

# Medical Ethics

## Ethics committee registration and re-registration with the regulatory authority in India

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### ABSTRACT

**Background.** All ethics committees (ECs) that review and monitor clinical trials in India must be registered with the regulatory authority. We ascertained the status of registration and re-registration of ECs till December 2017.

**Methods.** The ECs registered and re-registered with the Indian regulatory authority till December 2017 were extracted. The status of ECs was analysed according to the state, institute category and registration.

**Results.** A total of 1260 ECs were registered, of which 14% were based in medical colleges, 2% in dental colleges, 61.2% in hospitals other than medical colleges and 8% as independent ECs. Of the recognized medical and dental colleges, only 37.3% and 10.9%, respectively, and 45.9% of ECs from teaching hospitals (other than medical and dental colleges) had registered with the regulatory authority. Of the 911 ECs eligible for re-registration, 516 (56.5%) had re-registered.

**Conclusion.** A low proportion of registrations of ECs from eligible academic health institutions raises concern about adherence to regulatory guidelines and conduct of clinical trials in India. The lower re-registration of ECs helps in the identification of factors which should be addressed to facilitate clinical research in India.

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### INTRODUCTION

Research ethics committees (RECs) are responsible for the protection of rights and well-being of patients. The Declaration of Helsinki<sup>1</sup> and the Good Clinical Practice (GCP) guidelines of the International Conference on Harmonisation (ICH) of Technical Requirements for Registration of Pharmaceuticals for Human use<sup>2</sup> have set international standards for ethics review of clinical research. In India, the Indian Council of Medical Research (ICMR) Policy Statement for Ethics was published in 1980, which mandated an EC to oversee all types of research.<sup>3</sup> The ICMR guideline was revised in 2000, 2006 and recently in 2017.<sup>3,4</sup>

In India, clinical trials are governed by Schedule Y of the Drugs and Cosmetics Act introduced in 1988.<sup>5</sup> Schedule Y requires that the study protocol be reviewed and approved by an REC, following the ethical guidelines for biomedical research issued by the ICMR. Schedule Y was amended in 2005 and 2016.<sup>6,7</sup> The conduct of clinical trials is governed under the Indian

GCP.<sup>8</sup> In view of the exponential rise in clinical trials and instances of research misconduct, the Government of India made several amendments in the regulation of clinical trials in India in 2013. The Gazette notification G.S.R.72(E) dated 8 February 2013 required all ECs, which review and monitor clinical trials, to be registered with the Central Drugs Standard Control Organization (CDSCO).<sup>9</sup> This was to bring transparency and some control over the constitution and functioning of ECs and ensure quality during the conduct of clinical trials. The ECs are required to apply for registration along with supporting documents citing the constitution, experience of members, function and documentation of protocols reviewed by the EC. Based on the review and if found suitable, the CDSCO registers the EC for 3 years. The ECs are expected to apply for re-registration before the expiry of the 3-year period. After due diligence, the CDSCO re-registers an EC for a further period of 3 years. The list of ECs along with the registration and re-registration letter is uploaded on the CDSCO website ([www.cdsc.nic.in](http://www.cdsc.nic.in)). We documented the progress and pattern of registrations and re-registration of ECs over 5 years. We also documented the distribution of ECs registered and re-registered all over India.

### METHODS

To map and describe the ECs registered and re-registered with CDSCO, India, till 31 December 2017, we manually extracted the data available at the CDSCO website ([www.cdsc.nic.in](http://www.cdsc.nic.in); last updated 23 October 2017). The ECs were organized according to the states and year of registration and re-registration. We obtained the list of medical colleges (Medical Council of India; [www.mciindia.org](http://www.mciindia.org)),<sup>10</sup> dental colleges (Dental Council of India [DCI]; [www.dciindia.org.in](http://www.dciindia.org.in)),<sup>11</sup> hospitals with Diplomate National Board (DNB) courses (National Board of Examinations; [www.natboard.edu.in](http://www.natboard.edu.in))<sup>12</sup> and hospitals accredited with the National Accreditation Board for Hospitals and Healthcare Providers (NABH; [www.nabh.co](http://www.nabh.co)).<sup>13</sup> The list of the Scientific and Industrial Research Organization (SIRO) recognized by the Department of Science and Industrial Research (DSIR) was sourced from their website ([www.dsir.gov.in](http://www.dsir.gov.in)).<sup>14</sup> We extracted data from various sources during 7–15 January 2018 and updated them during 2–7 February 2018. The descriptive analysis was done for the information extracted from different sources using Microsoft Excel.

### Ethical issues

As the data used for this study were obtained from publicly available information and were not linked to any identifiable individual, explicit individual consent was not required. The protocol was reviewed by our institutional EC and exempted.

