Journal of Ayurveda and Integrative Medicine 9 (2018) 151–154

Contents lists available at ScienceDirect

Journal of Ayurveda and Integrative Medicine

journal homepage: http://elsevier.com/locate/jaim

Discussion Kernel

Ethics Committees in Ayurvedic PG institutions: Losing opportunities of making an impact

Sanjeev Rastogi

State Ayurvedic College and Hospital, Lucknow, India

ARTICLE INFO

Article history:
Received 17 June 2017
Received in revised form
22 September 2017
Accepted 25 October 2017
Available online 26 May 2018

Keywords:
Ethics committee
Ayurveda research
Research committee
Clinical research

ABSTRACT

Ethics is a crucial component of medical practice world over and also an indispensable part of medical research. Ethics in medical practice primarily refers to not harming the patients by the proposed interventions; similarly ethics in research refers to assuring optimal care of the participants and causing no harm to them on account of research. Ethics in research has come a long way from its voluntarily application on moral grounds to a mandatory condition regulated by the state of law. Ethics Committees (ECs) have been erected at research institutions to safeguard the interest of patients, to ensure their safety during any such trial and to assure the accountability of the researcher in case of any unforeseen event. Such committees therefore have a noble role to play in the form of promoting ethical practices in research. Ayurvedic clinical research also follows the similar path by erecting ECs at its research institutions. However, in reality, such committees are found much away from the principle of their inception and method of functioning. In the absence of accountability and clear objectivity, such ECs at Ayurvedic research institutions are not serving any purpose. This article critically examines the positioning of ECs at Ayurveda research institutions and suggests pragmatic mechanisms to ensure their role in improving the quality of research in Ayurveda.

Ethics is a critical component of research pertaining to any domain of knowledge. It is even more sensitive and critical when humans or animals are involved as a composite entity in the research protocol. Institutional Ethics Committees (IECs or ECs) are instituted at research organizations (sometimes independently also) as the custodians to look at the ethical issues referring to human participation in research whereas, Animal Ethics Committees (AECs) look at similar issues referring to animal participation in research. The importance of such committees in research can be understood by the observation that currently no clinical research proposal can be applied for funding, conducted, or sent for publication unless it has an approval from the appropriate committee on ethical grounds.

Consideration of ethics in medical practice is a pertinent issue and has a long history. '*Primum non nocere*' or 'First Do No Harm' has been the principle guiding dictum in medical practice all around the world. Ancient Ayurvedic literature also deals elaborately on various aspects of ethical issues involved in clinical practice. It further has an explicit definition of do's and don'ts for a physician dealing with a patient.

Ethical issues emerged in medical research during the transition of observational to experimental studies. Exposing the group of interest to some interventions, known or unknown, in order to see the benefits (sometimes hazards also) soon became the core method of clinical research globally. Gradually, the clinical research methods got further refined by introduction of ideas of randomization, controls, blinding and placebo into it in order to improve the reliability and reproducibility of the results.

A number of ethical issues related with the design of study, method of selection of the patients and consequences of any unforeseen adversities of an intervention have arrived. Priority or convenience sampling in a vulnerable population, exposing the people to potential risk and remaining unaccountable for the consequences of the research were certain issues which alarmed the global community about the methods of conducting clinical trials; as a consequence, an ethical consideration of the trial before it is actually executed became a necessity. It is noteworthy to see that such ethical considerations too have observed a transformation from being a moral and personal value initially to a binding regulation mandatory to be observed, subsequently [1].

