ABSTRACTS

Group P1: Research among vulnerable groups

Ethics in prison research: health and human rights issues affecting women in prisons in Maharashtra

Leni Chaudhuri, Reena Mary George

A primary study was conducted on health and human rights issues affecting women in prisons in Maharashtra. The paper brings out the ethical issues which emerged while conducting the study. The paper aims to discuss the following:

A prison being a closed institution, getting permission to conduct the study was a major issue. The paper endeavours to discuss the challenges faced during the process of gaining ethical approvals and permissions.

Direct interaction with the prisoners was a complicated task laden with practical difficulties. The paper dwells on the ethical dilemmas posed while dealing with gatekeepers for the purpose.

Motivating a group which is otherwise not free to consent to anything that affects their lives to give "informed consent" to the study was quite a challenge. The paper documents the researchers' struggle to discriminate between "informed consent"; and "assumed consent".

Challenges posed by gatekeepers, lack of physical space in the prisons and "standards" proposed in the prison manual, affected the ground level situation. The discomforts and challenges faced by the researchers in complying with the above, while attempting to maintain confidentiality and anonymity, are discussed.

The paper seeks to highlight the ethical dilemmas faced by the researchers in being privy to sensitive information which was beyond the scope of the study and to provide important insights and learning for future research in prisons and other institutions.

Community engagement in global health research: the case of the Majengo observational cohort study, Nairobi, Kenya

Sunita V S Bandewar

With the growing recognition that communities can suffer research-related harm and exploitation, community engagement (CE) has become an important ethical requirement for research.

We conducted a case study of the CE initiative in the long-standing Majengo observational cohort study (MOCS), Nairobi, Kenya, as one of a series of 10 case studies, to examine what makes CE effective, from a range of stakeholder perspectives. The MOCS has been critiqued for exploitation of its cohort members, women in sex work, to advance science. This empirical enquiry into CE was intended to appreciate this contradiction between the exploitation claims at MOCS and its durability.

The study combined case study and grounded theory research methods. We examined the MOCS CE process among a sample of 51 key MOCS stakeholders and observed CE activities.

The findings of the study underscore the key contribution of CE to the formation of the "cohort community". Some of the key concepts such as relationships of care, trust, and social capital that emerge from the data help explain the complexities and contradictions between the claims of exploitation at MOCS and its durability.

The findings demonstrate the importance of some of the less obvious benefits of participation in research, namely the evolving experience of the community and the accompanying gains in personal security and solidarity that have kept the women in the cohort, some for 20 years or more.

Ethical dilemmas in mental health research among internally displaced people

Chesmal Siriwardhana

Internally displaced people (IDP) form a minority, along with refugees. But they do not have any basic human rights according to the laws of many countries - unlike refugees - being displaced and confined within the borders of their own country. Although a lot of research has been conducted on mental health issues among refugees all over the world, almost nothing has been conducted among IDP.

Muslim IDP in the Puttalam district in the northwest of Sri Lanka are a group initially displaced in 1991, and settled in Puttalam. A recent national mental health survey showed that Puttallam has the highest rates of depression and anxiety. At the time of the survey, it did not have the services of a specialist psychiatrist. Against this backdrop, a study was proposed to observe the prevalence of common mental disorders among IDP, and their resilience (COMRAID study). However, this study presents many ethical dilemmas.

The ethical dilemmas include confidentiality of participant information, difficulties in eliciting information on past trauma, and dealing with participants identified to be suffering from serious mental illnesses. Other ethical dilemmas stem from religion, culture, traditions, using non-Muslim researchers, and using gender-matched research assistants.

Potential ethical issues should be addressed by following strict ethical guidelines. The confidentiality of data should be assured,

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participant privacy must be protected and the possibility of using "self-completed, sealed envelope" formats can be considered. If a participant is identified to be suffering from mental illness, specialist mental health care must be provided.

Group P2: Building bioethics theory

Is the notion of "human dignity" a sufficient basis for global bioethics?

Sridevi Seetharam

The notion of "human dignity" is the bedrock of most international treatises and conventions related to bioethics. However, it is an inadequate basis for global bioethics. The term still lacks conceptual clarity. There is plurality in its interpretation and implementation. The philosophical depth of the concept is too immense to be grasped by all.

This paper presents arguments as to why "human dignity" is an inadequate basis for global bioethics. "Human dignity" is an intensely anthropocentric concept. It reflects a fragmented view of the cosmos and of the position of humans within it. This concept can provide a sufficient basis only for medical ethics applied to human subjects and is far from providing the ideal solution to the growing list of global bioethical challenges. Therefore, "human dignity" does not adequately address issues of equity and justice in an all-encompassing way.

This paper presents an alternate basis for an ethical attitude, supported by perspectives from Indian philosophies and quantum physics. It proposes a concept that incorporates cosmic, ecological and other angles to human existence.

It concludes that there is a need for a broader interpretation of both the words "global" and "bio". When dignity is interpreted in a cosmic sense, it transcends and steps beyond the "human" domains of dignity, and sharply reminds us of how intertwined man's existence is with the environment. This interpretation provides a more comprehensive basis for global bioethics.

Ethico-legal dilemmas in euthanasia

Sanjeev Sood

End-of-life medical care involves complex issues affecting doctors, patients, relatives and society at large. Of the large number of individuals dying in medical facilities, a few may be forced to choose to avoid some kind of life-sustaining treatment by euthanasia or assisted suicide due to terminal or irreversible illness, or some other situation where life is perceived as unbearable. Most societies, including India, and common law tradition, have disapproved of both euthanasia and assisted suicide. The same view has been endorsed by the World Medical Association (1987).

This paper analyses and synthesises the intense and polarised public policy debates that surround the issues of euthanasia and assisted suicide. The outcome of that debate will profoundly affect family relationships, interactions between doctors and patients, policy, and concepts of basic ethical behaviour.

The Kantian model respects dignity and autonomy of life and views it as a priceless gift of God, whereas, the Utilitarian model perceives ethics as a matter of consequences and address questions like: "Isn't it cruel to let people suffer pointlessly and live a life of misery?"

Many of the bioethical and medico-legal dilemmas about end-of-life decisions can be seen as resulting from complex situations and differing frameworks, especially the Kantian vs Utilitarian models. There is a need to further analyse, debate, and resolve these contentious and multidimensional issues from the perspectives of all stakeholders.

The patient in question: is it only a one way relationship with regards to ethics, equity and justice?

Anil Kumar

Ethics is an important term, particularly with respect to human health, drugs and procedures, trials, or treatment practices. Ethics is defined as "a system of moral principles" or "rules of conduct recognised in respect of a particular class of human actions". The objective of medical ethics is to ensure the right available care that one deserves to receive to cure the ailment one has, or to prevent the ailment that one is likely to develop. However, according to ethical principles, it is not only the service provider or researcher who must protect the people in question; the affected people must also behave in such a manner that they do not become responsible for spreading disease to other susceptible persons in the neighbourhood or the society in which they live.

Why then does a person with a highly infectious disease sometimes refuse to undergo treatment, and thus risk transmitting the disease?

The paper will discuss experiences and observations related to the subject

Group P3: Ethical challenges in first contact care

Governance quo vadis: disguised private practice and the challenge of ensuring ethics

Biraj Swain, Manohar Agnani

Since the Alma Ata Declaration of "Health for All" in 1998, emphasising access to health care for the masses, the load on public institutions has increased.

Those who work in medical colleges and public hospitals in India face strains caused by structural adjustments, including having to care for indigent patients. Their counterparts in other developing countries also work under conditions shaped by inadequate resources, shortages of health workers, and weak health care systems. Worldwide, the working conditions of physicians increasingly prevent them from keeping to their ideals. One possible consequence is "ethical violence".

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Besides checking service provider perversion which may bleed public health systems, the focus needs to be on humanising medicine to recover the humanity of physicians. Can the quality of patient care be linked only to techno-infrastructural responses? Can the lack of medical ethics be blamed on a heavy patient load or case load? Is self regulation the only remedy in the fiduciary patient-healthcare giver relationship? When the goal is a welfare state, what is the state's role in tackling public policy challenges?

This presentation will investigate the above challenges from the point of view of a state's remit. It will compare the culture and practices of an ethics-adherent institution with the state of Madhya Pradesh, and glean lessons for the state from a cross-sectoral viewpoint

The paper will also consider the bioethics implications of: the applicability of a code of medical ethics to the public health sector, with post-recruitment orientation to be provided by health departments. It will also look at the need to consider the suffering of physicians; and the need to redefine the regulatory function of national and state medical councils.

Addressing maternal and newborn health services by general practitioners for Mumbai's urban poor: a case of unregulated quality

Ashifa Sarkar, Gayatri Chavan, Anjali Suryawanshi, Anjali Gokarn, Ashish Malekar, Benazir Patil, Shanti Pantavaidya, Neeta Karandikar

SNEHA Sure Start (SSS) works to improve maternal and newborn health (MNH) through community behaviour change and health care system strengthening in N Ward, Mumbai. Supported by the Program for Appropriate Technology in Health, SSS covers a population of 200,000 urban poor. A baseline survey done showed 51.4% of pregnant women in the intervention areas accessed antenatal care from general practitioners (GPs) with varying qualifications.

Working with GPs to improve MNH outcomes raised the following ethical dilemmas: motivating GPs for quality, standardised MNH practices despite the existence of popular practices and in the absence of regulation; monitoring their services with little access to records or opportunity to observe practice; and the issue of not legitimising their practice.

MNH protocols were developed and GPs trained in these protocols using continuous medical education (CMEs) and individual interactive and group demonstration sessions. GPs' adherence to protocols was monitored.

SSS had limited success in standardising GPs' quality of MNH care despite only focusing on preventive and promotive aspects of MNH care and appropriate referrals. GPs' participation in trainings declined in CMEs due to time constraints. 22% of GPs scored over 40% in basic examination skills. 44 out of 80 (55%) women who accessed GPs received antenatal care as per protocols.

Despite multiple strategies, ensuring that GPs followed MNH protocols was difficult. GPs' benefits from current clinics outweighed the benefits of attending training. Without incentives to change the current unregulated structure, GPs' practices will remain questionable. It is imperative to have a standard regulating body for GPs, like the public system, to maximise good MNH outcomes.

Exploring gender issues and needs of family care providers of PLHA: a case study from Pune, India

Rewa Malhotra Kohli 

In India, family members take care of the sick, often unwillingly, and in cases of HIV, they assume the role of family care providers (FCPs). We studied the needs of urban FCPs to inform policymakers in order that they focus on this otherwise neglected component of the HIV care package.

A community-based, qualitative exploratory study was conducted in two slums of Pune, using 20 case studies and eight focus group discussions. The study was approved by an ethics committee. Informed consent was taken from all respondents and confidentiality was assured. Data were analysed to explore the ethics surrounding the needs of home based care givers.

