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Impact of recent regulatory notifications on an institutional ethics committee

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Abstract

The Government of India came out with a slew of notifications to streamline clinical research in the beginning of 2013 in response to the Supreme Court's orders and a Parliamentary Standing Committee's report. The notifications greatly influenced the structure, review process, outcomes and administration of ethics committees across India. In this study, we attempted to objectively evaluate the impact of these notifications on our institutional ethics committee's (IEC) structure, review process, outcomes and administration. The results revealed that though the number of regulatory studies reviewed by our IEC remained the same, the number of studies actually approved decreased with an increase in the turnover time. The number of serious adverse events (SAEs) reported also fell, although the number of meetings held to discuss these SAEs increased significantly. The administrative workload rose with increased documentation. Though the annual income of the IEC fell marginally, the expenses shot up. We believe that the notifications definitely had an impact on the structure, review process, outcomes and administration of our IEC, although it remains to be seen whether they had a real impact on the research participants' safety and well-being.

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Introduction

Schedule Y, first introduced in 1988 as the 8th Amendment of The Drugs and Cosmetics Act, 1940, described the requirements for and guidelines on clinical trials in India for the import and manufacture of a new drug. The first applicant for marketing a drug already approved/marketed in other countries had to conduct a clinical trial in at least 100 patients at 3–4 centres in India before marketing permission was granted. Global studies could be initiated at one phase behind that in the global development cycle (1). The Indian Good Clinical Practice (GCP) Guidelines (2) were introduced in 2001, and got regulatory standing with the amendment of Schedule Y in 2005 (3). Apart from providing comprehensive and pragmatic definitions and setting out the responsibilities of all stakeholders, this amendment also laid down detailed requirements for the conduct of clinical trials. Importantly, the amended Schedule Y (2005) allowed clinical trials in India,

parallel to the global development phase. This led to a boom in clinical research in India, and the number of trials registered on *clinicaltrials.gov* increased from a mere 145 in 2005 to more than 359 in 2010 (4).

While concerns were voiced over this sudden increase in clinical trials (5–7), things took a serious turn after the 59th Parliamentary Standing Committee's report (8) was tabled. The report severely criticised the working of the Central Drugs Standard Control Organisation (CDSCO) (9), the body which is headed by the Drugs Controller General of India (DCGI) and is responsible for implementing drug regulations. Public interest litigation in the Supreme Court of India (10) gave a further impetus to reforms. In response, the Government of India issued a slew of regulations from early 2013 (Table 1). All stakeholders, including ethics committees, were affected by these notifications. We have two institutional ethics committees, named Institutional Ethics Committee (IEC) I and II. Both are registered with the CDSCO and apart from the mandatory compliance with national regulations and guidelines, they are also currently operating according to the international standards set by the Forum for Ethical Review Committees in Asia and the Western Pacific (FERCAP) (13, 16). We felt it was important to assess the impact of these new regulations on the structure, review process, outcomes and administration of our IECs and, therefore, conducted this audit.

Table 1
The new regulations issued for clinical trials in India with timeline

GSR No.	Date	Notification
53 E	30.01.2013	SAE reporting and compensation (11)
63 E	01.02.2013	Conditions to be fulfilled by the sponsor to conduct the clinical trial (12)
72 E	08.02.2013	Registration of ethics committees (13)
GCT/20/SC/ Clin./2013 DCGI	19.11.2013	Audiovisual recording of written informed consent (14)
Office order		Formula to determine quantum of compensation in case of SAE death (15)

Methods

This was a retrospective audit. We received administrative approval and an exemption from ethics review from both the IECs (I & II) [EC/OA-95/20/3]. The confidentiality of all documents and stakeholders was maintained strictly.

The following documents were used as source data: standard operating procedures (SOPs Version 3.1, 4) (17), project registers, project files (whichever needed) and minutes of meetings. The data were collected from June 2011 to September 2014.

