REPORTS

Conference on emerging issues in ethics and regulation of medical research

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A one-day conference on emerging issues in ethics and regulation of medical research was organised by the Department of Research, Deenanath Mangeshkar Hospital and Research Centre (DMHRC), Pune, on January12, 2013. The meeting was attended by 270 participants.

The conference was inaugurated by **Dr Dhananjay Kelkar,** Medical Director of the hospital. He summarised the **current situation in medical research** and stressed the necessity for clinical research to focus on the health needs of the country rather than being donor driven. In the present scenario, he said, there is every chance of conflict of interest due to the incentives attached to clinical research. He also pointed out that if we do not follow ethics, we will be bound by regulation. *He encouraged the delegates saying that this conference would serve as an important step on the path to forming a better society, better science and a better future.*

The keynote speech was delivered by **Dr Roli Mathur**, Scientist 'C', Indian Council of Medical Research (ICMR), on the **current scenario and prospects in clinical research in India**. She said that though India is a hot spot for clinical trials, its contribution is inadequate compared to other countries. We should use this opportunity to develop new drugs that will be beneficial and affordable for our own people and for the diseases that concern them. Bodies like the ICMR are ready to provide funding but they need to ensure that the research being done is ethical. She gave examples of unethical research which show that doctors are turning into businessmen and there is erosion of public trust in the medical profession. She added that the ICMR is accountable to agencies like the National Human Rights Commission for such lapses and for preventing them. She drew attention to lacunae in regulatory systems and the need to correct them, especially in the light of the Supreme Court's recent criticism of the conduct of clinical research in India. She also touched upon problems with ethics committees (ECs) such as the lack of periodic assessment of research projects; members' insufficient understanding of protocols and their own roles, and their assessment of adherence to guidelines. Dr Mathur also informed the delegates about the upcoming Biomedical and Health Research Regulation Bill which will regulate medical research as well as the functioning of ECs. She stressed that an EC is no longer a part-time activity. She pointed out the importance of initial and continued training to EC members, not only on good clinical practices (GCPs) but also on basic knowledge of various research areas like clinical medicine and epidemiology. She advised EC members to be more vigilant in reviewing research involving a product which does not require market authorisation.

Dr Sunil K Pandya, Editor Emeritus of the *Indian Journal of Medical Ethics,* spoke on **current issues in the ethics of medical research**. Dr Pandya focused on worrying aspects of today's medical research, primarily regarding researchers. He stressed that only qualified researchers should do research and they should do only research that needs validation on the Indian population. He elaborated on some prevailing practices adopted by researchers that raise questions about their commitment to the cause. According to him, research is often substandard and done in a haphazard manner. He touched upon the practice of selling products at exorbitant prices without any justification. He gave the examples of stem cell research and anti-ageing therapies.

Dr Pandya talked about the evolution of the informed consent process in medical research. He stressed that consent must be *truly* informed consent. We must find ways to ensure that the fruits of research reach the participants. At least a small proportion of the monetary benefits should reach the participants who have given their tissues for research. Often, researchers have little say in what is published. Therefore we need to be very vigilant. Researchers must take care that what is being published is the whole truth, and not just what is palatable or convenient. He gave examples of types of fraud in medical research. He concluded by calling for serious action against persons committing fraud.

Mr Mudassir Khalil, Deputy Manager – Liability Insurance, Bajaj Allianz, spoke on **insurance for clinical trial participants.** Mr Khalil explained that a compensation agreement was a pre-decided agreement which mentions the kind of insurance available for specific injuries. He threw light on some issues that an EC should look for while evaluating the insurance for a research study: checking that the trial period was within the insurance period and ensuring that the policy is renewed in time to avoid gaps; checking that the trial site is within the geographical limits of the policy; and insisting that the sponsors acquire insurance cover for an extended reporting period in studies involving drugs which may cause long-term or delayed side effects. Other relevant questions to be asked are: What are the possibilities of injury? What is the expected severity of a serious adverse event (SAE) if it occurs? What are the social parameters regarding the trial population? How many subjects are involved in a study?

Mr Khalil clarified that the insurance company' liability is limited to the amount covered in the agreement; any compensation beyond this, if required, would be the sponsor's responsibility.

Further, all phases and types of studies are covered under insurance; the difference is in the sum insured and the premiums. The company does not cover pre-existing conditions; failure of the drug to do what it was intended to do; or radioactive contamination unless the study involves the use of such drug. Payment is both for compensation for injury as well as the legal costs. He also explained how the company processes claims. If a pre-existing condition gets aggravated due to participation in the study, it is covered. Mental problems and agony are not covered under the policy unless they lead to a disease.