Medical care for minor ailments using over-the-counter drugs, emotional care, and nutrition were routinely provided by the FCPs. In addition, FCPs were involved in care during medical emergencies, hospitalisation and saline infusion.

Women were the primary caregivers, both in HIV-discordant and -concordant settings. Women in discordant relationships wanted their infected spouses to be healthy so that they could earn money. They did not discriminate against their spouses and continued care, even putting themselves at risk.

The study documents women's vulnerability while providing care to HIV-infected individuals, irrespective of whether they are themselves HIV-infected. The study reveals that structural reforms for male involvement for care can prevent burnout. Home-based care programmes can be supported if FCPs' ability is enhanced, though training, to identify and handle both emergency and routine needs of patients.

Group P4: Health finance and access to health care

Social justice versus efficiency: the ethics of revenue generation through user fees in the public health sector

Meghana Chandra

User fees are defined as the "contributions to costs by individual users in the form of a charge per unit of service consumed, typically in the form of cash". The imposition of user fees has three arguments in its favour: enhancement of scarce resources, efficiency, and equity. It is important to ask where the economically deprived fit into this picture and, furthermore, whether the concept is viable in India.

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The authors of the abstract "Exploring gender issues and needs of family care providers of PLHAs: Case study from Pune, India" are: Rewa Kohli, Latika Karve, Vridula Purohit, Vinod Bhalerao, Shilpa Kharvande, Sheela Rangan, Seema Sahay

The ethical issue that arises is whether the imposition of user fees upholds the principle of equity in the provision of health care, with due emphasis on income and quality of life. The second issue is whether efficiency trumps equity in the public health scenario. The discussion will study the impact of the imposition of user fees in health care facilities in three countries - India, Cambodia, and Kenya - with relatively low incomes and contending with scarce resources and a demanding population. It will take into account the impact of user fees on resource utilisation, and the resource gap in providing public health facilities to all levels of the population.

An economic analysis has revealed that in most countries, imposition of user fees has resulted in a decline in utilisation of health care facilities. Thus, the practice of extracting a fee when a person uses any public health service is detrimental to the notion of a welfare state. An increasing need for efficiency cannot allow for economic barriers to be imposed on services to which everyone is entitled.

Medicare in the USA: a review of 45 years of health provision

Helen Sheehan

Medicare, the USA federal health insurance for seniors 65 and over, and for disabled persons under 65, celebrates its 45th anniversary this year. 2010 also marks the introduction of major health care reform in the USA. Medicare will serve as the laboratory for testing measures of efficiency and effectiveness in health care services, administration, and education. This paper will review the policy, politics, and economics involved in the passage of Medicare legislation in 1965, and in its proposed reformative role in health care in the coming years. Medicare serves as a provider of health care but also as a springboard for reform. Over the years, there have been successes and failures, based in the strengths and weakness of both the American health care system and the American political ethos. As an example of governance in the provision of health care, this paper will discuss whether Medicare's model is viable only within American society, or if it offers examples useful for health policy beyond USA borders. The purpose of the paper is to provide a historical and sociological review of a long-standing health programme designed to meet principles of equity and ethics, and to discuss how and if these goals are met.

Public health and policy infidelity: an enquiry into the nature of health provisioning in India

Md Ziauddin Khan, Rabi Narayan Parhi

When globalisation hit the country, it brought in not only world class technology and super specialty hospitals, but also a new idea of governance and policy making. What characterises the provisioning of public health services in India today is a consequence of that idea. The result of vertical technological concentration is an increasing exclusion of the poor from even minimal primary health care -- a logical consequence of a planned disconnect.

This paper attempts to revisit over five decades of policy making in health administration in India, and critically unravel the thoughts that led to the conception of the National Rural Health Mission. The paper is divided into three sections. Section I retraces the recommendations and suggestions of various committees constituted to advise the government of India on its health policy. Section II attempts to critically examine the plethora of programmes assembled under the National Rural Health Mission and decipher the underlying unity of its conceptualisation. It studies whether the programmes under the NRHM are in line with the broader claims and commitments that the government appears to make. Section III presents the lessons learnt from a hands-on experience of facilitating district health planning in a rural district in Bihar (Bhagalpur), as envisaged under the NRHM; and the complexities that one comes across in the implementation of health policies. It raises ethical and political concerns vis-à-vis the rights of people, and how far our policies and the system are prepared to meet the imperatives of equity and distributive justice.

Group P5: Medical education

In search of a "medical ethics education" grounded in the Indian reality

Daphne Viveka Furtado

Over the past decade, having been more directly involved with bioethics education, I have often heard ethics referred to as the new moral imperialism of the West, a foreign import from North America and Europe, adopted exactly as developed in the countries of origin. The question: "Is there an Indian bioethics?" is the inspiration underlying this paper.

The challenge was to look for an ethics based on our own systems of philosophy, supported by these words of the Indian philosopher Radhakrishnan: "Any ethical theory must be grounded in metaphysics ... in a philosophical concept of the relation between conduct and the ultimate reality. As we think the ultimate reality to be, so we behave; vision and action go together."

An appropriate bibliography in philosophy was systematically studied and some aspects incorporated into classroom teaching, as a dialogue relating theory and ethical outcomes.

The Indian reality is multicultural and multi-religious, but there is an integral, intuitive approach to life which is not merely anthropocentric but views the human being as part of the cosmic reality. The transcendent, the human and the natural world are closely connected and in dynamic equilibrium. The concept of Advaita - the unitive vision of reality - contrasts strongly with Cartesian mind-body dualism. Students relate more readily to these concepts than to principlism.

The study provides a philosophical framework with important implications for the Indian setting. This presentation suggests ways in which medical ethics education can be made more relevant for tomorrow's Indian doctors.

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The importance of teacher role models in students' moral development: a review of literature

Nalini Annaswami

Traditionally, the art of medicine, which focused on creating "virtuous physicians", was learned by students by observing their teachers. Later, formal curricula in medical ethics were introduced. Formal curricula help to equip students with the necessary tools for ethical deliberation, and the "hidden curriculum" helps in the development of moral perception.

The objective of this study is to analyse the available literature on medical students' perceptions regarding the influence of role models, an aspect of the hidden curriculum in ethics education.

The databases Pubmed, Google scholar and ERIC were searched using the search terms: "medical ethics education", "hidden curriculum" and "role modelling". Among 64 retrieved journal articles in English, published from 1980 to 2008 on ethics education, 19 dealing with the perceptions of undergraduate and postgraduate medical students on hidden curriculum were analysed. Six articles focused extensively on role modelling.

According to many senior clerks and residents most of their teachers do not display a humanistic attitude towards patients and junior colleagues. Interest in learning about medical ethics and satisfaction regarding one's career choice are shown to be related to encountering good role models. Negative role modelling is detrimental to the moral development of students. The need for role model consciousness is brought out and also the duty of senior doctors to give proper feedback when they observe unethical behaviour in their juniors.

Role modelling is central to the professional development of medical students, and strategies must be developed to ensure good role modelling by teachers.

Group P6: Participation and informed consent in research

Research ethics in developing countries: results from a participatory approach to ethical dilemmas, Mumbai, India

Tamara Livshiz, David Osrin, Ujwala Bapat, Glyn Alcock, Sushmita Das, Neena Shah More

Reconciling international guidelines for ethical research with local realities and perceptions is essential, but no easy task. In developing research ethics, we need to take account of the influences within cultural contexts.

As part of an evaluation of a previously conducted trial of a maternal and child health intervention in Mumbai's unplanned settlements, we examined some relevant ethical issues.

We randomly selected 48 mothers, who had participated in our study in the preceding six months, from 12 purposively selected communities. The women were asked a series of questions about research ethics, particularly on the issues of written consent, community consent, hospitality and confidentiality.

Results revealed that the most common reason given for agreeing to be interviewed was an obligation to be hospitable (41%), but post interview, 74% women felt that it was a good use of their time. 59% remembered oral consent being taken and 54% said that they preferred it to a written one. Nearly half of the women (48%) were interviewed in the presence of other people; 88% of them reported that having others around brought them comfort. Lastly, 72% of respondents said that they believed that community consent was necessary.

Our formative study was conducted to help us understand how to improve future research methods, and we should be wary of over-interpreting the findings. Nonetheless, ethical standards relating to written consent, community consent, confidentiality and hospitality need to be re-examined if researchers are to be sensitive to participant needs.

Cluster randomised trials and the problem of informed consent

Angus Dawson

In the cluster randomised trial (CRT), the unit of randomisation is a group or cluster, rather than an individual as in a traditional randomised clinical trial (RCT). Methodological and statistical aspects of the CRT have recently attracted considerable attention in the literature, but associated ethical implications have received less scrutiny. This paper will examine the ethical issues that arise in CRTs in relation to informed consent. Informed consent is generally regarded as an ethical prerequisite for a clinical trial; such consent can be to the study occurring and to the receipt of a particular treatment within the trial. In some CRTs, however, there is little scope for patients to opt out of either the trial or the treatment to be received. It could be argued, however, that one would not normally expect to give consent for treatment policies implemented at a practice, village, community or hospital level. Alternatives to the intervention being tested may be unavailable or logistically problematic, consent from controls may induce contamination, and special problems will emerge with non-competent members of a cluster. Thus, individual consent to treatment is possible, but may be inert or give rise to methodological difficulties. Alternatives to the traditional model of informed consent may therefore be required in the CRT. Arguments will be illustrated using examples of CRTs conducted in India.

Review of patient information leaflets and consent forms used in genetic research studies at a cancer hospital in Pakistan

Natasha Anwar, Mariam Hassan, Saima Faisal

The investigators of a study are responsible for providing patients with complete, clearly written documents to safeguard patient autonomy and ensure ethical conduct of their projects. To evaluate the content of consent forms of genetic research studies recruiting participants, we conducted the following analysis.

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We included English and the translated Urdu forms from four studies. All studies had prior IRB approval. The forms were evaluated to determine i) appropriate content recommended by the Office of Human Subjects Research (OHSR), the National Institute of Health, US and ii) clarity calculated using Microsoft Office Word readability statistics. In the absence of a readability index for Urdu text, we assessed the level of Urdu by comparison with the Punjab Text Book Board's general science book for high school students.

There were no illustrations in the forms. A comparison of the Urdu forms to the science textbook revealed that, although the words for terms such as "cancer", "genes", "genetic mutations", "stomach", and "virus" were common, those for other more complicated terms such as "tissue", "pathology sample", "biopsy", "hereditary cancer", were not.

The content of the forms compared poorly with OHSR criteria and they were not easy to read. The Urdu forms contained terms more complex than terms found in a high school level general science book. High school level English and Urdu may not be appropriate for our patient population, the majority of whom have not attended high school. Therefore, we plan to conduct a survey to assess the comprehension of the forms used.