The variables recorded were:

I. ***Structure:*** constitution of the IEC – number of members, qualifications required, training received by members.

II. ***Review process***: changes in standard operating procedures (SOPs), changes in the review process – number of queries/ comments raised in informed consent document, clinical trial agreement and insurance that pertained to regulatory notifications.

III. ***Outcomes:*** number of studies approved and turnover time in days for approval, number of serious adverse events (SAEs) reported, number of SAE sub-committee meetings, number of participants to whom compensation was provided.

IV. ***Administration:*** office infrastructure, staff, budget, number of documents sent and received.

The data from June 2011 to January 2013 (referred to as the BEFORE period) were compared to those from February 2013 to September 2014 (referred to as the AFTER period). The data are presented using descriptive statistics. The Mann-Whitney U test was used to compare the turnover time for approval of projects between the two study periods at 5% level of significance. SPSS software version 22 was used to analyse the data.

Results

The observations regarding the impact of the regulations on the structure and function of the IECs are described in the following sections.

I. *Structure*

Constitution of the IEC

a. The name of our ethics committee was changed from institutional review board to institutional ethics committee after registration with CDSCO.

b. The maximum number of members in the committee was reduced from 17 to 15, while the minimum number of members remained the same (7). The regulation required an MCI-recognised postgraduate qualification for clinician members, which was not specified in the BEFORE period.

c. Training in ethics, GCPs and SOPs became mandatory after registration, though this was being done in our committee in the BEFORE period too.

II. *Review process*

a. *Standard operating procedures* (18): our IEC had 23 SOPs in place before the new regulations came into force. After that, two new SOPs were added and two underwent major revision. One of the new SOPs was for the protection of the vulnerable population and the other for constituting a subcommittee to review SAEs. This had earlier been a part of another SOP. The SOPs that underwent major revision pertained to the review of SAE reports and the format for the informed consent document. The authorities to whom SAEs are to be reported, along with the respective timelines, were specified in the revised version, as was the method for review of the SAE report (including the relatedness of the injury to the clinical trial and the

need for and quantum of compensation). Regarding the format of the informed consent document, it was now mandatory to include clauses stating compensation for SAEs, relatedness to the clinical trial and details of the nominee in case of payment of compensation for death.

b. *Conflict of interest*: Although our IEC recorded conflict of interest earlier, as per the registration letter from the CDSCO, for each project/ meeting, a separate conflict of interest declaration (where such exists) has to be signed now by the IEC member and countersigned by the Chairperson (18).

c. *Number and type of query:* The number and type of queries raised on legal issues increased from zero to 23 [queries on clinical trial agreement (CTA)] and zero to 20 (for insurance coverage).

The queries on CTA were related to the protection of the rights and well-being of trial participants in case of premature termination of the trial and the place of arbitration in case of dispute. The queries on insurance were related to the clause on lack of or unacceptable compensation, unacceptable exclusion criteria and indemnity in case of negligence.

III. *Outcome*

a. A significantly lower number of studies [12/57 (25%)] was approved AFTER as compared to BEFORE [24/60 (40%)].

b. The average (±SD) turnover time for approval increased significantly ($p<0.05$), from 178.39 ± 70 days (range 56–426 days) to 313.41 ± 14 days (range 104–523 days).

c. From the 83 active studies in the BEFORE period, 18 reported 61 SAEs, while in the AFTER period, only 12 SAEs were reported from 11 studies of the 61 active protocols.

d. The number of SAE subcommittee meetings doubled from 27 in the BEFORE period to 54 in the AFTER period.

e. Free medical treatment was recommended in all cases BEFORE and AFTER the mandate.

f. 1/61 SAEs were deemed related in the BEFORE period and compensation was recommended by the IEC in all. In the AFTER period, 2/12 SAEs were considered related and compensation was recommended in both.