E-mail: rastogisanjeev@rediffmail.com
Peer review under responsibility of Transdisciplinary University, Bangalore.

https://doi.org/10.1016/j.jaim.2017.10.005

ECs in its current format have a short history in India. The first ICMR guidelines (Justice HR Khanna committee report, 1980), recommended that the research proposals were to be reviewed by the IEC, though it was voluntary. Although preliminary in nature, this report was clear in opinion that independence should be hallmark of such committees. ICMR has subsequently developed a detailed guideline for the effective functioning of IECs with a liberty to develop the individualized standard operative procedures (SOP) as per one's organizational needs and prospects related to the type of projects mainly dealt within the institution [2]. Although such guidelines were not mandatory initially, it became essential in 2002, when Medical Council of India (MCI) asserted in its code of ethics that a medical doctor doing research, requires to follow ICMR guidelines. These guidelines got further legal backing through the 2005 amendments in the Schedule Y of Drug and Cosmetics Act of India. This amendement has clearly defined that the observance of GCP related to a clinical trial is the principal responsibility of ECs [3].

Seeing the prospects and importance of quality research in Ayurveda and other traditional systems of medicine in India, Ministry of AYUSH has taken an initiative to standardize research practices in Ayurveda, Siddha and Unani (ASU). A detailed guideline pertaining to the Good Clinical Practices in Ayurveda, Siddha and Unani (GCP-ASU) therefore came into existance. This document dealt elaborately with issues related to clinical trial designing and its effective execution [4]. This document also dealt adequately with the issues of ethics pertaining to Ayurveda research and guided about the role and functioning of IECs in Ayurvedic teaching or research institutions.

In an attempt to make Ayurvedic research at its academic institutions more stringent, focused and rigorous, Central Council of Indian Medicine (CCIM), a regulatory authority on the matters of Ayurveda practice and education has made a mandate that every research proposal of the Ayurveda post-graduate students be passed through IEC before it is actually accepted and submitted to respective university [5]. Many universities also have included the clearance of Departmental Research Committees (DRC) (sometimes also referred as Departmental Review Board) and IEC as a mandatory condition, before accepting any research proposal as a part of their post-graduate training programs [6].

At ground level, every post-graduate Ayurvedic college in India is directed to have their respective DRC to review the research proposals submitted by their PG students in respective departments (every department has its own research committee). Subsequently these are to be reviewed and cleared by IEC.

Clinical Trial Registry of India (CTRI), again an ICMR initiative had been registering clinical trials since 2007. Initiated as a voluntary measure, since 15th June 2009, trial registration in the CTRI has been made mandatory by the Drugs Controller General (India) (DCGI). Supporting their cause, editors of 11 major biomedical journals from India have declared not to consider non-registered trials for publication [7].

Interestingly, the EC clearance and CTRI registration both are mandatory to do a clinical trial in India but they have not been linked together. A CTRI registration although asks about EC clearance, has not made this disclosure essential for registration. Similarly, ECs also do not essentially require a trial to be registered in CTRI before it is given a EC clearance. Although CTRI invites the trials coming under the mandate of AYUSH also to get registered, the same has not been made essential by the regulatory authorities of AYUSH [8]. A good movement of registering Ayurvedic clinical trials at CTRI was therefore seen initially which died away gradually in the absence of clear directives from the authorities about its need [9].

Looking at this complex flow of research approval process, one may feel inspired that Ayurvedic researches particularly those done at its PG institutions are being done in the same spirit and rigor as is adopted in other spheres of science on the matters of research. Unfortunately, on the ground, the things are not as glittering as these appear to be in Ayurvedic PG institutions.

The primary crisis in Ayurveda academic institutional ECs arises from their absolute independence. Unlike their counterparts in biomedicine, ECs in Ayurveda PG institutions are functioning *suo-moto* with no one to monitor their working standards or decisions. In the absence of such monitoring, these ECs are unaccountable of their acts and hence victims fall to prejudice, preference and premonitions. Such questions of ethics of ECs have been raised and observed in biomedicine too, but mechanisms have been made to counter the malfunctioning of an EC. Ayurvedic drugs not being regulated by DCGI and Central Drug Standard Control Organization (CDSCO), ECs at Ayurveda PG Institutions do not come under the purview of their regulations and hence enjoy an unbridled status for being not watched for their conducts and behaviors. Under rule 122 DD Registration of Ethics Committee this is stated that no EC shall review and accord its approval to a clinical trial protocol without prior registration of the committee with the licensing authority as defined in clause (b) of rule 21. An application for registration of EC shall be made to the licensing authority in accordance with the requirements prescribed in schedule Y-1 [10].

