the parallel paper presentation sessions. Eleven workshops are scheduled in the parallel workshop sessions and there are at least three hours of film viewing time. In addition, the WHO-Geneva is also organising a pre-conference satellite workshop on ethical issues in international health research. That will provide an opportunity to invited participants to learn and interact with experts invited by the WHO.

In less than three days participants will be able to learn, share and debate on a number of wide-ranging issues in bioethics, and at one place. We hope that the learning from this conference will spread all over the country, stimulating more education and training in bioethics in biomedical, social science and non-governmental institutions, strengthening the bioethics movement in India. We also hope that this conference will make all of us determined to have regular conferences of this kind (perhaps every two years) so that we all can establish a common platform for developing bioethics – as a discipline, as a source of ethical medical practice and a strategy for improving health care services.

## FROM THE ORGANISERS

### Concept note

#### ORGANISING COMMITTEE

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The development of bioethics in India over the past three decades is the product of a number of pressures. The failure of political commitment to universal health care led to the creation of the voluntary community health movement critiquing the bureaucratisation of health care. The increase in private health care – and its subsequent commercialisation – and the struggle for patients' and consumers' rights brought issues of medical malpractice to the fore. The movement for rational therapeutics and drug price controls examined the pharmaceutical industry's influence on prescription practices of doctors. Finally, one of the strongest voices during these times has been that of the women's movement, which exposed the politics of population control and ethical violations in contraceptive trials.

While such movements emerged from the specific political realities that exist in our country, they were also a response to international interventions in the health sector in India. The process of "opening" up for global capital has accelerated the development of the pharmaceutical industry and private corporate health sectors. The phenomenal rise in relatively cheap drug trials, the decline of the public health sector and the rise in inequities have complex national and global interconnections. These are also associated with an increase in violence, conflict and fundamentalism. This provides the setting for as well as the ethical challenges in health care.

#### **Conference sub-themes**

While this broad theme binds deliberations at the conference, there will be four focus sub-themes: ethical challenges in HIV/AIDS; ethics of life and death in the era of high-tech health care; ethical responsibility in violence, conflict and religious strife, and ethics and equity in clinical trials

#### **Ethical challenges in HIV/AIDS**

The advancing epidemic of HIV/AIDS and the extremes of cultural, religious, professional, biomedical and policy responses to it have posed severe ethical challenges in clinical practice, research, public health and health policy. This is partly because the epidemic has disproportionately affected the poor and marginalised, including women engaging in sex work, individuals who inject drugs, migrant populations, and men who have sex with men. HIV infection is viewed as a disease of "others," and elicits considerable stigma and discrimination, devastating the personal, social and occupational lives of infected individuals. This has led to direct interventions by people living with HIV/AIDS in defence of their human rights, including their right to treatment.

The response of health professionals, researchers, policy makers and society in general to HIV/AIDS has come under scrutiny.

Health professionals and services are criticised for harbouring the same prejudices as a less knowledgeable society. They have also been criticised for practising discrimination and refusing care. Researchers are criticised for reinforcing stigma against marginalised groups in the course of their research. The judiciary is criticised for its insensitivity to stigmatised groups and to people suffering from the disease. Policy makers have come under attack for neglecting other diseases and at the same time for mismanaging the massive funds available for HIV/AIDS. They also seem to be failing in their responsibility to make treatment available free or at affordable prices. In essence, HIV/AIDS seems to be an arena where massive bioethics, human rights and public health battles will be fought.

We expect this conference to look into such criticism and also find ways to mitigate it. The discussion needs to be positive, and it needs to evolve strategies to overcome shortcomings, change the conduct of professionals, and put appropriate regulations in place.

#### **Ethics of life and death in the era of high-tech health care**

The rapid development of medical technology has transformed the practice of medicine and also changed the manner in which we understand life and death. Technology holds out the promise of saving lives and improving the quality of life for the seriously ill, for whom earlier there was no remedy or relief.

However, in developing countries, technology is being introduced at a time when there is declining investment of basic health care and increasing social inequality. Thus, while even the most rudimentary provisions required to be fulfilled and the health needs of the masses are not assured, substantial medical resources are flowing into high-tech care. Existing inequities (between nations and social groups) ensure that the benefits of high-tech care are available only to a small proportion of people. All this is at the cost of the vast majority who cannot be assured even the most basic health care by the public health system.

Thus, high-tech care raises ethical challenges at two levels. First, the increased investment in this area raises issues of justice. For example, can medical tourism (which involves substantial capital investment) be a thrust area for public investment for a country like India, where even primary health care is out of the reach of the poor, in both rural and urban areas? At the same time, the unrestrained growth of the private sector creates imbalances in resource allocation, both financial and human, to the detriment of many. The gains of high-tech care are linked fundamentally to the market, making it difficult to utilise technology to improve the general standard of health and health care. This raises several

questions about inequity in access.

At the same time, technology has severely challenged our understanding of life and death. Matters such as foetal sex selection, prolonging human life, transplanting organs, and choosing characteristics and genetic traits which were hitherto considered beyond human intervention can now be influenced by technology. However, all these developments raise ethical issues.

This sub-theme will address issues of inequity in India's rapidly changing health care system. It will look at the impact of a rising biotechnology industry on the life of ordinary Indians and at issues such as palliative care and euthanasia.

### **Ethical responsibility in violence, conflict and religious strife**

Violence can be seen both in specific, overtly violent situations as well as in long-term processes of violations rooted in the basic structures of society. In such situations, it is not enough to consider whether the usual provisions available; one must also ask if other specific vulnerabilities engendered by violence have been addressed.

Health care providers encounter individual violence – gender-based violence (rape, sexual abuse, domestic violence), torture of persons in custody (whether in jails, closed or partially closed institutions) and violent crime (assaults, murders, etc). There is mass violence such as in war, insurgency, ethnic violence and genocide, in which large numbers of people are affected and where complications may arise because of the involvement of the state or specific social groups. Third, there are long-term processes involving continuous violations of people's rights, because of their identity or their political or social status. This includes discrimination and oppression faced by scheduled castes, tribal people or minorities; by victims of forcible evictions, involuntary resettlement, forced migrations and displacement; and by stigmatised, marginalised groups such as sexual minorities, illegal migrants, sex workers, mentally ill or the disabled.

In each case, the provider has ethical obligations to provide adequate and appropriate care. Other obligations include providing adequate and unbiased documentation, protecting the privacy and confidentiality of victims. Ethical dilemmas sometimes relate to the extent of professional responsibility. Can providers claim absolution from the doctor-patient relationship, or does the obligation consist merely of providing treatment or does it extend to the more prolonged process of securing justice?

Another ethical responsibility in violence is related to the question of dual loyalty. Often, providers are in a position to bring perpetrators to book but they do not do so – instead, they may even assist such violence – because of their subordinate positions within the hierarchy, or due to self-interest. On the other hand, several providers have faced victimisation or even prosecution for refusing to participate in activities which violate ethics.

The third set of issues in clinical practice is related to discrimination against individuals or socially excluded groups and includes differential treatment, institutional barriers limiting access to care, or dissuasion by the use of terror.

The fourth set of issues is related to the practice of medicine during situations of violence, such as when health care institutions are themselves under attack, or when people are living in conditions which make them vulnerable – in refugee camps or resettlement colonies.

The fifth set of issues relate to the special needs of survivors of violence and the ethical issues that emerge from these. Special protection or care may be difficult to provide through a health care system that is not equipped to deal with such needs.

There are several ethical issues which arise during investigations of human rights violations, as well as during structured research on violence. These relate to the protection of the privacy and confidentiality of survivors, preventing further trauma. There are also ethical issues involved in preventing exacerbation of violence due to participation in research. Another issue related to research in violent situations is the procedure of obtaining informed consent. Typically, violent situations are very volatile and it may not be sufficient to obtain one-time consent. Yet another set of issues relates to the protection of vulnerable groups in the context of fair selection of participants. For example, groups such as prisoners and inmates of homes may be used repeatedly for research while certain excluded groups may be consistently left out of research.

Another ethical issue is related to the development of guidelines for ethical behaviour during "unusual circumstances" where existing safeguards may be insufficient or not relevant. One example is in seeking informed consent from survivors of sexual assault, in order that they receive treatment. Another is in protecting the privacy of individuals and communities in studies on violence, where there are legal implications of exposure as well – for example in research with illegal migrants, or trafficked persons.

### **Ethics and equity in clinical trials**

The sub-theme on clinical trials examines issues arising from the growth in the number of clinical trials in India in recent times. A number of these trials have come under fire. It has been argued that multinational pharmaceutical companies exploit vulnerable populations in such trials and benefit from the low cost of research and the lack of stringent regulatory mechanisms here. The concern has also been voiced that the bulk of research in developing countries relates to problems in the developed world. Research being done by developing country institutions has also raised apprehensions. Contraceptive research has been questioned for its focus on population control, and the development of potentially coercive methods. Collaborative research, particularly research between researchers from developed and from developing countries, has also been viewed as being exploitative of both researchers and participants in resource-poor settings. It is feared that basic principles such as justice and respect for persons may be disregarded. Finally, the

review and monitoring processes need strengthening.

The past decade has also seen the development of new ethical guidelines and regulatory processes. Even as international guidelines have been debated and revised, the ICMR developed ethical guidelines for biomedical research on humans. This is the first comprehensive document guiding biomedical research ethics in India. Since then, important regulatory changes relevant to ethics of clinical trials include the revised Schedule Y, reportedly to enable India to realise its potential for hosting clinical trials, and the amended Patent Act as part of compliance with TRIPS/WTO. Changes in developed country regulatory systems, permitting the inclusion for clinical trial data from other countries, will also raise questions related to research ethics in India.

This section will enable participants to exchange ideas and information on a range of existing and emerging issues in clinical

trials in India and other developing countries. It will look at ethical issues in clinical trials from the perspectives of protection to participants, the scientific merit and social relevance of the trial, the standard of clinical care provided during such trials and the public health dimensions of the increased activities in this field. It will also examine the information available on clinical trials in the public domain, the reasons for the lack of this information and the measures needed to ensure that there is transparency in clinical trials conducted in India.

### **Conclusion**

It is hoped that this conceptual framework will enable a fruitful discussion on the various topics to be discussed at this national bioethics conference.

*This paper is based on material written by members of the sub-groups appointed by the organising committee.*

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## KEY-NOTE ADDRESSES

### Biomedical ethics

**P N TANDON**

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The practice of medicine has since time immemorial been guided by ethical principles as enunciated originally by the Ayurvedic physicians Charak and Susruta and the Greek physician Hippocrates. Many of the guidelines provided by them are still valid. However, the world has changed since then – socially, culturally, economically and scientifically – and so has the practice of medicine. Initially, ethics was concerned primarily with professional conduct, i.e. doctor-patient relationship. The revelations of Nazi atrocities during World War II about using human subjects for unethical scientific research aroused the global consciousness to prevent such experimentation. This resulted in the formulation of the Nuremberg Code, followed by a series of other international declarations such as the Helsinki Declaration by the World Medical Association in 1964, which has been amended in 1975, 1983 and 1989; also by the Council for International Organizations of Medical Sciences (CIOMS), Geneva in 1992 and which was revised in 2002.

The unprecedented advances in modern biology, genetics and genomics, artificial reproductive technologies, stem cell research, neurobiology and allied fields of biomedical sciences during the last couple of decades, having immense potentials for human welfare, have at the same time created complex ethical dilemmas for scientists and medical practitioners alike. This has given birth to a whole new discipline of bioethics. Recognising the importance of this field, UNESCO has established an International Bioethics Committee in 1993 which has already issued the Universal Declaration on the Human Genome and Human Rights (1997) and an International Declaration on the Human Genetic Data (2003). It is currently finalising the Universal Declaration on Bioethics and Human Rights.

In India, in addition to the Code of Medical Ethics formulated by the Medical Council of India, in recent years, ICMR has brought out a comprehensive document, *Ethical Guidelines for Biomedical Research on Human Subjects* (2000), supplemented by the Department of Biotechnology on *Ethical Policies on the Human Genome and Genetic Research and Services* (2002).

Notwithstanding the recent advances in science and technology, the unique status of human beings in the cosmos, the preciousness of human life and the universal acceptance of the Universal Declaration of Human Rights (1948) constitute the basis of all ethical principles related to the practice of medicine or biomedical research. These principles are based on the recognition of the ideals of autonomy of the person, and therefore, of his/ her human rights and human dignity. These in turn dictate the principles of beneficence (to do the right thing) and maleficence (to do no harm). Translated into practical guidelines, these require to ensure informed consent;

confidentiality; voluntary decision-making; equality; justice and equity; non discrimination and non-stigmatisation, and social responsibility with due attention to cultural diversity and religious sentiments. The prevailing socio-economic environment in the country adds to our special concerns regarding the poor and the underprivileged in respect to equity, access and affordability of the best possible health care for one and all.

Instead of dealing with issues concerned with professional conduct, this presentation will highlight special ethical issues resulting from the recent advances in the biomedical field.

#### **Ethics in the post genomic era: genetic testing and genetic screening**

While the general principles of bioethics mentioned above are equally applicable to investigations/ research on the human genome and their clinical application, special care is required in obtaining informed consent and there must be strict maintenance of confidentiality of the findings. Few of the ethical dilemmas created by the growing commercial interest in human genetics are as complex or as potentially explosive as those related to the “ownership” of human genetic material and data and the related issues of intellectual property rights and equitable sharing of benefits accruing from them. Imagine the consequences of the current tendency to patenting which could tie up every single gene or its product to one company or other for 20 years. It is reported that already 40 per cent of human genes have been patented in the USA by some corporate body or institution in spite of the fact that the Universal Declaration on the Human Genome and Human Rights states that a human gene in its natural state cannot be patented.

**Genetic testing** is increasingly being used for the diagnosis of suspected genetic disorders. Ethical problems arise in the case of diseases where the probability of risk is still uncertain or in cases of disease predisposition later in life. Should a girl child be informed that she has a 70 per cent chance of developing breast cancer in adulthood? Should a person be told that he or she is more likely to develop Alzheimer's disease than the average individual? The psycho-social implications of such information need to be heavily weighed. Under no circumstances should the results of the investigation be revealed unless facilities are available for providing expert counselling.

**Genetic information** must be treated with utmost confidentiality because of its sensitive nature and its implications for the family extending over generations. Detailed guidelines on the subject are available in UNESCO's International Declaration on Human Genetic Data available at [www.unesco.org/shs/ethics](http://www.unesco.org/shs/ethics).

**Gene therapy and genetic engineering:** There is a general consensus that there are not many ethical, social and legal problems in respect to somatic cell gene therapy as long as its safety (which still remains a matter of concern) is ensured. However, "germ cell" manipulation should be forbidden in the present state of our knowledge. Gene therapy for enhancement of genetic characteristics (so called "designer babies") should not be attempted.

**Reproductive medicine, ART and related issues:** There are a number of sensitive issues in respect to prenatal diagnosis (especially gender selection and detection of congenital malformations), artificial insemination using sperm from healthy donors in the case of male infertility, and surrogate motherhood. There are complex social psychological or legal implications. These issues have acquired new concern in view of the growing demand from offspring of such technologies to know their biological parents.

The psycho-social, cultural and religious issues related to abortion continue to be subjects of global concern. The ethical issues are concerned with the conflicting dictates of the right to life versus the individual's right of autonomy. The Medical Termination of Pregnancy Act, Government of India, 1971, provides necessary directions in this respect.

**Organ transplantation, embryonic stem cell therapy and regenerative medicine:** Following extensive debates, we now have the Transplantation of Human Organs Act, 1994, and the Transplantation of Human Organs Rules, 1995, to guide the profession. These have resolved the issues related to death, brain death, etc. Major ethical concerns still remain regarding equity, equitable distribution of available resources, the prohibitive cost of treatment, etc. However, an important unresolved ethical issue, globally a subject of debate, relates to embryonic stem cell research and therapy. This hinges around the most important questions: "When does life begin?" and "When does an embryo become human?" While every country prohibits human reproductive cloning, at least two-thirds of the world favours therapeutic cloning. Time will not permit me to elaborate this any further but my recent presentation on the subject, 'Ethical Aspects of Stem Cell and Regenerative Medicine', presented at the Second International Conference of Science and Technology for Society (STS Forum) at Kyoto in September this year, will soon be available on the website of the STS Forum.

Time will also not permit me to even enumerate the large number of ethical issues emerging as a result of phenomenal advances in science and technology. However, these demand the existence of committed, dynamic organisations to discuss, debate and formulate guidelines, codes of conduct and, where necessary, legislation to deal with such issues.

## KEY-NOTE ADDRESSES

### Ethical issues in HIV/AIDS care provision in India

SUNITI SOLOMON

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“Eight-year-old Sekar had an automobile accident when travelling with his parents from Bangalore. Both his parents died, leaving Sekar with multiple fractures. He was taken to a private hospital where he was given blood transfusions and his fractures were fixed. The cost of treatment of almost Rs1.5 lakh was paid by his grandparents. Two months later he had to go for follow-up. His lab tests showed he was HIV positive. He was refused treatment.”

About 60 million people have been infected with HIV since the first detection of this virus in 1981. Approximately 20 million are dead. It is estimated that 6 million of the remaining 40 million living in developing countries are urgently in need of antiretroviral therapy (ART) just to stay alive. However, only about eight per cent of those who need ART are on treatment. When the demand for ART exceeds the ability to deliver them, some receive it and live a good quality of life and the others will die. Such a situation poses serious ethical issues. But such a situation for access to health care also is present in other diseases such as cardiac surgery, nephrology (kidney transplant), etc. There is also a serious ethical concern about the potential diversion of resources from other health and social needs to scaling up of ART.

Access to ART is only one of the ethical issues in India when caring for people with HIV/AIDS. Right from testing for HIV to

research there are many ethical issues, listed below, which will be discussed.

1. Testing for HIV diagnosis: voluntary vs mandatory
  2. Confidentiality
    - Informing the spouse about the partner's status
    - Family, if the person is below 18
    - Other medical colleagues
    - Workplaces, especially if surgeons are HIV positive
  3. Ethics of managing HIV positive persons and discrimination against people with HIV/AIDS
  4. Legal issues and ethics – treatment of IDUs, MSM, FSW.
  5. Gender issues and ethics
    - Antenatal clinics and informed consent
    - Equitable access of ART for women
  6. Access to ART – how does one decide who gets it?
  7. PMTCT – are we creating orphans? How do we prevent this?
  8. Is it ethical to start an ART programme if sustainability is not ensured?
  9. Care for participants who took part in research projects.
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## KEY-NOTE ADDRESSES

### Ethical responsibilities of researchers involved in clinical trials

**M D GUPTA**

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The World Medical Association's Declaration of Helsinki has clearly brought out the ethical principles for medical research involving human subjects. The latest available statement (2004) has enunciated the relevant principles for a clinical trial researcher as given below:

- "The health of my patient will be my first consideration.
- "Medical progress is based on research which ultimately must rest in part on experimentation involving human subjects.
- "In current medical practice and in medical research, most prophylactic, diagnostic and therapeutic procedures involve risks and burdens
- "Medical research is subject to ethical standards that promote respect for all human beings and protect their health and rights. Some research populations are vulnerable and need special protection. The particular needs of the economically and medically disadvantaged must be recognized. Special attention is also required for those who cannot give or refuse consent for themselves, for those who may be subject to giving consent under duress, for those who will not benefit personally from the research and for those for whom the research is combined with care.
- "Research investigators should be aware of the ethical, legal and regulatory requirements for research on human subjects in their own countries as well as applicable international requirements. No national ethical, legal or regulatory requirement should be allowed to reduce or eliminate any of the protections for human subjects set forth in this Declaration.
- "It is the duty of the physician in medical research to protect the life, health, privacy, and dignity of the human subject.
- "Medical research involving human subjects must conform to generally accepted scientific principles, be based on a thorough knowledge of the scientific literature, other relevant sources of information, and on adequate laboratory and, where appropriate, animal experimentation
- "The design should be clearly formulated in an experimental protocol. This protocol should be submitted for consideration, comment, guidance, and where appropriate, approval to a specially appointed ethical review committee, which must be independent of the investigator, the sponsor or any other kind of undue influence
- "Medical research involving human subjects should be conducted only by scientifically qualified persons and under the supervision of a clinically competent medical person. The responsibility for the human subject must always rest with a medically qualified person and never rest on the subject of the research, even though the subject has given consent.
- "Careful assessment of predictable risks and burdens in comparison with foreseeable benefits to the subject or to others should be made. The design of all studies should be publicly available.
- "Physicians should obtain the subject's freely-given informed consent, preferably in writing. If the consent cannot be obtained in writing, the non-written consent must be formally documented and witnessed.
- "Both authors and publishers have ethical obligations.
- "Preserve the accuracy of the results – negative as well as positive results
- "Sources of funding should be declared.
- "The benefits, risks, burdens and effectiveness of a new method should be tested against those of the best current

#### Footnotes

1. The WMA hereby reaffirms its position that extreme care must be taken in making use of a placebo controlled trial and that in general this methodology should only be used in the absence of existing proven therapy. However, a placebo-controlled trial may be ethically acceptable, even if proven therapy is available, under the following circumstances:
  - Where for compelling and scientifically sound methodological reasons its use is necessary to determine the efficacy or safety of a prophylactic, diagnostic or therapeutic method; or
  - Where a prophylactic, diagnostic or therapeutic method is being investigated for a minor condition and the patients who receive placebo will not be subject to any additional risk of serious or irreversible harm.
 All other provisions of the Declaration of Helsinki must be adhered to, especially the need for appropriate ethical and scientific review.
2. The WMA hereby reaffirms its position that it is necessary during the study planning process to identify post-trial access by study participants to prophylactic, diagnostic and therapeutic procedures identified as beneficial in the study or access to other appropriate care. Post-trial access arrangements or other care must be described in the study protocol so the ethical review committee may consider such arrangements during its review.

prophylactic, diagnostic, and therapeutic methods. This does not exclude the use of placebo, or no treatment, in studies where no proven prophylactic, diagnostic or therapeutic method exists.<sup>1</sup>

- "At the conclusion of the study, every patient entered into the study should be assured of access to the best proven prophylactic, diagnostic and therapeutic methods identified by the study."<sup>2</sup>

I would like to elucidate these principles in the context of clinical trials developed and conducted in India.

It is impossible to dissociate science from ethics. If the proposal of a study is unscientific then the study is also unethical.

I will consider these factors and the principles in the context of developing a clinical trial in various steps. Essentially a clinical trial is an experiment on human beings. For the progress of science and medicine and for the well being of human beings, these experiments are essential experiments. A clinical researcher has to be fully aware of his responsibilities while conducting these experiments.

Sometimes clinical trials are divided into therapeutic and non-therapeutic. Therapeutic trials may be of immediate benefit to the volunteer / patients and non-therapeutic trials are for future patients. One has to stringently and carefully follow ethical guidelines particularly in the case of non-therapeutic patients.

### Research design

We have to consider good clinical practices and the so-called Gold Standard, placebo controlled, randomised controlled trial.

The place of the placebo needs to be discussed specifically. Where standard therapy is available, the placebo cannot be easily justified, though there could be a possibility of using a placebo even in a situation where the standard therapy is available.

A clinical trial will bring out results for the patient population based on the sample recruited in a clinical trial. The representativeness of the sample is a very important criterion.

Recently there has been a very interesting dialogue in the *BMJ* on these situations. Randomisation and opt-in recruitment may not be an ideal way to get a representative sample of patients for a clinical trial.

Before initiating the research study, the written protocol is an absolute requirement.

Role and responsibilities of clinical trial researchers and the institutional review board / institutional ethics committee – local, national and global – is a very critical area.

Disclosure policy has several sensitivities.

Patients' sensitivity with respect to signature on the informed consent needs to be taken into account in diseases such as AIDS.

Biological samples – present and future use and the wrong practices adopted – are a matter of concern.

Data safety and monitoring are also similar issues.

Effective treatment and the future availability of this treatment to patients need to be ensured.

Documentation and dissemination and the ethics in these areas are a separate important area.

Certain special situations – multi-centric studies, multinational studies, clinical research organisations and outsourcing – are issues not to be ignored.

### Conclusion

I would like to reiterate again from the WMA guidelines:

"Principal Investigator's Responsibilities:

"Medical research involving human subjects should be conducted only by scientifically qualified persons and under the supervision of a clinically competent medical person. The responsibility for the human subject must always rest with a medically qualified person and never rest on the subject of the research, even though the subject has given consent."

## KEY-NOTE ADDRESSES

# Violence as a public health and human rights issue

MANISHA GUPTA

This presentation tries to establish the linkages between violence and public health, the fact that ethical issues are of prime concern when violence is addressed in the clinic (or community) setting and that a public health and human rights framework helps not only to recognise violations and address them, but also to confront and prevent them. Putting responsibility on the State, the family and the community, and sensitising medical and paramedical personnel on issues of violence, especially that committed against marginalised sections of society, become essential strategies.

### 1. Why violence occurs

**Violence is rarely a randomly committed act.** It is a tool to terrorise those who dare to oppose the status quo. Most acts of violence are committed by those who have more power against those who have less or no power. In fact, that is the reason as to why the perpetrator can usually get away with violence; because often it is impossible for the victim to resist, report or question the act. The perpetrator is thus able to function with impunity. In a few cases, violent acts can also occur as a reaction to constant exploitation and abuse. Here, however, the backlash can be more severe than the act of violence itself. Thus we find that people, especially women in the case of domestic violence, usually direct violence "inwards," by refusing to eat, or by attempting suicide. Women may also vent their frustrations on someone more vulnerable than themselves, such their young children.

**Violence is not a personal or private affair,** even if it may sometimes seem so. Even when a husband beats his wife, it is because of the social, economic, cultural and emotional power he holds in the home and outside it. As long as the house, the fields and other assets belong to the men in the house, they will be in a position to use violence to keep the family under control.

**Violence occurs when a particular group or person in society is discriminated against** - especially minorities. By minorities, one means all those who do not get their fair place in society and are forced to live on its margins. Such minorities could be religious groups, tribal groups, dalits, the poor, and women - especially single, deserted, widowed or divorced women, homosexual men and lesbian women, people whose belief systems or political convictions are different from the majority, and so on.

**Violence creates terror.** For example, if a woman is raped in a school or college, for many other girls it often results in the immediate termination of their education. The consequences are borne not only by the victim but by her sub-group too. For the individual who is constantly subjected to violence, the damage can be life-long. Thus it serves as a deterrent to all who

dare to digress from social norms. Violence is an act committed to put down someone, to silence her/him, to keep someone under control, and it is carried out with the intention of hurting or humiliating her/him.

**Violence occurs when a person or a party within a relationship is economically, physically or emotionally vulnerable or dependent on the other** - children, women, elderly people, people who are physically or mentally challenged, a junior at work, younger siblings, and so on.

**Violence against women is perpetrated mainly by the family or in intimate relationships.** Studies have shown that most women who die under suspicious circumstances die within the home, that women are mostly beaten by family members (husbands, in-laws, natal family members, grown-up children) and that most women are raped by men they know and trust.

**Violence occurs because of the power and control that a person or section holds** over another. Violence is not normal and cannot be justified under any circumstances - a culture that believes in resolving its conflicts through violence is not very cultured.

**Violence occurs among all classes,** castes, races, religions and nationalities.

### 2. Violence as a public health issue

Violence results in physical and emotional hurt. Injuries, bruises, fractures, burns, vaginal tears, psychiatric problems such as depression, distress, self-harm or suicide attempts, miscarriages or repeated abortions, sexual assault, infections - including HIV/AIDS, and unwanted pregnancies are a few examples. Unfortunately, violence has been steadily emerging as one of the main reasons of death for women in the reproductive age group, world-wide, including in India. The two-way linkages between violence and health are also evident in women's lives, as ill health and disclosure of illness increase the element of violence in women's lives. Women with tuberculosis, mental illness or HIV/AIDS are likely to be thrown out of the house, and therefore they are reluctant to disclose their disease to their families or get their illnesses diagnosed. If a woman has white discharge, she may be accused of sleeping with other men; if she repeatedly falls sick, she may not get medical attention. Thus women are more vulnerable to illness because of their low status in society and low access to food, rest and recreation. This, in turn, increases the probability of violence in their lives. Being dependent on husbands and in-laws for health care silences a woman and when she does get to the health centre, notions of family honour and the consequences of speaking out may keep

her silent about the violence in her life. A vicious circle is thus set in motion.

Often, health professionals are unable or reluctant to identify violence in their client's life. Even if the bruises or fractures of a person in police custody or of a housewife do not match their account of the "accident," such as falling down the stairs, doctors will rarely ask questions to probe the incident or seek answers to these discrepancies. Often doctors are not aware of how to preserve evidence in the event of sexual assault, or how to present forensic evidence in a gender-sensitive manner. Most health professionals also want to avoid being called into the courtroom as an expert witness. Often, the professionals themselves have traditional ideas and biases (related to class, religion, gender, caste, disability, sexuality and so on) about why violence occurs, or they may have unresolved issues in their own lives that block their sensitivity to such cases.

### 3. Ethical issues in addressing violence, within and outside the home

One of the first places that a survivor – whether of domestic violence, armed conflict, riots wars or of police torture – will land up is in the clinic setting. Often, women find it easier to go to the hospital rather than the police station as the latter is an irreversible act, besides being one that is fraught with danger. It is therefore essential for health professionals to address issues of violence with the utmost ethical standards.

Some of the ethical issues that will be elaborated upon in the presentation are:

- Assuring privacy to the victim / survivor client.
- Assuring confidentiality, especially when counselling or therapy is conducted.
- Assuring safety and security.
- Being extra careful about the above, when group counselling or internet counselling is used.
- Listening carefully to the client without interference of one's own prejudices and belief systems.
- Being sensitive to the individual's personal and cultural beliefs and needs.
- Not discriminating on the basis of gender, class, caste, religion, disability or sexuality and, in fact, being sensitive to those who do not "fit" social norms.
- Respecting the survivor and not trivialising her / his experiences or perceptions.
- Never justifying the harm or violence that has been committed against the client.
- Appropriate assessment of the problem.
- Being sensitive to the laws of the country when writing reports (such as involuntary reporting of child abuse, suicidal / homicidal tendencies or mentioning "depression" on the case paper when a woman's case for her children's custody is in court.

- Assuring high quality, timely and multi-disciplinary care to the client.
- Using interventions that are effective. The provider has an ethical responsibility to update and acquire new skills that improve service delivery.
- When research is conducted on survivors of violence, one has to be very careful about the harm, stigma, risks or backlash (both personal and social) that the respondent may face, weigh the above vis-a-vis the benefits, seek informed consent, take care to see that the exclusion or inclusion of certain groups is not discriminatory and share the findings of the study with the respondents in whichever way possible. Making useful recommendations, reaching them to policy makers (within hospitals, cities, districts, etc) so as to improve survivors' physical and economic access to services that are accountable, transparent and answerable to the survivor should be a primary reason for any bio-medical research on violence.
- No healing is complete without redress, justice and assurance of non-repetition.

Thus the family, society and the State have the obligation and commitment to provide these to the victim / survivor. Health professionals cannot shirk from the crucial role of making violence visible, preserving forensic data for court trials, being a non-biased witness and clearing bio-medical obstacles in the survivor's quest for justice

### 4. Using the human rights framework while dealing with violence issues, either in the clinic or community setting

- The human rights framework helps to establish a benchmark or standard for assessment and treatment for survivors of violence. It moves from merely looking at people as victims to firmly establishing violence against a person or people as a violation of their human rights – their dignity, personhood, autonomy and so on. It shifts the discourse from family or cultural "honour" to the victim's "rights".
- It removes the artificial blur between the private and the public sphere. Even though "rights" may mean different things for different people in different settings, human rights are non-negotiable for all people, being universal, intrinsic, inalienable, indivisible, non-hierarchical and inter-dependent
- It helps to understand the gendered, class, caste colours of violence – how women's bodies become the battlegrounds in riots, war and in conflict situations or how religious fundamentalism (especially that of the majority religion) creates a climate of violence against the minorities.
- It reiterates the State's obligation to respect, protect and fulfil its people's rights
- It makes State parties answerable to international human rights treaties when it fails in any of the above obligations, and especially so when it perpetuates violence.

