Association of Indian Universities Roundtable of Vice Chancellors of Health Sciences Universities

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Organized by

Sri Venkateswara Institute of Medical Sciences, Tirupati
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SESSION-IV – 11.10.2017

Sub theme: Trends and Issues in Health Science Research

Chairperson: Prof. A.G. Ahangar, Director, Sher-I-Kashmir Institute of Medical Sciences

Panelists: 1. Dr. Arun Risbud, Director Research, Krishna Institute of Medical Sciences University, Karad, Maharashtra
2. Dr Amarendra Pani, Director Research, AIU, New Delhi
3. Dr. Shashanka Devdatta Dalvi, Pravara Institute of Medical Sciences, Loni

1) **Development of an inter-University paradigm for funding, monitoring and recognizing Research in Health Sciences**

Speaker: **Dr. D.M.Thappa, Director, NEIGRIHMS, Shillong**

Lead Panelist: **Dr. P.Kumar, Dean Academics (Medical Sciences), Teerthankar Mahaveer University, Moradabad, Uttar Pradesh.**

Key points discussed:

- Emphasized successful granstsmanship is predicated on novelty of proposal.
- Enumerated the funding agencies for medical research - Government agencies like ICMR, DST, DBT, DRDO, NIN, CSIR, AYUSH. Non Government organizations (NGO) like Bill and Melinda Gates Foundation, Public Health Foundation of India. Professional bodies like Cardiological society of India and many more.
- Pharma funding to be tapped for clinical trials and Intramural funding allocation by various universities to jumpstart research.
- Four essential elements for attaining a grant – 1) Good and Innovative idea, 2) selecting appropriate agency, 3) Proper filing of application 4)Relevance to India
- Issues of sensitivity regarding trials on humans, transfer of data and confidentiality in multi centre trails discussed.
- Population groups, IPR
- Special ethical concerns

- Proper collaboration with pre and para-clinical branches to have good outcome
- Awards, MCI promotion and grants of patents to stimulate research
- To Improve Research culture
- To Start Zonal research bodies, State research coordinating body, Inter university collaboration
- Develop process that encourage cooperation

Consensus:

1. Set up an inter-university Research fund under the aegis of Research Division of AIU.
2. Solicit contributions to establish the corpus of this research fund through :
   a) Individual university contributions
   b) Pharmacological Companies
   c) Corporate Social Responsibility of other non-pharmacological companies need to be tapped to encourage contributions.
   d) AIU consortium can represent at various government departments for research funds (eg. DBT, DST, DRDO, ICMR)
3. Establish a research office under AIU to help us central resource (eg. Office of grants and contracts in premier universities abroad) to manage the fund, solicit research proposals from universities and to disburse grants and to monitor the progress of research resulting from the award of the grant.
4. To institute cash awards and certificates to recognize those with outstanding research output using the research fund on an annual basis.

2) Promoting Collaborative research between universities – The Multicentre studies, complementary research and formation of clinical trials group

Speaker: Prof. N.R.Biswas, Director, IGIMS, Patna

Lead Panelist: **Prof. Dr.Sateesh Kumar Bhandary**, Dean, K.S. Hegde Medical Academy Nitty University, Mangaluru

Key points discussed:

- Enumerated different types of universities for collaboration
- High quality clinical research in academia is key to closing the gap and underpins innovation and improvement in health services.
- Collaborative research decreases the '**translational gap**' between basic scientific discovery and innovation that will benefit patients and society as a whole.

- Mobilise research communities of collaborative universities by sharing the quality research out- puts that adds value to the research outcome.
- Promote funding for inter-university collaborative research.
- Attract fresh graduates and post graduates into science by giving them teaching opportunity and set up modern facility for S&T education and research.
- Focus should be given to the medium productive universities and colleges to enhance not only their quantity but also quality of research output.
- Improvement in the Universities & College sector is required in terms of the technical and computing infrastructure, course-content, teaching methods, faculty development in new and interdisciplinary fields, creating better linkages with research organizations.
- Universities should strengthen collaboration with developed and emerging economies
- Emphasis should also be on decreasing the cost of treatment as many are unable to spend. Even in India percapita expenditure is less than 15 dollars.
- Large clinical study conducted cooperatively at multiple centers has a number of important advantages over a small study performed at a single center or small number of centers.
- Multicenter studies have the advantage of increased generalization of the results. Therefore spontaneous research on same topic at different universities can authenticate the results in wide ethnic groups.
- Enumerated different phases of clinical trials
- Enumerated Different steps in getting approval of clinical trial Discuss idea with peers and colleagues
- Stressed upon the importance of Clinical Research organisations which reduce time to release new drugs, sponsors fixed costs and provides ready access to needed expertise and/or technology, Greater access to potential investigators.
- Research funding needs to be doubled (currently 0.9 percent of GDP and most of which goes on regular maintenance and human resources).
- Appreciated the efforts of MCI which is mandating research in post graduation and publications for promotion etc.
- MCI can take steps to promote collaborative research between medical universities.
- Emphasised on collaboration of research with adjacent basic science universities which helps the basic topics like human genetics.
- Emphasised the role of central research laboratory.