An amendement in schedule Y in 2005 has put more light upon the responsibilities of ECs, although it has also clarified the clinical trial as “a systematic study of new drug(s) in human subject(s) to generate data for discovering and/or verifying the clinical, pharmacological (including pharmacodynamic and pharmacokinetic) and/or adverse effects with the objective of determining safety and/or efficacy of the new drug” [11]. Under this new definition of the clinical trial, many actually escape to come under the grind of the same and therefore do not require a registration under CDSCO if they do not deal with new drug. Many institutions have started putting two ECs, for the same reason; one to deal with new drugs and hence requiring registration with CDSCO and the other with known drugs functioning independently.

In Ayurveda, the clinical trials done with extracts and active principles do come under the category of new drugs and hence require the same method as is adopted for biomedical clinical research upon new drug. If an EC is dealing with herbal drugs made of active principles, it needs a registration with CDSCO. As Ayurveda PG institutions do not do the research on active principles and rather make a clinical trial of the formulations, they do not come under the purview of CDSCO. GCP-ASU on the other hand also do not throw any light upon how such ECs can be made accountable for their acts referring to their accord of a clinical trial on a formulation from their system.

In the absence of clarity on their roles in Ayurvedic formulation research, such ECs at Ayurvedic institutions have become ritualistic only rather than offering any significant input in terms of improving quality of research with due consideration of ethics in whole formula research at Ayurvedic institutions. This input is even more important when we see Ayurvedic PG institutions increasing in number continuously. As of now, there are about 115 institutions offering PG education in Ayurveda in various specialities [12]. There are many among these who deal exclusively with PG education in Ayurveda. This number is supposed to grow further in coming years.

As per amended schedule Y, the responsibilities of an EC is to review and accords its approval to a trial protocol to safeguard the rights, safety and well being of all trial subjects. Special care is required to be observed to protect the rights, safety and well being of all vulnerable subjects participating in the study. EC is also required to document its ‘standard operating procedures’ and should maintain a record of its proceedings. EC is also required to make the review of the ongoing trials for which the accord was

given. In case an EC revokes its approval accorded to a trial protocol, it should immediately be communicated to the investigator as well as to the Licensing Authority.

GCP-ASU on the other hand is largely derived from ICMR guidelines for ECs and also includes the basic responsibilities as entailed under Schedule Y. It agrees on points like documenting SOP for its effective functioning. The responsibilities of an IEC under GCP-ASU include protection of the dignity, rights and well being of the potential research participants; ensuring that universal ethical values and international scientific standards are expressed in terms of local community values and customs; assisting in the development and the education of a research community responsive to local health care requirements. The second point in here pertains to the customization of universal ethical values and international scientific standards in reference to the local values and customs. Similarly the role of an ASU EC is also understood as to assist the development and education of a research community responsive to local health requirements.

Unfortunately, without understanding the meaning and purpose of their establishments, such committees at Ayurveda PG institutions are found busy scrutinising the technical component of the proposal by suggesting changes in various components of protocol. Translating the universal ethical values to local customs is something very crucial in reference to Ayurveda clinical research done with formulations. Many drugs in Ayurveda are composed of animal products including *panchagavya*; also as per the custom of certain religions, a few of the specified animal products are not welcomed. In Muslims, one month fasting is customary during the month of Ramadan. This day time fasting does not allow them to consume any medicine unless this is supposed to be life saving. The schedules of medicine consumptions are usually modified as per schedule of fasting. Such are the customs, where a value of local traditions and customs is required. In Ayurveda ECs, we rarely come across any such discussions which pertain to local values. GCP-ASU also visualizes ECs in Ayurveda as the instruments of change in terms of assisting the developments and education of a research community responding to local health requirements. Unfortunately, in its current format, such ECs have become means of oppression rather than becoming the means of illumination.