Group P7: Disability and ethics

Ethics and pragmatics of research on disability

Renu Addlakha

Bioethics and disability studies are inextricably linked across a range of disciplines and practice contexts. Disability, for instance, is invoked by both the pro-life and right-to-die lobbies, the biotechnology industries and the medical profession. Disability-selective abortions are a raging issue in public discourse as testified to by the recent Chandigarh Nari Niketan case. However, there is almost no representation of persons with disabilities in such debates. Indeed, persons with disabilities are largely ignored, whether by academics, clinicians, the media or the state. Apart from highlighting the achievements of pioneering disabled individuals, or momentarily focusing on headline-hitting cases, the issue has not been explored seriously, particularly in the Indian context.

However, in this paper I would like to highlight ethical issues involved in disability research. Ethical issues, such as preventing harm, informed consent, beneficence, play a critical role at every stage of the research enterprise from the formulation of the problem and research questions, to presentation of the findings and publication. Using my personal experience from a research project on sexuality and reproductive health of young people with disabilities in Delhi supported by the MacArthur Foundation in India, and my ongoing research on gender and disability at the Centre for Women's Development Studies, New Delhi, I will highlight the different ethical dilemmas that I faced and tackled at different stages. It is hoped that the paper will sensitise researchers to the critically important ethical dimensions of research in disability and result in the development of equitable research methodologies, technological innovation, clinical and pedagogical practices in different sectors.

The implications of the UNCRPD on the governance of health care of persons with disabilities

Smitha S Parakkal

The concept of health aims to promote the all round well-being of individuals. The medical profession has been ethically charged with respecting and enhancing the value of the life of all human beings. Yet when it comes to the well-being of persons with disabilities, primary prevention has been perceived as an accepted health intervention.

Consequently, prevailing laws, health policies, and health care programmes intended for persons with disabilities are founded on the primary prevention of disability. These policies allow for termination of foetuses detected with disability as an effective mode of preventing disability. The unproblematic acceptance of disability-linked abortions shows that disability is seen as per se undesirable and life with disability is seen as not worth living. Current health care policies diminish the value of persons with disabilities by presenting the prevention of their birth as a justified health care intervention.

The disability rights scenario questions this fundamental denial of the right to live to persons with disabilities. The United Nations Convention on the Rights of Persons with Disabilities recognises the inherent human dignity of all human beings. It treats persons with disabilities on an equal basis with all other human beings.

This paper seeks to explore whether making primary prevention the bulwark of health care for persons with disabilities is ethically and legally justifiable. Does not this choice of law and policy devalue the life of persons with disabilities?

Amendments to the Mental Health Act, 1987 and ethical issues

Harish T, Santosh Kumar Chaturvedi

The Mental Health Act (MHA) of 1987 replaced the Indian Lunacy Act, 1912. Recently, the government of India released a draft document with proposed amendments to the MHA.

The draft document dated May 23, 2010, prepared by the Indian Law Society, Pune, with the proposed amendments to the MHA, was accessed online. The document was read carefully to identify ethical issues in the proposed amendments.

The draft makes several new provisions like "carer", "nominated representative" "supported decision making" and "advance directive", for persons with mental illness.

The draft makes several provisions which are "beneficial" to the patients. The draft supports "supported decision making"

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over the "best interests" principle and offers an option to make an advance directive on treatment issues. The draft also makes a provision for supported admissions. The proposed amendments bring in a fair degree of autonomy to patients, which is not explicitly stated in the original Act. The draft mentions the practice of non-discrimination while treating patients with mental illness. In cases of research involving patients with mental illness, the draft mandates obtaining free and informed consent, and following of ethical principles. The draft details the confidentiality issues of patients. The proposed amendments highlight the role of ethical issues in formulating a public health policy.

Group P8: A gender critique of the health system

Medical ethics: a case study of hysterectomy in Andhra Pradesh

S V Kameswari, Prakash Vinjamuri, Kavitha Kuruganti, Prajit K Basu

In this paper, we seek to explore the relations between medical science and ethics through a case study among rural women of Andhra Pradesh, who had been advised, and have undergone, hysterectomy operations. We present the current practice in the field and compare this with medical ethical guidelines of the Indian Council of Medical Research, to see where these have been followed and where the shortcomings lie, including in the question of informed consent. The paper is based on the experiences of the Life-Health Reinforcement Group, a not-for-profit organisation, which came across an unusually high incidence of surgical treatment that has become common practice in the region of Andhra Pradesh where the group works. One of several reasons for this appears to be the power wielded by medical practitioners to influence the decision.

This study also analyses, to some extent, the recent debates on medical ethics in India as reflected in the Indian Journal of Medical Ethics, to understand the state of medical ethics in India. This analysis is taken up as a reflection of the on-going process of medical community-based re-conceptualisation of the physician's ethical obligation. It also aims at uncovering the process of reconstruction of the doctor's figure (especially ethical obligations), the profession's world views and practice (interrelation between medicine and society) and a re-definition of the doctor-patient relationship, as a means to contextualise the ethical concerns raised by compulsory hysterectomy and the ethical challenges and alternatives explored and implemented by the Life-Health Reinforcement Group. Finally, it raises the issue of the ethics of ignorance.

When the political is personal: state discourse through the National Population Policy and the Maharashtra state population policy

Supriya Bandekar

In India national development has been linked to population control. A look at the population policy of Maharashtra in the light of the National Population policy reveals the approach to family planning and maternal health. I will be situating this in the discourse of state and gender to see how this has an impact on the way the autonomy of the woman is conceptualised and understood through these policies.

This research uses secondary data and literature review.

The analysis of policies has implications for understanding how the state conceptualises reproductive health and how this has implications for justice and autonomy. These policies seem to take carry forward the legacy of the International Conference on Population and Development (1994) which advocated the need to do away with the idea of "targets" The recent policies do not use the word "target", but their incentivisation of "family welfare" carries a strong sense of targets. In fact it even goes on to penalise those who do not follow the two-child norm, denying them employment, housing schemes and so on. When we take into account the focus of both these policies on women as responsible for reproduction, and women's health as solely linked to reproduction, and the added coercive element in it, we see the implications that these policies have for rights, autonomy and justice.

Need for better governance in responding to cases of sexual assault in the health sector

Sana Contractor, Sangeeta Rege

Despite the well established role of the health sector in responding to cases of sexual assault, this issue remains a blind spot in health care governance. With no standard protocols in place for managing such cases, women and children reporting sexual assault continue to receive substandard care, and malfunctions of the health system result in lack of justice.

This paper draws on the experience of engaging with the health sector to develop a comprehensive response to survivors of sexual assault. In 2008, we implemented an action project to streamline procedures in responding to sexual assault, at two peripheral municipal hospitals in Mumbai. This included implementation of a kit for sexual assault examination and forensic evidence collection, capacity building of health care providers, and provision of psychosocial support for survivors.

Several gaps were found, with regard to consent seeking, admission procedures, treatment, and coordination with police and forensic laboratories, that rendered services inadequate and often impinged on the autonomy of survivors. The lack of protocols for preserving evidence provided scope for tampering. Health professionals considered their role to be largely medico-legal, and their ethical responsibility towards caring for the patient was compromised

Some problems we encountered were rectified through formulating standard operating protocols and guidelines, which both compelled doctors to adhere to them and empowered doctors to defend their good practices.

We end by critiquing the recent moves made by the government to implement guidelines for such cases and suggest how this could be better accomplished if services

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are provided to survivors of sexual assault in an ethical and comprehensive manner.

Group P9: Organising health services for equity and justice

Challenges and dilemmas in institutionalising a crisis centre for women facing domestic violence in the public health system.

Rupali Gupta, Sangeeta Rege

Domestic Violence (DV), well recognised as a public health concern worldwide, is still missing, as a concern, from the Indian public health system. In public hospitals, which are the only viable health care option for a majority of the socio-economically marginalised population, the issue of DV is still on the distant horizon of public health reforms. Hence, CEHAT felt the urgent need to bring it on to the radar of the public health system. Dilaasa, the first public-hospital based crisis counselling centre in India, was established in collaboration with the Municipal Corporation of Greater Mumbai in two public hospitals in Mumbai.

Since 2001, Dilaasa has been engaged in providing counselling and psycho-social support services to women facing violence, and a training cell was set up to sensitise the hospital staff on DV. CEHAT was involved in demonstrating the crisis intervention model for DV response, merging the centre with the hospital's medical services, and later in monitoring its services after handing over charge of both the centres to the hospital management in 2006. CEHAT implemented different mechanisms for monitoring of the centre, but ensuring the quality of services provided by the centre has always been a challenge.

The hospital management provided infrastructure and resources for DV counselling and training, but issues such as transfers of deputed staff, a lack of reporting mechanisms or clear cut policies for referrals, and a lack of efforts to institutionalise the training cell, among others have been surfacing as on-going challenges. The Dilaasa experience highlights governance issues in institutionalising the issue of DV within a public health institution.

Equity through exemptions? User fees in a municipal hospital in Maharashtra

Oommen C Kurian, Prashant Raymus, Jui Ranade - Sathe

In India, most states continue to collect user fees, despite the on-paper consensus that phasing out user fees is an urgent pre-requisite in achieving health equity goals. Despite the influx of funds through the National Rural Health Mission to improve the health care infrastructure, officials acknowledge that rogi kalyan samitis, that could potentially play a role in improving equity, are perceived by the public as a mere vehicle of user fee collection.

This paper will explore the ethical case against user fees in health. User fees were introduced purportedly to achieve the objectives of reducing frivolous demand, increasing revenue, improving quality and coverage, and rationalising patterns of care. Equity considerations were to be protected primarily through exemptions systems. In Maharashtra, user fees were introduced in 1988, and the scope and scale have been steadily increasing, with no visible effort at any rollback.

Through a primary survey in a municipal hospital of Mumbai, the exemption systems in place and the efficiency of their implementation will be examined using qualitative interviews, while the flow of user fees collected will be mapped vis-à-vis the stated objectives, using secondary data sources. The status and relevance of these objectives will also be explored.

About 50% of the primary data has been collected by conducting semi-structured in-depth interviews with the clinical and administrative staff of the facility. Data collection will be complete in October and at the conference, we will present our analysis and observations.

Integration of AYUSH into primary health centres in Andhra Pradesh: lacunae to be explored

J K Lakshmi

In the milieu of rising chronic, metabolic, and immune disorders, and drug-resistant communicable diseases, it is expected that traditional, complementary, and alternative systems of medicine will be on the ascendant. The Indian government's appreciation of the relevance of Ayurveda, Yoga and Naturopathic Sciences, Unani, Siddha and Homoeopathy (AYUSH) in public health is articulated in policies to integrate AYUSH into mainstream health services. The National Rural Health Mission (NRHM) includes, inter alia, the establishment of an AYUSH component in every primary health centre (PHC). Andhra Pradesh (AP) has 1,525 PHCs, denoting the appointment of 1,525 AYUSH practitioners, and trained assistants, and the supply of relevant drugs and equipment.