- It makes it obligatory upon the State to actively remove discrimination against its people.
- Some treaties such as the Convention on the Elimination of All Forms of Discrimination Against Women (CEDAW) also make non-state parties (such as families, communities, employers, trans-national corporations etc) answerable.
- The State is expected to exercise due diligence in preventing, investigating, prosecuting, punishing and compensating.
- The State is also obliged to prove that it was unable, rather than unwilling to exercise due diligence and that it put its maximum available resources towards preventing and addressing violence.
- Acts of omission as well as acts of commission are taken into consideration.
- The State can be held responsible where reparation, justice and assurance of non-repetition are concerned.

We also need to make the State answerable for discriminatory practices such as assuming patrilocality for women after marriage, for coercive policies such as withdrawing civil and political rights of those who have more than two children and allowing fundamentalist and fascist groups to determine citizenship based on religion and gender. All these are precursors of violence against its most marginalised people.

##### **5. Non-discrimination, and eliminating discrimination as well as other structural determinants of violence**

- India is committed to the removal of discrimination based on religion, caste, class, etc, through its own constitution and by signing and ratifying international human rights

treaties, especially the CEDAW.

- India is therefore committed to make the above rights accessible to all people within its jurisdiction.
- Since discrimination is the basis of violence, removing it through temporary measures such as affirmative action (reservations) and by enforcing the principles of non-discrimination becomes essential.
- Ownership of property, assets as well as ownership over people's labour, reproduction and sexuality (wives, children, farmhands etc) creates a fertile ground for violence. An equitable distribution of resources and consumption is therefore necessary.
- Structural forms of discrimination such as the caste and class system as well as patriarchy are responsible for violence. They have to be addressed and eventually dismantled.
- When the State itself becomes the violator (as in Gujarat in 2002), it is only a civil society based on the principles of equality, democracy, secularism and non-violence that can eliminate violence within and outside the home. The role of health professionals in such cases becomes crucial for survivors to claim justice, to reconcile and to heal.

The presentation will make a case for health professionals and researchers to become active agents in empowering the client to address and confront the violence in her / their lives. It will highlight the fact that using an ethics and human rights framework helps us to learn the art of maintaining a balance between the immediate needs of the client and the long-term, structural goals of eradicating discrimination and violence.

# Indian Journal of Medical Ethics

## 1st NATIONAL BIOETHICS CONFERENCE

November 25-27, 2005

### CONFERENCE PROGRAMME OUTLINE

| DAY ONE, NOVEMBER 25, 2005   |  |                             |
|------------------------------|--|-----------------------------|
| TIME                         |  | VENUE                       |
| 9 -10.30 am                  | Plenary session I: Inauguration  | Rail Nikunj Hall/Auditorium |
| 11 am - 12.45 pm             | Plenary session II: Ethical challenges in biomedical and social science research in health               | Rail Nikunj Hall/Auditorium |
| 2 -3.30 pm                   | PARALLEL PAPER PRESENTATIONS I   | YMCA and Methodist Centre   |
| 2 -3.30 pm                   | Group 1: Ethics and end of life care   | HALL-1 YMCA ground floor    |
| 2 -3.30 pm                   | Group 2: Gender based violence and health research: ethical and medico-legal issues                      | HALL-2 YMCA ground floor    |
| 2 -3.30 pm                   | Group 3: Clinical trials: informed consent and partner involvement                                       | HALL-3 YMCA first floor     |
| 2 -3.30 pm                   | Group 4: Community and cultural dimensions of research   | HALL-5 Methodist Centre     |
| 2 -3.30 pm                   | BIOETHICS FILMS  | HALL-4 YMCA second floor    |
| 4 - 6 pm                     | PARALLEL WORKSHOPS I   | YMCA and Methodist Centre   |
| 4 - 6 pm                     | Workshop 1: Ethical guidelines for intensive care units  | HALL-1 YMCA ground floor    |
| 4 - 6 pm                     | Workshop 2: Perspectives in feminist bioethics on new reproductive and genetic technologies              | HALL-2 YMCA ground floor    |
| 4 - 6 pm                     | Workshop 3: Ethical issues in international health research  | HALL-3 YMCA first floor     |
| 4 - 6 pm                     | Workshop 4: Religious perspectives on bioethics and the role of faith-based organisations in health care | HALL-4 YMCA second floor    |
| 4 - 6 pm                     | Workshop 5: Bioethical issues in truth telling at the end of life  | HALL-5 Methodist Centre     |
| DAY TWO, NOVEMBER 26, 2005   |  |                             |
| 9 - 10.45 am                 | Plenary session III: Ethical responsibilities of providers in clinical practice and research             | Rail Nikunj Hall/Auditorium |
| 11 am -1 pm                  | PARALLEL PAPER PRESENTATIONS II  | YMCA and Methodist Centre   |
| 11 am -1 pm                  | Group 1: Bioethics in the context of disasters and research on vulnerable populations                    | HALL-1 YMCA ground floor    |
| 11 am -1 pm                  | Group 2: Concerns in community-based activities and programmes   | HALL-2 YMCA ground floor    |
| 11 am -1 pm                  | Group 3: Dilemmas in transplantations and terminal conditions  | HALL-3 YMCA first floor     |
| 11 am -1 pm                  | Group 4: Relevance of ethics and ethics training   | HALL-5 Methodist Centre     |
| 11 am -1 pm                  | BIOETHICS FILMS  | HALL-4 YMCA second floor    |
| 2 - 3.30 pm                  | PARALLEL PAPER PRESENTATIONS III   | YMCA and Methodist Centre   |
| 2 - 3.30 pm                  | Group 1: Economic dimensions of health services and research   | HALL-1 YMCA ground floor    |
| 2 - 3.30 pm                  | Group 2: Ethical issues in preventive health   | HALL-2 YMCA ground floor    |
| 2 - 3.30 pm                  | Group 3: Ethical issues in new technologies  | HALL-3 YMCA first floor     |
| 2 - 3.30 pm                  | Group 4: Regulatory mechanisms for research ethics   | HALL-4 YMCA second floor    |
| 2 - 3.30 pm                  | Group 5: Research on adolescents and reproductive and sexual health                                      | HALL-5 Methodist Centre     |
| 4 - 6 pm                     | PARALLEL WORKSHOPS II  | YMCA and Methodist Centre   |
| 4 - 6 pm                     | Workshop 1: Ethical controversies in day-to-day clinical practice  | HALL-1 YMCA ground floor    |
| 4 - 6 pm                     | Workshop 2: Sex selection: making doctors accountable, from rhetoric to action                           | HALL-2 YMCA ground floor    |
| 4 - 6 pm                     | Workshop 3: Role of Community Advisory Boards in clinical trials and clinical care in HIV/AIDS           | HALL-3 YMCA first floor     |
| 4 - 6 pm                     | Workshop 4: Moving towards ethical practice: experiences of one-stop crisis centres                      | HALL-4 YMCA second floor    |
| 4 - 6 pm                     | Workshop 5: Ethical issues in disaster management  | HALL-5 Methodist Centre     |
| 4 - 6 pm                     | Workshop 6: Ethical issues in international health research  | HALL-6 Methodist Centre     |
| DAY THREE, NOVEMBER 27, 2005 |  |                             |
| 9 - 10.30 am                 | PARALLEL PAPER PRESENTATIONS IV  | YMCA and Methodist Centre   |
| 9 - 10.30 am                 | Group 1: Ethics committees and ethics review   | HALL-1 YMCA ground floor    |
| 9 - 10.30 am                 | Group 2: POSTER PRESENTATIONS  | HALL-2 YMCA ground floor    |
| 9 - 10.30 am                 | Group 3: Role of informed consent in HIV testing   | HALL-3 YMCA first floor     |
| 9 - 10.30 am                 | Group 4: Drugs delivery and access   | HALL-4 YMCA second floor    |
| 9 - 10.30 am                 | Group 5: Ethical concerns in delivery of health care   | HALL-5 Methodist Centre     |
| 11.15 am -1 pm               | PLENARY SESSION IV: Bioethics and public health  | Rail Nikunj Hall/Auditorium |
| 2 - 4 pm                     | PLENARY SESSION V: Valedictory session   | Rail Nikunj Hall/Auditorium |

## CONFERENCE PROGRAMME

| TIME   |   | VENUE   |
|--|---|---|
| <b>DAY ONE, NOVEMBER 25, 2005</b>  |   |   |
| 9 - 10.30 am   | <b>PLENARY SESSION I: INAUGURATION</b>  | Rail Nikunj Hall/Auditorium,<br>Railway Officers' Rest House,<br>Mumbai Central |
|  | <b>Chair: Prof P N Tandon</b> , President, National Brain Research Centre, Manesar<br><b>Co-Chair: Prof Leela Visaria</b> , Director, Gujarat Institute for Development Research, Ahmedabad   |   |
|  | <b>Welcome</b><br><b>Ms Sandhya Srinivasan</b> , Executive Editor, <i>Indian Journal of Medical Ethics</i> , Mumbai   |   |
|  | <b>Objectives of the conference</b><br><b>Dr Amar Jesani</b> , Conference Coordinator and Centre for Studies in Ethics and Rights, Mumbai   |   |
|  | <b>Release of bioethics books</b>   |   |
|  | <b>Inaugural address</b><br><b>Ms P Kousalya</b> , President, Positive Women Network, Chennai   |   |
|  | <b>Key-note address</b><br><b>Prof N K Ganguly</b> , Director General, Indian Council of Medical Research, New Delhi<br><b>Ethical challenges in health care: global context, Indian reality</b>  |   |
|  | <b>Chairperson's remarks</b><br><b>Prof P N Tandon</b> , President, National Brain Research Centre, Manesar   |   |
| 10.30- 11am  | TEA BREAK   |   |
| 11 am - 12.45 pm   | <b>PLENARY SESSION II:<br/>ETHICAL CHALLENGES IN BIOMEDICAL AND SOCIAL SCIENCE RESEARCH IN HEALTH</b>   | Rail Nikunj Hall/Auditorium,<br>Railway Officers' Rest House,<br>Mumbai Central |
|  | <b>Chair: Dr Vasantha Muthuswamy</b> , Senior Deputy Director General, Indian Council of Medical Research, New Delhi<br><b>Co-Chair: Dr Jagruti Waghela</b> , Lokmanya Tilak Medical College and Municipal General Hospital, Sion, Mumbai |   |
|  | <b>Key-note address 1:</b><br><b>Prof V I Mathan</b> , ICMR Chair of Epidemiology, Vellore, Tamil Nadu<br><b>Ethical issues in research in high-tech medicine</b>   |   |
|  | <b>Key-note address 2:</b><br><b>Prof S Parasuraman</b> , Director, Tata Institute of Social Sciences, Mumbai<br><b>Ethical issues in conducting research on displacement</b>   |   |
|  | <b>Key-note address 3:</b><br><b>Dr Chandra Mohan Gulhati</b> , Editor, <i>MIMS</i> , New Delhi<br><b>Rational approach to allowing new drugs in India</b>  |   |
|  | Discussion and responses  |   |
|  | Chairperson's remarks   |   |
| 12.45- 1 pm  | Announcements and transfer to the YMCA  |   |
| 1-2 pm   | LUNCH   | YMCA  |
| 2-3.30 pm  | <b>PARALLEL PAPER PRESENTATIONS I</b>   | YMCA and Methodist Centre,<br>Mumbai Central                                    |
| 2-3:30 pm  | <b>Group 1: ETHICS AND END OF LIFE</b>  | HALL - 1 (YMCA ground floor)  |
|  | <b>Chair: Avinash Supe</b> , G S Medical College and KEM Hospital, Mumbai   |   |
|  | <b>1. Varsha Aithal</b> - <i>Death in the era of high- tech health care: the concept of death under Indian law</i>  |   |
|  | <b>2. Samar Jha, Sneha Jha</b> - <i>Euthanasia: to be or not to be</i>  |   |
|  | <b>3. Ashis K Das, Aravind R Menon</b> - <i>Ethics of physician-assisted suicides: a comparative analysis of India and the Netherlands</i>  |   |
| <b>4. Pierre Laplante</b> - <i>No code/DNR/No CPR Survey</i>                         |   |   |
| 2-3:30 pm  | <b>Group 2: GENDER BASED VIOLENCE AND HEALTH RESEARCH: ETHICAL AND MEDICO-LEGAL ISSUES</b>  | HALL - 2 (YMCA ground floor)  |
|  | <b>Chair: Ramesh Awasthi</b> , MASUM, Pune  |   |
|  | <b>1. Jonathan David</b> - <i>Double jeopardy- domestic violence: a paradigm "seen and heard"</i>   |   |
|  | <b>2. Prabha Chandra</b> - <i>Ethical issues in intimate partner violence research: reflections from the field</i>  |   |
|  | <b>3. Sangeeta Rege</b> - <i>Training for ethical practice in responding to gender based violence: experience of working with a public health system</i>  |   |
| <b>4. Amita Pitre</b> - <i>Medico-legal aspects of sexual assault</i>                |   |   |
| 2-3:30 pm  | <b>Group 3: CLINICAL TRIALS: INFORMED CONSENT AND PARTNER INVOLVEMENT</b>   | HALL - 3 (YMCA first floor)   |
|  | <b>Chair: Mala Ramanathan</b> , Achutha Menon Centre for Health Sciences Studies, SCTIMST, Thiruvananthapuram   |   |
|  | <b>1. Keri Oxley</b> - <i>Informed consent in the Indian context</i>  |   |
| <b>2. K. Mathiharan</b> - <i>Legal aspects of informed consent in vaccine trials</i> |   |   |

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| 2-3:30 pm   | <b>3. Nitin Mane, Seema Sahay</b> - <i>Process of informed consent for AIDS vaccine trial participation in India</i>   |   |
|             | <b>4. Aparna Parkhe, Neelam Joglekar, Smita Joshi, Usha Katti, Sanjay Mehendale</b> - <i>Covert use of microbicides: views of volunteers of 'Praneem polyherbal tablet' phase II trial</i>   |   |
| 2-3:30 pm   | <b>BIOETHICS FILMS</b>   | HALL - 4 (YMCA second floor)                |
|             | <b>Group 4: COMMUNITY AND CULTURAL DIMENSIONS OF RESEARCH</b>  | HALL - 5 (Methodist Centre)                 |
|             | <b>Chair: Suneeta Krishnan</b> , Visiting Faculty, Indian Institute of Management, Bangalore, and University of California, San Francisco, USA   |   |
| 2-3:30 pm   | <b>1. Aditi Iyer, Asha George, Gita Sen, Margaret Whitehead</b> - <i>Negotiating ethics in health equity research: lessons from conducting a household survey in Koppal district, Karnataka</i>  |   |
|             | <b>2. Sajitha OG, Mala Ramanathan</b> - <i>Application of ethical principles with cultural sensitivity: a case study of research in a tribal population</i>  |   |
|             | <b>3. Rajan R Patil</b> - <i>Community-based occupational/environmental health studies in developing countries: the challenges and the dilemmas</i>  |   |
|             | <b>4. Prakash Patole, Vikram Solas, Tejasree Gadgil, Altaaf Mujhawar, Mina Kurlekar, Vandana, Seema Sahay</b> - <i>Community support for biomedical research in HIV/AIDS: gender sensitivities</i>   |   |
| 3.30 - 4 pm | TEA BREAK  | YMCA  |
| 4-6pm       | <b>PARALLEL WORKSHOPS I</b>  | (YMCA and Methodist Centre, Mumbai Central) |
|             | <b>Workshop 1: Ethical guidelines for intensive care units</b>   | HALL - 1 (YMCA ground floor)                |
| 4-6 pm      | <b>Coordinators:</b><br><b>R K Mani</b> , President Elect, Indian Society of Critical Care Medicine, New Delhi<br><b>Nobhojit Roy</b> , Web Editor, <i>Indian Journal of Medical Ethics</i> and Centre for Studies in Ethics and Rights, Mumbai<br><b>Resource persons:</b><br><b>Farhad Kapadia</b> , Hinduja Hospital, Mumbai<br><b>Mathew Joseph</b> , Christian Medical College, Vellore<br><b>Ram E Rajagopalan</b> , President, Indian Society of Critical Care Medicine and Sundaram Medical Foundation, Chennai  |   |
|             | <b>Workshop 2: Perspectives in feminist bioethics on new reproductive and genetic technologies</b>   | HALL - 2 (YMCA ground floor)                |
| 4-6 pm      | <b>Coordinator:</b><br><b>NB Sarojini</b> , SAMA Resource Group for Women and Health, New Delhi<br><b>Discussant:</b><br><b>Rupsa Malik</b> , Programme Director, Centre for Health and Gender Equity (South Asia), New Delhi<br><b>Resource persons:</b><br><b>Lakshmi Lingam</b> , Professor, Tata Institute of Social Sciences, Mumbai<br><b>B Ekbal</b> , Consultant Neurosurgeon and KSSP, Kottayam, Kerala<br><b>Manjeer Mukherjee</b> , SAMA Resource Group for Women and Health, New Delhi<br><b>Puneet Bedi</b> , Consultant Gynaecologist, Apollo Hospital, New Delhi<br><b>Amit Sengupta</b> , Delhi Science Forum, New Delhi   |   |
|             | <b>Workshop 3: Ethical issues in international health research</b>   | HALL - 3 (YMCA first floor)                 |
| 4-6 pm      | <b>Coordinator:</b><br><b>Abha Saxena</b> , Staff Scientist, Research Ethics Review Committee, WHO-Geneva<br><b>Resource persons:</b><br><b>Alex Capron</b> , Director, Ethics, Trade, Human Rights and Health Law, WHO, Geneva<br><b>Dan Wikler</b> , Professor of Population Ethics, Harvard School of Public Health, USA<br><b>Richard Cash</b> , Department of Population and International Health, Harvard School of Public Health, USA<br><b>Mala Ramanathan</b> , Achutha Menon Centre for Health Science Studies, Sree Chitra Tirunal Institute of Medical Sciences and Technology, Thiruvananthapuram<br><b>Amar Jesani</b> , Centre for Studies in Ethics and Rights, Mumbai |   |
|             | <b>Workshop 4: Religious perspectives on bioethics and the role of faith-based organisations in health care</b>  | HALL - 4 (YMCA second floor)                |
| 4-6 pm      | <b>Coordinator:</b><br><b>Jagruti Waghela</b> , Lokmanya Tilak Medical College and Municipal General Hospital, Mumbai<br><b>Resource persons:</b><br><b>Nabeel M K</b> , Kannur Medical College, Kerala<br><b>Stephen Fernandes</b> , St Pius College, Mumbai<br><b>H Sudarshan</b> , Vivekanand Girjan Kalyan Kendra, BR Hills, Karnataka   |   |
|             | <b>Workshop 5: Bioethical issues in truth telling at the end of life</b>   | HALL - 5 (Methodist Centre)                 |
| 4-6 pm      | <b>Coordinator:</b><br><b>Jacob Alexander</b> , Consultant Psychiatrist, Palliative Care Unit, Christian Medical College, Vellore<br><b>Resource persons:</b><br><b>Deepa Braganza</b> , Consultant Psychiatrist, Chronic Pain Unit, Christian Medical College, Vellore<br><b>Basanth Kumar</b> , Tutor in Psychiatry, Christian Medical College, Vellore<br><b>I Hamilton</b> , Chaplain, Palliative Care Unit, Christian Medical College, Vellore  |   |

## PARALLEL PAPER PRESENTATIONS I: ABSTRACTS

### **Group 1: ETHICS AND END OF LIFE**

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#### **1. Death in the era of high-tech health care: the concept of death under Indian law**

*Varsha Aithal*

Death has been described as a process, not an event. Where one has lost all the signs of life, it is believed that such a process has already begun. The problematic question is: how does one end such a life with dignity? Who can end life? The determination of death is linked to the withdrawal or withholding of life-sustaining treatment, which can only be carried out after the patient has been declared legally dead. The doctor's role as healer is now coupled with the obligation to alleviate suffering and promote effective palliative treatment which may, foreseeably, hasten death. This change of role is attributed to the emergence of high-tech health care.

The legally accepted criterion of death is "brain death". Whole-brain theorists hold that a person can die only if he ceases to function as a "biological organism," which cannot occur till his entire brain stops functioning. The theory states that, as the brain is the regulator, it is only beyond the point of collapse of the brain that other systems cannot survive, with or without mechanical ventilation. The argument of the higher brain theorists is that since the capacity for consciousness is essential for existence, the absolute loss of the conception of "selfhood" among patients in a persistent vegetative state is sufficient for the declaration of death.

The Indian law's silence on this aspect is baffling. The judicial exposition on the withdrawal or withholding of medical treatment is unclear. However, the right to die with dignity has been recognised as part of the right to life in the case of a dying person who is terminally ill or in a permanent vegetative state. Indian law guarantees the right to a dignified procedure of death when death due to termination of life is certain and the process of natural death has already commenced. It does not guarantee the right to curtail the natural span of life.

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#### **2. Euthanasia: to be or not to be**

*Samar Jha, Sneha Jha*

Recently, in Hyderabad, Venkatesh, suffering from muscular dystrophy that left him paralysed from the neck down, pleaded to die. Unfortunately his plea was rejected, and he ultimately died a slow, painful death.

From time immemorial concerns have been expressed about what is probably the oldest medical problem in the world - dying with dignity. Has the time come for people to decide whether or not they can die with dignity? With constitutional

rights like the right to privacy and the right "to be left alone" coming into the picture, people have become anxious to see that death is not a humiliating and disgraceful experience. This is what euthanasia is all about. This paper goes into the legal intricacies of euthanasia.

In this paper, we have tried to present the Indian perspective on euthanasia and also propose suggestions to the problem regarding the ethics of euthanasia. The paper is divided into three sections:

The first delineates the current legal status of euthanasia in India, and its constitutional validity, asking the question of whether it can come within the ambit of a "right to life"; and also mentioning the constitutional debate between the "right to die" and "right to life".

The second part looks into both sides of the argument, the holistic view of the 'hardliners' propagating euthanasia and the other ethical side of the argument proposing penal provisions for it, even for passive euthanasia.

The last part makes suggestions, incorporating safeguards to prevent the exploitation and misuse of the practice, including the institution of a panel of experts to judge each case by its merits and also looking into foreign legislation (such as the Dutch Penal Code in the Netherlands) with statutes legalising euthanasia.

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#### **3. Ethics of physician-assisted suicide: a comparative analysis of India and the Netherlands**

*Ashis K Das, Aravind R Menon*

Through the ages, the role of the physician has inextricably been linked with the process of protecting and preserving life. This view does not address the quality of a patient's life. Technological advancements have not been entirely successful in eliminating pain or improving the quality of life. Over the years, patients have also become increasingly concerned about their own individual autonomy. As most commonly defined, patient autonomy points in the direction of personal liberty of action in accordance with a plan chosen solely by him or her. A natural extension of the principle of autonomy in health care confers upon patients the right to refuse treatment at times, in effect allowing them the option of terminating their own lives. The right to die with dignity is increasingly being seen to be as important as the right to life, an integral human right. The issue of Physician Assisted Suicides (PAS) assumes significance in this setting, as the doctor seems to be the most logical option to assist in the process of termination. As of today, PAS has been legalised in three countries - the Netherlands, Switzerland and Belgium. It is illegal in India, as interpreted by Article 309 of the Indian Penal Code.

It is proposed to study five cases of voluntary termination of life in India from 1985 to 2005 and to contrast them with comparable cases in the Netherlands during the same period. The study is designed to analyse the ethical implications of PAS in the Indian legal framework.

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#### **4. No code/ DNR/ No CPR survey**

*Pierre LaPlante*

Objective: There is a significant relationship between the "code status" (No Code/No CPR/ DNR-DNAR) of a patient, and the medical interventions and measures considered and provided. In turn, this is relevant to the provision of palliative or end-of-life care. In the Muslim world, it is not known or not documented (as research) whether variances exist between the nursing, physicians' and social workers' professions on the determinants of No Code/ No CPR/ DNR-DNAR. The questionnaire survey is to reflect three categories: personal, professional and cultural values. The participants (anonymously) are asked to rate (scale of 1-5) portions of code policies from different (anonymous) hospitals in different (anonymous) countries. Islam is common to all the participants. If cross-professional and cross-cultural variances exist, it is not known how strong these variances might be; or whether these variances are based more on Islam or on the respective cultures - ethnic or professional - or how these may be reflected (and function) in their practices. The ultimate purpose is to discern whether differences exist in Islam and its expression in different cultures, which might affect the provision of end-of-life or palliative care to Muslims, both in Canada and globally. This survey constitutes the first step in planned two-pronged research studies of Muslim health care practitioners and of Muslim populations. The staff at KFSH&RC comprises people from 60 countries. Among these, the presence of Muslim professionals from a variety of countries provides a rich resource for the conducting of such a study. This presentation will also address the problems encountered in attempting to explore this topic and to provide evidence-based research in an Islamic setting.

Paper: Presentation of preliminary results of 149 completed surveys (13% of distributed number)

Implications: (1) Evidence-based research demonstrating diversity among Muslim health care practitioners regarding end-of-life or palliative care: suggesting "culture" as a distinguishing factor. (2) Evidence-based research addressing potential variances in the decision-making process among multicultural healthcare professionals/teams.

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### **Group 2: GENDER BASED VIOLENCE AND HEALTH RESEARCH: ETHICAL AND MEDICO-LEGAL ISSUES**

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#### **1. Double jeopardy - domestic violence: a paradigm "seen and heard"**

*Jonathan David*

The effects of domestic violence compromise the quality of life of both mother and child. In many cases pregnant women commit suicide whereby both the life of the mother and foetus

comes to an end. Death can also occur soon after delivery or even later. The presenter during his nursing practice repeatedly encountered married pregnant women who pleaded for him to terminate their pregnancy. At the same they feared desertion by their husband, harassment by their in-laws, no support from relatives, and social stigma. The MTP Act does not explicitly permit abortion for the reasons of marital disharmony. Thus women in such situations are often denied medical abortion. However, they tend to resort to other sources of abortion leading to an increase in illegal abortions, and peri-natal and maternal mortality. "The paradigm of powerlessness begets death." Are we responsible? How do we deal with it?

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#### **2. Ethical issues in intimate partner violence research: reflections from the field**

*Prabha Chandra*

Research that discusses emotional and safety issues of vulnerable and at-risk populations forces researchers to take cognisance of several ethical issues. Often these issues surface only once the study is well on its way in the field. And despite being cautious in the research design, one is often faced with challenges and dilemmas that might not have easy solutions.

In behavioural research, the disclosure of violence - physical, psychological or sexual - has been reported to have a significant emotional impact, both on the subject and the researcher. Is the emotional support offered to subjects adequate and appropriate? How do researchers in the field feel about their training and skills in handling violence-related disclosure? What happens to the women once the researchers leave the field? How safe do women feel? These are some questions that have been discussed without definite answers.

Based on our experience in research in hospitals and the urban and rural communities in South India, we would like to present findings on the above issues and discuss possible solutions for ethical conduct of research on violence with women with special reference to its emotional impact.

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#### **3. Training for ethical practice in responding to gender-based violence: experiences of working with a public health system**

*Sangeeta Rege*

The focus of the health care system is on cure. The budget allocation for public health is dwindling. Yet most women facing domestic violence approach the public health system for treatment of injuries arising out such violence. In such a situation, health care providers play a unique role in responding to women.

Despite this crucial role of health care providers, their training curriculum does not address this issue. Added to this are their own perceptions of women living in violent situations. These have class, caste, gender and religious biases. Hence they fall short in screening, referring or even documenting the history of violence.

Dilaasa is the first initiative in India to have collaborated with a public health system in order to humanise and sensitise it to respond effectively to women facing domestic violence. The Dilaasa team was involved in in-depth interviews of health care providers (HCP) at all levels, systematic observations of interactions between HCPs and patients, and study of medico-legal registers at the hospital. The compilation indicated strong communal, class and gender biases amongst them.

There is a need to orient health care providers to understand the linkage between gender-based violence its health consequences, and the pivotal role that they can play in addressing this issue. Dilaasa is now accepted as a department of the hospital. It has established credibility through dialogue and capacity-building trainings. The public health system must institutionalise a training cell to ensure systematisation of training of HCPs in relation to gender-based violence. A cell would also ensure that it would be sustained within the public health budget. CEHAT, the partner NGO in the pilot project would be involved in the capacity building of the cell. The other aspect of training is also institutionalising perspectives on gender-based violence and the role of HCPs in addressing gender-based violence in medical education. This paper advocates training as a method in advocating the HCP's role in responding to women facing gender-based violence.

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#### 4. Medico-legal aspects of sexual assault

*Amita Pitre*

An important aspect of a physician's role is medico-legal work. This involves documentation of evidence in cases of assault, accidents, suicide, homicide, etc. It also helps courts understand the physical and emotional condition of the victim. Sexual assault is one such crime where medical evidence is crucial. We have tried to look at medical evidence presented to the courts and also at what the court had to comment on this. This was done in order to measure of the quality and appropriateness of response and also to better understand the role of such evidence in deciding the judgment. This is not to say that such observations are sufficient, either to judge the quality of evidence or to opine on what the doctors are supposed to do and how well or badly they are doing it. But taking a first-hand look at these observations is insightful and gives directions for further research.

This paper will look at judgments regarding sexual assault, primarily those from the Supreme Court. They will be examined with regards to the medical evidence presented. In some places the courts had very specific comments to make on the quality of the medical evidence, where doctors have been called "pro-accused" and without a conscience.

We have also tried to look at the actual evidence presented by the doctor. This clearly is what the courts were seeking a medical opinion on. Does it help the courts to draw an opinion? Is the doctor's evidence and opinion in tune with what the courts expect them to testify? Do these in fact hinder instead of help the courts? We know that law enforcement agencies work in a framework of patriarchy, and may deny basic justice to female

victims simply because of their perspective. Does medical intervention then come as a relief for the victim or add to her woes? We have tried to look at all these issues in this paper. We expect them to shed light on this neglected sector of medical ethics.

### Group 3: CLINICAL TRIALS: INFORMED CONSENT AND PARTNER INVOLVEMENT

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#### 1. Informed consent in the Indian context

*Keri Oxley*

The prevalence of a variety of diseases in a diverse population and the availability of competent physicians make India an attractive site for international collaborative research. However, on the research ethics front it is a challenging setting. This is due to the vast differences between the western and Indian socio-cultural contexts, the different perspectives of personhood and decision-making; much of the bioethics discourse is premised on the western philosophy. One such area of concern is informed consent. Although international and national ethical guidelines, such as those of CIOMS and the ICMR, have provisions for implementing the western demand for informed consent in cross-cultural settings, there are several issues around the choice of an appropriate methodology. The main focus of this study is to determine the aspects of Indian culture which conflict with the philosophical foundation and protocol guidelines for informed consent in community-based research. The primary objective is to develop culturally relevant modifications to the informed consent process, specifically applicable to Indian community research.

The insights and findings are based on an in-depth review of international and Indian literature on informed consent and about 20 expert interviews with individuals involved in developing the CIOMS International Guidelines, and the ICMR Guidelines. Additionally, leading physicians, philosophers, ethicists, principal investigators, researchers, and other academics were also interviewed. The institutions covered are: CMC Hospital, Vellore; AIIMS and ICMR, New Delhi; SJMC, Bangalore; CSER, Mumbai; GSMC, Mumbai and others from Pune, Chennai and Kolkata and participants at the ICMR Bioethics Conference, Thiruvananthapuram.

The data bring out that gender dynamics, the family unit, financial constraints, and religion influence the researcher-participant relationship as well as the decision-making processes. Based on the insights gathered, the study proposes innovative ways to address issues around informed consent, such as the use of recorded verbal consent, educating research participants on rights, obtaining family consent, and ensuring that the person soliciting consent and the participant are of the same gender and socioeconomic status. The findings allow novel solutions to informed consent to aid cross-cultural research.

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#### 2. Legal aspects of informed consent in vaccine trials

*K Mathiharan*

Context: The Helsinki Declaration requires that researchers obtain written informed consent from human subjects before

involving them in any vaccine and drug trials. This paper deals with some of the legal issues that confront medical researchers and practitioners of medicine in India concerning the legal age to give informed consent.

**Main observations:** In India, medical practitioners are traditionally held in high esteem and it is not uncommon for patients to have blind faith in their physician. This fact, coupled with the availability of a vast illiterate and semiliterate population, often encourages people conducting vaccine trials involving human subjects to be complacent about adhering to legal and ethical guidelines in getting informed consent.