IV. *Administration*

a. The office infrastructure had to be upgraded following the mandate and the staff had to be increased to handle the SAE subcommittee.

b. The IEC office had a total staff strength of 6 in the BEFORE period and this increased to 8 in the AFTER period.

c. In the BEFORE period, the number of computers with printers was 4 and that of cupboards for archiving was 16. In the AFTER period, the number of computers and cupboards increased to 7 and 21, respectively. In addition, we purchased a NASSBOX for back-up data, a LAN system and a photocopier machine with a higher capacity. The annual income fell from Rs 28,05,163 to Rs 25,33,180, while the expenditure increased from Rs 22,75,321 to Rs 25,07,711.

d. The documents sent and received increased from 1954 to 2530 after the new rules came into force.

e. The IEC began communicating with the regulators after the new notifications. Fifteen letters were sent to the DCGI in the AFTER period.

Discussion

Starting from January 2013, the Indian regulators introduced a slew of new rules to streamline the conduct of clinical research in the country. IECs also came under the purview of these new regulatory notifications (17). Our audit indicated that these regulatory notifications on clinical trials had a significant impact on the structure, review process, outcomes and administration of our IECs.

In this study, we have, for the first time, attempted to assess the impact of the regulatory notifications on the structure, review process, outcomes and administration of ethics committees by using various indicators as variables. The quality of discussion and the time spent on discussion would have been more robust indicators of the functioning of an IEC, but these were not available to us for analysis. Also, it would have been difficult to grade the quality of discussions even if we studied the minutes. Hence, we took the outcomes of the discussions as indicators. Similar metrics have been used as a self-assessment tool to improve IRB outcomes (18). We have used the same metrics but have observed the impact of the regulatory guidelines made mandatory by the Government of India for regulating research in the country.

The desired composition of an IEC is described variably in different guidelines. Thus, the International Conference on Harmonisation E6 Guidelines (Good Clinical Practice; ICH-GCP) (19) does not mention in detail the exact composition of an IEC, while the ICMR's ethical guidelines (20) state that the committee should have at least one independent, one non-institutional member, apart from stating that there should be a minimum of seven – nine and a maximum of 12–15 members for optimal functioning. The new regulation insisted that an IEC should have at least seven members and 15 at the most. Both our IECs had to be pruned to have only 15 and since our IECs oversee at least 60–80 regulatory projects, apart from around 350 academic projects annually, this cap on the maximum number of members meant that each member had to review more projects. This regulation put a burden on IECs like ours that reviewed a large number of research projects, necessitating either an increase in the frequency of meetings or the formation of another IEC in the institute. Considering that there are no separate bioethics departments in India (by and large), the workload on the Secretariat, especially the Member Secretaries, increases.

The ICMR guidelines clearly state that IEC members must be regularly trained (19). However, there have been reports that IEC members were either not trained or their training was not regularly updated or adequate (21–24). The importance of training cannot be overemphasised (25). Since our IECs are recognised by the Strategic Initiative for Developing Capacity in Ethical Review (SIDCER) (16), our IEC members are trained regularly. However, there is a need to formulate guidelines on the frequency of training, content of training (SOP, ethical review, GCP, SAE review, etc), and customised training for medical and non-medical members to increase the IEC's competence to review and approve research. In fact, laying down standards for such training is the need of the hour so that the training is uniform and of a particular level to enable a person to serve on an IEC, especially in view of the norms specified by the Quality Council of India for accreditation of IECs.

As per GSR 72 dated February 8, 2013 (13), the IECs should function according to written SOPs. We have a separate SOP on "Preparation of SOPs for Ethics Committee" SOP01/version 01 dated 14.11.2008. It also mentions the circumstances under which SOPs are to be revised and the procedures to be followed for the same. We had already made a few revisions since 2008. However, the current revision version 4 dated August 22, 2013 was needed to comply with the regulatory guideline.