The problem in EC functioning in Ayurveda actually arises due to non-observance of the set protocol of its formation and functioning. Although, GCP-ASU clearly defines the methods of constituting an IEC in Ayurveda institutions, the actual practice is solely based on whims and wishes of the institutional head. The operating procedures are never defined and not documented. There had never been a practice of observing the conflicts of interests among the members of IEC referring to the proposals evaluated. The decisions are often made on the basis of personal opinions in the absence of a real quorum. There are no exclusive funds to manage the daily affairs of IEC and hence the daily chorus of EC is largely affected in the lack of fund. Independence and competence which are stated to be the hallmarks of the IEC are therefore rarely observed in the functioning of such committees in Ayurvedic institutions.

Functioning of ECs have been challenged and questioned in biomedicine too [13] and therefore this is not something exclusive to Ayurveda. What is more important that elsewhere the stakeholders have started taking the initiatives to strengthen the system. In Ayurveda, such movements are however still far away.

There can be many pragmatic solutions to end this inertia and to make such IECs the real tool of change. The first and foremost recommendation to make ECs more effective and transparent is to make them accountable for their affairs. This accountability can easily be brought if such agencies are told to report to a higher monitoring agency. Ministry of AYUSH can take an initiative in this regard. The other gray area in the EC functioning is the poor acquaintance of its members about their responsibilities and possible impact of their work. In such case, a continuous movement of capacity building among the stake holders may be required. WHO has long been stressing about the capacity building in the area of ethics [14]. The same monitoring agency looking after the affairs of ECs in Ayurveda may also be given the responsibility of making its members more efficient by exposing them to newer knowledge and offering solutions to their queries. The formation of EC should essentially be cared for. It should simply be based upon the principle of competence and therefore nominations in the ECs should clearly be based upon research and ethics aptitude of the member. Mere positions in the college should not be the guiding principles in the absence of adequate aptitude and competence. There can be many informal ways of imparting knowledge among the members. Subscribing to quality ethics journals in institutional library can be one method to do so. National Accreditation Board for Hospital and Health Services (NABH) has recently offered an accreditation program for accreditation of IECs involved in clinical trials [15]. NABH is a part of Quality Council of India (QCI) looking at bringing the standards in health care services by offering accreditation to health care providers. NABH already deals with AYUSH in many areas, designing an accreditation program exclusive to Ayurveda IECs, therefore may not be difficult. Registration and accreditation of ECs is observed globally and is considered as an important step to monitor the affairs of ECs to assure them sticking to their values [16] There are many voluntary organizations working consistently to improve the functioning of ECs. Forum for Ethics Review Committees in India (FERCI) is one such organization working in India having a vision of fostering an integrated and sustainable ethical oversight mechanism and encourage a quality and ethical culture in health research in India. It also works for developing capacity for sustainable and integrated quality ethical review of health research with a focus on functioning of ECs [17]. FERCI happens to be a composite part of a larger organization representing Asia and western pacific region (FERCAP). These organizations organize various activities on regular basis, to empower EC members to function optimally.

Besides competence, independence is also a key word in optimal functioning of an EC. To assure independence, every EC should be provided with its minimal requirements to maintain its daily affairs. What we see in Ayurveda PG institutions, referring to the functioning of EC, is that there is nothing like independence. For every matter of functioning in the college, obviously the approval of institution head is required and this eventually limits the liberty of ECs in their own matters.

What we see here are number of mechanisms adopted by other streams of research to ensure fair and quality practices done by ECs. In Ayurveda also, such mechanisms are required to be adopted. Before we sum up, we need to stress that Ayurveda research is much different than that of conventional biomedical research. In biomedicine, there are huge resources and manpower existing to execute and to bring the change. In Ayurveda however, the clinical research is still in nascence. This would therefore be extremely productive in the long run if we can catch our stakeholders just in the beginning to tune them adhering to the quality of research. PG students of Ayurveda therefore can be considered as a future asset to Ayurveda provided they are being trained in a right way and under right perspectives. ECs at Ayurveda PG institutions can play a crucial role in achieving this goal if they themselves can understand their own roles to be played for the good of Ayurveda.