To complicate the issue, the legal age to give consent and the age at which the "right to confidentiality" can be asserted is yet to be defined either statutorily or by the courts. Finally, there is no effective monitoring for legal and ethical violations in clinical research involving living persons.

**Conclusion:** To strictly implement and monitor legal and ethical guidelines, a statutory body with adequate powers to punish violations in experiments involving human beings should be constituted. Appropriate amendments to existing statutory law with reference to consent should be introduced.

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### **3. Process of informed consent for AIDS vaccine trial participation in India**

*Nitin Mane, Seema Sahay*

Successful administration of informed consent in a population of great socio-cultural and linguistic diversity can be a challenge. The paper discusses the systems and processes conceptualised to maintain the spirit of informed consent seeking during the first Phase - I AIDS vaccine trial in Pune, India.

A national level expert group with a wide range of expertise was set up to develop the structure, content and language of the consent forms and the mechanism of administering the process. Two types of consent forms, one each for screening and enrolment, were formulated. We adopted a three-step process for eligibility screening to enable appropriate education of potential volunteers. This was mandatory for all potential volunteers. As a part of the enrolment consent process each volunteer took a comprehension test comprising six essential and 11 other questions on different relevant topics. Comprehension was considered "complete" for those who answered all the six essential questions and a minimum of seven out of the remaining 11 correctly.

From February 2005 to July 2005, 27 volunteers were deemed eligible for the first Phase-1 preventive AIDS vaccine trial in Pune, India. Of these, 20 finally consented to participate in the vaccine trial. Out of the 20 enrolled individuals, 17 could complete the comprehension test satisfactorily in the first attempt, while three had to repeat the test of understanding once. All the 20 volunteers enrolled so far have completed the required study visits, thereby indicating an adequate understanding of the importance of retention and follow-up. This can be attributed to adequate and effective counselling in the informed consent

process and the pre-screening information and education process.

Our experiences suggest that systematic efforts in developing and administering consent forms which allow opportunities to potential participants to interact with researchers enhances the quality of the informed decision-making process in clinical trials.

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### **4. Covert use of microbicides: views of volunteers of the Praneem poly-herbal tablet Phase II trial**

*Aparna Parkhe, Neelam Joglekar, Smita Joshi, Usha Katti, Sanjay Mehendale*

The vaginal microbicide is a female-controlled option that, in theory, does not require the knowledge or consent of the male partner. We assessed the process of decision-making among participants in a vaginal microbicide clinical trial. This presentation focuses on the possibility of use of a product without the knowledge of the partner and the reasons for such use.

Data are drawn from exit interviews with 30 women who completed trials out of 88 women enrolled with their partners' consent in the ongoing Phase II trial of the Praneem poly-herbal vaginal tablet. Information was collected on the product's characteristics, the partners' role, situations in which the product was used, reasons for participation in the trial, the possibility of the use of any product without the knowledge of the partner and the reasons for such use.

The findings suggest that there were issues related to covert use of vaginal microbicides. As regards the product characteristic, 40 % (12) of the women opined that a "product" that cannot be noticed by the partner would be preferable. Some women did not feel empowered to take a decision on their own; seven preferred to inform their partners; and to 11 it did not matter whether or not the male partner knew about it. Reasons presented favouring covert use were: it can be used if the partner were suspected of having STIs/HIV/AIDS and it could be "adventurous" to use. Women feared that partners would be violent if they noticed that it had been used covertly. Some favoured a joint decision to maintain harmony in the relationship.

Gender inequity affected women's choices regarding a vaginal product to be used to protect themselves. Such "covert usage" of a female microbicide needs to be extensively studied in the Indian cultural context, especially to understand the role of family and couple dynamics, including the possibility of domestic violence, on women's decision-making.

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### **Group 4: COMMUNITY AND CULTURAL DIMENSIONS OF RESEARCH**

#### **1. Negotiating ethics in health equity research: lessons from conducting a household survey in Koppal district, Karnataka**

*Aditi Iyer, Asha George, Gita Sen, Margaret Whitehead*

Health equity research must be just, because it involves examining power structures and their impact on marginalised

groups. Such research must also safeguard ethics, as it is a mediated process itself imbued with its own power relations. In principle, the ethical principles governing the conduct of health research should be universally applicable. In practice, however, ethical principles and guidelines cannot be literally translated without prior knowledge of the social context. Moreover, there is no straightforward application of ethical precepts into action; rather, ethics have to be negotiated through the webs of power that define social and health inequities.

Social and health differences are captured more accurately when marginalised individuals get opportunities to voice their needs and experiences freely. This requires considerable ingenuity in safeguarding privacy and confidentiality and creating safe spaces for individual articulation. In applying these strategies, moreover, researchers may need to be more nuanced and sensitive to local contexts and the power relations therein. When seen in this way, the concern for ethics in equity research has methodological implications that impact upon data quality and the relationships between interviewers and respondents.

These observations are based on our experience of conducting a household survey on health care access and affordability in Koppal district, northern Karnataka. The survey of 1,920 households, aimed to examine the crosscutting axes of caste, class, gender, and age and life stage. In our presentation, we intend to highlight questions, as much as to share insights, from our research in 60 villages of Koppal, a poor, drought-riddled agrarian region characterised by high illiteracy and adverse gender and caste hierarchies. It would also present other critical reflections from our survey which highlights how power differentials among various constituencies in the research setting challenge research ethics principles, and what implications it has for the data gathered.

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## 2. Application of ethical principles with cultural sensitivity: a case study of research among a tribal population

*Sajitha OG, Mala Ramanathan*

There is great heterogeneity in culture and practices among the Indian tribal groups. Yet the methods used for application of ethical principles follow a uniform norm. In general, those tribes who remained geographically isolated, in desert, hill, and forest regions or on islands, are able to retain their traditional cultures and religions for a longer period than other groups. But those who had been the subjects of the "integration process" at different stages are alienated from their own way of life which was very much in tune with nature. But they have not yet fully accepted the culture process of the "other". The relationship between these two cultures is not necessarily harmonious and this fact has implications for research undertaken in that setting. Researchers in tribal areas are not at all concerned with the principles of voluntariness and informed consent; apparently it is difficult to apply due to cultural sensitivity or due to ignorance of these principles. The human subject's individuality must be respected and cultural sensitivity must be valued during the research process. There should be measures to ensure non-exploitation while doing research with tribes as subjects.

The objective of this paper is to bring out the need to incorporate cultural sensitivity with ethical principles while doing social science research in tribal areas. Data collected and experiences from the tribal areas of Kerala were used for analysis by giving primacy to the principle of essentiality.

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## 3. Community-based occupational/environmental health studies in developing countries: the challenges and the dilemmas

*Rajan R Patil*

Occupational or environmental health studies are a challenge to execute according to the planned protocols, because of various peculiarities and idiosyncrasies. In work related to infectious disease works, there is a genuine desire for its eradication by the affected communities. There are no vested interest groups working hard to maintain the status quo. The dynamics are different in community-based environmental or occupational health studies. There are the additional dimensions of economic dependence, politics, fear, suspicion, pressure tactics, intense lobbying, etc, during the course of the study. It is not that these communities are unconcerned about their health, but their participation is very tentative in nature. Even after they are taken into full confidence, at the slightest risk they would rather want to play it safe and withdraw, since their economics is at stake. One must not forget vested interest groups who can go to any extent to sabotage good work favouring affected communities.

Researchers in environment or occupational health often find themselves in unenviable situations. It is well documented that this branch of science faces industry pressures to report negative studies and suppress study results antithetical to the interests of industry. Things get further complicated while studying minor working children. The problems start with the gate keepers (literally and symbolically) who refuse to acknowledge the very existence of child labourers.

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## 4. Community support for biomedical research in HIV/AIDS: gender sensitivities

*Prakash Patole, Vikram Solas, Tejasree Gadgil, Altaaf Mujhwar, Mina Kurlekar, Vandana, Seema Sahay*

Introduction: Community support is crucial for the success of a clinical trial. Various strategies need to be developed to involve community and recruitment. Many groups use strategies like advertisements and educational lectures involving the print and electronic media and stakeholders. In the context of a developing and culturally diverse country like India, specific strategies need to be formulated to gain community support and eventual voluntary and correct recruitment for clinical trials.

Method: We tried three strategies at the level of the community to sensitise and educate the community to generate interest in upcoming or ongoing clinical trials at the National AIDS Research Institute, Pune, India. The strategies are: 1. women-only meetings, 2. men-only meetings, and 3. couple meetings. These meetings were conducted as a recruitment strategy for the ongoing HIV Prevention Trial Network preparedness study,

for future microbicide trials in women and for prevention of secondary transmission among discordant couples. The qualitative experiences so gathered pertaining to these strategies are elucidated.

Results: We found that couples were more attentive than men and found decision-making easy, compared to men or women alone. Confidentiality, however, was an issue in the case of individuals opting for covert usage.

Conclusion and recommendations: Partner involvement can facilitate the decision-making process for participation in clinical trials. However, strategies to maintain confidentiality need to be looked into. Couple meetings can lead to a violation of autonomy and this possibility needs to be kept in mind. A positive aspect of couple meetings is that joint decisions address the challenge of domestic violence and create a supportive environment in the family setting.

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## PARALLEL WORKSHOPS I

### **1. Ethical guidelines for intensive care units**

#### **Coordinators:**

**R K Mani**, President Elect, Indian Society of Critical Care Medicine, New Delhi

**Nobhojit Roy**, Web Editor, *Indian Journal of Medical Ethics* and Centre for Studies in Ethics and Rights, Mumbai

#### **Resource persons:**

**Farhad Kapadia**, Hinduja Hospital, Mumbai

**Mathew Joseph**, Christian Medical College, Vellore

**Ram E Rajagopalan**, President, Indian Society of Critical Care Medicine and Sundaram Medical Foundation, Chennai

End-of-life care has come to be viewed as an important index of the quality of care in Intensive Care Units (ICU). In the developed world foregoing of life support takes place in 75-90% of patients dying in the ICU. Data on withdrawal of life support practices in India are few. The concept of limiting life support is relatively new in India and, until recently, no professional guidelines were available. Moreover, in the absence of legal guidelines, doctors are circumspect about advising withdrawal of life support.

Vast resources are dedicated to patients undergoing critical care. Such a commitment of resources may be criticised. It can be seen as part of the paternalistic physician behaviour prevalent in ICU practice, behaviour that does not respect a patient's autonomy. Effective end-of-life care would allow more a judicious use of available resources and limit wasteful effort and expenditure.

Limitation of care refers in general to the decision to stop aggressive treatment and restrict support to nutrition and palliative care. Recent US data suggest that about 20% of all deaths occur in ICUs. Earlier studies in 1990 and 1997, reported that there was a limitation of care for 51% and 90% of dying patients, respectively. Pendergast et al, in a 1998 survey of over 6,000 ICU deaths from 131 US centres, reported that there was limitation of care in 77% of them. Similarly, the ETHICUS study from Europe reported an overall limitation of care rate of 76% among dying patients with significant variation between different European countries. This study also revealed that limitations of care were associated with certain demographic factors such as patient age, diagnosis, ICU stay, and geography and religion.

Data from India are limited. Kapadia and colleagues, in a retrospective analysis from four Mumbai hospitals, reported

that between 19% and 50% of dying patients experienced limitation of care. The rate was the lowest from a large public hospital included in the report. The authors noted that the small percentages of limitation of care could be due to a different patient mix (young patients with no chronic illness in the public hospital), or due to futile care given to accommodate the relatives of the patient or to avoid conflict. However, this study lacked demographic analysis. In 2003, Mani reported a 22% limitation rate in a tertiary care centre in New Delhi. However, appropriate limitation of care has been largely ignored in India for lack of judicial, political, and legal support.

The Indian Society of Critical Care Medicine has recently developed a consensus position statement on end-of-life issues for critical care practice. This workshop is designed to highlight the challenges faced in the Indian context. The salient features of the position statement will be discussed in depth.

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### **2. Perspectives in feminist bioethics on new reproductive and genetic technologies**

#### **Coordinator:**

**NB Sarojini**, SAMA Resource Group for Women and Health, New Delhi

#### **Discussant:**

**Rupsa Malik**, Programme Director, Centre for Health and Gender Equity (South Asia), New Delhi

#### **Resource persons:**

**Lakshmi Lingam**, Professor, Tata Institute of Social Sciences, Mumbai

**B Ekbal**, Consultant Neurosurgeon and KSSP, Kottayam, Kerala

**Manjeer Mukherjee**, SAMA Resource Group for Women and Health, New Delhi

**Puneet Bedi**, Consultant Gynaecologist, Apollo Hospital, New Delhi

**Amit Sengupta**, Delhi Science Forum, New Delhi

"Just because we can do something, should we do it?" This question has plagued all of us in the last half of the twentieth century. The fields of reproductive medicine and genetic technologies in particular have faced this question - perhaps more than other specialities.

The workshop plans to look at the ethical dilemmas and concerns posed by the new reproductive and genetic techniques. It proposes to address the debates surrounding these technologies, including methods to prevent or terminate pregnancy (such as implants, injectables and vaccines), techniques to assist conception (such as in vitro fertilisation and the use of donors and surrogates), genetic screening and sex-selection techniques. It will also look at the ethical concerns around research on stem cell and cloning.

The workshop will put forward difficult questions for discussion. Why are hazardous contraceptives such as Norplant and Depo-Provera still available? Who has the power to decide the future of excess embryos created by in vitro fertilisation? Are frozen embryos entitled to inheritance? Can sperm and egg donors demand parental rights? Is it ethical to treat a fit woman for the infertility of her husband/partner? How and why does sex-selective abortion of the "wrong sex" continue in disregard of the law? What are the ethical dilemmas inherent in the debates on cloning, genetic enhancement and so on?

There is a tendency in mainstream debates on technology to leave the science untouched, to consider it separate from technology and from ethics, and to see it in isolation from society as a whole. These separations are artificial, and have served to obscure the most important issues. There is a two-way connection between science and society. Science is shaped by the politics and the mores of society, and it can also reinforce them. We require a more nuanced grammar of ethics to understand the evolving reproductive technologies and growing genetic determinism. The discussions on these issues will help to chart a future course of action.

The workshop will have brief presentations on ethical dilemmas around contraceptive technology, assisted reproductive technology, genetic screening and research on stem cell and cloning. The presentations will be followed by interactive sessions providing space for dialogue and debate.

### 3. Ethical issues in international research (WHO Geneva)

#### **Coordinator:**

**Abha Saxena**, Staff Scientist, Research Ethics Review Committee, WHO-Geneva

#### **Resource persons:**

**Alex Capron**, Director, Ethics, Trade, Human Rights and Health Law, WHO Geneva

**Dan Wikler**, Professor of Population Ethics, Harvard School of Public Health, USA

**Richard Cash**, Department of Population and International Health, Harvard School of Public Health, USA

**Mala Ramanathan**, Achutha Menon Centre for Health Science Studies, Sree Chitra Tirunal Institute of Medical Sciences and Technology, Thiruvananthapuram

**Amar Jesani**, Centre for Studies in Ethics and Rights, Mumbai

There has been a sharp increase in the number of clinical trials - either currently on-going or planned - in India mainly because

of a growing capacity for new drug development by the pharmaceutical industry in India, as well as the opening up of the Indian market for marketing of new drugs by multinational pharmaceutical firms. There is therefore a need to increase the awareness of researchers of the ethical issues in relation to the conduct of trials and of issues relating to the safety and rights of vulnerable populations in such trials, especially in relation to basic principles such as justice, autonomy and beneficence.

In response to this challenge, the Secretariat of the WHO Research Ethics Review Committee is organising a three-day workshop on ethical issues in international health research on November 24 to 26, 2005. This workshop brings together faculty from WHO, Geneva, the Harvard School of Public Health, and India. The workshop offers an opportunity to researchers and IEC/IRB members alike to strengthen their capacity to understand ethical issues in relation to research involving human subjects and to promote and implement international standards for conducting medical research with human subjects as set out in the Helsinki Declaration or the ethics guidelines of the Council of International Organization of Medical Sciences (CIOMS).

The first day of the workshop will be conducted as a one-day satellite workshop of the National Bioethics Conference. It will be devoted to discussion of basic principles of research ethics and how international guidelines can be applied while safeguarding local cultural contexts. (Note: The satellite workshop schedule appears at the end of this section.)

This will be followed by two-hour workshops on November 25 and 26. The first workshop will be devoted to the discussion of the informed consent process and how to (or how not to) prepare informed consent forms. The second day will continue discussions from the first day.

### 4. Religious perspectives on bioethics and the role of faith-based organisations in health care

#### **Coordinator:**

**Jagruiti Waghela**, Lokmanya Tilak Medical College and Municipal General Hospital, Mumbai

#### **Resource persons:**

**Nabeel M K**, Kannur Medical College, Kerala

**Stephen Fernandes**, St Pius College, Mumbai

**H Sudarshan**, Vivekanand Girjan Kalyan Kendra, BR Hills, Karnataka

**Chokhani R M**, Vipassana Research Institute, Igatpuri

Health care workers are trained to have scientific rational thinking and an egalitarian outlook. However, religious beliefs and socioeconomic conditions play a great role in the decision making process of patients. This is often in complete contrast to the processes which influence the decision making of health care workers.

As a result, the decisions of the health care worker can be incompatible with those of the patient. For example a Jain family can be more receptive towards organ donation than a Hindu or Muslim family. In the West, Jehovah's Witnesses refuse transfusions of blood or blood products, because of their

religious beliefs. The health care worker is in a dilemma as he feels that the transfusion can save the life of the patient but he fails to appreciate the decision of the patient. The role of religion in abortion and life and death issues is evident from the heated debates on the subject worldwide. This is also true for issues of organ donation and transplantation. Health care workers cannot override or ignore patients' religious beliefs. Another dilemma occurs when health care workers' own religious beliefs interfere when dealing with patients' health problems.

There are no easy solutions to the ethical challenges in this area. There are not much data on the influence of religious perspectives on health care issues in India though one cannot deny their existence in the decision making process. This workshop serves as a platform to discuss different religious perspectives towards health care issues. It will provide an opportunity to health care workers to express their dilemmas and discuss several processes involved in decision making in health care.

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## **5. Bioethical issues in truth telling at the end of life**

### **Coordinator:**

**Jacob Alexander**, Consultant Psychiatrist, Palliative Care Unit, Christian Medical College, Vellore

### **Resource persons:**

**Deepa Braganza**, Consultant Psychiatrist, Chronic Pain Unit, Christian Medical College, Vellore

**Basanth Kumar**, Tutor in Psychiatry, Christian Medical College, Vellore

**I Hamilton**, Chaplain, Palliative Care Unit, Christian Medical College, Vellore

The extent to which physicians should inform patients of their diagnosis and prognosis poses a difficult decision in clinical settings, especially in cultures like India where published information on this issue is sparse. A survey of the current clinical practice in local institutions reveals that physicians often prefer full disclosure to patients. However, this rarely takes place and often requests by patient relatives for collusion are acceded to. A competent patient's right to know - or not to know - is a cornerstone of today's medical ethics. This forum intends to elicit a discussion on why these rights are still incompletely respected in many countries, especially in India.

This effort is part of a larger initiative by the organisers to amass culture-specific information on truth telling in Indian clinical settings so as to inform our everyday practice. We feel that it is unethical to base such an essential part of everyday clinical practice on so little evidence, as is done currently.

## CONFERENCE PROGRAMME

| TIME                              |   | VENUE   |
|-----------------------------------|---|---|
| <b>DAY TWO, NOVEMBER 26, 2005</b> |   |   |
| 9 - 10.45 am                      | <b>PLENARY SESSION III<br/>ETHICAL RESPONSIBILITIES OF PROVIDERS INVOLVED IN CLINICAL PRACTICE AND RESEARCH</b>   | Rail Nikunj Hall/Auditorium,<br>Railway Officers' Rest House,<br>Mumbai Central |
|                                   | <b>Chair:</b> Dr Veena Shatrugna, Deputy Director, National Institute of Nutrition, Hyderabad<br><b>Co-Chair:</b> Dr Sujith Chandy, Christian Medical College, Vellore  |   |
|                                   | <b>Key-note address 1:</b><br><b>Dr Suniti Solomon</b> , Founding Director, YRG Care, Chennai<br><i>Ethical issues in HIV/AIDS care provision in India</i>  |   |
|                                   | <b>Key-note address 2:</b><br><b>Dr MD Gupte</b> , Director, National Institute of Epidemiology, Chennai<br><i>Ethical responsibilities of researchers involved in clinical trials</i>  |   |
|                                   | <b>Key-note address 3:</b><br><b>Prof Jayashree Ramakrishna</b> , National Institute of Mental Health and Neuro Sciences, Bangalore<br><i>HIV/AIDS policy and priorities: ethical dilemmas</i>  |   |
|                                   | <b>Discussion and responses</b><br><b>Chairperson's remarks</b>   |   |
| 10.45 - 11 am                     | <b>Announcements and transfer to YMCA</b>   |   |
| 11 - 11.30 am                     | TEA BREAK   | YMCA  |
| 11.30 am - 1 pm                   | <b>PARALLEL PAPER PRESENTATIONS II</b>  | YMCA and Methodist Centre,<br>Mumbai Central                                    |
| 11.30 am-1pm                      | <b>Group 1: BIOETHICS IN THE CONTEXT OF DISASTERS AND RESEARCH ON VULNERABLE POPULATIONS</b>  | HALL - 1 (YMCA ground floor)  |
|                                   | <b>Chair:</b> Shalini Bharat, Professor, Tata Institute of Social Sciences, Mumbai  |   |
|                                   | <b>1. Aravind R Menon, Ashis K Das</b> - <i>Ethical practices in provision of relief during disasters: tsunami relief work in Kerala</i>  |   |
|                                   | <b>2. Aasim Ahmad</b> - <i>Humanitarian aid workers or researchers? A misconception far greater than 'therapeutic misconception'</i>  |   |
|                                   | <b>3. Qudsiya Contractor</b> - <i>Research in the context of human rights violations: some ethical concerns</i>   |   |
|                                   | <b>4. Sonali Wayal, Maryam Shahmanesh</b> - <i>Conducting research and intervention among sex workers: some ethical concerns</i>  |   |
| 11.30 am-1pm                      | <b>Group 2: CONCERNS IN COMMUNITY-BASED ACTIVITIES AND PROGRAMMES</b>   | HALL - 2 (YMCA ground floor)  |
|                                   | <b>Chair:</b> Sunita Bandewar, Centre for Studies in Ethics and Rights, Mumbai  |   |
|                                   | <b>1. Tejasree Gadgil, Seema Sahay, Sanjay Mehendale</b> - <i>Increasing community involvement in HIV/AIDS research trials</i>  |   |
|                                   | <b>2. Mufid Baig, Ratnaprabha Bihade, Vikram Solas, Prakash Patole, Mrudula Phadke, Bharati Patil, Tejasree Gadgil, Seema Sahay</b> - <i>Home visits targeted at improving participants' retention in HIV/AIDS clinical research: ethical issues and concerns</i> |   |
|                                   | <b>3. Batool Fatima, Abdul Khalique Ghauri, Hedayatullah Hussaini</b> - <i>Ethical challenges in the implementation of voluntary counselling and testing (VCT) programme in Pakistan and strategies adopted</i>   |   |
| 11.30 am-1pm                      | <b>Group 3: DILEMMAS IN TRANSPLANTATIONS AND TERMINAL CONDITIONS</b>  | HALL - 3 (YMCA first floor)   |
|                                   | <b>Chair:</b> Sanjay Nagral, Forum for Medical Ethics Society and Jaslok Hospital, Mumbai   |   |
|                                   | <b>1. Rituparna Basu Choudhury, Savita Chavan</b> - <i>Ethical and legal issues in cadaver organ donation in India: an institutional experience</i>   |   |
|                                   | <b>2. Sujata Patwardhan, Rujuta Hadaye, Ajit Sawant</b> - <i>Costing of renal replacement therapies</i>   |   |
|                                   | <b>3. Shobha Mocherla</b> - <i>Alive to follow-up (retinoblastoma in children)</i>  |   |
|                                   | <b>4. Ingrid Miljeteig</b> - <i>When context matters more than guidelines in ethical decision making: a qualitative study of how doctors experience withdrawal of treatment in neonatal intensive care units in India</i>   |   |
| 11.30 am-1pm                      | <b>BIOETHICS FILMS</b>  | HALL - 4 (YMCA second floor)  |
| 11.30 am-1pm                      | <b>Group 4: ETHICS TRAINING AND RELEVANCE</b>   | HALL - 5 (Methodist Centre)   |
|                                   | <b>Chair:</b> Anant Bhan, Indian Journal of Medical Ethics and Centre for Studies in Ethics and Rights, Mumbai  |   |

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|---------------|--|---|
| 11.30 am-1 pm | <b>1. Prabha Desikan</b> - <i>Questioning the relevance of ethics</i>  |   |
|               | <b>2. Udaya Mishra</b> - <i>Randomisation: some ethical puzzles</i>  |   |
|               | <b>3. A Nalini, G Srinivas</b> - <i>Formal training in medical ethics is a felt need in undergraduate medical education.</i>   |   |
| 1 - 2 pm      | LUNCH  |   |
| 2 - 3.30 pm   | <b>PARALLEL PAPER PRESENTATIONS III</b>  | YMCA and Methodist Centre, Mumbai Central |
| 2-3:30 pm     | <b>Group 1: ECONOMIC DIMENSIONS OF HEALTH SERVICES AND RESEARCH</b>  | HALL - 1 (YMCA ground floor)              |
|               | <b>Chair: S Srinivasan</b> , LOCOST, Vadodara  |   |
|               | <b>1. Adeel Ahmed and Talha Abdul Rehman</b> - <i>TRIPS and the Indian pharmaceutical sector</i>   |   |
|               | <b>2. Sumit Shrimali, Ashwani K Singh</b> - <i>Medical care marketing: an ethical view</i>   |   |
|               | <b>3. Shubhangi Pathak, Supriya Bijlwan</b> - <i>Reinventing health care to suit the global economy</i>  |   |
|               | <b>4. M K Nabeel</b> - <i>Economic analysis in medical research</i>  |   |
| 2-3:30 pm     | <b>Group 2: ETHICAL ISSUES IN PREVENTIVE HEALTH</b>  | HALL - 2 (YMCA ground floor)              |
|               | <b>Chair: Sanjay Mehendale</b> , Senior Deputy Director, National AIDS Research Institute, Pune  |   |
|               | <b>1. Yash Paul, Angus Dawson</b> - <i>Compensation for polio cases</i>  |   |
|               | <b>2. Angus Dawson</b> - <i>Informed consent and routine childhood vaccination</i>   |   |
|               | <b>3. Sujata Patwardhan, Rujuta Hadaye</b> - <i>Ethics of timely referral of patients</i>  |   |
|               | <b>4. Lucy Riffat Hossain</b> - <i>Bangladesh police laws hampering HIV prevention programme</i>   |   |
| 2-3:30 pm     | <b>Group 3: ETHICAL ISSUES IN NEW TECHNOLOGIES</b>   | HALL - 3 (YMCA first floor)               |
|               | <b>Chair: NB Sarojini</b> , SAMA, New Delhi  |   |
|               | <b>1. Malhia Joshua</b> - <i>Ethical Issues in technology-assisted reproduction and sex selection</i>  |   |
|               | <b>2. Kamayani Mahabal</b> - <i>Sex-selective abortions unethical: convergence of feminist and disability rights perspectives</i>  |   |
|               | <b>3. Ananya Barua</b> - <i>Decision after detection of Down syndrome: ethical issues</i>  |   |
|               | <b>4. Sangeeta Udgaonkar</b> - <i>The ethics of human stem cell research</i>   |   |
| 2-3:30 pm     | <b>Group 4: REGULATORY MECHANISM FOR RESEARCH ETHICS</b>   | HALL - 4 (YMCA second floor)              |
|               | <b>Chair: Sandhya Srinivasan</b> , Forum for Medical Ethics Society, Mumbai  |   |
|               | <b>1. James V Lavery, Adnan A Hyder, Liza Dawson</b> - <i>Development and ethics: a conceptual framework for the oversight of research in developing countries</i>   |   |
|               | <b>2. Brady Beecham</b> - <i>Authority and organisation of Indian clinical trials</i>  |   |
|               | <b>3. Poornima M and others</b> - <i>Necessity of striking a balance between ethical regulations and their implementation during the conduct of clinical trials in HIV/AIDS</i>  |   |
| 2-3:30 pm     | <b>Group 5: RESEARCH ON ADOLESCENTS AND REPRODUCTIVE AND SEXUAL HEALTH</b>   | HALL - 5 (Methodist Centre)               |
|               | <b>Chair: Amita Pitre</b> , Joint Coordinator, CEHAT, Mumbai   |   |
|               | <b>1. Purnima Madhivanan, Mothi Sarvade, Swamy V H, Karl Krupp, V K Nataraj, R Sukumar</b> - <i>A question of consent: reproductive health care and HIV/STD research involving sexually active minors in India</i>   |   |
|               | <b>2. Suneeta Krishnan, Anupama Tantri, Rima Ghosh, Kalyani Subbiah</b> - <i>Ethical dilemmas in conducting reproductive and sexual health research with adolescent girls in rural south India</i>   |   |
|               | <b>3. Asha Kilaru and Akhila Vasan</b> - <i>Ethical dilemmas in researching adolescent reproductive health and sexuality</i>   |   |
|               | <b>4. Rajalakshmi</b> - <i>Informed consent in reproductive health services: results of a study conducted among private and public health care institutions in Chennai</i>   |   |
| 3.30 - 4 pm   | TEA BREAK  |   |
| 4 - 6 pm      | <b>PARALLEL WORKSHOPS II</b>   | YMCA and Methodist Centre, Mumbai Central |
| 4-6 pm        | <b>Workshop 1: Ethical controversies in day-to-day clinical practice</b>   | HALL - 1 (YMCA ground floor)              |
|               | <b>Coordinators: Sanjay Nagral</b> , Forum for Medical Ethics Society and Jaslok Hospital, Mumbai<br><b>Sanjay A Pai</b> , <i>Indian Journal of Medical Ethics</i> , Mumbai<br><b>Resource Persons: Nilesh Bakshi</b> , Senior family physician, INCHES Foundation, Mumbai<br><b>Arshad Ghulam Mohamed</b> , Surgeon, Association of Medical Consultants, Mumbai<br><b>Ratna Magotra</b> , Cardiac Surgeon, Mumbai<br>Association for Consumer Action in Safety and Health |   |

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|--|---|------------------------------|
| 4-6 pm   | <b>Workshop 2: Sex selection: making doctors accountable, from rhetoric to action</b>   | HALL - 2 (YMCA ground floor) |
|  | <b>Coordinator:</b> Sabu George, Centre for Women and Development Studies, New Delhi<br><b>Resource persons:</b> Akhila Sivadas, Centre for Advocacy and Research, New Delhi<br>Sabu George, Centre for Women and Development Studies, New Delhi<br>Elizabeth Vallikad, St Johns Medical College, Bangalore<br>Puneet Bedi, Apollo Hospital, Delhi<br>Kamaxi Bhate, G S Medical College and KEM Hospital, Mumbai<br>J Sesha Reddy, Ramchandra Reddy People's Polyclinic, Nellore<br>Arvind Kumar, IAS, District Collector, Hyderabad<br>Shilpa Bala, <i>The New Indian Express</i> , Bangalore<br>Asavari Sant, Parivartan, Belgaum |                              |
| 4-6 pm   | <b>Workshop 3: The role of the Community Advisory Boards(CABs) in clinical trials and clinical care in HIV/AIDS</b>   | HALL - 3 (YMCA first floor)  |
|  | <b>Coordinator:</b> Sanjay Mehendale, Senior Deputy Director, National AIDS Research Institute, Pune  |                              |
|  | <b>Organisers:</b> National AIDS Research Institute, Pune; in collaboration with YRG-CARE, Chennai  |                              |
|  | <b>Resource persons:</b> Seema Sahay, Senior Research Officer, NARI, Pune, and Coordinator, CAB of NARI<br>S Swarnalakshmi, IRB/CAB/Regulatory Coordinator, YRG-CARE, Chennai<br>Mrudula Phadke, NARI, Pune<br>V N Karandikar, Medical Director, Bharati Vidyapeeth, Pune and Chairperson, CAB of NARI  |                              |
| 4-6 pm   | <b>Workshop 4: Moving towards ethical practice: experiences of one-stop crisis centres</b>  | HALL - 4 (YMCA second floor) |
|  | <b>Coordinators:</b> Padma Deosthali, Coordinator (Designate), CEHAT, Mumbai<br>Theresa Balayon, Women's Crisis Centre, Manila, Philippines   |                              |
|  | <b>Organisers:</b> Dilaasa (Joint project of CEHAT & BMC), Mumbai, in collaboration with Women's Crisis Centre, Manila, Philippines   |                              |
| 4-6 pm   | <b>Workshop 5: Disasters and ethics: Ethical issues in disaster management</b>  | HALL - 5 (Methodist Centre)  |
|  | <b>Coordinators:</b> Shalini Bharat, Tata Institute of Social Sciences, Mumbai<br>Nobhojit Roy, <i>Indian Journal of Medical Ethics</i> and Centre for Studies in Ethics and Rights, Mumbai   |                              |
|  | <b>Resource persons:</b> Katy Gandevia, Tata Institute of Social Sciences, Mumbai<br>Srilata Juvva, Tata Institute of Social Sciences, Mumbai<br>K Sekhar, National Institute of Mental Health And Neurological Sciences, Bangalore<br>Athula Sumathipala, Sri Lanka<br>Aasim Ahmad, Aga Khan University, Karachi, Pakistan   |                              |
|  |   |                              |
| 4-6 pm   | <b>Workshop 6: Ethical issues in international health research</b>  | HALL - 6 (Methodist Centre)  |
|  | <b>Coordinator:</b> Abha Saxena, Staff Scientist, Research Ethics Review Committee, WHO-Geneva  |                              |
|  | <b>Resource persons:</b> Alex Capron, Director, Ethics, Trade, Human Rights and Health Law, WHO, Geneva<br>Dan Wikler, Professor of Population Ethics, Harvard School of Public Health, USA<br>Richard Cash, Department of Population and International Health, Harvard School of Public Health, USA<br>Mala Ramanathan, Achutha Menon Centre for Health Science Studies, Sree Chitra Tirunal Institute of Medical Sciences and Technology, Thiruvananthapuram<br>Amar Jesani, Centre for Studies in Ethics and Rights, Mumbai  |                              |
|  |   |                              |
| Note: this is a continuation of a two-day workshop. Please see the abstract in the previous day's section. |   |                              |

## PARALLEL PAPER PRESENTATIONS II: ABSTRACTS

### **Group 1: BIOETHICS IN THE CONTEXT OF DISASTERS AND RESEARCH ON VULNERABLE POPULATIONS**

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#### **1. Ethical practices in provision of relief during disasters: tsunami relief work in Kerala**

*Aravind R Menon, Ashis K Das*

Natural disasters are extreme, sudden and unexpected events caused by environmental factors. They can cause serious injury to people and damage to property. The relief and humanitarian aid following a disaster is often disorganised and chaotic.