Five years following the launch of the NRHM, the AYUSH mainstreaming scenario is below expectations, riddled with ethical and governance issues. Accounts from AYUSH doctors appointed at PHCs in various regions of AP reveal enormous lacunae in implementation: unfilled positions (only 700 filled); iniquitous emoluments; inadequate or absent infrastructure, assistance and supplies; unethical interpersonal arrangements; and limited support from non-AYUSH personnel at PHCs. The widespread negative impact of these conditions undermines the value of AYUSH, demotivating both practitioners and patients, and sapping public health.

A systematic evaluation of the integration of AYUSH into PHCs in AP, including observational data, and interviews with PHC personnel and patients, is proposed. Findings are expected to offer insights into the social, technical and economic obstacles faced, and ways to address them, to pave the way to a vibrant AYUSH component in the Indian public health system.

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Group P10: Humanising the patient-provider relationship

Expressions of equity: imbalances in the patient-clinician interaction

Shobha Mocherla, Usha Raman, Brien Holden

This article reports the partial results of a mixed-method study of clinician-patient communication in a tertiary eye care centre in southern India, that surveyed patient understanding and satisfaction.

Non-participant observations enabled us to map the sequence of communication opportunities in the clinical interaction, and in-depth interviews were used to identify patient perceptions of the content and clarity of clinician communication in a chronic disease clinic (glaucoma). A 60-item instrument was administered to 550 patients in the quantitative phase to explore associations between patients' expectations, their experiences and their satisfaction with the clinician's communication.

The qualitative results helped map the communicative aspects of the clinical interaction, highlighting the consequences of poor clinician communication. The quantitative phase showed that patients expected adequate explanation about the disease, the opportunity to ask questions, receiving supportive signals, and being treated as equals. We found a significant relationship between information provided by the doctor, and patient knowledge, and patient beliefs about their eye condition.

Most patients stated their information source on the disease was their doctor, leading us to conclude that clinicians must utilise communication opportunities optimally to ensure that every patient has an equal chance to correctly understand their disease and role in treatment. Such steps to empower patients are particularly important in chronic conditions such as glaucoma, where patient compliance is a major concern. Clinician awareness of patients' socio-cultural and economic backgrounds, fears and hopes, is important as it can moderate the clinical interaction. By consciously improving their communication, clinicians can help ensure effective treatment outcomes.

Ethical issues of the third gender

Radhika Taroor

A number of recent events have provoked substantial public interest in intersexuality and reconstructive genital surgery. Many transsexuals feel that their issues differ from those of other gender-variant people because of their expressed need to physically alter their bodies surgically; hence, they depend on medical professionals. Sex reassignment raises moral, ethical and legal concerns for both the physician and the patient. There is an issue of the long term health risks of cross sex hormonal therapy, despite research showing evidence that hormonal treatment is an acceptable and safe practice.

Most anti-discrimination laws do not protect transsexuals from inequity. Transsexuals are denied employment, housing, marriage and child custody and they face unique issues involving marriage, sex and fertility.

The findings are based on questionnaires and in-depth interviews with 15 transsexual individuals. Participants reported mixed experiences and felt they were deprived of human rights. They experienced a high degree of discrimination, intolerance and outright violence.

A major problem in health care is the provision of biased, inadequate and inappropriate services to transsexuals, due to the non-availability of adequate education and training to professionals.

There are many more people who cannot afford to access medical care and who live as the "other gender" without any medical treatment, or who are gender-nonconforming individuals.

There should be effective administration of sex reassignment surgeries which are accessible to people from different economic backgrounds. Simple procedures should be put into effect, that allow transsexuals to identify with the desired gender identity; an important step towards not only advancing their civil and political rights, but also integrating them into society

Experience of birthing: towards an ethics of relationality between the care giver and the birthing woman

Rakhi Ghosal

The picture of childbirth in India is divided between the institutional and the "outside-of-the-institution". Based on this dual approach that is then available for the birthing woman, this paper (i) argues that, notwithstanding innumerable interventions into this space, a holistic and ethical engagement with the birthing woman remains long overdue; (ii) looks for a possible ethics of relationality between the care giver and the birthing woman; and (iii) suggests a turn to her experience such that it can co-constitute knowledge produced of and on her.

The methodology involves generating narratives or psycho-biographies that co-constitute existing knowledge of reproduction. In itself, the project will also find a methodology that weaves together phenomenology and hermeneutics, to arrive at an ethics of birthing.

Ethical enquiry reveals that birthing experiences are a collage of joy, trepidation, and an occasional sense of violation and transgression. There is also a trivialisation of the woman's birth pain by medical attendants, and a lack of access to care. The paper will argue for collating these experiences so that a possible ethical relation between the care giver and birthing woman could be arrived at.

The research is premised on giving an ethical turn to existing knowledge - of woman, her body-womb-birthing-lactation - by returning to her experience. Its contribution to bioethics lies in

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the project's attempt to raise philosophical concerns pertaining to relationality and lived experiences. Bioethics is not just about informed consent and transparency; it is also about setting up an "ethical relation" - a relation of care (between the subject of knowledge - the obstetrician or dai - and the object of intervention, or the birthing woman) that exceeds the contractual.

Group P11: Assisted reproductive technology

Assisted reproductive technologies and stem cell research: standing at the crossroads?

Preeti Nayak

This presentation aims to chart out the ethical issues emerging from new medical technologies, specifically the assisted reproductive technologies (ARTs), and related concerns regarding human embryonic stem cell research.

In recent years, a host of newly emerging medical technologies has ushered in a range of ethical issues. These include, among others, the use and supply of human embryos for stem cell research, cross border trade in human eggs/embryos, and creating embryos solely for research purposes (moving beyond therapeutics). The debates have revolved around the concepts of "serving the greater good", exploitation of women for oocytes, and informed consent. With biotechnology demanding oocyte donation exclusively for research purposes, the implications for women's health are huge. Moreover, the unregulated proliferation of ARTs continues to pose a challenge in many countries, including India. This growing "birth market" combined with the commodification and commercialisation of reproductive tissues and embryos, has presented more dilemmas than answers. Increasing eugenic concerns with genetic screening, sex-selection, pre- implantation genetic diagnosis, commercialisation of gamete donation and surrogacy, and the citizenship and rights of the child born, are the direct ethical implications of these developments.

The presentation will be based on secondary literature.

While these advances have global repercussions, there is a need to move beyond the "choice" and "rights" discourse. The question one needs to pose is: where does one set the limit with regard to what these medical technologies have to offer, and which direction are these developments going to take?

Women, infertility and ethical issues involved in assisted reproductive technologies

Varada Madge

Biomedicine treats infertility as a "disease" that can be "cured" with assisted reproductive technologies (ART). The inability to conceive a child is now considered more as a public matter than a private one. I have attempted to explore ethical issues with regard to these technologies.

The study was carried out in two well-known private health care settings in Pune, Maharashtra. One hospital was selected on the basis of the researcher's acquaintance with the doctor, and the other on the basis of its popularity. I used the interview method to collect qualitative information from 25 women from December 2007 to April 2008.

Overall, the women felt that not only were ART treatments painful, the women were asked to sign an informed consent form though little information was provided regarding cost, success, failure and side effects of the medicines. None of them were able to achieve a pregnancy. In the first place, there was no uniform protocol justifying the use of intrauterine insemination; then, after several failed attempts they were enrolled for an in-vitro fertilisation programme. Thus the women's lives were burdened with medicalisation. The whole process appeared to be an experiment, a matter of trial and error.

These technologies are based on profit at the cost of women's lives. They should not become medical practice until they have undergone a scientific evaluation, which unfortunately has not happened.

Group P12: Governance of maternal and child health programmes

An ethical decision-making process under the Janani Suraksha Yojana: evidence from health care practitioners

Supriya Kumar, Aravinda Pillalamarri

Janani Suraksha Yojana (JSY) is a government programme that gives cash incentives to pregnant women who deliver in institutions. Accredited Social Health Activists (ASHAs) implement the cash transfer; and also draw up a "micro-birth plan" to counsel the pregnant woman for institutional delivery. Governance of JSY does not include a process evaluation of how providers weigh women's medical and socio-economic situation against the quality of available health centres in drawing up this plan. We aim to understand practitioners' current decision-making processes and provide recommendations for ethical governance of the programme.

Using the method of in-depth interviews with doctors and health workers in Jharkhand, Chhattisgarh, and Tamil Nadu, we assessed the decision-making process regarding institutional versus home delivery.

Preliminary results indicate that incentives provided to ASHAs and pregnant women may result in coercion of the poor. We will present the decision-making process among providers interviewed, and integrate our results into the decision tree, taking into account the woman's choice and her socioeconomic situation.

Finally, whereas JSY has increased institutional delivery, the impact on health in resource-poor areas is unclear. We propose that governance of the programme focus on its ethical implementation, ensuring the health and empowerment of both mother and child, by taking into account the mother's

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choice and the indications for institutional delivery, rather than merely aiming to increase institutional delivery rates.

A study of the role of ethical and moral notions in the delivery of routine immunisation in Kerala and Tamil Nadu

Joe Varghese

Several ethical principles and moral notions form the core of public health practice. These normative principles inform and influence not just policy decisions and programme implementation, but also the individual's and the community's behaviour. By reviewing the delivery of immunisation services in two states in India, Kerala and Tamil Nadu, this study throws more light on how normative and ethical principles affect how different stakeholders act.

The study used descriptive and analytical qualitative techniques for data collection and analysis. It included in-depth interviews with providers and beneficiaries, focus group discussions and participant and non-participant observations.

Though Kerala and Tamil Nadu are high immunisation coverage states in India, recent years have shown a reduction, particularly in the northern districts of Kerala. The point of analysis is the interplay of both synergetic and conflicting ethical and moral notions in the context of immunisation services. These include utilitarianism, beneficence and non-maleficence. The conflict in normative considerations in immunisation arises from a highly utilitarian state vis-à-vis moral obligation of parents towards children. Paternalistic interventions, like special immunisation campaigns against polio and Japanese encephalitis, generate reflexive thinking and create mistrust.

Understanding the ethical and moral notions involved and their complexity in public health delivery are important considerations for analysing how public health is governed.

Lack of government financing of safe motherhood: a clear case of denial of justice?

Indranil

Safety in pregnancy and childbirth is an issue of justice and fundamental rights. Government financing in health is accorded enormous ethical significance as it is necessary to ensure the equitable distribution of resources and thus ensure health. India is the largest contributor to the global burden of maternal deaths. The present effort is an investigation into the financing of the National Rural Health Mission (NRHM) and its implications for delivery and access to maternal health services, with special emphasis on identifying the implementation bottlenecks in the high focus states.