- Enumerated the results achieved by their institute with collaborative research like radiation protection with herbal products.
- Mandates for publication in postgraduates
- A central research lab in every medical college will facilitate interdepartmental cooperation and reduce duplication of expensive equipment.
- Financial incentives for faculty based on publication.

Consensus:

1. Multicentric trial or studies are much better than single centre trials due to their larger sample size, representation of more regional and ethnic groups and hence greater generalizability.
2. Hence universities should start working together to establish suitable cohorts and infrastructure to carry out longitudinal long term multicentre studies as are being carried out in developed countries. AIU may help to co-ordinate these studies through its Research division and even fund these through the aforementioned research fund.
3. Establishment of a central research laboratory in each university / college with uniform equipment across different universities will facilitate research by different departments through the same shared common laboratory as well as comparability of laboratory results across different universities.
4. Collaboration of Medical Colleges/ Universities with adjacent basic sciences universities (for eg. in genetic research) through inter-university MOUs could be another way towards a fruitful collaboration between universities to benefit the community
5. AIU can facilitate establishment of a platform for education/training in research methodology, study design, Biostatistics, Data Support and monitoring, Adverse event reporting etc.

3) **Implementing ICMR guidelines on Ethics in Medical Research - Role of Institutional Ethics Committee and importance of good clinical practice training.**

Speaker: **Dr.V.P. Gupta,** Principal, UCMS, Delhi University, New Delhi.

Lead Panelist: **Prof.P.V.L.N. Srinivasa Rao**, Dean, SVIMS, Tirupati.

Key points discussed:

- Ethics is the science of morality dealing with values, principles, beliefs, and opinions, what is right and what is wrong.
- Ethical Guidelines - Evolved from unethical Research and he quoted few examples
- Ethical guidelines evolved from The Nuremberg Code,1947 to present day. The Declaration of Helsinki and enumerated the salient points of each guidelines.
- Four Cardinal Principles are a] Autonomy b] Beneficence benefits outweigh risks C] Non-maleficence- do no harm D]Justice
- Any research on human beings must stick to following 12 principles a] Principles of Essentiality b] Principles of Voluntariness, informed consent and community agreement C]Principle of Non Exploitation d]Privacy and confidentiality e]Professional competence f]Accountability and transparency g] Principles of Precautions to minimize risk h] Principles of Maximization of the public interest and of distributive justice i] Principles of Institutional arrangements j] Principles of Public domain k] Principles of Total professional and moral responsibility l] Principles of Compliance
- Enumerated what all should be there in informed consent
- Need for fresh or re-consent in case of change in the topic
- Participants should be given post trial access
- Emphasised the composition of IEC and the need to be be independent and competent and should involve medical / scientific professionals and non-medical / non-scientific members
- Enumerated the responsibilities of IEC
- Emphasised the significance of Good Clinical practice and core principles of GCP.
- Enumerated prerequisites for conducting a clinical trial in India Permission from the Drugs Controller General, India (DCGI).Approval from respective IEC and Mandatory registration on the ICMR maintained website.

- Enumerated Additional safe guards and protection required with respect to research involving: Children, Pregnant and lactating women. Vulnerable participants Persons with diminished autonomy Issues pertaining to commercialization of research International collaboration.
- Suggested for training of IEC members at ICMR.
- Scientific validity is needed prior to ethical committee approval.
- Scientific aspects of the research should be analyzed
- Statistical analysis has to be made
- Need of Biostatisticians in ethical committee and research committee
- One Record Assistant to be appointed for ethics and One Professor to be incharge for maintenance of records of ethical committee proceedings.

Consensus:

1. Each institute conducting research should have an independent Institute Ethics committee which also includes Biostatistician, and a secured system for long term maintenance of records.
2. IECs should register with the Central Drugs Standard Control Organization (CDSCO) under the office of Drugs Controller General (India) in order to carry out drug trials.
3. Scientific validity of the study should be assessed by a Research protocol approval committee mandatorily prior going to ethics committee so that meaningless research with no value to society is not carried out .
4. All members of IEC should be trained in India Specific Good Clinical Practice (GCP) guidelines as specified under Schedule Y of Drugs and Cosmetics Rules 1946 as amended from time to time and is available on the website of CDSCO.