The Indian Ocean tsunami that struck on December 26, 2004, claimed 280,000 lives including 10,000 in India. As expected in the aftermath, a range of non-governmental organisations (NGOs) were involved with relief and rehabilitation efforts in affected areas. The assumption was that the organisations would ensure free and fair relief services. However, this was not the case. A section of the popular press alleged visible instances of caste- and religion-based discrimination in the process of aid disbursement. Human Rights Watch, an international NGO, confirmed these observations.

We propose to examine the dynamics that contributed to this form of discrimination and the ethics of care in this context through a review of coverage in the popular media during December 2004-March 2005, and through interviews with key personnel involved in the provision of immediate relief in the affected areas of Kerala.

Even if, as some commentators argue, disasters are not the time to press for social change, aid agencies must respect the principle of non-discrimination in delivery of emergency humanitarian relief. In cases where private actors perpetrate discriminatory behaviour, it is the government's responsibility to take all possible measures to end such inequity in distribution of relief services and support. At the very least, post-tsunami rehabilitation and development efforts should include public information campaigns (including media) to eliminate religious and caste-based prejudices. The process of rebuilding should involve government officials, political parties, NGO representatives, and community and religious leaders.

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#### **2. Humanitarian aid workers or researchers? A misconception far greater than 'therapeutic misconception'**

*Aasim Ahmad*

Man-made and natural disasters have plagued this world and will continue to plague it. These disasters bring with them not only mayhem and chaos but also hunger, disease and death. Many humanitarian agencies (like MSF, Oxfam to name a few) have been doing commendable work in providing victims of

these disasters with food, shelter and medical aid.

These workers, both medical and social, come across novel situations, resistant diseases and unique combinations of social and medical problems. These novel situations and their solutions (both the right and "not so right" ones) need to be documented so that this new knowledge or "research" can be shared by others when and if they face similar situations.

The concepts of autonomy and free will seem far fetched in these situations and it is presumed that it would be very difficult for these victims to say "No" to the researcher / aid giver. They are likely to have a misconception which would be far greater than the therapeutic misconception between the researcher/physician.

The ethical framework for doing research in disaster situations may be more similar to public health ethics than to clinical/research ethics. However it differs from public health ethics because those doing this research are usually (not always) from another country, they provide food, shelter and medicines, and the population is extremely vulnerable.

The generation of new knowledge or "research" in these situations is essential. Therefore one method to protect participants may be a speedy ethics review done by individuals who have some idea of disaster situations. However, most humanitarian organisations do not have an ethics review mechanism in place. Another resource may be a formation of an independent electronic-based ethics review committee that may review research involving disaster-affected populations.

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#### **3. Research in the context of human rights violations: some ethical concerns**

*Qudsiya Contractor*

Involuntary resettlement is an issue of much controversy. It has usually associated with large dams or mining. Resettlement also takes place due to developmental activities in urban areas. In the urban context, people living in slums are affected due to such changes. They happen to form the city's most vulnerable and marginalised groups. This paper is based on the experiences of working with a slum community in Mumbai that was recently resettled far from its original locality. It poses ethical issues arising from conducting research on human rights violations within the above-mentioned context.

We had not anticipated the mental trauma that women faced due to resettlement. The hardships associated with the resettlement were added onto their already painful lives. As we used mental health assessment tools, women narrated life experiences, which were not necessarily related to the resettlement. Often the interviews would end in women breaking down. Team members were then required to play a dual role of researcher and a person to respond to the women's mental distress.

In another instance, in the course of data collection, the community was faced with a water crisis. Research had to be stopped as all the women had to fetch water. Members from the community expressed their anguish as they expected the team to do something about the situation. The team increasingly felt distressed because they could not resolve the crisis. This situation required the researchers to intervene and address the crisis at hand.

This study raises a number of concerns regarding the ethics of research in situations of human rights violations. This experience tells us that very often when conducting research in such situations the community's expectation from researchers can go beyond the researcher's currently defined role. The paper deals with issues arising from the conflicting roles of researcher and interventionist.

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#### **4. Conducting research and intervention among sex workers: some ethical concerns**

*Sonali Wayal, Maryam Shahmanesh*

This paper describes ethical concerns emerging from the forced eviction of sex workers (SWs) during a study to develop an HIV prevention intervention in Goa. It is based on our experience of participatory research and consequent advocacy for the rights of SWs. The priorities of the community were integrated into our objectives. We became involved with advocacy to protect the rights of the community; we remained with the community during the demolition; and we provided relief in the aftermath.

Baina, home to hundreds of SWs in Goa since 1960s, was demolished in June 2004. During a police cordon in the months preceding the demolition, the community was starved and intimidated through restrictions on mobility.

National and internationally funded HIV-prevention organisations had been working in the area for a decade. The SWs accessed services from these organisations, for condoms, for treatment for sexually transmitted infections and testing for HIV. Despite this the majority of organisations dissociated themselves from the unfolding events and did not actively oppose the demolition.

The events pointed to several ethical failures: (a) The failure to protect participants from harm; (b) the failure to prevent events that increased vulnerability of women to HIV; (c) the inappropriate focus on HIV prevention when the community had different priorities, and (d) the failure to prevent HIV being used to target the SWs.

It also raised broader concerns about a strategy that aims to prevent HIV through targeting marginalised groups. Is it ethical to ignore the plight of the disenfranchised community with whom organisations work? Are the "target groups" merely laboratories where interventions are tested? Do the organisations have an ethical duty to address the structural forms of violence that increase the vulnerability of these groups or are we satisfied with the myopic perspectives of these interventions?

## **Group 2: CONCERNS IN COMMUNITY BASED ACTIVITIES AND PROGRAMMES**

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### **1. Increasing community involvement in HIV/AIDS research trials**

*Tejasree Gadgil, Seema Sahay, Sanjay Mehendale*

Community participation in HIV/AIDS research trials can be enhanced through meaningful involvement of the community and the stakeholders. This might ensure researchers' commitment to conduct high quality research, adhere to ethical norms and protect the community's interests, safety and welfare. This presentation is to share the experiences of the National AIDS Research Institute (NARI), Pune, India regarding the setting up of a Community Advisory Board (CAB) and networking with local NGOs. These are mechanisms to enhance community participation and peer-based community outreach.

NARI has a community involvement plan through which the CAB was constituted by inviting interested members with diverse experiences in community work. They were offered orientation and training. They participated in protocol development, finalisation of informed consent forms, and development of study information material. To involve NGOs, NARI approached groups active in the area of HIV/AIDS in Pune. It conducted a "training of trainers" for two individuals identified by each of these NGOs. A memorandum of understanding was developed with six NGOs who decided to work with NARI in community-based research. From each of these partner NGOs, between 10 and 20 peers were identified and trained.

This approach helped address the community's concerns and related issues around the community's feeling of being used as guinea pigs; and the fear of breach of privacy and confidentiality. It also helped to ensure voluntary participation of recruits; appropriate compensation for participation in trials; and post-trial benefits and services to participants. Such an approach made it possible to have gender-sensitive processes in place.

In sum, various concerns of the community and ethical issues involved in community-based research in the field of HIV/AIDS were successfully addressed through the active involvement of CAB and NGO partners in research. Researchers must find ways to make such established novel community support structures self-sustainable and self-supporting.

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### **2. Home visits for improving participants' retention in HIV/AIDS clinical research: ethical issues and concerns**

*Mufid Baig, Ratnaprabha Bihade, Vikram Solas, Prakash Patole, Mrudula Phadke, Bharati Patil, Tejasree Gadgil, Seema Sahay*

Introduction: Retention in clinical trials is essential to maximise their scientific validity. Home visits are effective retention tools in research studies in India. Social stigma, discrimination and misconceptions associated with HIV/AIDS are major challenges in the retention of participants in prospective studies on HIV/AIDS. The use of home visits for effective retention in these trials raises complex ethical issues.

Concerns or difficulties in home visits: Participants hesitate to provide accurate addresses; they do not notify of changes in address; they do not like enquiries being made and when visited they refuse to reveal their identity to visitors. Research participants are afraid that confidentiality might be breached during home visits. When female participants are visited, spouses, family members and neighbours may have suspicious responses and this could lead to marital and family disputes. Finding the most appropriate time for the home visit can be a challenge. Also, researchers' lack of familiarity with the socio-demographic conditions of the participants might further complicate the situation.

Solutions to facilitate home visits in an ethical framework: Home visits in research trials are recommended for tracking of research participants in resource-poor settings. An assurance should be given that personal information will not be disclosed to unauthorised persons. Procedures should be closely monitored. An adequate comprehension of consent to a home visit, and a clear understanding between researchers and participants about sensitive issues, can minimise problems in the field during a home visit. The researcher should clearly discuss the modalities of how the participants would prefer to have the home visits: the time, the day, the identity the visitor should use for himself/herself and participants and the preferred gender of the visitor. They should also actually decide the reason to be provided by the visitor provide in case they meet any other family member. We feel that introduction of the visitor to the whole research team is helpful. The focus should be on rigorous ethical training of researchers, extensive documentation of the process and careful implementation of the home visit protocol.

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### **3. Ethical challenges in the implementation of a Voluntary Counselling and Testing (VCT) programme in Pakistan and strategies adopted**

*Batool Fatima, Abdul Khaliq Ghauri, Hedayatullah Hussaini*

Voluntary counselling and testing (VCT) is considered a vital entry point to HIV/AIDS services, including prevention, clinical management of HIV-related illnesses, psychosocial and legal support, prevention of mother to child transmission (MTCT), providing access to ARV therapy and assisting in reducing stigma in the community.

Pakistan has recently introduced the concept of VCT and this programme is still in its infancy. It is intended to supplement national efforts to prevent HIV from becoming a concentrated epidemic in vulnerable populations and spreading to the general population. This should also avoid stigmatisation.

The programme is facing ethical challenges. The measures taken are: development of an ethical code of conduct for counsellors and team members, an oath of confidentiality to be taken by counsellors at the time of joining, the development of management information systems which ensures complete confidentiality, and constant supervision and stricter reporting of deviance from the protocol.

Ethical challenges are also faced because of the stigma the illness carries. For this, the centres are being projected as places to visit for a better future. For example, the centres have boards with the message 'Behtar Kal' ("a better tomorrow"). The rising sun from the blue sea forms the logo of these service centres. Also, the programme promotes these counselling care centres as comprehensive counselling care centres.

This strategy has proven to be highly effective. The VCT services are being looked at very positively throughout Pakistan. A large number of clients come to the centre to access the services without fear of stigma. People with HIV are sent to referral services and people are changing behaviour. All this also indicates that this strategy has been effective.

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## **Group 3: DILEMMAS IN TRANSPLANTATIONS AND TERMINAL CONDITIONS**

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### **1. Ethical and legal issues in cadaver organ donation in India: An institutional experience**

*Rituparna Basu Choudhury, Savita Chavan*

The availability of cadaveric organ donation can mean life to individuals with end-stage disease. But it has raised several ethical issues that have affected the success of the programme in India even with the passage of the Transplantation of Human Organs Act in 1994. The Act was meant to pave the way for cadaveric transplants. The experience of working as a transplant coordinator in a private hospital has been used to identify certain medical and legal dilemmas. Who should broach the sensitive topic to the family and when? Should factors like the family's wishes regarding the recipient of the organ, or financial concessions, be considered in a scenario where cadaver organs are scarce and the list of desperate recipients growing? In a medico-legal case, what are the legal concerns for a family should they consent to organ donation? What are the legal loopholes which dilute the effect of the law?

For a cadaveric organ donation, the family of a brain-dead person must be informed that their relative is brain dead and that they are in a unique position to actually help other individuals in their battle for life through their personal tragedy. It is apparent that consultants and professionals like social workers must provide a multi-disciplinary approach. They must raise this delicate issue subject at an appropriate time. Information regarding brain death, organ donation, the procedures involved and the law must be relayed at appropriate times to the family in order to obtain their consent. Medico-legal cases involve the machineries of the judiciary and the police. Medical personnel who are involved in transplant must be knowledgeable about the legalities involved. Finally, organ donations are a matter of ethics, personal and professional, which guide the approach to the bereaved family.

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### **2. Costing of renal replacement therapies**

*Sujata Patwardhan, Rujuta Hadaye, Ajit Sawant*

Introduction: Chronic renal failure is a debilitating disease affecting 90,000 people per year in India. The two options of

treatment include dialysis and transplant. About 3,500 receive a transplant. The rest continue with haemodialysis or probably die waiting on the waiting list.

**Material and methods:** The social and economic profile of patients on the waiting list for transplant and the ethical questions they pose are discussed, highlighting a few case histories.

**Discussion:** The health care system in Maharashtra places emphasis on primary care. Patients receive secondary health care, which would treat chronic renal failure, depending upon four factors: availability, accessibility, affordability and acceptability. The most important factor is affordability. Resource allocation is decided at three levels: by the government, by the institution, and at the level of the patient's family and health care providers. Extraordinary personal expenditure for health care can put the family in a crisis. To a small extent, financial help is provided by the state, the prime minister's fund and NGO support.

It is suggested that all physicians have the following responsibilities: they must contribute to preventive measures to protect and enhance the health of the public; they must contribute to finding long-term solutions by participating in public health and health education activities; they must identify and publicise adverse health practices; they must advocate for improvements in public health services; they must call for the expansion of health resources when they do not meet patient needs. Finally, they must exercise their responsibility for allocation of resource by avoiding wasteful and inefficient practices.

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### 3. Alive to follow-up (retinoblastoma in children)

*Shobha Mocherla*

This paper will provide a sociological perspective in a situation where parents of children who suffer from bilateral retinoblastoma, or eye cancer in both eyes, grapple with the problem of providing palliative care to their child. The paper will be based on interactions with 10 such families who are availing of the treatment at the LV Prasad Eye Institute, a charitable organisation in Hyderabad. The paper seeks to identify how parents come to terms with the diagnosis of cancer in both eyes and to what extent they are alive to the possibilities of life after removal of one eye or both eyes, which is the only possible treatment to save the child's life.

The paper will examine ethical issues at three stages of treatment - saving the child's life, saving the eye, and saving vision. The role of this tertiary eye care centre in ensuring that each family complies with the treatment and follow-up will be examined. The ethics of obtaining informed consent, advising the removal of the eye for saving the child's life and providing incentives to the family to bring the child for treatment in order not to miss a single date with the eye specialist will be discussed.

What role does the family's financial status play in the will to save a child's life? How does a family react when the child develops cancer in the second eye and / or metastasis? How do they seek help when more than one child is affected in the family? Is the

girl child particularly vulnerable in this situation? The paper will also address these questions.

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### 4. When context matters more than guidelines in ethical decision making: A qualitative study of how doctors experience withdrawal of treatment in neonatal intensive care units in India

*Ingrid Miljeteig*

**Background:** Increased knowledge and investment in high-tech health care can lead to improved survival for premature and/or sick newborns. This can also pose ethical dilemmas regarding the limits of treatment. This study aims to explore and describe how Indian doctors experience ethical dilemmas concerning the withdrawal of treatment among critically sick and/or premature neonates.

**Method** Qualitative data from interviews was analysed according to Giorgi's phenomenological approach. Fourteen doctors with various levels of neonatal experience were recruited from two state-owned neonatal intensive care units in India.

**Results:** All doctors reported situations where the question of withdrawal of treatment was experienced as the worst part of their job. They felt they lacked training in how to handle such dilemmas, and some had never talked about ethics before.

They were especially concerned about non-medical considerations that do not feature in current treatment guidelines. The informants stressed their sense of responsibility in situations where they knew that their decisions would influence a family's economy and reputation, the availability of food and education for siblings, other children's access to equipment in the unit, and the use of resources in an underprivileged population. Sometimes resource scarcity - usually a shortage of ventilators - forced them to make decisions about which babies would get the chance to live. Other reported dilemmas include difficulties co-operating with uneducated and poor parents, especially when the doctors sense that the gender of the child influences parents' considerations.

**Conclusion:** While western doctors and literature in ethics seem to focus on the rights and problems of the individual child, Indian doctors tend to refer to contextual consequences, for other children, parents and society. Further research is needed on ethical dilemmas and guideline implementation in different economic, cultural and religious contexts. Development of guidelines on how to prioritise and cope with insufficient resources is also required.

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## Group 4: ETHICS TRAINING AND RELEVANCE

### 1. Questioning the relevance of ethics

*Prabha Desikan*

Ethics is a much-hyped word, particularly in today's milieu. It is politically correct; it refers to the 'right path'; it sounds like we cannot go wrong if we follow it. However - and here is the crux of the issue - what is the right way? Does it remain the same

forever? Does it have different perspectives? Does it change with time?

Over a period of time, we as human beings have become impoverished due to the consequences of our reproductive behaviour. We are confused by religion, ideology and politicians. Exploited by consumerism, we indulge in hazardous lifestyles. How, then, is any one of us qualified to decide what is right for each individual, community or nation?

Bioethics, as an offshoot of ethics itself, is faced with a greater quandary. It deals with life sciences and has to handle time-bound, rapidly changing individual needs on either side of the fence. In such a situation, is it feasible to respect every individual's free will or choice? Does bioethics uphold the rights of one individual at the cost of another individual's choices / rights? Is being ethical without resorting to arbitrary conventions an achievable option? Is it possible to avoid institutionalisation of bioethics?

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## 2. Randomisation: some ethical puzzles

*Udaya Mishra*

Randomisation is a tool for enhancing the scientific merits of a study by reducing bias and increasing the ability to generalise the study findings. However there are complications. It involves the enrolment of subjects and obtaining informed consent. It also brings the psychological and social risks of trial participation. The use of randomisation is therefore referred to as a tool to weigh uncertainty over safety and efficacy. In a case-control circumstance, the control group could be chosen based on the differential premise of randomisation. Such randomisation could be in terms of allocation of patient recruits into the placebo or active treatment groups at random. In fact, the distribution of recruits in group is intended to provide a characteristic balance for scientific validity, while allocation to the placebo or active treatment at random may have no bearing on evaluating the efficacy of the drug.

The immediate puzzle therefore relates to whether or not to randomise high-risk subjects to placebo. A placebo is selected because it is presumed that it will have no effect on the outcome of interest. It also denies the potential benefit of an effective prevention. In addition, recruits at an increased risk of the disease in question might incur the risk of discrimination due to randomisation. Hence, the stage and type of randomisation has to be in conformity with the principle of preventive ethics, which involves preserving the rights of subjects to seek the treatment of choice and/or to withdraw from a trial. Randomisation in principle must ensure an equal chance of benefit/loss. Therefore users of randomisation are to blame for any ethical compromise due to randomisation.

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## 3. Formal training in medical ethics is a felt need in undergraduate medical education

*A Nalini, G Srinivas*

Objective: To analyse the current ways and experience of learning medical ethics by medical students and interns and to

make recommendations, in order to facilitate the planning of a formal ethics curriculum for medical undergraduate students.

Methods: A survey was conducted in four major medical colleges in Tamil Nadu. Data were collected from interns undergoing training after completing a four-and-half-year MBBS course, using a structured questionnaire. 184 participants responded.

Results: 68% of the interns felt that they had opportunities to learn about medical ethics in their MBBS course and were able to discuss ethical issues with the faculty. Most of them cited forensic medicine and community medicine as specialties where they learned about ethical issues. 75% wanted medical ethics as a separate subject because they felt that the study of ethics would have an impact in improving professionalism. The preferred teaching / learning methods were seminars, clinical teaching and lecture. According to most of the interns teaching of medical ethics should continue through all the phases of the undergraduate course. It should cover topics like patient autonomy, ethical theories, codes of medical ethics, the rights and duties of doctors, cost constraints for patients, the collection of fees by doctors, the doctor-doctor relationship etc. Oral presentation, quizzes, and multiple-choice tests were identified as preferred ways of evaluation in clinical practice. The influence of role models was emphasised.

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## PARALLEL PAPER PRESENTATION III

### Group 1: ECONOMIC DIMENSIONS OF HEALTH SERVICES AND RESEARCH

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#### 1. TRIPS and the Indian pharmaceutical sector

*Adeel Ahmed and Talha Abdul Rehman*

The concepts of data protection and secrecy can keep the benefits of scientific advancement away from those who need it the most. Patent laws are believed to contribute to such denial, especially in the pharmaceutical sector. A doctor uses drugs for treatment. Therefore, the legal denial of essential drugs is an ethical issue.

The paper summarises the history of patent laws in India coming up to the latest Patent Amendment bringing in the product patent regime in India. It discusses the concerns of both supporters and opponents of product patents. The harmonisation of patent laws under the TRIPS agreement influences the pharmaceutical sector in India. The product patent regime will have an effect on the health scenario. Reference is made to major threats such as AIDS in developing countries. TRIPS and the new patent regime is likely to affect the pharmaceutical market and influence prices of essential drugs, with the consequent denial of health care to the impoverished in third world countries.

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#### 2. Medical care marketing: an ethical view

*Sumit Shrimali, Ashwani K Singh*

Rapid privatisation of the health care sector has resulted in the application of principles of marketing to health service delivery.

This has serious implications for the nature and quality of health care delivery to different populations.

Using the 4 'P's of marketing - product (services in case of medical care), price, place and promotion - as a framework, we propose to analyse the potential for unethical practices in each stage of the marketing process.

**Product/ services:** Some issues are: wrong and ambiguous information about medical care services; exaggerating risk to patients; representing core medical care and augmented services such as hospitality as equally relevant; creation of unnecessary service demands; the gap between the services required and service delivered; and quality-based branding although quality is not easy to define and evaluate.

**Price:** Some of the critical issues are: high prices of services due to the service provider's own inefficiencies; the promotion of high quality at a high price although quality services can be provided with low prices also; price hikes due to marketing overheads and cut practices (profit sharing plans); and huge differences in the displayed price and billed price.

**Placement:** Some corporate hospitals assure all services to poor and below poverty line patients at reasonable rates or free of cost. But they restrict their entry to the premises, or discourage such use through restrictive and informal but widely practised policies.

**Promotion:** Trust hospitals are sometimes presented as "medical care at an affordable price", resulting in the promotion of tertiary care while reducing access at the primary or secondary level of care. Under-qualified staff are promoted as experts and a free check-up is one of many promotion efforts aimed at increasing the clientele base

This analysis can help us to develop an ethical framework for regulation of the private health sector.

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### 3. Reinventing health care to suit the global economy

*Shubhangi Pathak, Supriya Bijlwan*

Medical tourism is the provision of "cost-effective" private medical care in collaboration with the tourism industry for patients needing specialized treatment. This process is being facilitated by the corporate health sector and the tourism industry. A health tourism destination should have the right blend of many components.

Medical institutions need to be tourism oriented and make attractive service offerings. India is overhauling its health sector in order to attract "medical tourists". There is governmental support in the form of incentives, tax breaks, international health accreditation standards, breakthroughs in insurance coverage for overseas patients, easily available tourist visas, etc.

This paper will examine the viability of promoting private health care units, which are the forerunners of this revolution. The focus shall be on the augmentation of medical tourism industry in India vis- a-vis its impact on the public health system, the

increasing Foreign Direct Investment and joint ventures in this field.

Medical tourism suffers from certain inherent problems. By promoting the idea that medical services can be bought off the shelf from the lowest-priced provider, the government shrugs off its fundamental responsibility to provide comprehensive health care to its citizens. A forthcoming problem would be determination of the culpability and jurisdiction of courts in cases of medical negligence.

We examine the arguments propounded by the policy framers for promoting this industry. Researchers propose to strike a balance between the economic benefits of medical tourism vis-a-vis the adverse effects it will have on the public health care system by taking specialised medical facilities out of reach of the poor. To achieve this target there must be a concerted effort by various agencies besides the health care and tourism industry. We conclude with the benefits of holistic medicine, its popularity in the world of medical tourism and its commercial exploitation.

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### 4. Economic analysis in medical research

*Nabeel M K*

Principles of economic analysis are not new to medical research. A review of the literature shows that in general its use has increased over the years, although not proportionate to the magnitude of growth of medical literature. The dearth is felt in areas that needed it the most, such as the innovative modalities in health care - computer-assisted and robotic surgery and newer therapeutic agents. Apart from quantity, the quality of such analysis is another major concern. Searches for "cost-effectiveness" in medical literature would offer much material owing to the misuse of the term. However, many studies, especially those on newer treatment modalities, do not adhere to the basic analytic principles of cost-effectiveness and cost-benefit.

The paper presents basic concepts and some common analytical methodologies like cost-effectiveness, cost-benefit, cost-utility, and cost-minimisation along with some ethical issues. The critical tasks of any economic evaluation are to identify, measure, value and compare the costs and consequences of the alternatives under consideration. A fundamental concept in economics is that of the "opportunity cost". It measures costs in terms of the foregone alternatives. It is of greater significance to developing countries against the backdrop of increasing globalisation.

This approach permits a reasoned check on unnecessary expenditure and, in turn, resource allocation for more important matters. It would enable researchers to be conscious about cutting down costs. Some standard protocols are to be developed which, if followed, would make it possible to pool the results of many controlled trials and similar studies to arrive at more meaningful and valid conclusions. In the knowledge hierarchy, systematic reviews and meta-analyses are closer to scientific wisdom than individual studies on their own. Such an approach would help individual researchers to be ethically

more sound and responsible towards society in their pursuit for cost-effective solutions, and contribute to universalising equitable access.

## **Group 2: ETHICAL ISSUES IN PREVENTIVE HEALTH**

### **1. Compensation for polio cases**

*Yash Paul, Angus Dawson*

The World Health Organization's programme of polio eradication raises some ethical issues. The pulse polio immunisation programme has been carried out in India since 1995. It was expected that polio would be eradicated by the year 2000. Even after more than 10 years of concerted efforts polio has not been eradicated from India.

Many children are known to have developed polio even after taking five or more doses of the oral polio vaccine (OPV). This indicates that OPV had failed to protect these children against polio. No efforts have been made to identify the reasons for this poor performance by OPV.

OPV can cause paralysis in children because of mutant neurotoxic vaccine polioviruses known as vaccine-derived wild-like polioviruses (VDWL viruses). It is called vaccine associated paralytic poliomyelitis (VAPP). When this occurs in the vaccine recipient, it is called recipient VAPP case. If it occurs in a non-immune contact through secondary spread of VDWL viruses, it is called a contact VAPP case.

The risk of VAPP is very high in children who are immuno-compromised due to disease or drugs. OPV is contraindicated for such children, but as inactivated polio vaccine (IPV) is not available in India, such children are being administered OPV resulting in an unacceptably high incidence of VAPP.

Children who develop polio in spite of taking five or more doses of OPV (where the vaccine had failed to provide protection against polio), or who develop polio because of OPV as a recipient VAPP case or a contact VAPP case, are entitled to adequate compensation.

The polio eradication programme in India is a part of WHO's global polio eradication programme. Policies and strategies regarding the programme are formulated by WHO. Therefore, WHO should be held liable to pay compensation to children who develop polio because of this programme.

### **2. Informed consent and routine childhood vaccination**

*Angus Dawson*

Much has been written in medical ethics over the last 30 years supporting the requirement to gain informed consent before any medical procedure can take place. This paper explores the appropriateness of this idea in relation to routine childhood vaccinations. It is argued that even if we accept that this is an ideal worth aiming for, the empirical literature on informed

consent suggests a number of reasons for caution, if we choose to seek to make this a requirement before vaccination. For example, there is good evidence that there are problems in explaining possible risks of harm and also the nature of individual and population benefits following from vaccination to parents. However, even leaving this empirical issue to one side there might be ethical reasons not to require informed consent in the case of routine childhood vaccinations. This view might be supported by a number of different possible arguments. These different arguments are outlined and critically reviewed as potential justifications for a policy of minimal disclosure. They include appeals to the need to protect others from harm, the best interests of the child, and to the idea of population goods. It is claimed that these arguments have different degrees of success depending upon a range of empirical facts such as the nature of the particular disease and the particular vaccine etc. These arguments are illustrated by a number of examples taken from a comparison of the current routine vaccination policies in India and the UK. It is concluded that a policy of minimal disclosure can be justified in at least some cases given the benefits of herd protection.

### **3. Ethics of timely referral of patients**

*Sujata Patwardhan, Rujuta Hadaye*

Introduction: Ten per cent of the operative workload in the department of urology, LTMGH, Sion, Mumbai, is due to complications of surgeries done elsewhere. On analysing the cause, it is evident that many of them can be prevented. We propose to discuss the problems at various levels and their prevention

Material and methods: Case histories of urological surgeries referred after complication to the department of urology were analysed.

Results: Problems can be seen at various levels. Cases with complication are referred from both qualified and unqualified surgeons, both belonging to the general surgery and urology fraternity. It was noted that they were not abreast of recent techniques and a few attempted to do newer surgical techniques without hands-on training. Time-tested protocols in investigating any disease are not followed and short cuts are taken. A choice of treatment options is not offered to patients and blanket informed consent does not explain the consequences, complications and costs to the patient. Second, patient-related issues include increased costs, man-hours lost, physical and mental strain and organ damage such as nephrectomy.

Conclusion: Detailed verbal and written explanation and informed consent are required. There is a need for audit at all levels to minimise complications. Hands-on training in sub specialties should be conducted at Continuing Medical Education sessions at tertiary hospitals, and teaching institutions should be equipped for this. Written protocols for every disease as practised in the West, to decide investigations, treatment modalities, and referrals are non-existent in India. An organisational approach in the government and the private set-up should decide what services will be provided, who will

provide them (specialists, physicians, general physicians), where they will be provided and the ideal protocol for every disease.