The research method included tracking fund flow and utilisation from the national level to the level of blocks. Among the high focus states, Uttar Pradesh and Chhattisgarh were selected as sample states.

The study points out the lack of public investment on health in India as one of the reasons for the high maternal death rate. Despite the central government's claim that it provides greater attention to underdeveloped states, its funding priorities and design clearly favour the better-off states. Due to systemic deficiencies in the functioning of backward states, there are high levels of under-utilisation of funds. These systemic deficiencies have been caused by chronic under-investment on health in rural areas, especially since the introduction of economic reforms. The study reveals that instead of bringing about structural improvements in the rural health sector, there have been efforts under the NRHM to find short term solutions, thus further complicating the picture. Immediate course correction is required to ensure that justice is not denied to the most underprivileged sections of the country.

Group P13: Politics of global health

The Global Fund and the new imperialism of aid: Implications of governance for equity of health and HIV management

Anuj Kapilashrami

While curbing infectious diseases has always been a national health priority, recent years have witnessed a renewed interest in programmes for AIDS, tuberculosis, and malaria. A re-articulation of the problem, as economic and global security with heightened humanitarian urgency required to tackle warfare, has paved the way for the development of a number of financing and delivery mechanisms.

Among these, the Global Fund to Fight AIDS, TB and Malaria has gained prominence as an innovative policy mechanism. Set up in 2002, it has leveraged significant amounts of funding: US$ 19.3 billion for 572 programmes in 144 countries. The Fund's growing influence in country processes, its claim to supporting "country driven" programmes and priorities, and the conditions precedent through which it disburses and executes grant agreements, demand a better understanding of its governance at national and sub-national levels.

Combining insights from ethnographic fieldwork and 70 open-ended interviews with policy makers, project officers, and providers, conducted as part of a doctoral research programme, this paper considers the implications of the country-level governance of the Fund for equity in health care, and, particularly in HIV management in India.

The findings reveal that the Fund governance has pushed diverse actors with conflicting agendas to come together in response to the availability of funds. This gives rise to a number of structures which begin to assume a life of their

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own, leveraging control, competing for the same resources and acting as conduits of power. This new "imperialism of aid", increasingly linked to performance frameworks and conditions precedent, transforms the terrain of infectious disease control and fragments public health.

Clinical trials in India: the needs of the country and the focus of the sponsors

Deapica Ravindran, Girish Ingle

The number of clinical trials in India is rapidly increasing. The huge pool of treatment-naïve patients here is a major advantage to the clinical trials industry and is expected to grow at a compound annual growth rate of nearly 36%, between 2006 and 2011, and to register revenues worth US$ 546 million in the future.

We aim to study the clinical trials scenario in India in terms of the number of trials, the diseases with which they are associated, and their sponsors. We also intend to explore the relevance of these trials to the disease burden of India

From July 2007 until June 30, 2010, 1,081 trials were registered in the Clinical Trials Registry-India (CTR-I). We downloaded all information on these trials from the CTR-I database and used it for our analysis. We grouped the data into various categories and looked at two major categories, viz., types of sponsors and types of diseases. We have explored the relationship between these two variables. We also intend to explore and compare the disease burden of India and the US with these trials. Our sources are the WHO reports on health statistics and disease burden, and CTRI.

This study will give us an insight into the diseases various on which sponsors focus, and the relevance of these trials to the Indian population. There have been criticisms that most internationally sponsored trials in developing countries are commercially-driven, without much benefit to the host country's population. Our study will help us to understand whether the conduct of trials by multi-national sponsors on Indians is justified.

HPV vaccine trials in India: the collapse of governance, law and ethics

Anjali Shenoi

"Demonstration projects", implemented by the US-based NGO Programme for Appropriate Technologies, state governments and the Indian Council of Medical Research, administering three doses of HPV vaccine, were being conducted in Khammam, Andhra Pradesh and Vadodara, Gujarat. These "projects", aimed at generating data to influence decision-making on public sector immunisation programmes, included over 23,000 girls between the ages of 10 and 14. They were funded by the Bill and Melinda Gates Foundation as part of a four-nation intervention programme against cervical cancer.

In the West, concerns around the vaccines have largely focused on their safety and efficacy and the question of compulsory vaccination, especially of pre-teens. In the Indian context, however, additional questions have been raised regarding their public health value, the diversion of resources for an expensive vaccine, particularly in the absence of essential public health programmes, and the influence, on public health priorities, of international organisations that have invested vast resources in vaccine research and promotion. The experience of these "projects" has further highlighted the question of transparency, wherein sponsors are able to circumvent ethics through regulatory loopholes in cases where the scientific purpose of trials may be unclear.

In settings where populations are likely to be vulnerable, the conduct of research requires considerations of ethics and of human rights abuse. Thus, in the current scenario where public health priorities are largely influenced by several players globally, issues of governance and regulation involved in such forms of ambiguous clinical research need to be further examined.

Group P14: Decision making at the end of life

Conducting ethical end-of-life care research in the intensive care unit setting: challenges and solutions

Caroline Rumble, Wendy Prentice, Rachel Burman, Jonathan Koffman, Cathy Shipman, Phil Hopkins, Will Bernal, Sara Leonard, Jo Noble, Odette Dampier, Myfanwy Morgan, Irene J Higginson

This study, which is part of a larger on-going study, aims to identify the ethical complexities encountered whilst undertaking research into end-of-life care in the intensive care unit (ICU) of an inner-London hospital. Such research must consider principles of non-maleficence and beneficence, whilst respecting autonomy and considering fluctuating capacity.

Qualitative interviews were conducted with relatives of 20 patients approaching the end of life, in addition to observations of care and assessment of medical records. Data from ethics committee applications, research field notes, multidisciplinary steering group meeting notes and the researcher diary were systematically analysed, using the framework approach.

Analysis of the results revealed three main challenges and solutions. (1) It was difficult to gain consent to participate, as many patients had either fluctuating or no mental capacity. Consent was therefore treated as an on-going process and sought if capacity was regained. In cases where there was no opportunity to gain consent, assent was sought from a relative. (2) Confidentiality and careful anonymisation of all data were required whilst maintaining integrity of the data. (3) Collaboration between clinical and academic staff was central to the success of the study, but with clear role demarcation. Researchers could not access patient data without permission, and confidential interview data were not communicated to clinical staff without the interviewee's explicit permission.

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Perspectives from Pakistan after the transplant law: what next?

Aamir Jafarey, Farhat Moazam, Bushra Shirazi

Pakistan now has a transplant law, regulating transplantation and outlawing organ trade. It is obvious that live, related transplantation cannot meet the nations' transplantation requirements, especially as we move beyond kidney transplantation. A deceased donor programme will succeed only if there is wide public acceptance. This study aims at assessing knowledge regarding organ donation in a cross section of people of Karachi. One hundred and nineteen adults were interviewed for this study, using convenience sampling. Sex distribution was about equal, 90% respondents being 50 years old or less. Even in a largely literate group (81% literate), 39% were unaware of, or misinformed about, deceased organ donation as an option. Regarding living donation, 71% of the people were either ignorant of, or had incorrect knowledge about the religious position on the matter. Similarly, considering deceased donations, 87% of the respondents did not know the position their religion takes on the matter, or had inaccurate information. Considering the centrality of religion in this part of the world, this level of ignorance was surprising. Seventy four per cent of respondents felt that for deceased donation, in addition to the person, his family also needed to be involved in the consent process, underlining the importance of collective decision-making in such pledges. Any state policy regarding deceased donation pledges will need to consider this. Information gaps identified in this study need to be addressed for a transplant programme to flourish in the country.

Group P15: Experiments in public health

Framework for assessment of ethical legitimacy of placebo-use* in social interventions

Sunita V S Bandewar, Renaud Boulanger, T A John

The first decade of the third millennium witnessed increasing efforts invested in community-based social interventions to address various health issues in general and meeting the Millennium Development Goals in particular. Also, there is growing interest in the application of a biomedical research model to empirically test such social interventions for their "efficacy". It is believed that such an approach will enable evidence-based scaling of "efficacious" social interventions. Social interventions aimed at addressing neo-natal health as well as high neo-natal mortality rates in several parts of the developing world are one such example. However, the application of the biomedical research model raises concerns regarding placebo-use* as the standard of care, particularly in controlled trials of such social interventions which require attention. We propose a comprehensive framework for assessment of the ethical legitimacy of placebo-use* and/or no-intervention in the context of social intervention research which has drawn inspiration from the biomedical research model. To arrive at this comprehensive framework, we have drawn insights from (a) the standard of care and placebo-use* debate; and (b) the "exploitation discourse" in international biomedical research. We hope that this initial framework will facilitate more in-depth discourse on the topic in the future, and be relevant to wide ranging innovative social intervention trials in health and other developmental arenas.

Note: Placebo-use* connotes "placebo intervention" or "no-intervention" to control units when a known proven intervention exists for the health (or social) condition for which the new intervention is being tested.

Considering ethics in community eye health planning: perspectives from an existing model

Usha Raman, Sethu Sheeladevi

Despite the widespread acceptance of the principles of the Alma Ata Declaration of 1978 and the subsequent amendments, health for all has remained a distant dream in many parts of the developing world. Concerns such as the economic efficiency of health systems and their reach and coverage have dominated discussions of public health, with ethics remaining at best a shadowy set of assumptions or at worst completely ignored. Similarly, questions of ethics have been incidental or assumed in the design of public health models across sectors, and are rarely explicitly addressed.

This paper uses the experience of the L V Prasad Eye Institute's pyramidal model of eye health delivery to explore ethical issues in its design and implementation. This model evolved over time from its beginnings as a tertiary care centre to a network that spans all levels of eye care service delivery, from the community through primary and secondary levels, ultimately referring back to the tertiary level. In the process of subjecting what has been an organically grown model to post-hoc ethical enquiry, the authors evolve an analytical and indicative framework that could be used to address and build in ethics in other public health delivery models.

The ethics of social experiments in health in India: some questions and concerns

Neha Madhiwalla

Using evidence-based practice as a basis for social policy has become a more compelling idea in India recently, leading to an explosion of social and behavioural experiments in fields ranging from reproductive health to nutrition to health education. These experiments involve, variously, the use of new community mobilisation strategies such as the social marketing of contraceptives, economic strategies such as monetary incentives, and modes of health care delivery such as using peer educators to deliver health education. Generally, it is presumed that such research involves minimal harm and such research is cursorily reviewed by ethics committees, if at all. While it is imperative that such research also be brought under ethics review, the specific ethical concerns in research of this nature must be taken into account.