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## RESULTS

Of the 1273 ECs uploaded on the CDSCO website, 1260 were registered till December 2017 (registration for 8 ECs was rejected and for 5 it was duplicate). Till December 2017, a total of 516 ECs had re-registered with CDSCO.

### Registration

About half ( $n=653$ ; 51%) of the ECs were registered in 2013, followed by 258 (20%) in 2014, 136 (10.7%) in 2015, 101 (7.9%) in 2016 and 112 (8.6%) in 2017. Figure 1 shows the trend of registration and re-registration of the ECs during 2013–2017. Among the 1260 ECs registered, 175 (14%) were in medical colleges, 29 (2%) in dental colleges, 266 (21.1%) in hospitals with postgraduate DNB courses, 183 (14.5%) in research institutes and 506 (40.1%) in various hospitals. In addition, 101 (8%) independent ECs had been registered. The registered ECs were across 29 states and Union Territories (UTs; Table I). Maharashtra leads the list with 289 (22.9%) registered ECs followed by Gujarat ( $n=145$ ; 11.5%), Karnataka ( $n=136$ ; 10.8%) and Tamil Nadu ( $n=127$ ; 10.1%). No EC from three states (Manipur, Nagaland and Tripura) and four UTs (Dadra and Nagar Haveli, Daman and Diu, Arunachal Pradesh and Lakshadweep) was registered with CDSCO. Of the 469 medical colleges recognized by the Medical Council of India (MCI), ECs of 175 (37.3%) medical colleges were registered. Of

the 266 dental colleges recognized by the DCI, ECs of only 29 (10.9%) were registered. Similarly, ECs of 266 (45.9%) hospitals of the 579 with postgraduate and super-specialty courses recognized by the Diplomate National Board (DNB) were registered. In addition, ECs of 506 hospitals were registered. Of the 101 registered independent ECs, 57 belonged to one SIRO,

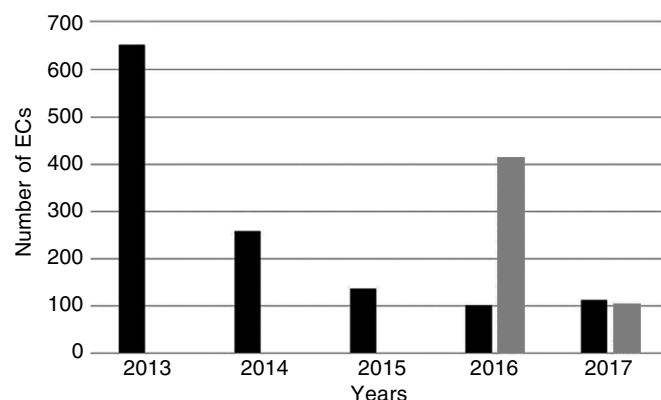


FIG 1. Trend of registration and re-registration (lighter bars) of ethics committees (ECs) with the Central Drugs Standard Control Organization

TABLE I. The distribution of ethics committees (ECs) registered with the Central Drugs Standard Control Organization (CDSCO) according to the type of institute and state/Union Territory

State/Union Territory	Medical colleges	Dental colleges	DNB institutes	Independent ECs	Research institutes	Other hospitals*	Total
Andaman and Nicobar Islands	1	0	0	0	0	0	1
Andhra Pradesh	7	1	13	7	10	59	97
Assam	1	0	2	0	2	5	10
Bihar	1	0	0	1	1	4	7
Chandigarh	1	0	0	0	0	1	2
Chhattisgarh	3	0	1	0	0	4	8
Delhi	5	1	7	4	21	30	68
Goa	1	0	0	0	3	4	8
Gujarat	10	2	17	23	24	69	145
Haryana	1	1	6	0	4	6	18
Himachal Pradesh	2	0	0	0	0	0	2
Jammu and Kashmir	2	0	0	0	0	0	2
Jharkhand	1	0	0	0	0	2	3
Karnataka	31	6	34	13	13	39	136
Kerala	4	5	23	3	6	28	69
Madhya Pradesh	6	1	2	0	0	7	16
Maharashtra	34	6	72	25	50	102	289
Meghalaya	1	0	0	0	0	0	1
Mizoram	0	0	0	0	0	1	1
Orissa	7	0	3	0	2	5	17
Puducherry	6	0	3	0	0	1	10
Punjab	3	0	5	1	0	14	23
Rajasthan	7	0	7	0	4	24	42
Sikkim	1	0	0	0	0	0	1
Tamil Nadu	16	3	36	14	24	34	127
Telangana	6	1	2	7	4	12	32
Uttar Pradesh	8	2	8	2	8	39	67
Uttarakhand	4	0	0	1	0	3	8
West Bengal	5	0	25	0	7	13	50
<b>Total</b>	<b>175</b>	<b>29</b>	<b>266</b>	<b>101</b>	<b>183</b>	<b>506</b>	<b>1260</b>

\* Hospitals accredited with the National Accreditation Board for Hospitals and Healthcare Providers excluding those with DNB courses (postgraduate and superspecialty)

No EC from Manipur, Nagaland, Tripura, Dadra and Nagar Haveli, Daman and Diu, Arunachal Pradesh and Lakshadweep has been registered with the CDSCO till December 2017.