#### **4. Bangladesh police laws: country HIV prevention programme**

*Lucy Riffat Hossain*

The paper presents a critical review of various legislations and the Bangladesh Penal Code 290 from the perspective of high-risk behaviour practising groups for HIV infection in Bangladesh. This includes sex workers, injecting drug users, men having sex with men and hijra communities. It also includes NGO outreach workers, facilitators and counsellors working with these groups for HIV prevention. It highlights how the state apparatus, such as the police, abuses them, affecting the HIV/AIDS prevention programme.

Four laws are looked into: BPC 54 (suspicious activities); BPC 290 (public nuisance); BPC 377 (perverted sexual activities), and the vagabond law. They were chosen since a study found that the police were imparted training in these laws and their implementation.

Section 377 (perverted sexual activities) of the Bangladesh Penal Code, 1860 criminalises "carnal intercourse against the order of nature". It effectively criminalises all forms of sexual intercourse other than penile-vaginal intercourse. BPC 290 (public nuisance) and the vagabond act allow the police machinery to arbitrarily raid, seize money and material belongings, physically assault, torture, and rape sex workers as well as NGO staff. BPC 54 allows them to arrest and detain any person at any time.

Such abuse of the law and constitutional instruments affects the HIV/AIDS prevention programme. For example, the fear of police harassment and the tendency to discriminate reduces the access of these groups to clean needles. Outreach workers feel harassed and therefore discouraged. Section 377, apart from violating the fundamental rights of sexual minorities, has the effect of pushing high-risk sexual activities among MSM underground and causing risky sexual practices.

This suggests the need to revisit the laws and policies for effective implementation of the country's HIV/AIDS prevention programme. During training of the police these gaps should be recognised and discussed. This was initiated in Bangladesh during the police training on prevention of HIV and AIDS in all police training centres. An effective strategy to prevent the spread of the HIV/AIDS epidemic would promote and protect the rights of all.

### **Group 3: ETHICAL ISSUES IN NEW TECHNOLOGIES**

#### **1. Ethical issues in technology-assisted reproduction and sex selection**

*Malhia Joshua*

Until recently, a couple's right to procreate had rarely been questioned. Because of the new reproductive technologies, the question has arisen about whether the right to procreate embraces the right to procreate using available technology

including donor gametes and a host uterus. Procreative libertarians argue that the role of providers is to offer the technology if it is medically appropriate, rather than to make judgments about who deserves to become a parent or how children should be created. They believe in patient autonomy, in each person's right to choose whether and how to procreate. Others feel strongly that when individuals or couples ask for assistance in procreating, care-givers have an obligation to protect the interests of children, even if they are not yet born or conceived.

This paper discusses ethical issues emerging out of the application of reproductive technology. These include issues around: (a) the destruction of unclaimed embryos, danger to the foetus, eugenics, sex selection and weakening of the family; (b) artificial insemination, the moral responsibilities of a sperm donor, the rights of the child born as a result of artificial insemination and the autonomy of the recipient of the artificial insemination; and (c) embryo transfer and surrogate pregnancy, the emotional and psychological trauma for the surrogate mothers and surrogacy as personal convenience.

Additionally, it explores the perspectives of major religious traditions on infertility and technology-assisted reproduction. It looks into the response of doctors in India to ethical issues relating to technology-assisted reproduction.

The paper is based on a literature review and data obtained through interviews with 30 doctors, and a questionnaire administered to 600 practising doctors.

The insights gathered through this study will be an addition to existing knowledge in the area of medical ethics. Medical practitioners and other care-givers will be better informed about the ethical issues involved in their decision-making and better equipped to arrive at ethically sound decisions in consultation with their patients.

#### **2. Sex-selective abortions unethical: convergence of feminist and disability rights perspectives**

*Kamayani Mahabal*

Medical technologies have been manipulated to validate the disenfranchisement of the marginalised, especially women and the disabled. This paper examines sex-selection techniques and their relationship to biased conclusions of sex and ability. Prenatal testing has furthered the medicalisation of pregnancy and childbirth, and also removed decision-making powers from the hands of women.

Prenatal diagnosis forces women to choose between different "types" of babies. Many disabilities are impossible to detect at the prenatal stage. Many disabilities occur at birth, in early infancy or during childhood. Just as feminists abhor the idea of sex selection because of the comment it makes about the relative worth of women in our society, so too people with a disability feel uncomfortable with disability-selective abortion. In recent years, the disability rights movement has attempted to question the ideology that regards abortion as the only option when

prenatal testing reveals a birth abnormality. This ideology is seen to reflect community attitudes that view the lives of people with a disability as tragic, worthless and overly burdensome. While concern has been expressed for the “unborn disabled”, prenatal testing and the ideology behind it are believed to have great implications for the lives and the quality of life of people with a disability. In this paper, I would like to compare and attempt to reconcile approaches made by feminists and disability rights activists to the issue of prenatal testing.

I will examine possible difficulties with these respective positions and how they might be resolved. The paper will further analyse problems associated with a disability rights perspective which does not allow women’s reproductive autonomy. Finally, I will look at the development of a feminist disability rights perspective on prenatal sex selection.

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### 3. Decision after detection of Down syndrome: ethical issues

*Ananya Barua*

While considering an abortion because prenatal testing indicates physical or mental disability, we are dealing with a foetus on the verge of becoming a baby. There can be many ethical questions around these choices people that make. I enumerate some issues.

(a) The diagnostic tests do not say anything about the severity of the challenge or disability. The child may be born with a very mild impairment. Should we kill a baby only on the basis of a probability? (b) The child could grow to become an individual with mild to moderate impairments. Take the example of a certain healthy person who meets with an accident and becomes physically and mentally less valid, and whose degree of invalidity may be more than the individual with the Down syndrome. Would this warrant killing the once-healthy but now-invalid person? (c) From the baby’s point of view, how could one judge between a disadvantaged life and no life at all (Harris, 1985; pp: 147)? (d) A child with Down syndrome in the developing country context may have to resort to begging. Such a life of pain and torture might be worse than no life at all (e) John Harris talks about a ‘happy oblivion’: “It is sometimes said that certain kinds of handicap, particularly severe mental handicap, leave their victims dependent but happy. They perhaps do not understand much of the world, but are capable of enjoying and do enjoy a wide range of physical pleasures and seem to be happy and content with their lives. It is argued that ‘viewed from inside’ so to speak, their existence is happy, so how, it is asked, can it be that they are in any way disadvantaged or have lives that are not worth living?” (Harris, 1985; pp: 148).

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### 4. The ethics of human stem cell research

*Sangeeta Udgaonkar*

Stem cell research is one of the most exciting fields of cutting-edge biology today. It has the potential to revolutionise medical treatment. At the same time, such research gives rise to a number of ethical issues. This paper will set out the ethical issues involved in human stem cell researches, which are being

debated internationally, as also the Indian position on these issues.

India has a number of regulations that would apply to such research. These have been issued by different agencies at different points of time. An analysis of these regulations reveals certain inconsistencies amongst the regulations as well as between different clauses within a single regulation. It is important that such inconsistencies be addressed at the earliest, if India is to take advantage of the scientific possibilities of this area and become a world leader in stem cell research.

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## Group 4: REGULATORY MECHANISM FOR RESEARCH ETHICS

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### 1. Development and ethics: a conceptual framework for the oversight of research in developing countries

*James V Lavery, Adnan A Hyder, Liza Dawson*

The challenges associated with the ethical oversight of human subjects research in low and middle-income countries (LMIC) are complex. They “reflect wider issues surrounding ...development and democratisation ...and cannot be addressed by regulatory processes alone”. There have been few attempts to articulate precisely how broad development challenges and other factors affect the ability of LMICs to develop and sustain the effective oversight of research. The WHO’s Health Research Systems Analysis (HRSA) initiative provides an ideal context for addressing this gap. The main goals of the HRSA initiative are to advance scientific knowledge and utilise that knowledge to improve health and health equity. Its four critical functions are described as stewardship, financing, creating and sustaining resources, and producing and using knowledge. Research oversight has been recognised as one of four components within the stewardship function. The exact elements that are necessary to fulfil this research ethics function in any health research programme may vary from one country to another. Thus, the challenge of describing the elements of research ethics and their relationships to one another has been hampered by the lack of a coherent conceptual framework. We describe a framework that provides an explicit account of the research oversight system as a component of the “stewardship” function of health research systems.

It situates research oversight against the backdrop of development and several broad pathways through which achievements in development impact on effective oversight. It describes some of the factors within these broad domains that might contribute to effective oversight, and therefore deserve consideration alongside the more familiar debates about ethical quandaries in research. It may also guide further research, particularly by developing country researchers and policy makers to study and evaluate aspects of their systems to generate knowledge that can contribute to on-going improvement. The framework may help LMIC to avoid the current situation in high-income countries in which a shortage of data and empirical analyses on research ethics systems hampers effective system evaluation and reform.

## 2. Authority and organisation of Indian clinical trials

*Brady Beecham*

To avoid restrictive regulation and prices in the developing world, clinical trials are increasingly being conducted internationally. To accommodate this, harmonised international standards have been enacted to allow worldwide data collection. In 2005, India amended Schedule 'Y' of the Drugs and Cosmetic Rules to attract clinical trials. However the type of trials and nature of collaborations that will occur is unknown. This paper examines clinical trials already occurring in India to project future trends.

Our data source was the clinicaltrials.gov online database, which includes all trials with at least one US study site since 1997. We surveyed these trials for those with an Indian site. Among these, we collected trial year, sponsor, and number of sites per country. Studies were grouped by sponsor. For each group the average number of study sites and countries, as well as the top 10 most frequent co-host countries were determined. A timeline of trials was compiled.

The search located relevant 32 studies. Of these, international pharmaceutical companies sponsored 21, and US government agencies or universities sponsored the remaining 11; none had an Indian sponsor. Pharmaceutical studies had an average of 77 study sites in 12 countries; eight of their top 10 co-host countries were developed countries. The non-pharmaceutical studies had an average of four study sites and one co-host country; eight of their top 10 co-host countries were developing countries. Since 1997, the number of trials has steadily increased.

International and national regulatory changes fully open India to multi-country trials, but even prior to these changes, both pharmaceutical and non-pharmaceutical trials were occurring. Recent regulatory relaxation may tip the balance of trials from developed to developing countries, but it is likely that control will remain firmly in the developed world.

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## 3. Necessity of striking a balance between regulations and ethical guidelines and their implementation during the conduct of clinical trials in HIV/AIDS

*Poornima M*

"The search for an HIV vaccine is a marathon which requires the commitment of the world's political leaders to make the best science and the best facilities available"

-Anbumani Ramadoss, Union Health Minister

The subject of HIV/AIDS is highly contentious. The bottom line though is the increasing prevalence of the condition within our country and the need to decelerate this trend. India is relatively new to the field of conducting clinical trials in HIV/AIDS. A trial has been pioneered by the ICMR and the International AIDS Vaccine Initiative and approved by the Ethics committee (NARI and ICMR), Drugs Controller General of India and the health ministry of the government of India. It is being monitored according to international standards. This has laid the foundation for clinical trials in HIV/AIDS within the country and has therefore opened a Pandora's box of doubts and questions, both ethical and

scientific.

The success of any clinical study largely depends on the transparency and professionalism practised by a responsible ethics committee and the informed consent process carried out in the trial. Therefore it is necessary to review and understand the regulations and ethical guidelines involved in clinical trials of HIV/AIDS.

We hope to present an analysis of existing laws and guidelines for conducting clinical trials in HIV/AIDS and debate various aspects.

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## Group 5: RESEARCH ON ADOLESCENTS AND REPRODUCTIVE AND SEXUAL HEALTH

### 1. A question of consent: reproductive health care and HIV/STD research involving sexually active minors in India

*Purnima Madhivanan, Mothi Sarvade, V H Swamy, Karl Krupp, V K Nataraj, R Sukumar*

Informed consent is a primary prerequisite for both the ethical provision of reproductive health care and the use of human subjects in research. Although progress has been made in clarifying the consent process in the developed world, little research has been done on whether current procedures are appropriate to local cultural norms and realities in India. Nowhere is this more apparent than in HIV/STD research and care involving sexually active minors. Issues of stigma, early marriage, multiple levels of consent including family and community members, and systemic discrimination against young women seeking reproductive health care all play a part in excluding minors from treatment and involvement in research.

This study explores the consent process in health care institutions providing reproductive health services and in research conducted in Mysore, India. This involves in-depth interviews with key stakeholders including: a) health care workers and doctors providing reproductive health services in public and private institutions; b) minors presenting for reproductive health care services; c) guardians of minors presenting for care; and d) members of institutional review boards responsible for overseeing research involving HIV and sexually transmitted diseases.

The goal will be to see how consent processes affect provision of healthcare and enrolment in research studies. Study results will help identify current gaps in research and healthcare ethics guidelines and help policymakers in drafting more culturally appropriate procedures for India.

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### 2. Ethical dilemmas in conducting reproductive and sexual health research with adolescent girls in rural south India

*Suneeta Krishnan, Anupama Tantri, Rima Ghosh, Kalyani Subbiah*

Adolescent girls, particularly post menarche, are typically a well-guarded and isolated population with limited autonomy in

rural agricultural communities in India. Therefore, conducting sexual and reproductive health research among adolescent girls can pose a number of ethical challenges. In this paper, we describe a key ethical challenge that we faced while conducting a community-based research study of adolescent sexual and reproductive health in rural Karnataka. The ethical challenge was to evolve a procedure for obtaining informed consent that was in line with local socio-cultural norms and laws, while at the same time incorporating principles contained in national and international ethical guidelines for research such as respecting the privacy, confidentiality, and autonomy of adolescent girls. Informed consent was requested at three levels: community, family (parents) and individual (adolescent girls). While this was beneficial in gaining familiarity and support of parents and community leaders, the publicity regarding the content of the research that resulted from the community consent process created considerable anxiety and reluctance among adolescent girls to participate in the study. We discuss our responses to this situation as well as the methodological implications of such ethical challenges. In conclusion, our paper highlights the need to develop context-specific research ethics guidelines, particularly in the case of vulnerable populations such as adolescent girls.

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### **3. Ethical dilemmas in researching adolescent reproductive health and sexuality**

*Asha Kilaru, Akhila Vasan*

Although international guidelines for conducting social science and biomedical research exist, applying these principles to research concerning young people in non-western cultural settings is fraught with tensions. For instance, western societies privilege the individual and "traditional" societies usually function with community consent within community norms. In such societies, young people's autonomy may not be recognised, more so in the case of young women.

In two recent studies undertaken among urban and rural youth in south Karnataka, numerous dilemmas were evident in the practical application of some of the core ethical principles. The paper discusses some of the conflicts experienced in these studies such as: balancing an adolescent's right to participate on one hand and adhering to the guidelines of seeking parental consent on the other; responding to adolescents' urgent need for services for problems and situations that the parents are unaware of; providing compensation while ensuring that it does not become an inducement, and so on.

Further, the changing role of the researcher in long-term, multiple contact studies, especially those involving qualitative

methods, is seldom addressed. There is a need to constantly examine and define the researcher-participant relationship to ensure a common understanding of expectations and consequences of the research. While these were often dealt with on a case-by-case basis, these tensions point to a need for a deeper understanding of the political and cultural context of research, the application of these guidelines in non-western cultures, particularly among youth, and in underprivileged settings where notions of objectivity and social expectations differ considerably.

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### **4. Informed consent in reproductive health services: results of a study conducted among private and public health care institutions in Chennai**

*Rajalakshmi*

There is considerable anecdotal evidence of violations of clients' right to Informed Consent (IC) in India, but there is little research that establishes its magnitude and the ways in which it is denied. This paper explores the issues around informed consent in the context of sterilization services. In that, views and experiences of both clients and service providers have been studied.

The paper is based on an ongoing study on informed consent in the settings of public and private health care facilities in Chennai, Tamil Nadu, India. The data are drawn from exit interviews of clients of sterilisation services (N=240), focus group discussions with women in community settings (N=3), and in-depth interviews with selected clients (N=6) and providers (N=20).

Our data suggest that clients perceive the client-provider interaction as a key element determining the quality of care. Clients are poorly informed of their right to information but appreciate information whenever it is given. Providers lack awareness about their ethical responsibility to seek informed consent from their clients. In the context of sterilisation services, providers are reluctant to discuss the alternatives and the risks of sterilisation. Both, clients and providers perceived a signature on consent forms as a mechanism to provide immunity to service providers against negligence.

These findings have significant implications for policies and programmes. There is a need to popularise informed consent and translate it to measurable indicators. It also indicates the need for ethics training of health professionals and the need to develop jurisprudence for addressing violations as well. One could argue, based on the study findings, that unless women are informed about their rights as clients and providers are sensitised, family planning clients' enjoyment of reproductive rights will not be fully realised..

## PARALLEL WORKSHOPS: II

### 1. Ethical controversies in day-to-day clinical practice

#### **Coordinators:**

**Sanjay Nagral**, Forum for Medical Ethics Society and Jaslok Hospital, Mumbai

**Sanjay A Pai**, *Indian Journal of Medical Ethics*, Mumbai

#### **Organisers:**

Forum for Medical Ethics Society, Mumbai

#### **Resource persons:**

**Nilesh Bakshi**, Senior family physician, INCHEs Foundation, Mumbai

**Arshad Ghulam Mohamed**, Surgeon, Association of Medical Consultants, Mumbai

**Ratna Magotra**, Cardiac Surgeon, Mumbai

#### **Association for Consumer Action in Safety and Health**

Beyond the classical ethical issues which are a part of standard international ethics discourses there are ethical problems faced by peculiar and specific to India. These are often articulated in informal discussions and through the media as "unethical" practices. However, the ethical context has not been well elucidated. Since these are partly related to the increasing commercialisation of medical practice in India, they have become more prevalent in recent years. With medical councils and associations remaining largely silent on these issues it is left to the ethics movement in India to come up with an analysis and critique based on established ethical principles - if, indeed, they apply to these practices. The workshop hopes to do this in the form of a panel discussion with practising doctors, consumer activists and office bearers of medical associations. Some of the issues likely to be covered include fee splitting, advertising in its various direct and indirect forms, the contribution of the relationship between hospitals and doctors in fueling unethical practices and finally the relationship between the pharmaceutical industry and the medical profession.

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### 2. Sex selection: making doctors accountable, from rhetoric to action

#### **Coordinator:**

**Sabu George**, Centre for Women and Development Studies, New Delhi

#### **Resource persons:**

**Akhila Sivadas**, Centre for Advocacy and Research, New Delhi

**Sabu George**, Centre for Women and Development Studies, New Delhi

**Elizabeth Vallikad**, St Johns Medical College, Bangalore

**Puneet Bedi**, Apollo Hospital, Delhi

**Kamaxi Bhate**, G S Medical College and KEM Hospital, Mumbai

**J Sessa Reddy**, Ramchandra Reddy People's Polyclinic, Nellore

**Arvind Kumar**, IAS, District Collector, Hyderabad

**Shilpa Bala**, *The New Indian Express*, Bangalore.

**Asavari Sant**, Parivartan, Belgaum.

Sex selection (female foeticide) is an extreme form of violence against women. Girls are not allowed to be born as a result of misuse of technologies by unethical medical professionals. Foetal sex determination started from the early 1970s in Gujarat and Delhi. The first substantive campaign against sex selection took place in Mumbai during the mid-1980s. This resulted in the enactment of the PNDT Act in 1988 by the state government. Another milestone was the passing of the national law by Parliament in 1994. However, both in Maharashtra and in the country as a whole, after the passing of the laws there was practically no implementation of the law and even less concern in civil society to stop this heinous crime. Given this indifference, there was extensive promotion of the modern technologies of sex selection. Punjab, Haryana and South Gujarat, among the regions where these technologies took deep root in the 1980s, had reported child sex ratios of below 900 girls (for every 1,000 boys) in the 1991 Census. Activists and demographers ignored this early warning. However, due to the efforts of civil society organisations, the Supreme Court, the 2001 Census authorities, and the Union Health Ministry there has been much discussion in the country about the rapidly declining child sex ratio against girls for the past five years. While recognising these recent developments, the inadequacy of all this to stop the decline in the coming decade must be recognised. This workshop will address the most important professional group involved in the act of eliminating girls before birth.

CWDS has been working with doctors to foster medical ethics for the past four years. We started with Karnataka in 2001 and in 2002 initiated efforts in Andhra Pradesh. We have worked with Vimochana, Jana Vignana Vedike and Parivartan to mobilise ethical doctors and medical associations in workshops. This workshop also highlights the context and specific actions taken by other stakeholders: the district administration, media and activists. We believe that it is imperative in a national conference, where there will be a lot of teaching and preaching of ethics, to show specific examples of how the mass malpractice of sex selection can be dealt with. This workshop will also energise our ethical doctors to move forward so as to take steps to stop the collusion between the silent doctors and the practitioners for whom sex selection is good business.

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### 3. The role of Community Advisory Boards in clinical trials and clinical care in HIV/AIDS

#### **Coordinator:**

**Sanjay Mehendale**, Senior Deputy Director, National AIDS Research Institute, Pune

#### **Organisers:**

National AIDS Research Institute, Pune; in collaboration with YRG CARE, Chennai

**Resource persons:**

**Seema Sahay**, Senior Research Officer, NARI, Pune, and Coordinator, CAB of NARI

**S Swarnalakshmi**, IRB/CAB/Regulatory Coordinator, YRG-CARE, Chennai

**Mrudula Phadke**, NARI, Pune

**V N Karandikar**, Medical Director, Bharati Vidyapeeth, Pune and Chairperson, CAB of NARI

Introduction to Community Advisory Boards (CAB): It is being increasingly felt that members representing various sections of the community should be actively involved in research planning and implementation both as direct and/or indirect stakeholders. They should act as effective bridges between researchers and communities. CAB can sensitise researchers to local issues and community concerns that can impact the implementation of the research agenda. CABs can also help researchers to disseminate information and research findings in the community. CAB members can draw from their professional as well as personal experiences to help the community understand various aspects of research, and ensure community engagement and involvement in biomedical research.

Objectives of the workshop: (1) To introduce the concept of CAB and its possible role in biomedical research; (2) to assess the CAB members' perceived role, expectations, commitment and sense of involvement in research; (3) to understand the investigators' perspective of effective CAB involvement in research; (4) to provide a forum for interaction between the audience, researchers and CAB members

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#### **4. Moving towards ethical practice: experiences of one-stop crisis centres**

**Coordinators:**

**Padma Deosthali**, Coordinator (Designate), CEHAT, Mumbai  
**Theresa Balayon**, Women's Crisis Centre, Manila, Philippines

**Organisers:**

**Dilaasa** (Joint project of CEHAT and Bombay Municipal Corporation), Mumbai, in collaboration with Women's Crisis Centre, Manila, Philippines

Violence against women is gradually being recognised as a health care issue. There have been several efforts made in the past decade to create awareness amongst health functionaries about violence being a health care issue. In many countries such efforts have paved the way for diverse interventions. Some to mention are developing protocols for health professionals for documenting cases of abuse, developing training curriculum for training of health care providers (HCPs) on the issue, and setting up services for victims of violence.

In South and South-east Asia, such efforts have led to setting up of a number of one-stop crisis centres in public hospitals. These were conceptualised with the understanding that the health system is often the first contact for any victim of violence and therefore it must be geared to respond to the specific needs of the survivors. These centres have been engaged in training of HCPs as well as providing social and psychological support

to women victims of violence. The experience of running such centres has been varied but the processes of humanising the system through these efforts have thrown up several issues and dilemmas to deal with. The reality is that health professionals are not trained to respond to violence and therefore the training has to address the resistance, the lack of awareness and their biases based on gender, class and religion.

Through this workshop, Dilaasa - the joint initiative of the Centre for Enquiry into Health and Allied Themes (CEHAT) and the Bombay Municipal Corporation in collaboration with the Women's Crisis Centre, Manila, Philippines, intends to put forth the ethical dilemmas that arise in the process of running such one-stop crisis centres. There will be speakers (trainers/service providers) from different countries in the region to generate a debate on the need to develop ethical guidelines for such work with the health care system.

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#### **5. Disasters and ethics: Ethical issues in disaster management**

**Coordinators:**

**Shalini Bharat**, Tata Institute of Social Sciences, Mumbai  
**Nobhojit Roy**, *Indian Journal of Medical Ethics* and Centre for Studies in Ethics and Rights, Mumbai

**Resource persons:**

**Katy Gandevia**, Tata Institute of Social Sciences, Mumbai  
**Srilata Juvva**, Tata Institute of Social Sciences, Mumbai  
**K Sekhar**, National Institute of Mental Health And Neurological Sciences, Bangalore  
**Athula Sumathipala**, Sri Lanka  
**P Unnikrishnan**, Action Aid, New Delhi  
**Aasim Ahmad**, Aga Khan University, Karachi, Pakistan

Introduction: It is difficult enough to address ethical issues in the provision of daily care within a structured health care system. In the disaster scenario, the complexities are overwhelming. Further, disasters are known to strike resource-poor nations three times more often than rich ones, accentuating the vulnerabilities of the poor, the marginalised and the dispossessed. We attempt to critically examine ethics in situations of natural disasters as well as in conflicts like riots. Panellists will explore the ethical dilemmas of rescuers, health professionals, mental health workers, rehabilitators, international agencies and the media. They will also discuss the broad objectives of the SPHERE project, which emphasises quality and accountability during emergencies resulting from disasters and conflicts, and the relevance of SPHERE in the Indian context.

The workshop is structured to address the various issues that come up at different stages of response to a disaster.

The acute phase of rescue: In the recent Asian tsunami, we witnessed an outpouring of sympathy, good intentions and long-distance aid. At the same, it was disturbing to see, for example, that European tourists were rescued before the locals, and there was inequitable distribution of aid. Also, hurried disposal of the dead in an inhuman way interfered with the normal grieving process. In the Gujarat riots, doctors denied treatment to certain communities.

Recovery and rehabilitation: Media attention wanes after the acute phase, and so does aid. There are few takers for the less glamorous jobs during the long haul of recovery. Mental health care is critical during this phase. This is when people rebuild their lives and homes, and social and occupational rehabilitation takes place. Social agencies tend to play the numbers game to compete with each other and faith-based aid organisations render aid selectively. Help has to be culture-specific, appropriate and sustained to benefit the traumatised victim.

Research in disaster areas: Needs assessment is necessary to determine interventions, but must be followed up with appropriate assistance. A lack of follow-up can cause enormous frustration to the affected people. Researchers can be identified as government officials. Also, "parachute researchers" conduct quick studies that may add to their resumes but may not mean much to those directly affected.

Media ethics: The media provides the eyes and the ears for the global community, which tends to set the priorities for

international concern. Ghastly reports for the news-hungry world are used by donor agencies to turn the philanthropy tap on. Is it right to invade people's privacy at their time of grief? And inaccessible areas that merit assistance may remain neglected because the media finds them of lesser interest.

International aid: Denial of aid - or refusal to accept it - can affect the quality of relief to disaster victims. The recent Pakistan earthquake can be discussed. Should politics stand in the way of receiving or giving aid? The problems can be compounded when multiple agencies and international assistance are involved. Overbearing aid can be dehumanising and destroy people's coping mechanisms and resilience.

SPHERE Against this backdrop, the SPHERE project is based on two core beliefs: first, that all possible steps should be taken to alleviate human suffering arising out of calamity and conflict, and second, that those affected by disaster have a right to life with dignity and therefore a right to assistance.

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## CONFERENCE PROGRAMME

| TIME   |   | VENUE                                     |
|--|---|---|
| <b>DAY THREE, NOVEMBER 27, 2005</b>  |   |   |
| 9 - 10.30 am   | <b>PARALLEL PAPER PRESENTATIONS- IV</b>   | YMCA and Methodist Centre, Mumbai Central |
| 9-10:30 am   | <b>Group 1: ETHICS COMMITTEES AND ETHICS REVIEW</b>   | HALL - 1 (YMCA ground floor)              |
|  | <b>Chair: Urmila Thatte</b> , Independent Ethics Committee, Mumbai  |   |
|  | <b>1. Anant Bhan</b> - <i>The rising trend of clinical trials and commercial ethics boards in India: coincidence or collusion?</i>  |   |
|  | <b>2. Anasuya Sengupta</b> - <i>Samuha's Institutional Ethics Committee with Samraksha</i>  |   |
| 9-10:30 am   | <b>3. Robyna Khan</b> - <i>Clinical ethics services at the Aga Khan University: utility and efficacy in a non-industrialised country</i>  |   |
|  | <b>Group 2: POSTER PRESENTATIONS</b>  | HALL - 2 (YMCA ground floor)              |
|  | <b>Chair: Jagruti Waghela</b> , Lokmanya Tilak Medical College and Municipal General Hospital, Mumbai   |   |
|  | <b>1. Shrinivas Darak, Vinay Kulkarni, Sanjeevani Kulkarni, Ritu Pant</b> - <i>Disclosing the wife's HIV status to the husband: challenges faced during the implementation of a PMTCT programme</i>   |   |
|  | <b>2. Sanjib Das Adhikary, R Raviraj</b> - <i>Ethical challenges of resuscitation following cardiac arrest in the operating room: a case report</i>   |   |
|  | <b>3. Sara Husain</b> - <i>Physicians and the pharmaceutical industry</i>   |   |
|  | <b>4. K Arun Kumar</b> - <i>Surrogacy: a legal perspective</i>  |   |
|  | <b>5. Ayesha Tahreem</b> - <i>Legal and ethical issues in foetal identification and termination of pregnancy</i>  |   |
|  | <b>6. Diwakar Tejaswi</b> - <i>Ethical considerations in AIDS vaccine development</i>   |   |
|  | <b>7. Seema Sahay, Tejasree Gadgil, SM Mehendale</b> - <i>Distributive justice and autonomy: ethical dilemmas in clinical trials</i>  |   |
|  | <b>8. Sabala and Meena Gopal</b> - <i>Neglecting ethical issues in sterilisation procedures: health services and women's reproductive rights</i>  |   |
|  | <b>9. Lakshmi Murthy and Sarika Samdani</b> - <i>Give and gather: the media wears different hats in the context of health and well being</i>  |   |
|  | <b>10. Arvind Singh</b> - <i>Article 21 and medical ethics</i>  |   |
|  | <b>11. F S Vaz</b> - <i>The declining sex ratio at birth in Goa: an ethical crisis</i>  |   |
|  | <b>12. Z Tabei L Bazrafkan</b> - <i>Saady's poem and the four principles of biomedical ethics</i>   |   |
|  | <b>13. K. Mathiharan</b> - <i>Torture and medical practitioners</i>   |   |
|  | <b>14. Mahvesh Alizadeh, Leila Bazrafkan</b> - <i>Professional attitudes of medical students by self-assessment and peer assessment</i>   |   |
|  | <b>15. Mahesh Kharat, Sudhakar Wankhede, Anand Divekar and Seema Sahay</b> - <i>The counsellor's role in voluntary counselling and testing in a biomedical research setting</i>                       |   |
|  | <b>16. DD Naik and D Balaiah</b> - <i>Facing ethical concerns in operational research</i>   |   |
| <b>17. Fateme Hashemi, Leila Bazrafkan</b> - <i>Humanistic qualities of medical students assessed by nurses</i>  |   |   |
| <b>18. Daniel Albuquerque</b> - <i>Case study: ethical issues in counselling the HIV and AIDS-affected and the role of NGOs in Goa</i>   |   |   |
| 9-10:30 am   | <b>Group 3: ROLE OF INFORMED CONSENT IN HIV TESTING</b>   | HALL - 3 (YMCA first floor)               |
|  | <b>Chair: Neha Madhiwalla</b> , Forum for Medical Ethics Society and Centre for Studies in Ethics and Rights, Mumbai  |   |
|  | <b>1. Sucheta Deshpande, Vinita Datye</b> - <i>Seeking informed consent for HIV testing: experiences of providers working in clinical and research settings in Pune, India</i>                        |   |
|  | <b>2. NS Joglekar, Kumar B Kishore, MP Kharat, KM Pardeshi, SN Navlakha, SR Wankhede, RC Bollinger, SM Mehendale</b> - <i>Informed consent comprehension in a non-IND cohort in Pune, India</i>       |   |
|  | <b>3. J Sastry, H Pisal, N Kapadia, M Phadke, A Bhore, K Bharucha, A Shrotri, R Bollinger, N Gupte, A Shankar</b> - <i>A tool to measure informed consent for HIV testing: experience and utility</i> |   |
| <b>4. Lincoln Choudhary, Shailaja Tetali</b> - <i>Ethical challenges in voluntary blood donation</i>   |   |   |
| 9-10:30 am   | <b>Group 4: DRUG DELIVERY AND ACCESS</b>  | HALL - 4 (YMCA second floor)              |
|  | <b>Chair: R K Anand</b> , Director, Jaslok Hospital, Mumbai   |   |
|  | <b>1. Suchitra Dalvie</b> - <i>The ethics of evidence based marketing of drugs to doctors</i>   |   |
|  | <b>2. Barun Mukhopadhyay, Sushmita Mukhopadhyay</b> - <i>Use of over-the-counter drugs: does ethics matter?</i>   |   |
| 9-10:30 am   | <b>3. Priya Nanda</b> - <i>Gender, AIDS, and ARV therapies: ensuring that women gain equitable access to drugs within US-funded treatment initiatives</i>   |   |
|  | <b>Group 5: ETHICAL CONCERNS IN DELIVERY OF HEALTH CARE</b>   | HALL - 5 (Methodist Centre)               |
|  | <b>Chair: K Mathiharan</b> , Institute of Legal Medicine, Chennai   |   |
|  | <b>1. Sridevi Seetharam</b> - <i>Ethical challenges in service delivery in the field of HIV/AIDS: practical issues</i>  |   |
|  | <b>2. Ritu Pant, Sanjeevani Kulkarni, Vinay Kulkarni, Shrinivas Darak</b> - <i>Ethical dilemmas in management of HIV-infected children</i>  |   |
| <b>3. H Pisal, N Suryawanshi, A Shankar, S Sutar, A Joshi, A Erande, P Naphade, A Shrotri, J Sastry</b> - <i>Second pregnancy in HIV-positive mothers: the why and the whether</i> |   |   |
| <b>4. L Bazrafkan, M Mosavibasab</b> - <i>Evaluation of altruistic aspect of clinical competence in interns</i>  |   |   |
| 10.30 - 11.15 am   | TEA BREAK   | YMCA                                      |

|                 |   |   |
|-----------------|---|---|
|                 | TRANSFER TO RAIL NIKUNJ AUDITORIUM  |   |
| 11.15 am - 1 pm | <b>PLENARY SESSION IV: BIOETHICS AND PUBLIC HEALTH</b>  | Rail Nikunj Hall/Auditorium,<br>Railway Officers' Rest House,<br>Mumbai Central |
|                 | <b>Chair: Prof Ghanshyam Shah</b> , Former Director, Centre for Social Studies, Surat, and Professor (Retired), Centre for Social Medicine and Community Health, Jawaharlal Nehru University, New Delhi<br><b>Co-Chair: Dr Sanjay Nagral</b> , Forum for Medical Ethics Society and Consultant, Jaslok Hospital, Mumbai |   |
|                 | <b>Key-note address 1:</b><br><b>Dr T Jacob John</b> , Christian Medical College, Vellore<br><b>Ethics, human rights and public health</b>  |   |
|                 | <b>Key-note address 2:</b><br><b>Prof Jayaprakash Muliyil</b> , Principal, CMC, Vellore<br><b>Clinical trials and public health bioethics</b>   |   |
|                 | <b>Key-note address 3:</b><br><b>Ms Manisha Gupte</b> , Co-convenor, Masum, Pune<br><b>Violence as a public health and a human rights issue</b>   |   |
|                 | <b>Discussion and responses</b>   |   |
|                 | <b>Chairperson's remarks</b>  |   |
| 1 - 2 pm        | LUNCH BREAK   |   |
| 2 - 4 pm        | <b>PLENARY SESSION V: VALEDICTORY SESSION</b>   | Rail Nikunj Hall/Auditorium,<br>Railway Officers' Rest House,<br>Mumbai Central |
|                 | <b>Chair: Dr B Ekbal</b> , Former Vice Chancellor, Kerala University<br><b>Co-Chair: Dr Sanjay Mehendale</b> , Senior Deputy Director, National AIDS Research Institute, Pune   |   |
|                 | <i>Key issues discussed and learnt from the conference</i><br><b>Dr Suneeta Krishnan, Dr Mala Ramanathan and Dr Anant Bhan</b> ,<br>Conference Rapporteur Committee   |   |
|                 | <b>Valedictory address</b><br><b>Prof Abhijit Sen</b> , Member Planning Commission, Government of India, Professor of Economics,<br>Jawaharlal Nehru University, New Delhi  |   |
|                 | <b>Chairperson's remarks</b>  |   |
|                 | <b>Discussion, future plans and vote of thanks</b><br><b>Dr Nobhojit Roy</b><br><i>Indian Journal of Medical Ethics and Centre for Studies in Ethics and Rights, Mumbai</i>   |   |
|                 | <b>CONFERENCE CONCLUSION AND TEA</b>  |   |

