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Editorial – IJPP

Does Current Human Ethical Guidelines Support Translational Research in Indian Medical Systems?

Indian Council of Medical Research has recently released National Ethical Guidelines for the Biomedical and Health Research involving human participants (1). It is available in the ICMR website for public access. ICMR policy statement on Ethical Considerations Involved in Research on Human Subjects was initially established in 1980s and those guidelines were revised in 2000 as Ethical Guidelines for Biomedical Research on Human Subjects. Covering newer areas, it was again updated and brought as Guidelines for Biomedical Research on Human Participants in 2006. The current guideline has been framed to address the concerns of all stakeholders in the area of research using human subjects. The current clarity in the guidelines is expected to give support and confidence among the researchers to undertake translational research.

One must remember that the evolution of clinical research in India has created lot of interest among several investigators in private and public Institutions after the GATT agreement. Clinical research had created a massive hype amongst students due to the demand of trained manpower in the related areas. During that time, the clinical trials involved in drug discoveries and other experiments were booming in India on one hand and the lack of adequate regulations left certain concerns unaddressed on the other. Privation of clear policies and guidelines in place, non-sensitization of public towards trial related issues, media trials resulting in abrupt change in policies of the Government have resulted in tremendous pressure on the clinical research armamentarium.

Transnational biomedical research through outsourcing of clinical trials by pharmaceutical companies from industrialized nations to low and middle income nations have always raised concerns about the vulnerability of study participants (2). The dynamism in the evolution of ethical standards differs between cultures in the back drop of economy and has to be addressed time to time without affecting the fundamentals of ethics. Clinical drug research in academic institutions is mostly conducted by comparing efficacy among same class of approved compounds for the indicated disease conditions. These kinds of investigator initiated clinical studies are conducted without the support of any external sponsors (like drug companies) only for academic interest and for the larger benefit of society in the particular country to add knowledge to the existing literature.

Due to the lack of active collaboration between the pharmaceutical drug discovery programs and academia, most of the Indian academic research projects are directed to herbal isolates and extracts which are limited only to preclinical studies with notable public funding. The volume of traditional knowledge resulting in preclinical research publications are spiraling with the supporting evidences using molecular biology techniques. But, seldom they get translated into the clinical studies for their therapeutic utility. Purifying or isolating a natural compound alone cannot afford patent eligibility. Due to lack of exclusive marketing rights, getting investment from a pharmaceutical agency for translational research is very unlikely. Without the chemical derivatisation of the active compound resulting in structural change evincing a corresponding functional difference, patent rights are not possible. In this scenario, current guideline gives enough space for clinical studies in Ayurveda, Siddha, Unani and Sowa Rigpa drug formulations (Box of 7.7 of NEG 2017) (1). For conducting such academic studies, required empowerment to the institutional ethics committee has already been provided by CDSCO.

For example, launch of BGR-34 by CSIR laboratories and IME-9 by AYUSH for type II diabetes in India showed the possibility of developing the vast knowledge available in the ancient Indian medical systems like Ayurveda, Siddha and Unani can be brought into clinical use. The aforesaid formulations are the offshoot of the plants derived from Ayurvedic literature. Now, more than 40 of such formulations are available in India containing the chief ingredient '*Gymnema sylvestre'* (Gudmar). It has also been sold in online shopping websites and in pharmacies. Although, it has been known for reducing blood sugar for more than 30 years, (Khare et al 1983 [3] published in Ind J Physiol and Pharmacol), inadequate scientific evidence according to the required standards is a major stumbling block for its understanding towards pharmacology and therapeutic utility at par with allopathy (4). To our surprise in the past two years, we see more than 2 tons of Gymnema extracts (Gymnemic acid) have been imported in Indian ports and more than 4 tons were exported as extracts and formulations to various other countries and used extensively in population.

Having more than 450 medical colleges and 1100 Pharmacy colleges in India involved in drug related research indicate the availability of potential population to undertake preclinical and subsequent translational studies. It should be considered that now is the ripe time for opting to translational studies in our Indian Medical systems. One must go through NEG-2017 and GCP-ASU-2013 to understand where exactly their plant extract or ASU formulation is coming under (1 & 5). In many cases, incorporation of an ASU practitioner is insisted by the guidelines for conducting the study. With the emphasis on mainstreaming the potential of AYUSH in the National Health Policy-2017, there is an expanding scope for affordable health care promotion and cure through wholistic and perceptive approach.

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