He reminded participants of the points to be remembered for a valid claim: timely feedback to the insurance company, an understanding of the process of claim by the researcher, and reporting of SAEs as defined in the agreement.

Mrs Suchela Srivatsa, Head-Integrated Site Services, for Quintiles India Pvt Ltd, Mumbai, discussed the **ethical challenges in research in India** that have resulted in today's tarnished image of India and the medical profession. She suggested that we need to work jointly on low-cost, sustainable models, establish more practical policies that are relevant for the Indian scenario, and partner with the media in educating patients about clinical trials. She discussed the ethical responsibilities of sponsors, trial / site investigators, EC members, contract research organisations, regulators and trial participants; and the scope for improvement by all these stakeholders in clinical research. She stressed the urgent need for patient education and said that patient registries would be useful to recruit the right type of patients.

Dr Urmila Thatte, Professor and Head, Department of Clinical Pharmacology, Seth GS Medical College and KEM Hospital, Mumbai, spoke on **accreditation for ethics committees**. Dr Thatte began by mentioning important reports regarding functioning of Institutional Review Boards in the USA. She gave the definition of accreditation as 'self assessment, external peer review against international standard' It is a voluntary and continuous quality improvement process. She discussed some benefits of accreditation: uniform standards for ECs across the country, improved public trust, preferential site selection, and research grant approval. She mentioned the agencies for accreditation --Strategic Initiative for Developing Capacity in Ethical Review and Association for the Accreditation of Human Research Protection Programs -- and explained the process by which they provided accreditation. She advised the delegates to become part of the Forum for Ethical Review Committees of India and support the building up of a system of national level accreditation. Dr Thatte stated that the accreditation process provided guidance about each EC member's duty; however, ECs should have their own guidelines. It is the chairperson's responsibility to ensure that each member makes their due contribution as an EC member.

The speakers were followed by researchers who spoke on research ethics from the perspective of their work.

Dr Manisha Paliwal, Associate Professor, Sinhgad Institute of Management, Pune, spoke of the **relevance of ethics in the field of nursing**. She explained how the interdisciplinary approach provided a theoretical overview and dealt with emerging ethical issues in nursing. She described the difference between medicine and nursing. Nursing compassionately helps people adapt to chronic illness and incapacity, and focuses on 'nurturing'. Medicine tries to defeat the conditions that produce chronic pain and incapacity, and focuses on combating illness, malfunction, and injury. She added that despite the differences in the two fields, ethical medical decision-making must integrate healing and nurturing.

Dr Anand Shinde, IVF Consultant and Director Andrology at DMHRC, spoke on the **importance of ethics in assisted reproductive technologies**. This new technology has provided solutions but posed many ethical dilemmas, which, he said, should be discussed in open public fora by couples, doctors, law makers, ethicists, and the lay public.

Dr Akshay Kulkarni, Microbiologist and Clinical Embryologist, spoke on how the three fundamental tenets of ethics – autonomy, justice and beneficence with non-maleficence -- apply to the patient of **in-vitro fertilisation**, and the embryo, in both applied and research scenarios. The ethics behind using human embryonic stem cells and induced pluripotent stem cells was discussed.

Dr Padmakar Pandit, Professor and Head of the Department of Clinical Pharmacology and EC Member Secretary, BJ Medical College and Sassoon General Hospital, Pune, spoke on **ethical issues in trials involving elderly patients**. He discussed the pharmacokinetic and pharmacodynamic changes that occur with age, and highlighted the importance of a pharmacological screen. There is a need for research on drug-drug interactions, with emphasis on interactions with drugs commonly used in geriatric populations. Also, elderly patients might benefit from appointing a legally authorised representative.

Dr Dakshayani Pandit, Consultant Microbiologist, Dr DY Patil Medical College and Research Centre, Pimpri, Pune, spoke on the subject of **informed consent in emergencies**. She highlighted the fact that 'voluntary' and 'informed' are two keywords in this concept. When consent from the subject is not possible in emergency situations, consent must be obtained from the LAR. In the absence of an LAR, measures listed in the protocol must be followed, with EC approval. She underlined the importance of the data safety monitoring committee, especially in the case of research on critical patients or in emergency situations.

A panel discussion in the post-lunch session concerned forming an association of ECs in Pune. About 60 EC members attended the session. Participants spoke on the need for such an association. It would be useful to conduct brain storming discussions, help each other resolve issues related to research ethics, train EC members, write on ethics, and strengthen ECs.

In conclusion, speakers at this one-day conference inspired all the participants, leaving them with much food for thought.