## PARALLEL PRESENTATIONS IV: ABSTRACTS

### **Group 1: ETHICS COMMITTEES AND ETHICS REVIEW**

#### **1. The rising trend of clinical trials and commercial ethics boards in India: coincidence or collusion?**

*Anant Bhan*

Biomedical research through clinical trials for drug development is an integral part of research and development activities of most pharmaceutical companies. Rising costs of drug development, the strict regulatory standards in the West and the conducive environment in developing countries have led to an increase in outsourcing of clinical trials. India is now a favoured destination for these trials. The Indian government is actively promoting this phenomenon and many Clinical Research Organisations have sprung up to facilitate the conduct of clinical trials in India. While this has led to some flow of foreign exchange into the country, it has also raised many concerns about the possible exploitation of communities and individuals participating in research conducted by these organisations, and violations of research ethics.

A parallel to the trend of increasing outsourced clinical trials in India has been the increase in the number of Commercial Research Ethics Boards (CREBs) in India. These are often subsidiaries of pharmaceutical companies or clinical research organisations, and they review research that is being conducted in-house. This raises concerns about conflict of interest. The issue of payment of Research Ethics Board members is still being debated and concerns have been raised that ethical review process are being turned into a business with possible profit margins. CREBs offer advantages like efficiency and a quick turn-around time. Nationally, there is a lack of regulation of ethics boards and committees. There is even a lack of information about how many boards or committees exist on the ground. The proposed legislation being processed by the Indian Council for Medical Research might bring some clarity to this field.

The increasing outsourcing of clinical trials and the rising number of CREBs in India present interesting insights into the interface between globalisation and health in India today.

#### **2. Samuha's Institutional Ethics Committee with Samraksha**

*Anasuya Sengupta*

Samraksha is an organisation working on HIV/AIDS, under the institutional umbrella of Samuha, a rural development organisation. In 2002, it began a research partnership with the University of California, San Francisco, to examine gender-related issues around sexuality and HIV/AIDS as well as a study on adolescent responses to the same issues. Since the gender study had to be approved by both the NIH, USA, as well as the ICMR, an Institutional Ethics Committee (IEC) was set up to

analyse and advise on the ethical considerations underpinning these research studies.

The IEC defined itself as an "enforcement... not implementing body" whereby considered that its guidelines and protocols would be conveyed to the researchers for consideration and adoption. It was felt that the IEC would make recommendations to the researchers, Samuha/Samraksha, inform the necessary institutions in cases of a violation of ethics and take extraordinary measures in a gross violation was perceived.

The paper looks at the institutional processes of setting up such an IEC, and the methodologies and practices evolved by the members of the IEC. It focuses on the difficulties encountered in ethical aspects of complex social situations, particularly related to gender and HIV/AIDS, including transparency in information, informed consent and confidentiality.

Such an IEC is still an unusual component of social science research in India, and the diverse skills and experiences that the IEC members bring to their combined analysis are some measure of the multiple perspectives and nuanced treatment required. With members who are experts in clinical research and community health, as well as socially committed journalists and activists, we believe that this diversity is at the heart of the effective processes of the IEC. Samraksha's and the research team's commitment to the ethical nature of their work has been another critical aspect. Finally, it has also been a steep but rewarding learning curve for the IEC and Samuha, particularly when other organisations or individuals have wished to collaborate with Samuha/Samraksha, and avail of the IEC's recommendations.

#### **3. Clinical ethics services at the Aga Khan University: utility and efficacy in a non-industrialised country**

*Robynga Khan*

Clinical ethics is an emerging field of bioethics in the non-industrialised world. In Pakistan, the first Hospital Ethics Committee was established in March 2000 at the Aga Khan University, Karachi. Ever since, it has been functional for clinical ethics consultative services within the university. The other major function of the committee has been self-education and education of clinical staff within the hospital and from other hospitals in the city and country. This presentation will deal with the mandate, day-to-day functioning, usefulness and effectiveness of the committee. It will specifically highlight the differences in approaches towards similar ethical issues, between a non-industrialised country and a developed country, as experienced by the presenter.

Conclusion: Clinical ethics service has been recognised to be useful and effective in dealing with the clinical ethical issues that are encountered by our health care personnel and patients. Sharing this experience with our Indian colleagues can be useful as we have similar social and cultural backgrounds.

## Group 2: POSTER PRESENTATIONS

### 1. Disclosing the wife's HIV status to the husband: challenges faced during implementation of a PMTCT programme

*Shrinivas Darak, Vinay Kulkarni, Sanjeevani Kulkarni, Ritu Pant*

### 2. Ethical challenges of resuscitation following cardiac arrest in the operating room: a case report

*Sanjib Das Adhikary, R Raviraj*

### 3. Physicians and the pharmaceutical industry

*Sara Husain*

### 4. Surrogacy: a legal perspective

*K Arun Kumar*

### 5. Legal and ethical issues in foetal identification and termination of pregnancy

*Ayesha Tahreem*

### 6. Ethical considerations in AIDS vaccine development

*Diwakar Tejaswi*

### 7. Distributive justice and autonomy: ethical dilemma in clinical trials

*Seema Sahay, Tejasree Gadgil, SM Mehendale*

### 8. Neglecting ethical issues in sterilisation procedures: health services and women's reproductive rights

*Sabala, Meena Gopal*

### 9. Give and gather: the media wears different hats in the context of health and well being

*Lakshmi Murthy, Sarika Samdani*

### 10. Article 21 and medical ethics

*Arvind Singh*

### 11. Declining sex ratio at birth in Goa: an ethical crisis

*F S Vaz*

### 12. Saady's poem and the four principles of biomedical ethics

*Z Tabei L Bazrafkan*

### 13. Torture and medical practitioners

*K Mathiharan*

### 14. Professional attitudes of medical students by self-assessment and peer assessment

*Mahvesh Alizadeh, Leila Bazrafkan*

### 15. The counsellor's role in voluntary counselling and testing in a biomedical research setting

*Mahesh Kharat, Sudhakar Wankhede, Anand Divekar and Seema Sahay*

### 16. Facing ethical concerns in operational research

*DD Naik, D Balaiah*

### 17. Humanistic qualities of medical students assessed by nurses

*Fateme Hashemi, Leila Bazrafkan*

### 18. Case study: ethical issues in counselling the HIV and AIDS-affected and the role of NGOs in Goa

*Daniel Albuquerque*

## Group 3: ROLE OF INFORMED CONSENT IN HIV TESTING

### 1. Seeking informed consent for HIV testing: experiences of providers working in clinical and research settings in Pune

*Sucheta Deshpande, Vinita Datye*

Objectives and focus of the paper: Nearly 60 years after the Nuremberg code of 1947, informed consent is hailed as a cornerstone of ethical practice in biomedical research and is increasingly seen as integral to medical practice. In reality there is widespread breach of ethical guidelines around testing in clinical practice. At the same time, informed consent in research trials has been criticised and looked upon as "empty ethics". In this paper, we debate whether informed consent is truly informed or whether it remains merely voluntary in nature.

Methods: We draw our data from in-depth interviews with 27 private medical practitioners (PMPs) focusing on their HIV management practices, and 13 counsellors examining their experiences and practices around HIV counselling and informed consent.

Results: We found that PMPs were unfamiliar with the concept of obtaining consent prior to an HIV test and saw consent as an imported concept. Patients were perceived to be poor, uneducated or unable to grasp the implications of consent. On the other hand, counsellors were adapting rigid consent procedures in socially and culturally appropriate ways to suit patients' needs. Despite their training and skills, counsellors reported their reservations about patients' true understanding of the procedure of informed consent.

Conclusion: We suggest that challenges of truly informed consent cannot be superficially addressed within the immediate clinical or research settings. It requires some consideration of the changing moral, cultural and political frameworks that underlie the social constructs of the "patient" and "provider" identity as well as the realities of their interaction.

## 2. Informed consent comprehension in a non-IND cohort in Pune, India

*NS Joglekar, B Kishore Kumar, MP Kharat, KM Pardeshi, SN Navlakha, SR Wankhede, RC Bollinger, SM Mehendale*

**Background:** Adequate comprehension of informed consent implies autonomy and is perceived as a difficult task for research studies in developing countries. This report assesses consent comprehension among participants of a non-IND cohort (HPTN 034 study) in Pune, India.

**Methods:** From September 2002 to December 2003, 264 HIV sero-discordant couples and 284 HIV sero-negative high-risk women were enrolled in a cohort study aimed at estimating HIV incidence and one-year retention. After informed consent, a structured questionnaire was administered to evaluate their consent comprehension. The comprehension scores were analysed by demographic factors and HIV risk factors.

**Results:** The median ages of sero-positive male index cases, sero-positive index females and high-risk sero-negative women were 34 years, 28 years and 28 years respectively. Although the cumulative comprehension scores were satisfactory, 39% participants had a complete understanding of the risks. Education above the primary level was an independent predictor of informed consent comprehension only in the case of HIV-negative high-risk women (AOR =1.94, 95% CI 1.1-3.2, p=0.009) and HIV-negative female partners (AOR=1.94, 95% CI 1.0-3.0, p=0.05) among couples. Other demographic factors like age and type of occupation, or HIV risk factors like history of condom use, frequent injections and blood transfusion, generally did not affect consent comprehension. However, monogamous women were more likely to have better comprehension (AOR=2.04, 95% CI 1-4.1, p=0.05).

**Conclusions:** Risks involved in this study such as study-related procedures, blood and STI sample collection, confidentiality and privacy might not have been perceived as important by the participants. Generally, the consent comprehension was good and was not dependent on demographic factors and risk behaviour. This reduces the need to develop specialised consents to various populations groups with varying characteristics. However, as education was an independent predictor of better consent comprehension, more specialised and simple approaches like the use of visuals could be adopted for obtaining informed consent, particularly for explaining study-related risks to individuals with lower literacy levels.

## 3. A tool to measure informed consent for HIV testing: experience and utility

*J Sastry, H Pisal, N Kapadia, M Phadke, A Bhore, K Bharucha, A Shrotri, R Bollinger, N Gupte, A Shankar*

Informed consent is now a pre-requisite to HIV testing worldwide. Ethical issues regarding consent may be universal. However, there is a need to be able to measure the level of informed consent procedures. This is especially an issue among vulnerable populations such as socio-economically and/or educationally deprived people attending busy government hospitals in India. Our study in Pune, India, developed an easy-to-administer and reliable tool to measure informed consent

in a population of pregnant mothers. We were able to enhance women's understanding of education and counselling about HIV/AIDS provided within the antenatal clinic with culturally appropriate visual aids. In order to measure consent, we developed a set of eight easy-to-administer questions that were identified as key to the woman's understanding of the process. A woman was deemed to have passed the test of understanding if she answered at least six out of the eight questions correctly.

We found that of all the women who accepted to undergo testing (n+ 28,869), about 97% showed an adequate understanding. Understanding of the eight elements of informed consent were as follows: reasons for the procedure (93%), the right to refuse (94%), the consequences of refusal (82%), confidentiality (93%), the right to consult (88%), benefits (92%), risks (90%) and the meaning of one's signature (87%). Our data show that it is possible to assess the understanding of the complex constructs of informed consent even in populations with little education and within busy health care settings, so as to preserve individuals' rights. These tools require minimal effort for trained staff and we recommend that these tools be used routinely at any health facility prior to HIV testing in India.

## 4. Ethical challenges in voluntary blood donation

*Lincoln Choudhary, Shailaja Tetali*

**Objective:** To explore the ethical challenges in voluntary blood donation.

**Methods used:** Analysis of secondary data from a major blood bank in Kerala and in-depth interviews with three blood bank personnel.

**Results:** People who volunteer to donate blood consider themselves to be healthy. They have no infections to their knowledge and come to the blood bank with the intention of helping someone. They thereby become part of a health process through an implicit relationship and deserve the right to be told if their blood is unacceptable. In 2003-05, out of 12,631 voluntary blood donations, 357 tested positive for Transfusion Transmitted Infections (TTI), including 122 who were found HIV positive. These 357 people are oblivious of their status.

The Action Plan on Blood Safety (NACO, 2003) claims to bring about a paradigm shift in the disclosure of the donor's sero-status, which was not permissible earlier. Although the method of disclosure is the crux of the issue, it is not mentioned in the policy. It claims that donors will be offered the option of knowing their TTI status. If a donor tests positive for HIV, the blood bank will request him or her to re-visit by "simply" stating that the results are inconclusive and need to be confirmed. But in practice, this is not done. The onus is on the donor to find out the results. Only about 20% of donors contacted the blood bank in Kerala. None of them were HIV positive.

**Conclusion:** Health providers, under an oath of service to the patient, thereby miss a crucial opportunity to safeguard the donor's health. They face a serious ethical dilemma regarding notification to donors who may test positive but remain ignorant of their HIV status. HIV testing has an additional problem of a high false positive rate. Methods of disclosure must therefore

be carefully thought about, without jeopardising confidentiality and overburdening existing resources.

## **Group 4: DRUGS DELIVERY AND ACCESS**

### **1. The ethics of evidence-based marketing of drugs to doctors**

*Suchitra Dalvie*

It is well known that after qualifying and starting clinical practice, few doctors have the time, inclination or opportunities for academic pursuits. Information about drugs and prescriptions in particular depends heavily on past knowledge and on Medical Representatives (MRs) of the pharmaceutical industry. These MRs visit doctors on a daily basis with information about their products, old and new. The levels of evidence for the validation of their claims are often inadequate or unacceptable. Studies quoted have small sample sizes, they are not based on controlled trials and they are published in obscure journals. Drug companies often market "cross-pathway" drugs as well.

There is a need to identify the various mechanisms that should be put in place, requiring approval from a regulatory authority at all levels. This also applies to information given to doctors about the drugs and their efficacy and safety. Doctors often lack the training to analyse the credibility of the information.

Ethical considerations of patient care always start with 'First, do no harm'.

### **2. Use of over-the-counter drugs: does ethics matter?**

*Barun Mukhopadhyay, Sushmita Mukhopadhyay*

The use of over-the-counter (OTC) drugs is rampant in India. There are many reasons for this. Self-medication has long been a major problem, and it can pose adverse health problems for many. Though India has less than 12 approvable OTC drug molecules, medicines of immensely varied types are available from drug stores on request without medical doctors' prescriptions. This exploratory study was conducted in Kolkata adopting qualitative methods to examine the nature of OTC drug use and to dwell upon ethical dilemmas pertaining to such use. Data were collected from chemists' shops, medical doctors and people purchasing OTC drugs in different municipal wards of Kolkata. The findings highlight that poverty and illiteracy on one hand and drug dependence on the other lead to a higher use of OTC drugs. Ethical dilemmas related to lax implementation of drug laws, cost of medical consultation, non-availability of medical service, advertising and drug dependence are also discussed.

### **3. Gender, AIDS, and ARV therapies: ensuring that women gain equitable access to drugs within US-funded treatment initiatives**

*Priya Nanda*

The USA has committed to provide antiretroviral (ARV) treatment to at least 2 million individuals by the end of 2006. Currently, there are an estimated 40 million people with HIV worldwide. This initiative therefore represents only a modest beginning

to what must be an international commitment to prevent and treat HIV/AIDS.

Given limited resources, choices will inevitably be made about who will be treated, raising the issues of equity in access to treatment for sub-groups of those infected. In turn, these considerations dramatically underscore the need for specific efforts to ensure that treatment programmes reach those groups - women and other vulnerable populations such as sex workers and men who have sex with men - who, due to discrimination and lack of access to health care, already face a disproportionately higher risk of infection. Women represent over half of those infected with HIV worldwide. In many countries, the rate of new infections is highest among married women and adolescent girls. Failure to understand and address the barriers to treatment access faced by women and girls will undermine investments made by the USA to solutions to the global HIV/AIDS epidemic.

To ensure that US global AIDS strategies promote justice and equity and reflect international consensus on the ethical principles of health care, the US must take proactive steps to address the barriers to access faced by women. There is no consistent formula for ensuring equity in access to treatment. A set of standard considerations and guidelines must be formulated and applied to ensure that concerns for gender equity and social justice are incorporated into treatment access schemes. Such guidelines can ensure the consistent application of ethical principles to treatment access, while reflecting specific circumstances. They should be reviewed regularly in response to changes in the dynamics of the epidemic or as treatment access expands. Based on recent reviews of literature and exploratory field research, this paper highlights essential elements of a gender-sensitive approach to treatment access.

## **Group 5: ETHICAL CONCERNS IN DELIVERY OF HEALTH CARE**

### **1. Ethical challenges in service delivery in the field of HIV/AIDS: practical issues**

*Sridevi Seetharam*

The past decade has witnessed an explosion in information and activities in the field of HIV/AIDS in India. With international funding available for prevention, treatment and research, the number and range of players in the field have also grown proportionately. These players' exposure and commitment to basic ethical principles is variable and sometimes questionable. While the ethics of conducting research in this field has been well explored and regulated, practical issues in the actual service delivery are largely unaddressed. Likewise, national policy-makers often overlook the need to balance programmes between meeting targets and safeguarding ethical issues. Many NGOs and charities have taken on the mantle of service providers. While most of them have intentions of doing service and strive to do their best under the circumstances, the challenges they face and the choices they make offer opportunities for learning.

The Swami Vivekananda Youth Movement has been actively involved in the field of HIV/AIDS for the past six years. The service delivery in some aspects has been innovative. It also

plays a significant role in advocacy related to national and state policy in HIV/AIDS. Its experience of the ethical challenges faced, the lessons learnt and some of the successes, will be shared.

Specifically, issues of confidentiality, reduction of stigma and discrimination, integration into routine hospital care, waste management, counselling services, pre-operative testing, the PPTCT programme, provision of ART, post-exposure prophylaxis and policy-making are discussed.

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## 2. Ethical dilemmas in management of HIV-infected children

*Ritu Pant, Sanjeevani Kulkarni, Vinay Kulkarni, Shrinivas Darak*

Antiretroviral Therapy can provide increased longevity and a better quality of life to HIV-infected children. However, there exist many complexities in managing paediatric HIV.

One of the most important issues is that the basic principles of ethics in adults - confidentiality and informed consent - are difficult to apply to children. This complicates the issue of disclosure to the child of his or her HIV status. It is difficult to decide when and how to disclose. This may depend upon the child's level of understanding and health status.

Experiencing repeated hospitalisations, frequent visits to the doctor, the burden of taking medicines for a prolonged duration, the illness of parents or even their death, and allusions about this issue in the family - all give rise to the feeling of being different. The child is bewildered by many questions.

While unaware of their HIV status, children's understanding of the disease will be based on the messages they receive from their surroundings. They will demand appropriate answers to their questions though such demands may not always be expressed explicitly. Answering such questions would mean partial disclosure, running the risk of wider disclosure to others. The family may face discrimination as a result.

In this context it is difficult to decide at what age this information should be disclosed to the child. What should the content and the process of disclosure be? Should the health care provider disclose the status to the child when the parents do not consent for this? If not, what are the rights of the child in this context? There is an urgent need for public discussion to find out innovative approaches to deal with this situation.

We shall discuss these issues and the possible answers based on our experience of caring for HIV infected children.

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## 3. Second pregnancy in HIV-positive mothers: The why and the whether

*H Pisal, N Suryawanshi, A Shankar, S Sutar, A Joshi, A Erande, P Naphade, A Shrotri, J Sastry*

31 HIV-positive pregnant mothers who came for a second pregnancy to Sassoon Hospital's antenatal clinic in the past year were interviewed using a semi-structured questionnaire. The purpose was to understand why the woman underwent a second pregnancy when she knew the risk of HIV transmission.

Knowledge about contraception was assessed. Condoms were the well-known methods of contraception; approximately 65% (20) women reported knowledge of condoms and 86% (27) women who used contraception used only condoms. Prior to the current pregnancy, only 55% (17) of women had discussed contraception with their husbands. About 86% (27) of those who used contraception had used condoms.

Regarding the current pregnancy, our data show that women are not making decisions about their pregnancies. 22 out of 31 pregnancies were unplanned. Of the planned pregnancies (9 out of 31), the husband desired four and both husband and wife desired four, while one was because of a previous stillbirth. Regardless of planning, only 32% (18) of women, along with their husbands and other family members, wanted to have the baby. Regarding disclosure of women's HIV status, in 42% (13), only the couple was aware of their HIV positive status. Three women did not disclose their status to anyone. 16% (5) women had disclosed their status only to their family (parents) and not to their husbands. Seventy percent (22) of women were worried about their current pregnancy because of their HIV status.

There is an urgent need to provide repeated and intensive counselling to HIV-positive couples from the time of the first pregnancy to prevent unplanned pregnancies. Provision solely of condoms, without any other women-empowering contraceptive methods, is insufficient.

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## 4. Evaluation of altruistic aspect of clinical competence in interns

*L Bazrafkan, M Mosavibasab*

Introduction: Physicians are required to be honest with their patients, respect patient confidentiality, and maintain appropriate relations. The clinical training period is one of the most important and critical phases in medical education in this situation. The teaching of professional issues is difficult and assessment is complex. Evaluating the clinical competence of senior medical students is very critical and is the aim of our study.

Methods: The study is of the analytic-descriptive type and evaluates the clinical qualification of interns in relation to potential altruistic physicians by using the OSCE technique.

Results: The findings revealed that 86.7% of the subjects were competent enough in their practice but 13.3% had not acquired sufficient qualification to treat the patient. The performance of students in tests for non-cognitive criteria and professionalism was impaired.

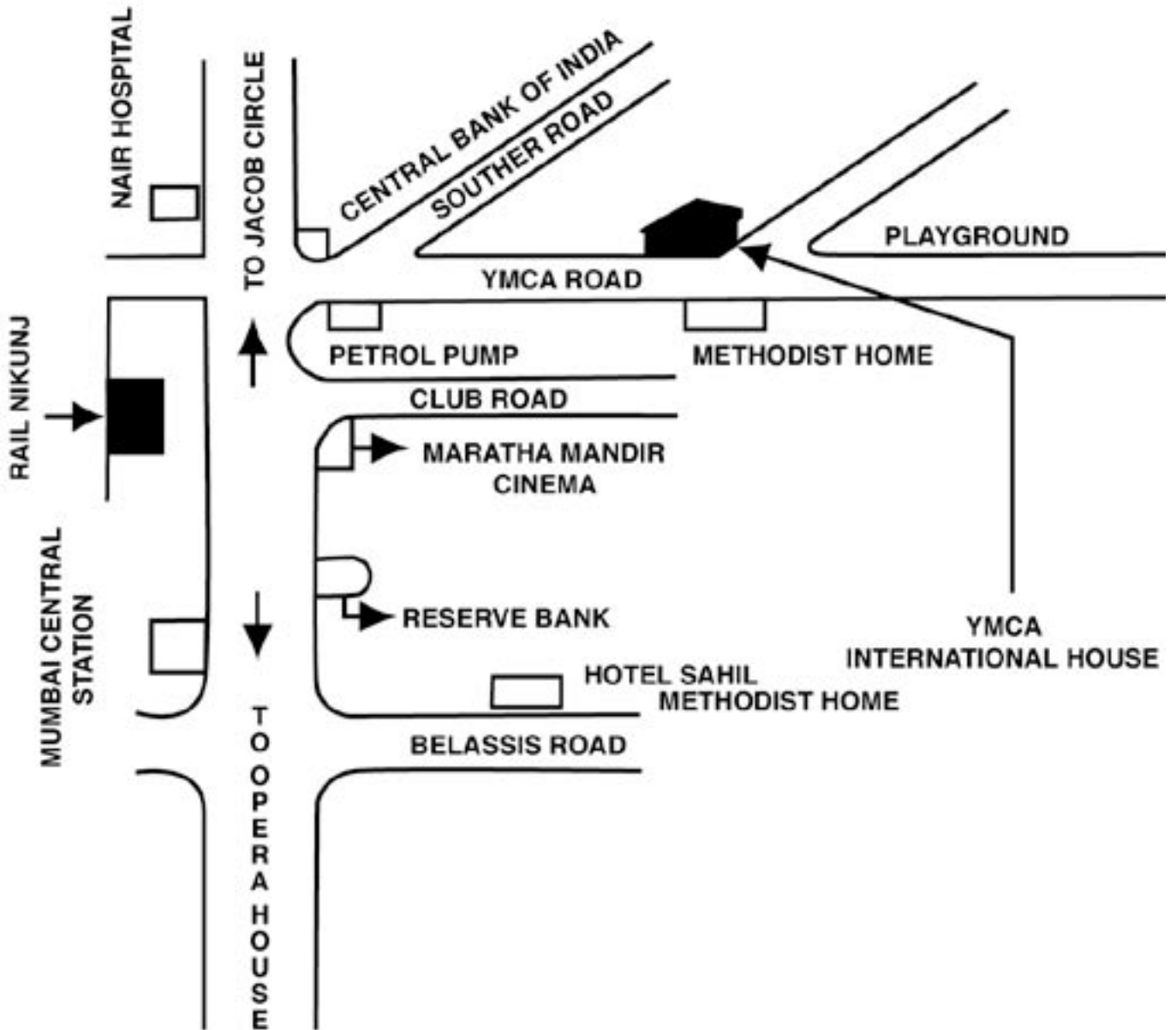
Conclusion: Although the students demonstrated sufficient clinical knowledge in the field of medicine, their professional performance concerning issues such as maintaining patient confidentiality and communication skills was not satisfactory. Education in these areas requires a review and a proper approach to medical education in these areas. However, more research is needed to see if we can better identify potential altruistic physicians and assess the impact of this attribute on their careers in medicine.

**Ethical issues in international health research**  
**DRAFT AGENDA**  
**VENUE: YMCA AND METHODIST CENTRE, MUMBAI CENTRAL**  
**NOVEMBER 24 -26, 2005**

**Objective of the workshop:**

1. Strengthen capacity of researchers to understand ethical issues in relation to research involving human subjects and
2. Strengthen capacity of IRB members to promote and implement international standards for conducting medical research with human subjects as set out in the Helsinki Declaration or the ethics guidelines of the Council of International Organization of Medical Sciences, while ensuring that local contexts are protected.

| <b>DAY ONE (BASIC) - November 24</b>   |  |                             |
|--|--|-----------------------------|
| 9.00AM - 9.15 AM   | Introduction and background  | Abha Saxena                 |
| Ethical issues - Moderator Alex Capron   |  |                             |
| 9.15AM - 10.00AM   | Case studies   | Alex Capron                 |
| 10.00AM - 10.30AM  | Principles of ethical conduct in research  | Alex Capron                 |
| 10.30AM - 10.45 AM   | Tea/coffee break   |                             |
| 10.45AM - 11.15AM  | Discussion of the principles of ethical conduct in research  | Moderated by Alex Capron    |
| Global issues, local contexts - Moderator Richard Cash                             |  |                             |
| 11.15AM - 11.45AM  | Case studies on standard of care, best available treatment vs locally available treatment, placebo-controlled trials, etc. | All faculty                 |
| 11.45AM - 12.15PM  | Issues related to standard of care   | Dan Wikler                  |
| 12.15PM - 12.45PM  | Comments by national faculty Amar Jesani, Mala Ramanathan  | Moderated by Richard Cash   |
| 12.45 PM - 2.00 PM   | Lunch  |                             |
| Ethical issues in behavioural and social sciences research - Moderator Alex Capron |  |                             |
| 2.00PM - 3.15PM  | Ethical issues in behavioural and social sciences  | Mala Ramanathan             |
|  | Discussion   | Alex Capron                 |
| 3.15PM - 3.30 PM   | Tea/coffee break   |                             |
| Privacy and confidentiality- Moderator Richard Cash                                |  |                             |
| 3.30PM - 4.30PM  | Case studies followed by discussion  | Dan Wikler and Amar Jesani  |
| Institutional Review Boards - Moderator Richard Cash                               |  |                             |
| 4.30PM - 5.00 PM   | IRBs: What are they for, and how can they do it better   | Dan Wikler                  |
| 5.00PM - 5.30PM  | Ethics Review Committees - the Indian context  | Vasantha Muthuswamy         |
| 5.30PM - 6.00PM  | Discussion   |                             |
| Moderator - Richard Cash   |  |                             |
| <b>DAY TWO - November 25</b>   |  |                             |
| Informed consent - Moderator Richard Cash  |  |                             |
| 4.00 PM - 5.00PM   | Background information   | Richard Cash                |
|  | The informed consent process - case studies  | Richard Cash and Dan Wikler |
| 5.00PM - 6.00PM  | Understanding informed consent through role play   | All faculty                 |
| <b>DAY THREE- November 26</b>  |  |                             |
| WORKSHOP CONTINUED 4-6 PM AT HALL 6, METHODIST CENTRE                              |  |                             |



## BIONOTES

### **Ahmad Aasim**

Aasim Ahmad is chief nephrologist at the Kidney Centre, Karachi, and honorary senior lecturer in bioethics at the Aga Khan University, Karachi. His main area of interest has been postgraduate education in bioethics. He has developed several modules and conducted workshops for residents under the auspices of the Post Graduate Medical Education Committee. Dr Ahmad received his master's degree in bioethics at University of Toronto in 2003. He is chairperson of the Bioethics Group at AKU. He is a member of the following committees: Ethics Review Committee, AKU; Ethics Review Committee, MÇdecins Sans Frontières, and the Committee for Revision of the Pakistan Medical and Dental Council Code of Ethics. He has several peer-reviewed publications to his credit. He is a recipient of grants from the NIH (USA) and Wellcome Trust (UK) for educational programmes in bioethics.