DNB Diplomate of National Board

recognized by the DSIR. There were 337 SIROs recognized by the DSIR, 81 under the social science category and 256 under the medical sciences category. ECs from only 2 SIROs under the social sciences category and 55 under the medical sciences category were registered with the CDSCO. According to the information available in the public domain, there are 2414 healthcare institutions (medical colleges, dental colleges and hospitals) and medical research institutions, which are likely to have ECs for oversight of research activities involving human participants. According to the list of ECs registered with the CDSCO, 1260 (52.2%) ECs from these institutions were registered.

*Re-registration*

The ECs registered with the CDSCO are expected to re-register at the end of 3 years after the initial registration. Of the 911 ECs eligible for re-registration (registered during 2013–14), 516 (56.5%) ECs had re-registered till December 2017. The re-registration for ECs from states with high number of registered ECs ranged from 31% to 80% (Table II and Fig. 2).

**DISCUSSION**

This is possibly the first effort to describe in detail the profile of ECs registered and re-registered with the CDSCO in India. We found that of the 2414 eligible institutions (medical colleges,<sup>10</sup> dental colleges,<sup>11</sup> teaching hospitals,<sup>12</sup> NABH-accredited hospitals<sup>13</sup> and medical sciences SIROs<sup>14</sup>), ECs of about half were

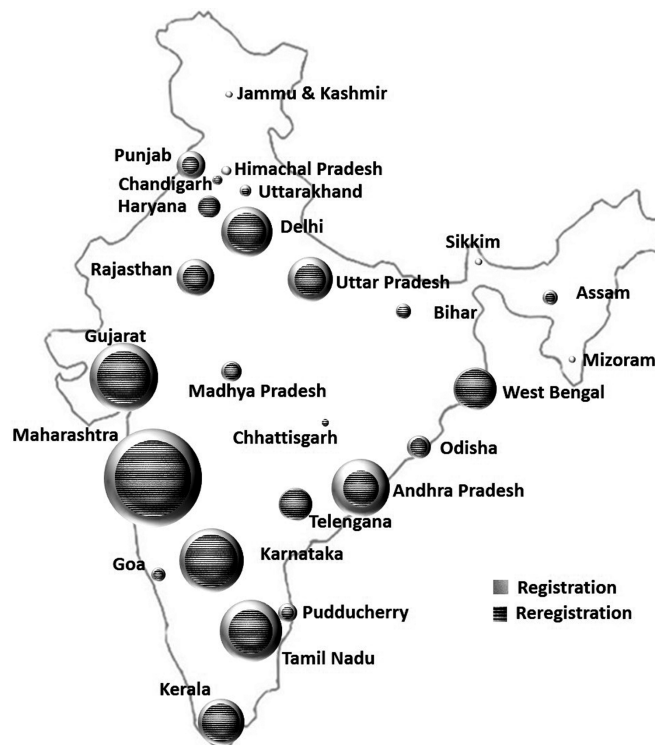


FIG 2. Geographical distribution of registration and re-registration of ethics committees with the Central Drugs Standard Control Organization in India

TABLE II. The status of registration and re-registration of ethics committees with the Central Drugs Standard Control Organization (CDSCO) from different states/Union Territories

State/Union Territory	Registration (2013–2014)	Re-registration (2016–2017)
Andhra Pradesh	75	28 (37.3)
Assam	5	2 (40)
Bihar	5	3 (60)
Chhattisgarh	1	1 (100)
Chandigarh	2	1 (50)
Delhi	58	33 (56.9)
Goa	4	2 (50)
Gujarat	106	63 (59.4)
Haryana	11	9 (81.8)
Himachal Pradesh	2	0 (0)
Jammu and Kashmir	1	0 (0)
Karnataka	93	61 (65.6)
Kerala	48	31 (64.4)
Madhya Pradesh	9	5 (55.6)
Maharashtra	219	130 (59.4)
Mizoram	1	0 (0)
Odisha	12	6 (50)
Puducherry	8	3 (37.5)
Punjab	18	6 (33.3)
Rajasthan	31	14 (45.2)
Sikkim	1	0 (0)
Tamil Nadu	87	43 (49.4)
Telangana	25	20 (80)
Uttarakhand	3	1 (33.3)
Uttar Pradesh	45	21 (46.7)
West Bengal	41	33 (80.5)
<b>Total</b>	<b>911</b>	<b>516 (56.6)</b>