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In this paper, I wish to examine two broad ethical questions pertaining to experimental research in the field of reproductive and child health. First, what could be an acceptable framework for making ethical judgments about the kind of experimental research being conducted in India? Is the research relevant, beneficial, essential and just? Second, I would like to examine the suitability of current mechanisms of ethical oversight, developed primarily to monitor clinical trials in a laboratory setting, for reviewing and monitoring such research. This study is based on a review of published research in the field, supplemented by my own observations and experience as a researcher involved in such studies.

Group P16: Regulating the use of human tissues

Pakistan's cell and organ transplant law and recent events

Tashmeem Fatima Razzaki

It is well known that until recently, Pakistan was known, on the one hand, for its high profile presence in the illegal kidney transplant trade, and on the other, for its lack of significant activity in stem cell research and its clinical applications.

The Sindh Institute of Urology and Transplantation (SIUT) was in the forefront of the struggle to codify laws to ensure ethical transplantation, and to have the highest level statutory bodies of the country approve voluntary cadaver donation, which would improve the availability of organs, and thereby discourage selling of organs by the hapless, disenfranchised poor.

In this context, two recent happenings have prompted this abstract:

1. Pakistan's transplant laws permit the donation of a kidney exclusively by a blood relative. However, a court recently permitted donation by the sister-in-law of a prospective recipient. What are the ethical implications of this judgment? Will it reopen the floodgates to commercial transplants?
2. A heart patient was transplanted with his own bone marrow stem cells and the surgeon reported a 20-30% improvement after six months. Other such cases will follow. How will the Human Organ Transplant Authority be able to monitor and ensure that ethical issues are not swept under the rug, as the stampede begins? What is the experience in India, where stem cell therapy is routinely practised, with often rather tall claims of success?

Contested bioethical governance: a case study of stem cell science in India

Shashank Tiwari

India is now emerging as one of the leading centres for stem cell based research, having a significant number of public hospitals, private clinics and companies active in this area. However, there is a widespread perception that the proliferation of stem cell procedures in India does not meet international rules and regulations. Various clinics and companies have been accused of making false claims relating to a wide range of stem cell treatments and, in some cases, even giving fake declarations of having approval from governing bodies. As a result, India is described as a global locale for "maverick" science, where universal ethical norms are violated. On the other hand,, the development of stem cell science in India is also seen in terms of national competitiveness in research and hence as a threat to the long-established western dominance in the area of science and technology. These disparate opinions offer challenges for using universal bioethical principles in developing a framework for governance. This paper aims to present different notions of bioethical principles by different stakeholders related to stem cell science in India. Following a summary of survey data on key projects in this area, the paper will draw on interviews with scientists, clinicians, bioethicists and policy makers associated with the development of stem cell science, to examine the governance of stem cell science in India; the framing of ethical principles and narratives by different actors, and how science is governed in different cross cultural settings.

The afterlives of afterbirth: placental waste economies in Chennai, c1980-2010

Sarah Hodges

This paper discusses the results of interview-based and ethnographic and historical research conducted in Chennai during the first half of 2010. It documents and analyses changes in human placental waste economies in Chennai over the course of the past three decades. I use the term "placental waste economies" to refer both to practices of ritual placental disposal as well as to the commercial reclamation of placental materials for subsequent biomedical and cosmetic, therapeutic uses. The primary findings address how the relatively recent practice of new parents' public and mainly private banking of umbilical cord blood-derived stem cells in Chennai repackages a cluster of extant south Indian traditions surrounding conjugality, progeny and progress. Childbirth exists simultaneously as a physiological process and a social one. In both its physiology and its sociability, childbirth represents a conjuncture of possible dangers and vast rewards/value/treasure. Because childbirth occupies such a special ritual and material status of power and danger, the material by-products of childbirth - principally the placental afterbirth - also possesses this dual status of power and danger. By investigating umbilical cord blood stem cell banking in Chennai alongside a broader set of longstanding placental waste economies, this study provides a more comprehensive understanding of the impact of the globalisation of biotechnology on local traditions, and vice-versa. Does a post-liberalisation placenta, in fact, possess new economic value as well as new affective value? Perhaps, but the endurance of patriarchal lines (genetic as well as economic) is remarkable.

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Group P17: Responding to public health emergencies

Ethical language usage and pandemic plans of South Asia

Chhanda Chakraborti

Post-SARS literature on pandemic planning and the World Health Organization strongly recommend that ethical values should be included in national pandemic planning to guide action plans and strategies. However, the response from countries has been varied. This study tries to gauge the position of pandemic plans of India and its neighbours, Nepal, Bangladesh, and Sri Lanka, on this issue. This densely populated south Asian region is particularly vulnerable to a future pandemic.

The content of available national pandemic plans has been checked for certain ethical terms proposed by scholars. The working assumption is that ethical language usage in a pandemic plan signifies awareness of ethical issues that may arise, and reflects the degree of ethical commitment to address these properly.

The findings are: (a) the use of ethical terms is disappointingly meagre in all plans, but strikingly scant in India though Nepal and Bangladesh are in relatively better positions; (b) certain important ethical terms are conspicuously absent in all the plans, and (c) the use of ethical terms occasionally appears as fortuitous, rather than the outcome of a conscious, ethical deliberation.

This has implications for bioethics. To avoid adding injustice to injury, pandemic plans for this vulnerable region must be ethically sensitive. Basic bioethical principles behove us to ensure that a proper pandemic response in this region is guided by the principle of doing the least possible harm with the least possible injustice and transgression of dignity, while staying within the ambit of an ethical framework of human rights and inclusiveness.

Open communication between communities and the government: an ethical imperative in planning for a public health emergency

Supriya Kumar, Sandra C Quinn

Socially marginalised communities bear a disproportionate burden of morbidity and mortality in an emergency. Their voices are unheard and, consequently, their needs are often neglected in planning and implementing strategies to mitigate crises. Pandemic planning must put equity at the forefront, so that the needs of the most vulnerable are addressed.

We examined the original influenza pandemic plan published by the government of India in 2009 and asked if it included a focus on existing inequalities. We studied government and media response to the H1N1 pandemic by examining the Ministry of Health and Family Welfare website, media articles, and peer-reviewed publications.

Whereas the pandemic plan focused on the law and order aspects of adherence to social distancing measures, it did not take into account the different capabilities of communities to adhere to such measures. Communities and organisations that work with populations at risk, such as pregnant women, people living in crowded conditions including slums, and indigenous people, were not consulted during the planning or implementation phases. Finally, the plan did not include ongoing engagement of the media.

In planning for a public health emergency, the government should engage the media and community-based organisations to elicit their advice about the resources necessary for the diverse populations that they reach to adopt non-pharmaceutical interventions. This will save lives as well as increase people's trust in the public health system. We will discuss open and visible communication as an ethical principle that can bring a social justice focus to pandemic planning.

Planning and response to the Influenza A (H1N1) pandemic: ethics, equity and justice

Mahesh Devnani, Anil Kumar Gupta

The world is facing an influenza pandemic for the first time in 40 years. The importance of ethics to pandemic planning is in the "the application of value judgments to science" because scientific information alone cannot drive decision making. This paper, based on institutional experience gained during the actual response phase to the pandemic at PGIMER, Chandigarh, aims to highlight three ethical considerations related to influenza pandemic planning and response -- ethical allocation of scarce resources, the obligations and duty of health care workers to treat patients, and the balance between conflicting individual and community interests. Among these, the most challenging question facing bioethics is how to allocate scarce, life saving resources given the devastating social and economic ramifications of the pandemic. In such a situation, identification of clear overall goals for pandemic planning is essential in making difficult choices. The dilemma between the duty of health care personnel to save patients and their right to protect their own lives and health is a key question. To what extent is it reasonable to expect health care personnel to be ready to sacrifice their lives? During the course of a pandemic, the functioning of society may also be threatened, requiring limits on individual freedom in order to protect individuals as well as entire communities. Yet, individual liberty should be restricted with great care, and only when alternative approaches to realising the goal of weathering the pandemic are not likely to be effective.

Pandemic influenza planning and response should be a cooperative and shared responsibility that balances community and individual interests.

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Group P18: International collaborations in health research and delivery

Ethical issues related to medical tourism

R K Sharma, Prateek Bhatia

Medical tourism involves travel across national borders for medical procedures such as surgery or organ transplantation. Why do patients from developed countries travel abroad for treatment? Most commonly they do so for cosmetic treatment or services such as surrogacy, not covered by health insurance in their own country. Second, the treatment, on an average, costs 10 to 20% of what they would pay in their own country. An individual on a waiting list for a transplant may seek transplantation in countries where illegal and unauthorised donors are readily available to sell their body organs. This leads to low and middle income countries actively marketing themselves as destinations for medical tourists with no restrictions, and at a very low cost. Medical tourism raises a range of difficult ethical issues. The primary challenges are: assuring the quality of health care out of the country; planning of continuity of care on returning, and creating mechanisms to address the liability concerns of all stakeholders. The most perplexing ethical concerns for medical tourism are the impact on the host country as the economically less-developed countries are already facing a "brain drain" of professionals, and a poor health infrastructure. Regarding transplantation, there is reason to believe that organs are being sold and, at times, taken by force, from the underprivileged. Medical tourism will expand. The question is whether medical tourism is ethically defensible, and if it is not, whether any reform and regulation can make it ethical. This question keeps recurring and must be dealt with.

Contract research organisations in the clinical trials sector: boon or bane?

Divya Bhagianadh

India is fast emerging as a clinical trials hub and it is expected that by 2011 nearly 15% of all global trials will be conducted in India. It is estimated that the contract research organisation (CRO) sector in India has a market size of $ 0.3 billion. There is a need to understand the way that CROs are functioning in India, the rules and regulations related to the sector and also the drawbacks and challenges associated with the same.

The study design was descriptive and used in-depth interviews with different stakeholders including those from the CRO sector, institutional ethics committees (IECs), clinical investigators, journalists and regulatory authorities.

The study found that in spite of existing guidelines and regulations, there is a lack of transparency and accountability in the sector with vague interpretations of responsibilities by the different stakeholders. There is a need to streamline the functioning of IECs and to register IECs as well as CROs.

Increased revenue earnings, job opportunities and the development of India's research and development capacity were pointed out as the benefits from the sector. The Clinical Trials Registry-India and the move to register IECs as well as CROs were viewed as steps in the right direction by the participants of the study.

In the context of India becoming a global centre for clinical trials, the phenomenon of CROs cannot be ignored. The need of the hour is that they are properly regulated and there is capacity building at all levels.

The ART of regulation: a critical look at the Assisted Reproductive Technology (Regulation) Bill, 2010

Renuka Mukadam

Considering the exponential growth of the assisted reproductive technologies (ARTs) industry, especially over the last decade, with a sharp rise in the number of clinics, and other allied services across the country, the need for monitoring and regulation cannot be overstated.