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### **Aithal Varsha**

NALSAR University of Law, Hyderabad.

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### **Alexander Jacob**

Jacob Alexander is consultant psychiatrist at the Palliative Care Unit, Christian Medical College, Vellore.

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### **Anand R K**

R K Anand is a senior paediatrician. He is former professor of paediatrics at the T N Medical College, Mumbai and founder president of the Association for Consumers Action on Safety and Health (ACASH). Currently he is director of the Jaslok Hospital and Research Centre, Mumbai.

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### **Awasthi Ramesh**

Ramesh Awasthi is co-convenor of Masum (Pune), a rural women's organisation well known for both its activism and development initiatives. He has a degree in chemical engineering and a doctorate in economics. He has made significant contribution in the development sector. He worked for several years in the Foundation for Research in Community Health.

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### **Baig Mufid**

Mufid Baig pursued his master's degree in social work and is currently working as a research assistant and community worker at the National AIDS Research Institute, Pune. He is involved in providing pre-test and post-test counselling, community outreach work, home visits for retention, networking with NGOs and CBOs, and collecting qualitative and quantitative data, as well as work related to various ongoing studies at NARI.

### **Bala Shilpa**

Shilpa Bala is a young journalist who has worked with leading newspapers in Bangalore - Vijay Times, The Times of India and, currently, The New Indian Express. In August 2005, with the assistance of concerned local individuals in Belgaum, Shilpa undertook a detailed investigation of the practice of foetal sex determination. New Indian Express and Kannada Prabha gave prominent coverage to this media campaign for many days. This has been the second such investigative reporting from Belgaum by the New Indian Express since 2002.

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### **Balayon Theresa D**

Theresa D Balayon is from the Women's Crisis Centre, Raquel Edralin-Tiglao Institute for Family Violence Prevention, at the East Avenue Medical Centre in Diliman, Quezon City, Philippines. She is an independent consultant engaged in gender-responsive education, training, project planning and management, monitoring, and evaluation. Ms Balayon designs and conducts training workshops on gender-fair education, gender and power dynamics, gender-responsive planning, assertive communication, conflict management, women's leadership, cultural development, participatory assessment, feminist counselling, feminist ethics, and prevention of gender-based violence against women with an emphasis on domestic and family violence, teenage dating violence, reproductive health, and sexual harassment. She has conducted extensively training in countries of Asia and the Pacific. Ms Balayon was coordinator for the Centre for Women's Studies at the Philippine Women's University from 1984 to 1989. At present she is the coordinator of the Raquel Edralin-Tiglao Institute for Family Violence Prevention, the training arm of the Women's Crisis Centre.

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### **Bandewar Sunita**

Sunita Bandewar is a medical anthropologist. She has done her master's degree in bioethics from the Joint Centre for Bioethics, University of Toronto, Canada and her PhD from University in Pune. She is a faculty member and programme director at the Centre for Studies in Ethics and Rights, Mumbai. She has extensive experience working in the voluntary sector and in reproductive health research, especially on abortion. She is on the editorial advisory board of IJME.

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### **Barua Ananya**

Ananya Barua is the final year of her master's degree in philosophy at the University of Hyderabad, Hyderabad, Andhra Pradesh.

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### **Basu Choudhury Rituparna**

Rituparna Basu Choudhury graduated from Tata Institute of

Social Sciences with a master's degree in social work in 1998. She worked with Akshara, an NGO, for nearly two years in the areas of resource management, career guidance and gender sensitisation with youth and women in various forums. In 2000, she joined Jaslok Hospital and Research Centre as a medical social worker. Since then, she has been actively involved in organ transplant and donation, organising blood donation camps and arranging financial assistance for needy patients.

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### **Batool Fatima**

Fatima Batool is a clinical psychologist by profession. She is currently working for the Marie Stopes Society, Pakistan, as a manager, counselling services, in the voluntary counselling and testing programme. She has been working in psychosexual health issues since 1999. She is a master trainer of voluntary counselling and testing and also develops training manuals, protocols, ethical guidelines and supervision and monitoring tools. She has conducted various trainings on HIV/AIDS and counselling for HIV/AIDS. She is an LDM fellow (Leadership Development Mechanism, Pakistan) and is also actively involved in developing behaviour change communication activities for preventive health including the prevention of HIV/AIDS.

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### **Bazrafkan L**

L Bazrafkan is from the Shiraz University of Medical Sciences, Iran.

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### **Bedi Puneet**

Puneet Bedi studied obstetrics and gynaecology at Maulana Azad Medical College, Delhi, and trained in foetal medicine at London. He has served on the faculty of the All India Institute of Medical Sciences, New Delhi. At present, he is a foetal medicine specialist working at Apollo Hospital, Delhi. Dr Bedi is also a well known activist who has campaigned against female foeticide for more than two decades. Over the last four years he has travelled all over the country speaking out against the unethical practice of sex selection.

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### **Beecham Brady**

Brady Beecham is originally from Lincoln, Nebraska, USA. She has degrees in biology and environmental science at Duke University, USA and is currently an MPH scholar at Sree Chitra Tirunal Institute of Medical Sciences and Technology in Thiruvananthapuram. Ms Beecham's original introduction to public health was to water issues. This was while working in a US-based groundwater NGO focused on community activism. Before coming to India Ms Beecham worked as an epidemiologist at the Nebraska health department investigating outbreaks of Hepatitis and West Nile virus, an arthropod-borne flavivirus. She has lived in Spain and Brazil and speaks both Spanish and Portuguese; her Hindi and Malayalam are still embryonic.

Among Ms Beecham's current areas of interest are trans-boundary health issues. Her master's thesis will focus on the

ethics of clinical trial outsourcing to developing countries. She plans to return to Nebraska to do her MD and hopes to return to India soon after.

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### **Bhan Anant**

Anant Bhan is a young physician with an interest in public health, bioethics, global health, gender and equity. He did a fellowship in community health at Bangalore and then spent a year working on a project for mainstreaming gender in medical education at Thiruvananthapuram. He recently finished his master's in bioethics at Toronto. He now works at the Centre for Studies in Ethics and Rights, Mumbai, and is associated with the University of Toronto Joint Centre for Bioethics. He is currently the Assistant Executive Editor of IJME. He has published extensively in various national and international journals, and presented in various conferences. He is also an Executive Committee member of the Medico Friends Circle.

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### **Bharat Shalini**

Shalini Bharat has a doctorate in psychology. She is professor and head of the Unit for Family Studies, Tata Institute of Social Sciences, Mumbai, where she teaches and conducts research in the areas of HIV/AIDS, reproductive health, gender and family studies. Her work on HIV/AIDS has contributed to a greater understanding of the household and community responses to AIDS in India; the gender dimension of AIDS; the linkages of the epidemic with reproductive health issues; stigma and discrimination related to AIDS, and the structural vulnerabilities to HIV. As team member of the UNAIDS South Asia Advocacy Project, she has developed the database for behavioural research in India for doing evidence-based advocacy with political leaders and policy makers. In 2002 she co-organised the first South Asia region conference on women and AIDS at Mumbai. In 2004 she moderated the first electronic discussion forum - Challenging AIDS stigma in South Asia - with participants from Pakistan, India, Bangladesh, Sri Lanka, Nepal, and Afghanistan.

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### **Bhate Kamaxi**

Kamaxi Bhate is professor of community health at King Edward Memorial Hospital, Mumbai, and is well known to activists in Mumbai for over 20 years. She is among the first doctors who were actively involved in the historic Maharashtra campaign against sex selection in the 1980s. Over the last few years, she has been developing educational material for patients and is involved in developing gender-sensitive curricula for the medical profession.

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### **Bijlwan Supriya**

Supriya Bijlwan is a final year student of B.A.B.L (honours) at NALSAR University of Law, Hyderabad. During her integrated course she became fascinated by the intersection of law with issues of medical ethics. She realised that tort law in the present scenario is also not very developed and often results in failure to seek remedies.

**Birhade Ratnaprabha**

Ratnaprabha Birhade has completed her master's in social work and is presently working as a research assistant counsellor, at the National AIDS Research Institute, Pune. She is involved in providing pre-test and post-test counselling, community outreach work and home visits and networking with NGOs and CBOs at NARI.

**Braganza Deepa**

Deepa Braganza is a consultant psychiatrist with the Chronic Pain Unit, Christian Medical College, Vellore.

**Capron Alex**

Alex Capron is the first director for Ethics, Trade, Human Rights and Health Law at the World Health Organization, Geneva. He earned his LL.B at Yale University, USA, and bachelor of arts (high honours) at Swarthmore College, USA. He specialises in health policy and medical ethics. He joined WHO in October 2002 to establish the ethics and health unit in the director general's office. He previously taught law, medicine, and ethics at Georgetown, Pennsylvania, Yale and most recently at the University of Southern California where he was University Professor, Henry W Bruce Professor of Equity, Professor of Law and Medicine, and co-director of the Pacific Centre for Health Policy and Ethics.

**Cash Richard**

Richard Cash has degrees in medicine and public health. He is currently senior lecturer on international health at the department of population and international health at the Harvard School of Public Health, USA. He is also the principal investigator of a NIH training grant on ethical issues in international health research. Professor Cash was previously the principal investigator of the Applied Diarrhoeal Disease Research Project, a programme which assisted developing country scientists to develop their research abilities by conducting their own research projects. His publications and international research projects have focused on ethical issues in international health research in the developing world.

**Chandra Prabha**

Prabha S Chandra is currently additional professor of psychiatry at the National Institute of Mental Health and Neurosciences, Bangalore. Her main research interests have been in the areas of women's mental health and socio-behavioural aspects of HIV infection and cancer. She has been particularly interested in the interface between reproductive health and psychiatry, and the impact of intimate partner and sexual violence on the mental health of women. She is a member of several national and international organisations and has served as a temporary advisor to WHO and UNAIDS. She has nearly 75 publications in the above areas of research and has edited several books. She has been an editor of the Indian Journal of Palliative Care. She

has several ongoing and completed national and international research collaborations

**Chandy Sujith**

Sujith Chandy is reader, clinical pharmacology and head of pharmacy services at the Christian Medical College and Hospital (CMCH), Vellore. At the CMCH he is member of the clinical ethics committee, the medical education cell, the drug and therapeutics committee, the antimicrobial policy committee and the clinical epidemiology unit. In bioethics, his areas of interest include clinical trials, pharmaceutical industry issues, drug use issues and communication ethics.

**Chavan Savita**

Savita Chavan graduated from the Tata Institute of Social Sciences, Mumbai, with a master's degree in social work, in 1999. She joined Jaslok Hospital and Research Centre in 2000 as a medical social worker after working with the MGM hospital, Kalamboli, as a psychiatric social worker for nearly one year. She is also a director with Swayam Sanghatana, Thane, a women's organisation looking into income generation programmes.

**Chokhani R M**

RM Chokhani, is a consultant psychiatrist and counsellor at the Sunflower Hospital in Mumbai. He is also honorary secretary of the research council, Vipassana Research Institute, Igatpuri. The Vipassana Research Institute was established in 1985 with the principle aim of conducting scientific research on Vipassana meditation. It has accordingly undertaken a number of research and dissemination projects related to the the impact of vipassana on human concerns.

**Choudhary Lincoln**

Lincoln Choudhary is studying for his master's degree in public health at the Achutha Menon Centre for Health Sciences Studies, Sree Chitra Institute of Medical Sciences and Technology, Thiruvananthapuram.

**Contractor Qudsiya**

Qudsiya Contractor is researcher at the Centre for Enquiry into Health and Allied Themes, Mumbai

**Darak Shrinivas**

Shrinivas Darak is from Prayas, Pune

**Das Ashis K**

Ashis K Das is studying for the master's degree in public health at the Achutha Menon Centre for Health Sciences Studies, Sree Chitra Institute of Medical Sciences and Technology, Thiruvananthapuram.

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**David Jonathan**

College of Nursing, Christian Medical College, Vellore.

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**Dalvie Suchitra**

Suchitra Dalvie is the medical director, Family Planning Association, India.

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**Dawson Angus**

Angus Dawson is senior lecturer in ethics and philosophy and director of postgraduate research at the Research Institute for Law, Politics and Justice at Keele University in the UK. He studied for his first degree in philosophy at the University of Sussex before moving to the University of Liverpool to study for an MSc in the ethics of health care. He studied law for a year at the College of Law at Chester before returning to postgraduate study in the department of philosophy at Manchester University where he completed his PhD in 1999. He has been at Keele since 1998. His main research interests are in issues relating to problems in obtaining informed consent (particularly in a research context) and public health ethics. He is currently writing a series of articles about the ethics of vaccination policies.

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**Deshpande Sucheta**

Sucheta Deshpande is currently senior research assistant at the Maharashtra Association of Anthropological Sciences, Pune. She has done her master's in social work from the Karve Institute of Social Sciences. She has had more than five years of practical experience in HIV counselling and research. This ignited her interest in ethical issues surrounding HIV/AIDS. Her concerns are health systems research in the field of HIV focusing on the innovative programmatic approach. She has had recent publications in two peer-reviewed journals and has made presentations at international conferences and symposia.

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**Deosthali Padma**

Padma Deosthali is coordinator (designate) of the Centre for Enquiry into Health and Allied Themes, Mumbai. She is also coordinating Dilaasa, a women's crisis centre at the KR Bhabha Municipal Hospital, Bandra, Mumbai.

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**Desikan Prabha**

Prabha Desikan completed her MBBS in 1988 at the Mahatma Gandhi Institute for Medical Sciences, Sewagram (Nagpur University). She obtained an MD in microbiology from the same institute in 1992. She has worked as lecturer in microbiology at the Mahatma Gandhi Institute of Medical Sciences, Sewagram and in the Christian Medical College, Vellore. In addition, she has worked as a senior specialist in microbiology at the Riyadh National Hospital, Riyadh, Kingdom of Saudi Arabia. At present, she is associate professor and in charge of the department of microbiology at the Bhopal Memorial Hospital and Research Centre, Bhopal. Her work involves organising and co-ordinating the functions of the Institutional Review Board at the Bhopal

Memorial Hospital and Research Centre. She is a member of the American Society for Microbiology as well as the Indian Association of Medical Microbiologists.

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**Datye Vinita**

Vinita Datye is a research supervisor at the Maharashtra Association of Anthropological Sciences, Pune. She has a master's degree in social work from the Tata Institute of Social Sciences, Mumbai. She has over three years of experience in conducting research in the field of HIV/AIDS. Through her work she has gained a greater understanding of, and a special interest in, this field, especially around ethical issues in HIV/AIDS such as informed consent, confidentiality and counselling. Her broad areas of interest are health systems and qualitative research and she is keen on further research in the field of HIV counselling and testing that will feed into policy and programmes. She has recent publications in two international peer-reviewed journals and has made presentations at international conferences and symposia.

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**Ekbal B**

B Ekbal is a consultant neurosurgeon in Kottayam, Kerala. He has been a professor of neuro-surgery in the department of medical education, Kerala. He is also the former vice chancellor of the University of Kerala and has served as a member of the Kerala State Planning Board. He is an active member of Kerala Sastra Sahithya Parishad (People's Science Movement) and has functioned as its President. He is currently national convenor of Jan Swasthya Abhiyan.

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**Fernandes Stephen**

Stephen Fernandes completed a licentiate and doctorate at Accademia Alfonsiana, Rome, in ethics and moral theology and is currently professor of ethics and moral theology, St Pius College, Mumbai. He is theological consultant, Catholic Medical Guild of St Luke, Mumbai, and life member, National Catholic Bioethics Centre, Philadelphia, USA. He is co-convenor, certificate courses in biomedical ethics, FIAMC Biomedical Research Centre, Mumbai. He is a member of the ethics committee at Holy Family Hospital Medical Research Society, Mumbai; member of the ethics committee of Dr L H Hiranandani Hospital, Powai, Mumbai, and member of the Association of Moral Theologians of India.

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**Gadgil Tejasree**

Tejasree Gadgil pursued her master's in social work and is designated as community co-ordinator at the National AIDS Research Institute, Pune. Her work activities include networking with NGOs, CBOs, research institutes and key persons.

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**Gandevia Katy**

Katy Gandevia is reader at the department of medical and psychiatric social work, Tata Institute of Social Sciences, Mumbai

**Ganguly N K**

N K Ganguly is director general, Indian Council of Medical Research, New Delhi. He specialised in infectious diseases and biotechnology. He has also served acting director of the Post Graduate Institute of Medical Education and Research, Chandigarh, and president of the National Academy of Medical Sciences, New Delhi. With more than 530 research papers and many books to his credit, Dr Ganguly has contributed significantly to the medical sciences.

**George Sabu**

Sabu George works with the Centre for Women's Development Studies, New Delhi. He has spent 20 years working on girl child issues. Sabu worked with communities to ameliorate girl child malnutrition, undertook research on female infanticide in Tamil Nadu and since 1995 worked on sex selection (female foeticide). He also conducted research in Haryana. He has been involved in litigation in the Supreme Court, passing PNDT Amendments by Parliament and in implementation of the law. He collaborated with the Census 2001 authorities in disseminating the findings on declining child sex ratios (2001-2005).

**Gulhati Chandra Mohan**

Chandra Mohan Gulhati is editor of MIMS, India (Monthly Index of Medical Specialities), a journal devoted to drugs. He graduated from M G M Medical College, Indore and did his post-graduation in internal medicine and tropical medicine from England. He worked as a clinician in hospitals in India and the United Kingdom. For over eight years, Dr Gulhati worked as director of programmes on health and medical education with the International Institute for Education, Brussels, in charge of English-speaking Africa and Asia.

**Gupte Manisha**

Manisha Gupte has been part of the women's movement since the mid 1970s and has also been an activist in the health and civil rights movements in India. In 1987, she co-founded MASUM, a rural women's organisation based in Pune, and has been its co-convenor since then. She spent a year in the department of international health at the Johns Hopkins University, Baltimore as a visiting fellow. She is actively associated with pro-people and progressive organisations nationally, regionally and internationally as an advisor, trainer or board member. She has participated in and has promoted campaigns related to women's health, violence against women, sexuality and minority rights. She was the coordinator of the 10th International Women and Health Meeting that was held in New Delhi in September 2005.

**Gupte M D**

MD Gupte is director, National Institute of Epidemiology, Chennai. His field of specialisation is epidemiological data collection and analysis. He is the life member of the Indian Association of Epidemiologists, the International Epidemiological Association and the International Leprosy Association. He has served in

various capacities, from having been professor and head at the Mahatma Gandhi Institute of Medical Sciences, Sevagram, to director of the Institute for Research in Medical Statistics. He has participated in many conferences of importance such as that of the WHO Advisory Group and most recently in the IAVI Clinical Trials Subcommittee Meeting in the USA.

**Hadaye Rujuta**

Rujuta Hadaye is from the department of preventive and social medicine, Lokmanya Tilak Medical College and Municipal General Hospital, Sion, Mumbai

**Hamilton I**

I Hamilton is chaplain at the Palliative Care Unit, Christian Medical College, Vellore.

**Hossain Lucy Riffat**

Lucy Riffat Hossain is a national programme officer for Bangladesh at the International Organisation for Migration.

**Iyer Aditi**

Aditi Iyer is at the Indian Institute of Management, Bangalore.

**Jacob John T**

T Jacob John is a public health expert, especially in infectious diseases from the Christian Medical College, Vellore. He has published widely and served as consultant to national and international organisations.

**Jesani Amar**

Amar Jesani is coordinator of the Centre for Studies in Ethics and Rights, Mumbai, India. He is also coordinating a training programme in research ethics for HIV/AIDS researchers for a collaborative project of Samuha (Bangalore) and the University of California, San Francisco (USA). He is a member of the board of trustees/governing board of the Anusandhan Trust. In 1998-2000, he coordinated a national committee to formulate, for the first time in India, Ethical Guidelines for Social Science Research in Health. He is also one of the founders of the Forum for Medical Ethics Society and its journal Indian Journal of Medical Ethics.

**Jha Samar**

Samar Jha is currently in the third year, B A B L (honours) at the NALSAR University of Law, Hyderabad. He has attended and written or presented various papers in different conferences such as the Liberty and Society Seminar, organised by the Centre for Civil Society, in 2005 at Hyderabad.

**Jha Sneha**

Sneha Jha is currently in the second year of B A B L (honours.)

at the NALSAR University of Law, Hyderabad. She has attended a seminar organised by the Centre for Civil Society, namely Liberty and Society Seminar held at Hyderabad in 2005.

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### **Joglekar Neelam**

Neelam Joglekar completed her master's degree in biometry, health and nutrition. She is currently a behavioural scientist at NARI, Pune. She is involved in descriptive epidemiological studies and clinical trials in the field of HIV/AIDS, where her focus of work is microbicides. She has worked as a study coordinator for the Phase I safety and acceptability study of PRO 2000 Gel. Her main research area is microbicide acceptability. She is involved with the safety and acceptability study of the Praneem Polyherbal tablet, an indigenous microbicide. She has also participated in national and international meetings, primarily on vaginal microbicides. She is trained in good clinical practices, ethical issues related to the clinical trials as well as qualitative research methodology, data analysis and HIV counselling.

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### **Joseph Mathew**

Mathew Joseph is the head of the neurosurgery intensive care unit at the Christian Medical College, Vellore.

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### **Joshua Malhia**

Malhia Joshua is chaplain at the Christian Medical College, Vellore.

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### **Juvva Srilata**

Srilata Juvva did her doctorate from the National Institute of Mental Health and Neurosciences, Bangalore. She is currently a lecturer at the Tata Institute of Social Sciences, Mumbai.

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### **Kapadia Farhad**

Farhad Kapadia is chief of intensive care at the Hinduja Hospital, Mahim, Mumbai.

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### **Khan Robyna**

Robyna Khan is a lecturer and consultant anaesthetist at the Aga Khan University, Karachi, Pakistan. She has trained in bioethics at the University of Toronto, Canada.

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### **Kilaru Asha**

Asha Kilaru is a public health researcher from Belaku Trust, Bangalore

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### **Kousalya P**

P Kousalya is President, Positive Women Network, a self-help organisation of women living with HIV in India. She is also joint secretary of the Indian Network of People Living with HIV

(INP+); a member of the Global Coalition on Women and AIDS, UNAIDS, and a trustee member of the international community for Women Living with HIV/AIDS (WLHA) representing the Asia-Pacific region. She has been working extensively for the rights of women living with HIV in India. She was awarded a Macarthur Fellowship for Leadership Development recently.

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### **Krishnan Suneeta**

Suneeta Krishnan is currently visiting faculty at the Centre for Public Policy, Indian Institute of Management, Bangalore, and research faculty in the department of obstetrics, gynaecology and reproductive sciences at the University of California, San Francisco, USA. She has a doctorate and is an epidemiologist. She is conducting community-based research on the links between gender and other social inequalities and reproductive and sexual health in India. She is running a study in Bangalore, India, funded by the US National Institutes of Health, on gender-based power and susceptibility to HIV/STIs. She is a co-investigator on studies related to gender adherence to anti-retroviral therapy and AIDS-related stigma in India. She is a recipient of the 2004 US Presidential Early Career Award for Scientists and Engineers.

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### **Kumar Arvind**

Educated at St Stephen's College in Delhi and the Indian Institute of Management, Ahmedabad, Mr Arvind Kumar is respected for his commitment to justice and people. For three years, he initiated a campaign against sex-selective abortions in Khammam where he was the district collector. Over the last year, Mr. Kumar has been active in Hyderabad, unearthing unregistered clinics and seizing over 90 scan machines for violations of law. The chief minister of Andhra Pradesh has repeatedly publicly acknowledged these contributions to protect the rights of the girl child. Apart from this Mr Kumar also led a public campaign to raise the status of the girl child.

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### **Kumar Basanth**

Basanth Kumar is a tutor in psychiatry, Christian Medical College, Vellore.

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### **Laplante Pierre**

Pierre Laplante has worked as a nurse for 33 years. His initial training was with the US Navy during the Vietnam war. He specialised in the care of AIDS patients in Los Angeles. After emigrating to Canada, Mr Laplante served with MÇdecins Sans Frontières (MSF) on two missions in Central Africa. Following his first master's degree, he worked with aboriginals in arctic Canada, and then went on his third MSF mission. In recent years, palliative care has commanded his interest and focus. He also has a master's in bioethics and is now doing doctoral studies in nursing at McGill University in Montreal, Canada in a collaborative agreement with the Institute for Islamic Studies, also at McGill.

### **Lavery James V**

Jim Lavery is a research scientist in the Centre for Research on Inner City Health and Centre for Global Health Research, St Michael's Hospital, and an assistant professor in the department of public health sciences at the University of Toronto. He received master's and doctoral degrees at the Institute of Medical Science and the Joint Centre for Bioethics at the University of Toronto. Subsequently he received a post-doctoral fellowship in applied ethics and health policy from the Social Sciences and Humanities Research Council and the Canadian Health Services Research Foundation. Most recently, Prof. Lavery spent three years at the Fogarty International Centre and the Warren G. Magnuson Clinical Centre's department of clinical bioethics, both at the National Institutes of Health in Bethesda, Maryland, USA. His current research interests are in ethics and health research systems in developing countries, the US Common Rule regulation on equivalent protections in international research, and ethical issues in research with marginalised populations. He has recently edited a book of case studies in international research ethics with colleagues at the NIH, which will be published in 2006 by Oxford University Press.

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### **Lingam Lakshmi**

Lakshmi Lingam is a professor in the Women's Studies Unit, at the Tata Institute of Social Sciences, Mumbai, India. She has been on the faculty since 1988. She has been teaching courses on gender and health to master's students in social work and health administration at the institute. She holds a doctorate from the Indian Institute of Technology, Mumbai. She had carried out several research projects and has published several papers on the subjects of women-headed households, the girl child, sex selective abortions, women's studies, reproductive rights, occupational health, women's health, migration, structural adjustment policies and gender. She has edited a book, *Understanding women's health issues: a reader* (1988), published by Kali for Women, New Delhi. This is widely used in Indian universities as a textbook. She has several papers in reputed journals and monographs.

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### **Madhivanan Purnima**

Purnima Madhivanan graduated from Mysore Medical College in 1994. Her interest in HIV, from clinical, prevention and treatment perspectives, was stimulated during her work with YRG CARE, Chennai, India. As a Fogarty fellow, she trained in the epidemiology of HIV in women at Brown University and conducted research in women's health and HIV in India. She completed her master's in public health at the University of California School of Public Health in 2003. She is currently a doctoral candidate in epidemiology at the University of California and is conducting her dissertation research at Asha Kirana Hospital, Mysore, in the sexual transmission of HIV and HSV among women.

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### **Madhiwalla Neha**

Neha Madhiwalla is a social scientist involved in health research and education activities and is working at the Centre for Studies

in Ethics and Rights, Mumbai. She has done extensive research on women's health issues and on the problems of poor people displaced and involuntarily resettled due to government policy. From 2004 to 6, she was awarded the MacArthur Foundation fellowship for Leadership Development to design and implement a health and life skills programme for adolescent girls. At present she is the managing trustee of Chehak Trust, which runs Sahyog, a community-based initiative for primary health and education with a specific focus on women and girls. In addition to providing access to basic services, Sahyog is also a resource organisation for training of trainers in life skills programmes and women's health.

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### **Mahabal Kamayani**

Kamayani Mahabal is a lawyer involved in work on health and human rights at the Centre for Enquiry into Health and Allied Themes, Mumbai.

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### **Malik Rupsa**

Rupsa Mallik is currently programme director at the South Asia Office, New Delhi of Centre for Health and Gender Equity (CHANGE), a US based international reproductive health and rights organisation. She leads CHANGE's in-country work in India with a particular focus on population policies, sex selection and reproductive and contraceptive choice and access. She has a master's in development studies from the Institute of Social Studies, the Netherlands. Prior to joining CHANGE in 2001, Rupsa worked for the National Foundation for India (NFI) from 1994 to 2001 as a senior programme officer. Much of her work at NFI focused on defining and implementing the Foundation's work in one of its core programme areas, gender equity and justice.

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### **Mamdani Bashir**

Bashir Mamdani was born in Tanga, Tanzania, and did his initial medical training from Seth GS Medical College, Bombay. He trained as a nephrologist and retired in 1998 as associate chairman, department of medicine, Cook County Hospital, Chicago, IL USA. His special interests include critical care and quality assurance.

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### **Mamdani Meenal**

Meenal Mamdani did her undergraduate studies at Seth GS Medical College, Bombay. She obtained training in neurology at Mount Sinai Hospital, Chicago, and joined the staff of VA Hospital, Hines IL, USA, retiring in 2000 as assistant chief of the department of neurology. She has a special interest in epilepsy and sleep medicine.

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### **Mane Nitin**

Nitin Mane has a master's in social work and is working as a counsellor at the National AIDS Research Institute, Pune. He is engaged in organising focus group discussions (FGD) and

conducting individual interviews, transcription, translations of FGDs and interviews, counselling, screening, enrolment, pre and post-test counselling, etc. He is also involved with administering informed consent, completing the follow-up visits of volunteers, volunteer recruitment, organising community meetings of various target groups and arranging meetings of additional informational sessions of interested volunteers.

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### **Mani R K**

R K Mani is a senior consultant with Indraprastha Apollo Hospitals, New Delhi. He is president (elect) of the Indian Society of Critical Care Medicine where he is also chairperson of the committee for end-of-life issues in critical care.

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### **Mathiharan K**

K Mathiharan passed his completed his MBBS and MD in forensic medicine from Madurai Medical College and Madras Medical College respectively. He received his doctorate from the Dr MGR Medical University on the subject: 'Res Ipsa Loquitur: its application in medical negligence cases under the Consumer Protection Act.' He later joined the faculty of the Institute of Forensic Medicine, Madras Medical College as assistant professor. He is editor of the 23rd edition of Modi's Medical Jurisprudence and Toxicology. In 1996, he founded the Institute of Legal Medicine, in Chennai, a data centre on medical law and ethics, consumer rights, human rights and other issues involving the relationship of the life sciences to the social sciences and humanities. At present, he is a practising consultant in legal medicine.

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### **Mathan V I**

VI Mathan is retired professor of medicine and gastroenterology and former director of the Christian Medical College, Vellore, Tamil Nadu. He is at present the ICMR Chair of Epidemiology.

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### **Mehendale Sanjay**

Sanjay Mehendale is senior grade deputy director of the National AIDS Research Institute, Pune, Indian Council of Medical Research. He has worked in the field of epidemiology of viral diseases for past 19 years. He is a member of the ethics committee of the National Institute of Virology, Pune, and a member of the project advisory committee of the KEM Hospital and Research Centre, Pune. He is a member of the Technical Resource Group on Counselling and also of the Technical Resource Group on Research and Development of the National AIDS Control Organisation. At the international level, he is member of the Indo-French [ICMR-INSERM] joint working group, the Indo-US joint working group on maternal and child health and the executive committee of the HIV Prevention Trial Network.