IEC is proposed to safeguard the dignity, rights, safety and well being of all actual and potential research participants. The goals of research, however important, should never be permitted to override the health and well being of the research subjects. In reality, it has a noble role of reviewing the research proposal finally from multiple angles to make it fool proof before it actually sails off. This

therefore happens to be the last opportunity of looking into the preciseness of a proposal and hence a chance to make an impact upon the whole research proposal and eventually on whole community which is supposed to be benefitted by the research. In the absence of a clear objective, vision and mechanism, Ayurvedic ECs can prove to be contrary. We therefore need to think seriously from preventing them from becoming the bankrupt custodians losing the opportunity of acting in favor of the real spirit of science and humanity and of making their own science any better.

Sources of funding

None.

Conflict of interest

None.

References

[1] Bhatt A. Evolution of clinical research: a history before and beyond James Lind. Perspect Clin Res 2010;1(1):6–10.
[2] Guidelines for preparing Standard Operating Procedures (SOP) for Institutional Ethics Committee for Human Research, Available at: http://icmr.nic.in/ethics_SOP.pdf.
[3] Bhatt A, Sewlikar S. India steps towards globalization-reforms to schedule Y regulations. CR Focus 2007;18:21–6.
[4] Good clinical practice guide lines for clinical trials in ayurveda, siddha, unani medicine (GCP-ASU), Available at: http://ayush.gov.in/sites/default/files/5110899178-Final%20Book%2028-03-13_0.pdf.
[5] Indian Medicine Central Council (Post Graduate Ayurveda education) Regulation 2016. Available at: https://ccimindia.org/pdf/rul-reg-mse-ay-2016-9.pdf.
[6] University of Lucknow, PhD Ordinance 2016. Available at: http://admission.lkouniv.ac.in/phdprogramme/pdf/phd_ordinance_2016.pdf.
[7] Pandey A, Aggarwal A, Maulik M, Seth SD. Clinical trial registration gains momentum in India. Indian J Med Res 2009;130:85–6.
[8] Clinical Trial Registry-India, Available at: http://ctri.nic.in/Clinicaltrials/login.php.
[9] Sridharan K, Sivaramakrishnan G. Clinical trials in Ayurveda: analysis of clinical trial registry of India. J Ayurveda Integr Med 2016;7(3):141–3.
[10] http://www.cdsco.nic.in/573(E).pdf.
[11] Schedule Y, amended version (CDSCO), Available at: https://www.rgcb.res.in/uploads/2014/07/Schedule-Y.pdf [Last Accessed on 22 September 2017].
[12] Ayush in India 2016, Available at: http://ayush.gov.in/sites/default/files/12.%20Medical_Education.pdf [Last Accessed on 20 September 2017].
[13] Jesani A. Ethics in ethics committees, time to share experiences, discuss challenges and do a better job. Ind J Med Ethics 2009;6(3):62–3.
[14] Research ethics committees, Basic concepts for capacity-building, Available at: http://www.who.int/ethics/Ethics_basic_concepts_ENG.pdf [Last Accessed on 22 September 2017].
[15] Information Brochure for Ethics Committee Accreditation Program, Available at: http://www.nabh.co/Images/PDF/CT_Brochure.pdf [Last Accessed on 20 September 2017].
[16] Walanj AS. Research ethics committees: need for harmonization at the national level, the global and Indian perspective. Perspect Clin Res 2014;5(2):66–70.
[17] FERCI, Forum for Ethics Review Committees in India, Available at: http://ferci.org/vision-mission-statement/ [Last Accessed on 20 September 2017].