Responding to the situation, the Ministry of Health and Family Welfare (MoHFW) and the Indian Council for Medical Research (ICMR) have drafted the Assisted Reproductive Technology (Regulation) Bill and Rules, 2010. The Bill envisages registration and monitoring of ART clinics but does not take into consideration all the players in the ART market. It is silent on critical issues like the maximum age limit for accessing the technologies. There is ambiguity on several other crucial matters dealing with the health and rights of women using ARTs, oocyte donors and surrogates. With regard to surrogacy, the focus of the provisions is more on citizenship issues, and does not adequately address other pertinent issues. Importantly, the Bill is not located within the framework of the country's health policy, population policy and other relevant policies.

This paper takes a critical look at the draft Bill and points out gaps which need to be addressed for a more effective regulatory mechanism The presentation will look at "regulation" in a more holistic manner, incorporating women's health and rights issues within its ambit.

Group P19: Ethics in designing of health research

Designing and evaluating action research: analysis through an ethical lens

Anuska Kalita

Action research is comparative research on the conditions and effects of various forms of social action. There is a dual commitment in action research: to study a system, and, concurrently, to collaborate with members of the system in changing it, in what is together regarded as a desirable direction. However, often, these two commitments come into conflict.

In public health, the efficacy of community-based interventions has been studied in action research studies, often using experimental methods - of comparing outcomes in

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intervention versus control/comparison groups. The Reduction of Low Birth Weight Project in Jharkhand is such an action research study intended to evaluate the effectiveness of community-level interventions in improving related maternal and child health outcomes, in the context of mandated public health services, through a quasi-experimental design with cluster randomisation at the health sub-centre level.

This paper attempts to analyse some ethical dilemmas in action research, illustrated through this case study, in the light of the principles of biomedical ethics proposed by Beauchamp and Childress: beneficence, non-maleficence, respect for autonomy, and justice.

The ethical concern confronting the researcher is the choice between health interventions for all in underserved communities (beneficence and justice), and maintaining a rigorous research design to establish the evidence (non-maleficence, towards greater beneficence and justice). What is the relevance of "respect for autonomy" in cluster randomisation, in which entire geographies are selected for the intervention or the control group? Action research for evidence-based interventions is an ethical goal, but what are the compromises in this pursuit?

Cluster randomised trials: some dilemmas in methodology and ethics

Raman Kutty

The number of cluster randomised trials (CRTs) has shown a sharp increase recently, particularly in developing countries. A growing body of literature looks at the ethical issues involved in CRTs. Many of the dilemmas identified relate to informed consent, representativeness of gate keepers to consent, and the inability of individuals to opt out.

This paper examines the ethical challenges inherent in the methodology of the CRT, particularly, the statistical assumptions that form the basis for interpretation of results.

One of the stated advantages of the CRT is reduced costs. However, this comes at a trade-off: if the inter-cluster variability is high, the number of clusters needed may be so numerous that there is no particular advantage to doing a cluster design, except when the intervention can only be administered at the group level.

In the CRT, there is an implicit assumption that the within-cluster variation is low, and between-cluster variation is high. If within-cluster variation is high, the risk-benefit ratio will vary across individuals within a cluster, and it is quite possible that a subset may be exposed to a larger potential for harm with little benefit.

There is a need to highlight the ethical dilemmas of estimation of risk in CRTs and the statistical assumptions that underpin such estimations. These have serious implications for public policy, as often public health policy is dictated by evidence from such interventions.

P21: Ethical problems in everyday medical practice

Managing ethical issues around barriers to anti retroviral treatment adherence in Maharashtra, India

Neelam Joglekar, Ramesh Paranjape, Rekha Jain, Girish Rahane, Ratnaprabha Potdar, Seema Sahay

Successful HIV treatment requires a high adherence to antiretroviral therapy. Adherence to treatment is a very patient-centred issue which needs to be studied holistically and addressed empathetically. We examined patient-related barriers to ART adherence at three selected ART centres in Maharashtra, India.

Between January 2009 and March 2009, in-depth interviews were conducted by trained investigators with 32 consenting patients from three ART centres in Maharashtra. The convenience sampling method was used to select participants, on the basis of their record of a missed visit or non-adherence. Qualitative data were collected and analysed.

Issues like financial constraints [18/32(56.25%)], socio-cultural pressure to attend family functions [12/32 (37.5%)], time constraints because of long waiting hours and resultant work absenteeism [15/32 (46.87%)], emerged as the reasons behind patients' inability to report to ART centres within the scheduled time frames. Negative attitudes towards medication and adherence [10/32 (31.25%)], and self perceived stigma were the additional patient-related barriers [9/32 (28.12%)] identified in the study.

In pursuance of the ethical principle of beneficence, for visiting convenience of patients' on scheduled dates, we recommend morning and evening OPD hours at ART centres, so that time can be managed well, while work absenteeism can be prevented. In view of the principle of autonomy, the counselling package should allude to the patient's beliefs and practices regarding medication, the cultural need to fulfil social obligations and the benefits of optimal adherence. Empathetic counselling strategies, especially the understanding of internalised stigma, can help immensely to improve adherence.

Public health ethics: questions on the breach of confidentiality of HIV/AIDS patients: a study of selected case law in India

Arathi M.

New medical interventions and the emergence of new diseases can invoke moral issues and related ethical debates in every society. The state has addressed these ethical issues through the instrument of law. Legalisation of a medical process is the way all societies resolved medical and bioethical issues. This paper looks at the judicial response in an Indian case [Mr X. v. Hospital Z (1998)8 Supreme Court Cases 296] as a legal response, while reviewing existing laws related to the breach of confidentiality of HIV/AIDS patients.

The purpose of this paper is to generate academic discussions on the complex public health ethical issues related to this case law, for the protection of the vulnerable sections of society who may be victims of imbalanced judicial interventions.

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This paper is a product of primary and secondary reviews of literature related to the above mentioned case law, collected as part of upcoming doctoral work, along with the analysis of a draft law, the HIV/AIDS Bill, 2006. The methodology considers case law as a case study to explore multifaceted ethical and legal issues in depth.

This paper will view the public health ethical issue of breach of confidentiality through the lens of the basic bioethics principles of autonomy, beneficence, non-malfeasance and justice. The whole judicial process in this case law is made up of challenges to basic elementary jurisprudential principles, while misrepresenting the issues, such as the right to marry of the fiancée of an HIV/AIDS patient.

Perceptions of privacy and confidentiality: "Do I want them to know?"

Bushra Shirazi, Aamir Jafarey

Privacy and confidentiality are concepts in bioethics that are based on respect for the individual and non-maleficence. The principles of biomedical ethics are rooted primarily in western philosophical traditions and may not work as well in our setting. These concepts need to be examined in our milieu.

This paper reports on an ongoing study of medical students, nursing staff, patients and doctors. It uses focus group discussions to understand how these groups perceive privacy and confidentiality, and what their comfort level is in sharing personal information. The study has been approved by the ethics review board of Ziauddin University.

The preliminary results indicate that it is acceptable for information about routine surgeries to be shared with the immediate family and to some members of the extended family. However, working class men do not want their parents to be given medical information, and cite various reasons for this. The need for confidentiality was viewed as more important with regard to communicable diseases like HIV, hepatitis and other venereal diseases, because of the stigma associated with such diseases.

While respondents placed limited importance on the need for personal medical information to be kept confidential, issues of privacy were viewed differently. It was felt that examinations should be done by the primary physician, without the presence of the families. Further, respondents had strong reservations about being examined in the presence of a person of the opposite sex.

P22: Ethics of monitoring ethics: research ethics boards

Ethical diversity and regulatory harmonisation for effective governance: an empirical exploration of the research ethics committees in India.

Suresh Kumar K

Despite the range of formal guidelines and theoretical recommendations as to how Research ethics committees (RECs) should be run, from an empirical point of view we have very little understanding of how these work as regulatory bodies within the clinical trials framework; they have been largely unexplored by social scientists. This raises diverse concerns on how far harmonisation should go for effective governance of RECs.

Hence, for the future development of ethics regulation in India, it is important to gain a greater understanding of the functioning of RECs in India, by reflecting on RECs in developed countries, and building an effective research ethics governance framework for India.

The key learning objectives would be: to impart knowledge on evidences available from developed countries; to enhance regulatory harmonisation, and to develop a national governance model that can incorporate ethical diversity for RECs in India.

The method followed in the presentation will be: to disseminate the evidence available on the topic from developed countries through a systematic review of literature and "new learning", and to bring out the significance of the topic in the field of bioethics. Reflecting on successful strategies of developed countries will support decision makers in creating policies and systems for regulatory harmonisation and ethical governance of RECs in India.

Ethics committee deregulation in India: an emerging epidemic

Nilay N Suthar

Ethics committees (ECs) now exist in most hospitals and have an elevated status in many ways. EC approval grants immunity to those who take approval and follow their advice.

There is a significant lack of data on the effectiveness of ECs, and EC members often lack the requisite education and skills for effective participation in review processes in India. Hence, there is an urgent need for research on ECs with national and global quality standards.

I conducted this study for the evaluation of ethics committees in Ahmedabad, India.

A qualitative, cross-sectional study, of 165 questions containing a modified SIDCER self assessment tool (V3.2) based questionnaire, was used for the study of 20 ECs in Ahmedabad city. The chairperson or member secretary answered questionnaires which were anonymised and analysed in view of the current guidelines from the World Health Organization, the International Convention on Harmonisation-Good Clinical Practices, and the Indian Council of Medical Research, stating the minimum EC requirements.

The results demonstrated that in comparison to standard guidelines, 61% of ECs have partial or no introductory or ongoing training. 39% of ECs do not comply, partly or fully, with administrative requirements. On an average, 34% of ECs do not comply with membership requirements. 32% of ECs do not comply fully with review process standards.

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The results of the study reveal non-uniformity and irregularities of ECs in the region, in spite of international and ICMR guidelines. These unregulated ECs may endanger research participants in the region, and hamper the credibility of research conducted there. This could be similar to the condition of other Indian cities. India must mandate EC accreditation urgently.

Evaluation of regulations on clinical research in Turkey: ethical and legal aspects

Elif Atici, Teoman Atici

Experimental studies on animals have been carried out in Turkey, according to international standards, since 1960. However, the number of clinical studies (especially drug studies), which meet these standards are not many. The first ethics committee in Turkey was established in 1986; and since 1993 obtaining approval from an ethics committee has been a legal requirement before commencing any medical research. In January 2009, in order to overcome deficiencies in existing regulations, regulations on clinical research were established in accordance with legislation in the European Union regarding drugs. The regulation relates to the procedure and principles for providing scientific and ethical standards in the planning, implementation, recording, reporting and validity of all kinds of clinical studies, and the protection of rights of volunteers. All previous regulations were repealed after the new law. Thus, all separate rules and regulations related to drug research and treatment were combined into one set of rules. However, due to certain ethical and legal concerns, proceedings have been opened for the suspension and cancellation of certain provisions of these regulations by the Head of the Central Council of the Turkish Medical Association. Following this, the enforcement of certain articles of the regulations was halted by the Council of State and after amendments to some articles. They have again come into force, since March 2010.