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### **Menon Aravind R**

Aravind Menon is at present studying for his master's in public health at the Achutha Menon Centre for Health Sciences Studies,

Sree Chitra Institute of Medical Sciences and Technology, Thiruvananthapuram.

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### **Mishra Udaya**

Udaya Mishra did his doctorate from the International Institution of Population Sciences, Mumbai. He currently is a faculty member at the Centre for Development Studies, Thiruvananthapuram.

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### **Mocherla Shobha**

Shobha Mocherla is an audio-visual producer at the LV Prasad Eye Institute, Hyderabad, India. She is involved in the production of training videos for ophthalmologists and patient education videos on eye care and rehabilitation of the blind and visually impaired. She completed her masters programme from the University of Hyderabad in 1992.

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### **Mosavibasab M**

M Mosavibasab is from Shiraz University of Medical Sciences, Iran.

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### **Mujhawar Altaf**

Altaf Mujhawar pursued his master's in social work and is designated as health outreach worker at the National AIDS Research Institute, Pune. He is involved with community outreach work, home visits for the purpose of retention, networking with NGOs and CBOs, collecting qualitative and quantitative data, arranging community-based meetings for the vaccine trial, conducting couple meetings for enrolment in the Praneem study and organising peer training programmes.

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### **Mukherjee Manjeer**

Manjeer Mukherjee is pursuing her doctorate in sociology from the Jawaharlal Nehru University, New Delhi, and working in SAMA Resource Group for Women and Health, a New Delhi-based women's organisation working on issues related to women and health from a gender and rights perspective. At SAMA she is currently coordinating an action research project on the medical and social implications of assisted reproductive technologies on women, especially artificial insemination, in-vitro fertilisation and surrogacy. She has been actively engaged in the civil society deliberations around sexual and reproductive rights and right to health care in India.

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### **Mukhopadhyay Barun**

Barun Mukhopadhyay is an anthropologist who has long been researching the bio-cultural determinants of health and health care among the tribal populations of Sikkim and Darjeeling. Bioethics in general and health care ethics in particular have been among his major interests. He is at present associate professor in the biological anthropology unit of the Indian Statistical Institute, Kolkata.

**Mukhopadhyay Sushmita**

Sushmita Mukhopadhyay obtained her doctorate in anthropology from the University of Calcutta. Her research interests include evaluation of the health status of women over their entire life span, and the relation to work outside the home. She has conducted research on various health issues, involving women in different occupational categories to find out how the family support system, work and non-work factors reduce the stresses on couples who must effectively perform dual roles. At present she is engaged in research on reproductive health with an emphasis on ethical issues of reproductive health. She is assistant professor in the biological anthropology unit of the Indian Statistical Institute, Kolkata.

**Mule Meena Dyaneshwar**

Meena Dyaneshwar Mule pursued her master's in social work and is currently designated as health visitor at the National AIDS Research Institute, Pune. She is involved with community outreach work, networking with NGOs and CBOs, collecting qualitative and quantitative data, arranging community-based meetings for vaccine trials and conducting couple meetings for enrollment in the Praneem vaginal microbicides study.

**Muliyil Jayaprakash**

Jayaprakash Muliyil is an epidemiologist and public health specialist. At present he serves as principal of the Christian Medical College, Vellore.

**Muthuswamy Vasantha**

Muthuswamy is the senior deputy director general, Indian Council of Medical Research, New Delhi. She heads the division of basic medical sciences, traditional medicine and biomedical ethics at the ICMR. Dr Muthuswamy played an important role in assisting the national committee that formulated the ICMR's Ethical Guidelines for Biomedical Research. She is a member of the editorial advisory board of IJME.

**Nabeel MK**

Nabeel MK is from Kannur Medical College and the Academy of Medical Sciences, Kerala.

**Nalini A**

Nalini A is from Dr MGR Medical University, Chennai, Tamil Nadu.

**Nanda Priya**

Priya Nanda is senior programme associate at the Centre for Health and Gender Equity (CHANGE), Maryland, USA.

**Oxley Keri**

Keri Oxley is a second-year student at the Yale University School

of Medicine, U S A where she is also accepted in its School of Epidemiology and Public Health, specialising in global issues. Ms Oxley is a 2004 graduate of the University of Notre Dame. She was selected to aid in Hurricane Mitch relief efforts near San Lorenzo, Honduras. She has also spent the summer of 2002 in Kolkata, India, where she served in Mother Teresa's Home for the Destitute and Dying. She studied in Toledo, Spain, during the Fall 2002 semester and gained proficiency in Spanish. Expanding on her undergraduate philosophy major, she has continued her interest in bioethics. She anticipates her Yale medical thesis to be on informed consent in Indian medical research. This is under the mentorship of Dr Robert Levine, chairperson of the Yale Bioethics Project.

**Pai Sanjay A**

Sanjay A Pai graduated from the Grant Medical College, Mumbai. He obtained his MD in pathology at Tata Memorial Hospital, Mumbai, where he subsequently worked as a consultant. He is at present consultant and head, department of pathology, Manipal Hospital, Bangalore. He has been associated with the *Indian Journal of Medical Ethics* since 1996 and is a member of the editorial board. He is also on the working committee of the *National Medical Journal of India*. Dr Pai is a regular contributor to the *BMJ* and other national and international journals. His areas of interest include ethics and history of medicine.

**Pandya Sunil K**

Sunil K Pandya retired as head of the department of neurosurgery at the KEM Hospital, Mumbai and is at present a consultant neurosurgeon at the Jaslok Hospital, Mumbai. He is editor emeritus, *Indian Journal Medical Ethics*.

**Pant Ritu**

Ritu Pant is from Prayas, Pune.

**Parkhe Aparna**

Aparna Parkhe pursued her master's in social work and L L B. She is currently senior investigator in an international collaborative research project between the National AIDS Research Institute, Pune, and the Johns Hopkins University, Baltimore, USA. Her work involves clinic coordination, administration and supervision of clinic-based data management. She conducts group counselling for women who visit for antenatal care and provides information about HIV/AIDS with reference mother to child transmission. She is involved in clinical trials in the field of HIV /AIDS. She has worked on the Phase I safety and acceptability study of the Praneem Polyherbal tablet. She is trained in good clinical practices, and ethical issues related to clinical trials.

**Parasuraman S**

S Parasuraman is at present director of the Tata Institute

of Social Sciences, Mumbai. He holds a master's degree in social anthropology from the University of Pune (1977), and a doctorate (Science) in demography from the Indian Institute of Technology, Bombay, the International Institute for Population Sciences, Bombay, and the University of Bombay (1982). He has been a United Nations Fellow on population and development at the Institute of Social Studies, The Netherlands (1988) and Senior Fellow at the Institute of Social Studies, The Hague (1993). He has been regional policy coordinator for Asia for Action Aid, Thailand. He was senior advisor to the commission, and team leader of the secretariat on the World Commission on Dams. He also served as programme director of Oxfam GB, India.

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### **Patil Bharati**

Bharati Patil pursued her master's in social work and M Phil. Since May 2005, she has been working as community coordinator for the IAVI HIV/AIDS Vaccine Trial Project in India. She is involved with the overall administering, monitoring and coordinating of community outreach work at NARI, Pune. She has been a lecturer at the department of social work at the Shivaji University, Kolhapur, Maharashtra.

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### **Patil Rajan**

Rajan R Patil is an epidemiologist and a vocal public health activist with a penchant for adventure and exploration. His field work has taken him across various states in India in an effort to operationalise the best of theoretical concepts into action. His core areas of research include vector-borne diseases and occupational/environmental health. His contributions have been published in national and international peer-reviewed medical journals. He is part of different national networks associated with various movements and issues related to health. He is of the strong conviction that science and activism complement each other in evolving innovative and effective public health interventions. He is currently working with the United Nations.

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### **Pathak Shubhangi**

Shubhangi Pathak is a student of law currently studying in the fourth year B A B L (honours) at NALSAR University of Law, Hyderabad. She has interned with the Commonwealth Human Rights Initiative, the Trial Court and the Delhi High Court. Her work on family law and criminal law (criminalisation of AIDS) has been published in the Andhra Law Times and the Criminal Law Journal respectively.

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### **Patole Prakash**

Prakash Patole pursued his master's in social work and currently holds the designation of community educator at the National AIDS Research Institute, Pune. He is involved in community outreach work, home visits for the purpose of retention, networking with NGOs and CBOs, collecting qualitative and quantitative data, arranging community-based meetings for vaccine trials, conducting couple meetings for enrolment in the Praneem study and organising peer training programmes

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### **Nagral Sanjay**

Sanjay Nagral is a consulting surgeon at the Jaslok Hospital, Mumbai, with expertise in liver transplantation. He is also chairperson of the Forum for Medical Ethics Society, Mumbai and on the editorial advisory board of the Indian Journal of Medical Ethics.

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### **Patwardhan Sujata**

Sujata Patwardhan is from the department of urology, Lokmanya Tilak Medical College and Municipal General Hospital, Sion, Mumbai

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### **Paul Yash**

Yash Paul is a consultant pediatrician, Maharaja Agrasen Hospital, Jaipur, Rajasthan.

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### **Phadke Mrudula**

Mrudula Phadke pursued a master's in social work and is a senior investigator at the National AIDS Research Institute, Pune. She is involved in coordinating operational research on school-going adolescents and teachers about reproductive and sexual health issues and developing a research proposal for the National Institute of Health (USA) for HIV-infected and affected children in India.

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### **Pitre Amita**

Amita Pitre is joint coordinator of the Centre for Enquiry into Health and Allied Themes, Mumbai. CEHAT is involved in socially relevant and pro-people research, action and advocacy on matters of health and access to health care. She is a graduate in ayurvedic medicine with a master's in health sciences from the University of Pune.

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### **Pradeep T**

T Pradeep initiated the development organisation 'Samuha'. Pradeep has been in development, disaster management and communications since 1972. In 1986, he was regional field director for Andhra Pradesh, Karnataka and Goa for ActionAid. He decided to go back into the field and to use the development overview that he had gained to develop a professional organisation. Samuha was registered as an independent society in August 1986, and started off with a small 24-village project in 1987. Pradeep's development experiences range from volunteer stints to heading institutions, from desilting salt pans to remote sensed micro applications.

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### **Rahman Adeel Ahmed**

Adeel Ahmed Rahman is advocate at the Lucknow Bench, Allahabad High Court

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### **Rajagopalan Ram E**

Ram E Rajagopalan is consultant and head of the department of critical care medicine at the Sundaram Medical Foundation, Chennai. He is also President of the Indian Society of Critical Care Medicine.

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### **Ramakrishna Jayashree**

Jayashree Ramakrishna is currently additional professor and head of the department of health education at the National Institute of Mental Health and Neuro Sciences, Bangalore. Her research areas include the socio-cultural aspects of reproductive health, alcohol, epilepsy, sexuality, HIV/AIDS and tropical diseases. Her areas of interest include women's health issues, reproductive health, sexuality and sexual behaviour, qualitative research methods, tropical diseases and social change.

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### **Ramanathan Mala**

Mala Ramanathan has master's degrees in statistics and medical anthropology and a doctorate in population studies. She is an associate professor at the Achutha Menon Centre for Health Science Studies, Sree Chitra Institute of Medical Sciences and Technology, Thiruvananthapuram.. She is currently an Ethics Fellow at the Programme on Ethical Issues in International Health Research, department of population and international health, Harvard School of Public Health, USA. She is a member of two ethics committees in India and works on issues related to gender and health and ethics in international health.

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### **Rehman Talha Ahmed**

Talha Ahmed Rehman is student at the NALSAR University of Law, Hyderabad.

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### **Reddy J Sessa**

J Sessa Reddy is head of the Ramachandra Reddy Memorial People's Polyclinic, Nellore. He is widely respected all over Andhra Pradesh for his commitment to providing quality health care for the poor. Dr Reddy joined Madras Medical College in 1947 and since the mid 1950s has been at the Nellore Hospital. His hospital has trained over 200 doctors who are working all over state. He has motivated the mass organisation Jana Vignana Vedike to take up the campaign against sex selection in Andhra.

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### **Rege Sangeeta**

Sangeeta Rege is with the Dilaasa Crisis Centre for Women, Centre for Enquiry in Health and Allied Themes, Mumbai

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### **Rajalakshmi**

Rajalakshmi is a graduate in psychology with a master's in social work from the Tata Institute of Social Sciences, Mumbai. She also has a postgraduate diploma in medical law and ethics from the National Law School of India University (NLSIU), Bangalore. She

is a current recipient of the Health and Population innovation programme fellowship 2004 awarded by the Population Council (MacArthur Fellowship). Her present project, on informed consent in reproductive health services, is one of the few empirical studies exploring an important ethical dimension of reproductive health services. Earlier she was a research assistant at the Centre for Women and Law, NLSIU. Her article on de-linking trafficking and prostitution was published in Canadian Women's Studies Journal. She also has experience as a coordinator and gender trainer in health projects reaching to urban communities.

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### **Roy Nobhojit**

Nobhojit Roy is the head of the department of surgery at the BARC Hospital, which is a 300-bed community health-care provider for 100,000 beneficiaries in the metropolis of Mumbai, tied together under a health insurance scheme. The department handles secondary and tertiary surgical referrals from 12 other hospitals around India. His academic responsibilities include mentoring two postgraduate candidates every year in general surgery for national board accreditation. Within bioethics, his areas of interest are the impact of high-tech medical technology (especially biotechnology); ethical drug promotion, patenting and essential medicines; end-of-life options and the study of ethics in complex humanitarian emergency settings. He is a faculty member at the Centre for Study in Ethics and Rights, Mumbai, and web editor, IJME.

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### **Sajitha OG**

OG Sajitha is working as a research assistant at the Achutha Menon Centre for Health Sciences Studies, Sree Chitra Institute of Medical Sciences and Technology, Thiruvananthapuram. She completed bachelor's degrees in mathematics and in education and a master's degree in demography. She was awarded a lectureship (NET, UGC) in population studies and joined the department of demography for her doctoral studies at the University of Kerala. She was awarded the Indian Council of Social Science Research doctoral fellowship by the ministry of human resources development, government of India, for her doctoral work on reproductive health challenges of tribal women in Kerala. Currently she is among the state resource persons of the Kerala State Literacy Mission Academy, government of Kerala.

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### **Sahay Seema**

Seema Sahay holds master's and doctoral degrees in anthropology. She is currently a senior research officer at the National AIDS Research Institute [NARI], Pune. For the past 10 years, she has worked in ethnographic research, human cytogenetics and reproductive health of tribals in the Chota Nagpur area. For the past six years she has worked in the field of HIV/AIDS at NARI, Pune. She is currently working in the field of social and behavioural sciences, descriptive epidemiology of HIV disease closely associated with human subject research and ethical issues pertaining to it. Her major areas of research are:

care and support of HIV-infected individuals, particularly their adolescent reproductive and sexual health, clinical trials, HIV vaccine trials and community issues associated with trials.

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### **Sant Asavari**

Asavari Sant is a pathologist by training. She has been motivated by Parivartan activists to join efforts to stop the widespread practice of foetal sexing in Belgaum. For over three years, Dr Asavari has publicly been involved in raising this issue with fellow medical professionals. Most recently, she wrote a piece in the *District IMA Bulletin*, which she edits.

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### **Sarojini N B**

N.B Sarojini is the founder of SAMA Resource Group for Women and Health, New Delhi, a non-profit organisation which believes in confronting all forms of discrimination, primarily in the area of health, reproductive rights, violence. SAMA focuses on equality, empowerment and rights of women, especially from marginalised communities. Sarojini has been working a health activist in the field of women's health for the last 15 years and is actively involved with the women's movement. She has been involved in Shodhini, a national-level research network on traditional medicine and alternative health system for women. She has been closely associated with different progressive organisations and networks such as the Medico Friend Circle and the People Health Assembly.

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### **Sastry Jaygowri**

J Sastry is involved in the John's Hopkins University-MIT study at the BJ Medical College, Pune.

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### **Sawant Ajit**

Ajit Sawant is from the department of urology, Lokmanya Tilak Medical College and Municipal General Hospital, Sion, Mumbai

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### **Saxena Abha**

Abha Saxena is currently staff scientist at the WHO Research Ethics Review Committee (ERC), Geneva. An anaesthesiologist by training, till December 1999 Dr Saxena was heading the unit of anaesthesiology at the Institute Rotary Cancer Hospital, a Regional Cancer Centre affiliated to the All India Institute of Medical Sciences, New Delhi. She started the cancer pain and palliative care services for the Cancer Centre in 1993, and also established home care services for patients with terminal cancer. A training course in research ethics at the Harvard School of Public Health stimulated the desire to continue working in research ethics, and an offer of a job with the WHO allowed her to do so. At the WHO RERC, she has been coordinating the activities of the committee and ensuring that all research that is supported by WHO follows international recommendations for protection of study participants. She has initiated training workshops for WHO staff working in the area of health research.

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### **Seetharam Sridevi**

Sridevi Seetharam is trained in medicine and pathology at Mysore Medical College and at the PGIMER, Chandigarh. She is at present head of diagnostic services at the Vivekananda Memorial Hospital, Saragur, Mysore District. She is a core team member of the Swami Vivekananda Youth Movement. She heads the voluntary testing and counselling centre and the blood storage centre at Vivekananda Memorial Hospital, both pioneering efforts in government - NGO collaboration for HIV/AIDS intervention in rural and underserved areas. She also heads the counselling department, which is an innovative and comprehensive model of integrating HIV issues into general health care. She chairs the Bio-medical Waste Management Committee at the hospital. Her special interests include cytology, haematology, cancer screening, immunology, training and capacity building in HIV/AIDS, and ethical issues in clinical care and biomedical research.

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### **Sekhar K**

K Sekhar is from the department of psychiatric social work at the National Institute of Mental Health And Neurological Sciences, Bangalore. He has prepared the psychosocial care manual in the context of disasters.

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### **Sen Abhijit**

Prof Abhijit Sen has a doctorate in economics from the University of Cambridge. He has joined the Planning Commission on leave as professor of economics in Jawaharlal Nehru University, New Delhi. He earlier held teaching posts at the Universities of Sussex, Oxford and Cambridge and is currently on the Senate/Executive Committees of NT, Delhi and National Centre for Agricultural Policy.

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### **Sengupta Amit**

Amit Sengupta is associated with the Delhi Science Forum, a public interest organisation working on science and technology policy issues. He is trained in medicine, and works on issues related to public health, pharmaceuticals policy, Intellectual Property Rights and other science and technology issues. He has been involved in several projects of the department of science and technology, government of India. He has been the secretary of the All India People's Science Network and is member of the international secretariat of the World Social Forum.

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### **Sengupta Anasuya**

Anasuya Sengupta completed the economics programme (honours) at Lady Shri Ram College, Delhi University. She then worked as a programme officer for Samuha, a rural development NGO in north Karnataka. She went on to do an M Phil in development studies, as a Rhodes scholar at the University of Oxford. For the past three years, she has been coordinator of a UNICEF project with the Karnataka police, working on violence against women and children. She is also a facilitator

and researcher for gender at work, supporting action learning processes of development organisations in South Africa and India, and advisor to a maternal mortality campaign in North Karnataka, run by the government of Karnataka and the Indian Institute of Management, Bangalore. She was a member of the first Young Women and Leadership International Advisory Committee for the international organisation Association of Women's Rights in Development, and continues to be a trustee of JournalServer.Org (for free access to online journals), and member-secretary to the Institutional Ethics Committee of Samraksha, an NGO working on HIV/AIDS. She has just completed editing, along with Shamillah Wilson and Kristy Evans, AWID's anthology of young feminist perspectives from around the world, published by Zed books (October 2005), *Defending our dreams: global feminist voices for a new generation*.

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### **Shah Ghanshyam**

Ghanshyam Shah is former director of the Centre for Social Studies, Surat, and professor (retired) at the Centre for Social Medicine and Community Health, Jawaharlal Nehru University, New Delhi. He has had 35 years of research and teaching experience at some of the best institutions in the country. In 1995 he was a visiting faculty to the University of Amsterdam. In 1996, he was part of the Indian Council of Social Science Research's delegation to Vietnam. He has been the recipient of many national and international awards, including the University Grants Commission's National Lecturer for 1985-86 and the Fulbright Award under the United States Educational Foundation in India for 1984. He has made a tremendous contribution to his field as a prolific writer of books, articles and editorials.

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### **Shahmanesh Maryam**

Maryam Shahmanesh works with the Positive People's Network, Goa.

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### **Shatrugna Veena**

Veena Shatrugna is the deputy director, National Institute of Nutrition, Hyderabad. Her areas of work include nutritional issues of women and children.

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### **Shrimali Sumit**

Sumit Shrimali has a master's degree in hospital administration from IMS, DAVV, Indore, specialising in health care marketing. He has had three years of managerial experience in hospitals. He is at present pursuing a master's degree in public health from the Achutha Menon Centre for Health Sciences Studies, Sree Chitra Institute of Medical Sciences and Technology, Thiruvananthapuram.

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### **Singh Ashwani K**

Ashwani K Singh has a master's degree in business administration

(hospital administration) with specialisation in finance from IMS, DAVV, Indore. She has had five years of managerial experience in hospitals. She is at present pursuing a master's degree in public health from the Achutha Menon Centre for Health Sciences Studies, Sree Chitra Institute of Medical Sciences and Technology, Thiruvananthapuram.

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### **Sivadas Akhila**

Founder of the Centre for Advocacy and Research, New Delhi, Akhila Shivdas is a familiar face on television on media issues. CFAR has been active in the campaign against sex selection for more than five years. It ensured that the judgements of the Supreme Court were widely disseminated in the media and the Census 2001 findings were exhaustively covered. In collaboration with Centre for Women's Development Studies, New Delhi, CFAR has organised seven major media workshops since January 2003. Starting in mid-2005 it has initiated work in Rajasthan to stop sex selection.

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### **Solas Vikram**

Vikram Solas pursued a master's degree in social work. He is at present a research assistant and community worker at the National AIDS Research Institute, Pune. He is involved with community outreach work, doing home visits for the purpose of retention, networking with NGOs and CBOs, collected qualitative and quantitative data, arranging community-based meetings for a vaccine trial, conducting couple meetings for enrollment in the Praneem vaginal microbicides study and organising peer training programmes.

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### **Solomon Suniti**

Suniti Solomon is the founder director of the Y R Gaitonde Centre for AIDS Research and Education (YRG CARE) in Chennai. She and her colleagues documented the first evidence of HIV infection in India in 1986. As a professor of microbiology at the Madras Medical College and the Government General Hospital, she established the first voluntary testing and counselling centre and AIDS Research Group in Chennai. Dr Solomon is a member of the advisory board of International AIDS Vaccine Initiative, India, member of the scientific committee of the National AIDS Research Institute, Pune, a permanent member on the microbicides committee of the Indian Council for Medical Research, member of the technical review panel of the Global Fund to fight AIDS, Tuberculosis and Malaria, and member on the board of AVAHAN.

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### **Srinivas G**

Srinivas G is from Dr MGR Medical University, Chennai, Tamil Nadu.

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### **Srinivasan S**

S Srinivasan is the managing trustee of the LOCOST, Baroda.

He pioneered the movement on rational therapeutics and has consistently led advocacy on pro-people drug policy reforms. He is currently editor of the *Medico Friend Circle Bulletin*.

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### **Srinivasan Sandhya**

Sandhya Srinivasan is a freelance journalist and consultant with master's degrees in sociology and public health. She writes on health and development for various publications and websites, and was a Panos Reproductive Health Media Fellow in 1998, writing on the infertility industry in India. She is consultant on health and population for the development website [www.infochangeindia.org](http://www.infochangeindia.org). Ms Srinivasan is executive editor of the *Indian Journal of Medical Ethics*, member of the editorial board of *Developing World Bioethics* and member of the institutional review board of the National Institute for Research in Reproductive Health. In 2002, she was awarded Ashoka Fellowship for work in medical ethics.

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### **Sudarshan H**

H Sudarshan graduated as a doctor in 1973 and started working with the Soliga tribals in BR Hills, Karnataka in 1979. He founded Vivekanand Girjan Kalyan Kendra in 1981. He has been, at various points, vice-president of the Voluntary Health Association of India, member of the Independent Commission on Health in India (1998) and member of the Indian Planning Commission's steering group for the development of Scheduled Tribes. He has been a member of the Bangalore University Senate since 1988. He has received the Parisara (Environment) Award from the Government of Karnataka in 1993 and is president of two other NGOs.

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### **Sumathipala Athula**

Athula Sumathipala is a psychiatrist from Sri Lanka. He is associated with the Institute of Psychiatry, King's College, London.

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### **Supre Avinash**

Avinash Supre is professor and head of surgical gastroenterology at KEM hospital, Mumbai. He has held academic positions at the University of Mumbai and the Tata Institute of Social Sciences. He has been director of medical education at the Maharashtra University of Health Sciences. He has been the global faculty advisor, ECFMG, FAIMER, Philadelphia and conducted WHO-ICMR workshops on ethical issues in research. He has to his credit 131 published articles and 135 papers presented at national and international conferences. He has been organiser and faculty member on 162 surgical and educational workshops. He is currently Member of the institutional ethics committee at KEM Hospital, Mumbai.

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### **Suryawanshi Vandana Sanjay**

Vandana Sanjay Suryawanshi pursued her master's in social work

and is designated as health visitor at the National AIDS Research Institute, Pune. She is involved with community outreach work, networking with NGOs and CBOs, collecting qualitative and quantitative data, arranging community-based meetings for the vaccine trial and conducting couple meetings for enrolment in the Praneem vaginal microbicides study.

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### **Swarnalakshmi S**

S Swarnalakshmi is a member of the institutional review board, community advisory board and regulatory coordinator at YRG CARE, Chennai.

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### **Tandon P N**

Prakash Narain Tandon received his medical education at KG Medical College, Lucknow, graduating in 1950. He founded the department of neurosurgery at the All India Institute of Medical Sciences, New Delhi. His vision led to the establishment of a National Brain Research Centre (NBRC) by the department of biotechnology, government of India. He was nominated as the first president of the NBRC Society and chairman of its Scientific Advisory Committee. He has been honorary surgeon to the president of India and member, science advisory council, to the prime minister. He was awarded the Padma Shri in 1973 and the Padma Bhushan in 1991.

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### **Thatte Urmila**

Urmila Thatte is member secretary of the Independent Ethics Committee, Mumbai. She is also professor and head of the department of clinical pharmacology, Topiwala National Medical College and BYL Nair Charitable Hospital, Mumbai. She has an MD and doctorate in pharmacology from the University of Mumbai, as well as a diplomate of the National Board of Examinations, New Delhi, in clinical pharmacology. She heads the Dr Dahanukar Advanced Centre for Ayurveda Research, Training and Services and is also co-ordinator of the Maharashtra Unit of the WHO-India Essential Drugs Programme. She has served as faculty on the Drugs and Therapeutic Committees Course sponsored by WHO and has convened and served as faculty on several courses pertaining to good clinical practices (GCP), research methodology and scientific communications. Recently she completed a project on developing training modules on GCP for the Drugs Controller General of India. Dr Thatte serves on the ethics committees of the National Institute for Research in Reproductive Health and the KEM Hospital, Mumbai as well as on the Independent Ethics Committee. She is secretary of the Forum for Ethics Review Committees in India.

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### **Thomas George**

George Thomas was born in Chennai. After schooling at the St George's Anglo-Indian High School, he studied economics for two years at The Loyola College, Chennai. During this time he came into contact with several marxist groups and developed an interest in issues related to poverty

and development. He then joined the Kilpauk Medical College for medical training which he completed in 1983. Here he met people who were in the Medico Friends Circle, a group of people interested in health care issues in India. He did a postgraduate diploma in orthopaedics at the Trivandrum Medical College. He has been working in the Railways since 1987. He is editor of the *Indian Journal of Medical Ethics*.

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### **Udgaonkar Sangeeta**

Sangeeta Udgaonkar is an advocate and intellectual property rights consultant, in Bangalore, Karnataka.

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### **Vallikad Elizabeth**

Elizabeth heads the department of gynaecologic oncology at St Johns Medical College, Bangalore. Educated at St Johns and CMC Vellore, Dr Elizabeth did her doctorate while working at the Kidwai Cancer Hospital, Bangalore. She served in this public hospital for 16 years. She has been involved in cancer prevention efforts in collaboration with primary health centres in Karnataka. Dr Elizabeth is deeply committed to medical ethics.

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### **Vasan Akhila**

Akhila Vasan is from the Foundation for Research in Health Systems, Bangalore

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### **Visaria Leela**

Leela Visaria holds a doctorate from Princeton University. She has been a professor at the Gujarat Institute of Development

Research since 1987 and is now director. She co-authored a book: *Contraceptive use and fertility in india: a case study of Gujarat* (1995). She has co-edited publications including *Maternal education and child survival: pathways and evidence* (1997) and *India in the 21st century*. Since 1996, she has served as a coordinator of the network of non- governmental organisations, researchers and women activists - HealthWatch. Her research interests include historical demography, field-based studies on problems of health, family planning, education and demographic transition. Her articles have appeared in several scholarly journals.

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### **Waghela Jagruti**

Jagruti Waghela is a surgeon at the Lokmanya Tilak Medical College, Mumbai. She has done her post-graduation studies in bioethics at the Monash University in Australia and is a member of various ethics committees.

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### **Wikler Dan**

Daniel Wikler is Mary B Saltonstall Professor of Population Ethics in the department of population and international health at the Harvard School of Public Health. Prof Wikler served as the first "staff ethicist" at the World Health Organization in Geneva. His current fields of interest include ethical dimensions of health resource allocation; the ethics of experimentation with human subjects; and ethical dilemmas of global public health practice. His published work addresses many issues in bioethics. In recent years it has focused on population health, including issues resource allocation, and global public health.

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## COLLABORATING INSTITUTIONS (Members, Organising Committee)

1. Tata Institute of Social Sciences, Mumbai (**Prof Shalini Bharat**)
2. Sree Chitra Tirunal Institute of Medical Sciences and Technology, Thiruvananthapuram (**Dr Mala Ramanathan**)
3. SAMA, New Delhi (**Ms N B Sarojini**)
4. National AIDS Research Institute, Pune (**Dr Sanjay Mehendale**)
5. MASUM, Pune (**Dr Ramesh Awasthi**)
6. LOCOST, Vadodara (**Mr Chinu Srinivasan**)
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The financing of the First National Bioethics Conference has been as participatory as its organisation. Twenty institutions comprising the Organising Committee have fully sponsored six delegates each – including their registration, accommodation and travel. In addition, many delegates have paid for their expenses. Totally, over 40 per cent of expenses of the conference have been paid for by such participatory methods.

In addition, some members of the organising committee contributed additional amounts for various expenses at the conference:

**CSER** and **CEHAT**, through their trust, Anusandhan Trust; **Samuha**, Bangalore (from its UCSF project); **Tata Institute of Social Sciences**, Mumbai; **Jaslok Hospital**, Mumbai; **Independent Ethics Committee**, Mumbai

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(Articles and contributions do not necessarily represent the views of the editors or the Forum for Medical Ethics Society.)

## National Bioethics Conference

This supplement to the journal has been published for the First National Bioethics Conference. Messages from the organisers and keynote addresses set the stage for discussions. These are followed by the conference programme and abstracts for paper presentations and workshops. Finally, the last section contains bionotes on participants and resource people at the conference.

We hope this is a useful resource for the conference duration and after.

The *Indian Journal of Medical Ethics* (formerly *Issues in Medical Ethics*) is a platform for discussion on health care ethics, with special reference to the problems of developing countries such as India. It hopes to involve all cadres of, and beneficiaries from, this system, and strengthen the hands of those with ethical values and concern for the underprivileged.

The Journal is owned and published by the Forum for Medical Ethics Society, a not-for-profit, voluntary organisation. The FMES was born out of an effort by a group of concerned doctors to focus attention on the need for ethical norms and practices in health care.

Contributions to the journal, in the form of original papers, research findings, experiences in the field, case studies, debates, news and views on medical ethics, are welcome. All submissions must be in English and are subject to editorial review.

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