No ethics committee (EC) was registered during 2013–2014 from Jharkhand, Meghalaya and Andaman and Nicobar Islands. No EC from Manipur, Nagaland, Tripura, Dadra and Nagar Haveli, Daman and Diu, Arunachal Pradesh and Lakshadweep has been registered with the CDSCO till December 2017.

registered with the CDSCO. It was also apparent that the ECs of a majority of teaching and training institutions including medical colleges (62.7%), dental colleges (89.1%) and hospitals with DNB postgraduate and super-specialty courses (54.1%) were not registered with the CDSCO. According to the Gazette notification G.S.R. 72 (E), under Rule 122DD, all ECs which review clinical trial protocols must register with the CDSCO, the licensing authority. As a result of this notification 1260 ECs registered with the CDSCO till December 2017, though only 911 (72.3%) were registered during 2013–2014. The registration of ECs continued through 2015–2017 with over 100 ECs registering annually. Still, the number of registered ECs have reached about half of the expected ECs in India. The number of applications from ECs for registration under review, rejected or not pursued are not available in the public domain. There is a need to explore why the ECs of the institutions have not registered with the CDSCO. The possible reasons could be that these institutions are not doing any clinical research or they are not aware about the requirement to register. The situation is alarming for dental colleges with only 10% of the ECs registered. A report on status of medical research and publications found that of 579 medical institutes (316 under the MCI and 263 under the NBE) in India, 57.3% of institutes did not have a single publication over 10 years (2005–2014).<sup>15</sup> These two observations may be correlated to assess the priority given to research in our major institutions.

A little over half (56.5%) the registered ECs were re-registered with the CDSCO. The factors for a relatively lower proportion of re-registration of ECs also need to be explored. Some reasons may be that the ECs are not reviewing/have not reviewed clinical trial protocols for some time or they may not be clear about the need for re-registration if the EC is only reviewing observational studies. The re-registration guideline and checklist is silent on the

requirement for the ECs which do not review protocols for clinical trials. The EC registration guideline focuses on clinical trials and is relatively silent on observational studies involving human participants.<sup>9</sup>

According to an earlier report, by 1 August 2016, 1083 ECs were registered with the CDSCO with Maharashtra, which has the highest number of registered ECs ( $n=259$ ; 23.9%), followed by Gujarat ( $n=125$ ; 11.5%) and Karnataka and Tamil Nadu ( $n=112$ , 10.3%). While some states (Himachal Pradesh, Jharkhand, Sikkim and Jammu and Kashmir) had either one or two registered ECs, several states and UTs (Arunachal Pradesh, Manipur, Meghalaya, Tripura, Andaman and Nicobar, Dadra and Nagar Haveli, Daman and Lakshadweep) did not have a single EC.<sup>16</sup> The National Ethical Guidelines for Biomedical and Health Research Involving Human Participants by ICMR (2017) recommends that ECs should register with the relevant authority as per the regulatory requirements. It also mentions that the certification and accreditation by ECs are voluntary exercises and help in quality assurance and quality improvement to ensure adherence to best practices in protecting the dignity, rights, safety and well-being of study participants (section 4.15, page 48).<sup>17</sup>

Our study has limitations. We used only the information published on websites of the concerned agencies, which may be incomplete or there may be a lag period in announcement or posting of the information. We may have incorrectly categorized the EC if the name of the EC did not bear the name of a college, hospital or institution.

The efforts by the Government of India to streamline clinical research and bring transparency as well as an accountable oversight mechanism through amendments in the Drugs and Cosmetic Act and updating of the national ethical guidelines for biomedical and health research are welcome.<sup>7,17</sup> The current description of the status of registration and re-registration of ECs and distribution by institutions raises several concerns. First, the low proportion of registration by ECs from medical colleges, dental colleges and institutions with DNB postgraduate and super-specialty courses needs to be addressed. The pattern of registration and re-registration was similar across the states. The possible challenges and determinants in this context need to be explored. The inclusion of a registered EC with the appropriate competent licensing authority may be considered as a requirement for recognition of the medical college or dental college or DNB institute, especially for postgraduate and super-specialty courses. Second, the factors responsible for the low proportion of re-registration by the already registered ECs should be identified. The stand on the requirement of re-registration for the ECs which review non-regulatory type of studies and observational studies should be clarified. Third, similar to the requirement of registration of ECs with the CDSCO

for clinical trials, an effort for registration of ECs which review observational and studies other than clinical trials, with a suitable agency such as the ICMR may be considered to bring transparency, uniformity and accountability of the ECs for protecting the rights of study participants.

*Conflicts of interest.* None declared

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