In this presentation, positive and negative aspects of the regulations are evaluated in terms of ethics.

P23: Health information in the public domain

The third party in decision making: the role of web-based medical facilitators in medical tourism

Suchitra Wagle

Cross border travel is now a decade-old phenomenon. Web-based health resources have emerged as an important aspect in seeking care. A new angle to this web-based information is the spurt of medical tourism facilitators in recent years. In no time, the facilitator has become the crucial connector of patients to the host country. These tourism facilitators guide medical travellers and navigate them through different countries, doctors and specialties providing combinations of arrangements.

The facilitators tend to be numerous, operating without any ethical guidelines, influencing the decision making of the patients, but for the medical tourist it means more choices and wider variety. Little attention has been paid to the ethical aspects of the information provided by the facilitators, or the authenticity of it.

The most remarkable factor is that, despite its origin in a developed country, it results in accelerating the movement of patients to a foreign third world country.

This paper reviews and analyses the available web based information with special focus on the emergence and development of medical tourism facilitators and their present status. The paper deliberates on different kinds of facilitators, their characteristics and the way this would influence the medical traveller's behaviour. It compares various facilitators across India, the USA and the UK. The paper indicates that though the field is at an early stage, some indicators emerge with regard to ethical standards.

Ethics in literature searching

Vasumathi Sriganesh

Medical ethics usually refers to the moral rights and wrongs arising in the context of the practice of medicine. This paper refers to ethics in the context of doing a thorough job in one's profession and focuses on the area of literature searching for medical writing, documentation, education and practice. Searching medical literature correctly and systematically requires professional expertise. For the practice of evidence-based medicine, getting the best is a very important building block. When conducting a clinical trial, an improper or incomplete literature search can result in an investigator not knowing about the adverse effects of a drug. This compromises the safety of the trial. If authors of systematic reviews do not have all the available randomised controlled trials (RCTs), they will produce a review that has a flawed meta-analysis. With such RCTs and systematic reviews, one does not get real evidence. A thorough literature search is possible when one knows about the scope, coverage and features of all databases, and knows how to arrive at correct search strategies. One also needs to learn to trust one's instincts to find out if one has carried out an adequate search based on one's own domain knowledge. Working with an information specialist to retrieve all the necessary important literature involves learning enough about how to communicate with the specialist, and interpreting his/her work. Literature searches that are inadequate or improper are unethical, when viewed from the angle that there is a lack of professionalism that may actually cause harm.

Media coverage of the official response to a malaria outbreak in Mumbai

Sweta Surve

During the months of June-August 2010 there was an outbreak of malarial disease in Mumbai. Preventive and curative services provided by the Brihanmumbai Municipal Corporation (BMC) during this crisis came under much scrutiny and were discussed

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widely in the media. The state and public administrative bodies and the civic body are mainly responsible for providing basic health facilities to the people. The media's job is to report impartially and cover all sides of the picture. It should not be the accuser, prosecutor, defence lawyer, jury and judge at the same time. The media is the fourth pillar of democracy. Its basic responsibility is to help strengthen and support democratic processes.

This paper looks at the dynamics operating between administrators of the BMC, politicians and the media. It also tries to explore whether the media shows ethical responsibility while reporting health emergencies and crises. It is based on secondary data analysis and literature review on the topic. Articles regarding the malaria outbreak have been collected from leading English and Marathi newspapers, websites, blogs and other related sources. These resources have been analysed, based on our objectives.

The paper will give us an understanding of how major issues relating to health administration in the BMC, like cleanliness and hygiene, staff and equipment shortages, and preventive and curative measures, are covered in the media. It will also focus on how the media carried out its ethical responsibility, in the context of the malaria outbreak.

P24: Regulation and access to rational drugs

Are Indian drug stores operating ethically by practising the policy of free/paid home delivery of drugs to customers?

Vishvas Garg, Mehak Garg

Thousands of drug stores operating across the nation in India practise the business strategy of free or paid home delivery of drugs either as incentives for customers to switch to them from their current drug store, or to prevent their current customers from switching to another drug store. This home delivery system, however, has many ethical issues associated with it. This paper attempts to throw light on these ethical issues.

On the one hand, freeor paid home delivery is very effective in providing timely drug supplies to patients of certain demographics such as senior citizens, bed-ridden people, those with limited transportation facilities, and those with no or limited time to fill up their prescriptions by going to drug stores. On the other hand, home delivery can be viewed as unethical, as it can be categorised as unfair trade practice in the pharmacy profession; it can alienate a patient from his or her community pharmacist as most delivery boys are not qualified for drug dispensing; it can incentivise self-medication among patients, and it increase prescription errors as orders are generally taken over the phone, instead of in person.

Free or paid home delivery has comparatively higher costs than benefits associated with it. It is unethical and sometimes illegal too, as in the case of schedule H drugs, to provide home delivery of drugs unless otherwise urgently required.

The practice of free or paid home delivery of drugs in unethical and relevant steps should be taken to eradicate it.

Microbial resistance and implications for public health: exploring ethical dimensions

Anant Bhan

Rising microbial resistance in countries such as India has serious implications for individual patient care as well as public health. This presentation will use the controversy around the bacteria with the New Delhi metallo-ß-lactamase 1 (NDM-1) gene, the so-called "superbug", as a case study to explore the related ethical issues.

The presentation will use public health ethics frameworks to analyse the causes of the spread of microbial resistance, such as widespread indiscriminate use of antibiotics, lack of a rational use of medicine policy, as well as inefficient laboratory and surveillance mechanisms for bacterial resistance.

Public health ethics principles such as paternalism, reciprocity, necessity, the harm principle and social justice will be used to advocate a population focus in health system decision making with regards to microbial resistance.

There are cost, quality, infrastructure and governance implications in the spread of microbial resistance. Use of public health frameworks will help evolve possible solutions to prevent the spread of microbial resistance. The context of microbial resistance containment ranges from individual patient care to public health at large; hence there is a need to further explore this important area in the bioethics community.

Health services: the gaps need to be minimised

Moinul Md Islam

After independence, marked improvements have been noticed in the Bangladesh public health sector, both in medical institutions and in health service delivery centres. At present, it is a fairly strong system within the subcontinent. Despite that, questions arise regarding the quality of services provided. Here, the key issues are the staff shortages in the public sector, as also a lack of medicines and equipment. As a result, only a few people take treatment from the public health set-up. We see less public care and increasing private practice, every day. Hence, several challenges arise here.

People rarely receive proper doses here. Prescriptions are nothing but chemical checklists of pharmaceutical products; because the doctor is busy seeing as many people as possible within an hour. Over all, there is nobody to supervise or control public issues here. It is a peculiar practice in Bangladesh that, some essential drugs like paracetamol, antacids, pain killers, antihistamines, and the narrow spectrum antibiotics such as cotrimoxazole, metronidazole, chloramphenicol and amoxicillin are widely used, without prescriptions from registered physicians. Simultaneously, people consume medicines of their own choice, or as suggested by the pharmacist, without hesitation.

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The above scenario demands immediate control of medicine trading and use in Bangladesh, to protect the population from drug resistance and other complexities, due to irregular, inferior and over medication.

P25: Surveillance and epidemiological research

Ethical issues in epidemiological studies

Prakash C Gupta, Avinash U Sonawane

Epidemiological research often makes use of sensitive, individually identifiable, private information, through surveys and interviews and may link this information with additional information obtained from public or private records, such as employment, insurance, or disease registries. Epidemiological studies often present significant problems regarding both privacy and confidentiality; therefore, approvals from epidemiological research ethics committees are almost always required. The range of data can be very wide, from a well structured interview process with biological sample collection to an opinion poll type of survey without any identifying information.

Obviously the requirement for human protection procedures and approvals would be different in each case. While collection of biological samples would almost always require a signed consent, a simple questionnaire study without questions of a sensitive personal nature may require only a verbal consent, while in yes- no type answers to a few questions, it may be argued that giving answers implies consent. There can be other issues as well. To give some examples: in an air quality study in public spaces such as hospitality venues, we have argued that since no human subjects were involved, nor was there interference with any personal property; no permission was required. In another observational study where investigators sat in a hookah bar and lounge, they were asked to observe and record physical characteristics of the place, clustering of customers and their ordering pattern. However, there was no recording of individual behaviour, because no consent was taken. Thus different types of studies pose challenges toward ethical considerations.

Length of the consent process: lessons from field research on the use of helmets by motorised two-wheeler drivers

Nurani Subramanian Vishwanath

An informed consent is indicative of a research participant's intention to engage with the researcher after being informed of the purpose of research. The assumption is that there is information asymmetry in the relationship between the researcher and the participant. To what extent can this be taken to be true in other settings where the balance of power rests with the participant?

A field survey to examine the perception of risk with regard to the use of helmets among two-wheeler drivers, as part of a policy study on helmet legislation in the state of Kerala, provided an opportunity to examine this issue with regard to informed consent processes.

Interviews about risk perception form a part of understanding the reasons for non-use among motorcyclists. However, the researcher is seen as an added nuisance in the parking lot by most drivers. The ability of motorcyclists to decline participation is absolute, and there is very little scope for exploitation. In the 10-minute interview, the consent process takes up 60-180 seconds. Should not the nature of the study decide the length of this consent process?

When the principle of autonomy is not compromised, do we need to pay elaborate attention to the process of taking consent, which could actually even compromise the research process itself - at times resulting in refusal? Graded consent forms that take into account the level of risk of violation of autonomy would serve to solve such problems, and not in any way compromise the application of the other principles of ethical research.

Surveillance versus research ethics

Michael Selgelid

Health surveillance is widely considered to be one of the most basic public health activities. Though health surveillance is closely related to medical research-and though the two often involve the very same activities, such as medical record review - the two are treated very differently in practice.

Bioethics, to a large extent, grew out of research ethics, and research ethics is one of the best developed areas of bioethics. The situation regarding surveillance ethics is, at present, similar to that of research ethics prior to 1947 (when the Nuremburg Code was established), i.e., virtually nonexistent.

Key ethical issues arising in the context of surveillance include standards of care, informed consent, and confidentiality.

This paper aims to (1) clarify technical and/or moral differences between research and surveillance; (2) identify and analyse ethical issues associated with public health surveillance, and (3) propose a framework for analysis of ethical issues in surveillance.

Analysis of surveillance ethics may also shed new light on research ethics. If the interests of individuals should have absolute priority over the promotion of science and society in the context of research, the same should apply in the case of surveillance. If it is determined that the public health importance of surveillance makes prioritisation of individuals untenable, this might imply a need for revision of research ethics guidelines.

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