It was observed that very few IECs had detailed SOPs in place before the regulation came into force (26) and even in the case of those that did have them, there was no uniformity in the number, format or content of the SOPs (27–30). The Forum for Ethics Review Committees of India (31) has put up standard SOPs on its website and these could be used by IECs to develop their own SOPs. The government needs to declare what would be considered acceptable SOPs so that the IECs can all function according to one standard.

The requirement for soft as well as hard copies of all study-related documents and the need for IEC documents to be archived for a minimum of five years have increased the workload of the IEC secretariat, and also created a need for space. This has been challenging.

The GSR 53(E) dated January 30, 2013 (11) mandated that free medical treatment and compensation for research-related injury be provided by the sponsor. The documents reflecting that the sponsor is abiding by this notification are the Clinical Trial Agreement (CTA) and insurance policy, which need to be critically reviewed by the IEC, especially by the legal expert. After the rules changed, the review of these documents by the IECs and legal experts became more intense, leading to an increased number of queries regarding the CTA and Insurance and therefore increased turnover time.

It is interesting to note that although the number of projects submitted to our IEC for review before and after the notification remained the same, the number of projects approved by our IEC decreased substantially after the notification. The turnover time increased because the IEC reviewed the informed consent document (ICD), the CTA, and the insurance policy in greater detail to ensure that they complied with the changed notifications. Revised documents were re-reviewed by the IEC. This, too, increased the turnover time.

Surprisingly, there was a decrease in the number of SAEs reported to the IEC. The reason for this could not be ascertained from our study, although personal communication with the investigators indicated that they were being more vigilant towards patients to prevent SAEs. There was under-reporting of SAEs, the reasons for which are explained below. We reiterate that the number of SAEs is an indicator of the outcome of the IEC processes, which is mentioned in the revised version now.

Adams et al (18) also reported a similar reduction in the number of SAEs reported. They attributed this to the fact that fewer studies were completed during that period. It is very likely that fewer studies were active during the AFTER period, as the studies which had been approved in the BEFORE period would be recruiting participants and the studies in the AFTER period were still in the process of approval. Moreover, due to these notifications, the investigators and sponsors had to amend their legal documents, such as insurance, the CTA and ICDs. This not only prolonged the turnover time for approvals, but was also reflected in fewer approvals being issued during this period of time. However, the workload of the SAE subcommittee doubled in terms of increase in the frequency of meetings, increased documentation, and more direct communication with the DCGI. The SAE subcommittee as well as the IEC faced many challenges while determining the relatedness of injuries to clinical trials and, therefore, compensation. Although the IEC plays an important role in this activity, it works on secondary information. It is necessary both for the principal investigator and the sponsor to provide complete and clear documentation of the events that led to an SAE, as well as the various associated risk factors, for an accurate determination of the relatedness. Also, there is a need to train IEC members in the methods of determining relatedness. India has shown great originality in making the compensation notification, which is more stringent than that mentioned by the Council for International Organisation of Medical Sciences (CIOMS) (32) of US-FDA (33). However, it entails several challenges for IECs and appropriate training programmes must be held to empower IECs to perform this duty in a standard manner.

Our study revealed a tremendous increase in the workload. To cope with this, our expenditure also increased, but the income did not rise proportionately. There is a need for better institutional funding of IECs, to provide for enough office space and full-time employees. The aim of our study was to assess the impact of the new regulations on the structure, process, outcomes and administration of the IEC. For this reason, we looked at indicators before and after the rules came in. There were no other interventions at that time to explain the change. This is the first attempt to develop indicators to study the effect of the regulations. Our paper is limited by the fact that

the findings are borne out only by detailed document analysis.

Conclusion

To conclude, our study showed that the new notifications had an impact on the structure, review process, outcomes and administration of our IECs. Compliance with the new regulations is a challenge. It is crucial to study how these regulations have affected the participants. There is a need to develop the metrics for assessing the safety and efficacy of research participants as this will make the regulatory changes meaningful in the true sense.

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