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Audiovisual recording of the consenting process in clinical research: Experiences from a tertiary referral center

Parvan A Shetty, Mitesh R Maurya, Brinal H Figer, Urmila M Thatte, Nithya J Gogtay

Department of Clinical Pharmacology, Seth GS Medical College and KEM Hospital, Mumbai, Maharashtra, India

Abstract

The quality of the written informed consent process is one of the most important aspects of clinical research, as it is the single tool that serves as a metric of autonomy. Several challenges have been identified with the informed consent process in developing countries the most important of which is the ability to assimilate and understand the information presented in the consent form. In India, a unique aspect of the informed consent process is the need for audio-video [AV] recording of the process for vulnerable populations and new chemical entities. The present narrative summates authors' experiences as investigators with A-V recording of the informed consent process as also providing a brief narrative review of relevant literature. It also offers potential solutions for challenges faced during this process.

Keywords: Adequacy of consent, investigators' responsibilities, regulatory requirements for consent in India

Address for correspondence: Dr. Nithya Gogtay, Department of Clinical Pharmacology, Seth GS Medical College and KEM Hospital, Mumbai, Maharashtra, India.
E-mail: nithyagogtay@kem.edu

INTRODUCTION

The quality of the written informed consent process is one of the most important aspects of clinical research, as it is the single tool that serves as a metric of autonomy.^[1] In emerging economies, many challenges have been identified that make the informed consent process difficult. An important challenge is the ability to comprehend and assimilate information present in the consent form for a wide variety of reasons.^[2]

In response to a petition filed by an Indore-based group regarding the conduct of clinical trials in India, on October 21, 2013, a directive from the Supreme Court of India mandated audiovisual (A-V) recording of the informed consent process for all trials.^[3] The Central Drugs Standard Control

Organization (CDSCO) together with the Drugs Technical Advisory Board [DTAB] then issued an order on November 19, 2013, that, in all clinical trials, in addition to obtaining written informed consent, A-V recording of the informed consent process of each trial participant is necessary. This was done as a necessary step toward implementing the Supreme Court Directive.^[4] The original order was subsequently modified (July 31, 2015 [G. S. R. 611(E)]), making A-V consent mandatory only in cases of vulnerable populations and with research on new chemical entities.^[5]

Against this backdrop, the present narrative summates authors' experiences as investigators with A-V recording of the informed consent process. It includes both personal

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experiences as also published literature on the subject (both by the authors and other investigators) which may be of value to trialists in India.

A BRIEF NARRATIVE REVIEW OF LITERATURE

Will audio-visual recording of the informed consent process be accepted by trial participants?

A-V recording of the informed consent process is expected to serve as a means to better document understanding by potential participants. It also serves as a legal record for the investigator regarding the information provided to the participant in detail and can act as an effective tool for the sponsor, ethics committees, or regulators during the processes of monitoring, auditing, or inspections. While improvement in the quality of the conduct of the informed consent process and transparency can be viewed as potential advantages of A-V consenting, the process can present significant challenges.^[6] Chauhan *et al.* carried out a descriptive survey among 150 residents of rural South India to assess the acceptability of A-V recording with a hypothetical scenario of a clinical study. Once written informed consent was obtained, participants were asked whether they would consent for A-V recording. It was seen that 34% of those who gave written informed consent, declined A-V consenting for a variety of reasons.^[7]

Does audio-visual recording of the informed consent process actually improve understanding and comprehension of information?

At the point of the issue of the administrative order by the CDSCO in November 2013, a clinical trial (CTRI/2012/05/002709) investigating an antirabies monoclonal antibody was ongoing at our center. Forty-five patients had thus far been recruited after they gave written, informed consent. Subsequent to the notification that mandated A-V recording of the consent process, $n = 40$, more patients were enrolled all of whom underwent A-V recording of the informed consent process. In view of the fact that a single study fortuitously had participants who had undergone both consenting processes, the authors evaluated whether there was a difference in understanding between the two consenting processes using a 16-item validated questionnaire. A total of 21 patients in the A-V consent group and 17 patients in the written informed consent group (who consented) completed the questionnaire. The total score (mean \pm standard deviation) in the A-V consent group was significantly higher relative to the written, informed consent group (40.3 ± 5.9 vs. 34.8 ± 7.9 ; $P = 0.01$). With the A-V consent group, the

total score was significantly higher in the domain of rights and confidentiality ($P = 0.01$). Furthermore, proportion of participants who gave fully correct answers in the domain of purpose were higher in the former group (paper accepted for publication; National Medical Journal of India).^[8]

CHALLENGES FACED BY INVESTIGATORS DURING THE A-V RECORDING OF THE INFORMED CONSENT PROCESS AND POTENTIAL SOLUTIONS – A PERSONAL NARRATIVE

The challenges listed below are those faced by the investigator's team as also those identified by the Institutional Ethics Committee (IEC) during their monitoring of the site. The challenges are outlined. Both challenges and solutions are presented in Table 1. All challenges can actually be addressed by using detailed standard operating procedures (SOPs) and training of the study team members.

Operational challenges during the recording process

Both poor sound and poor visual quality can be found once the A-V consent is completed. This was found by the IEC during its monitoring. In addition, the IEC monitoring also found that the physician carrying out the consent, the patient or the legally acceptable representative was often not seen in the video frame, nor was the final signature process not seen.

Challenges regarding the total duration of the consent process

Most sponsors' monitors and IEC members at the time of monitoring/inspection view the duration of the consent process as a metric of adequacy of the consent process. This is almost never stated in their SOPs or mentioned at site initiation visits. Based on experience, they insist on 45 min to an hour for each consent. However, even before the start of the A-V recording, an investigator always explains the basic aspects of the trial and the various procedures to be done to the participant. Second, we have seen that participants often fidget or get restless or even switch off mentally when these aspects are repeated and reiterated during the A-V recording. Thus, even if the recording time is just 20 min or thereabouts, the actual process of consenting is much longer, and this needs to be borne in mind by both sponsors and IEC members.

When neonates and infants are participants

During an IEC monitoring of A-V consents done by us for a particular study done by us (that involved neonates

Table 1: Challenges faced during the audiovisual recording of the informed consent process and potential solutions

Challenges	Potential solutions
Infrastructure not available	Dialog between the sponsor, investigator, and institution where applicable to help establish this facility including cost considerations and long-term maintenance of the facility
Operational aspects-poor image and sound quality issues; visibility of the physician and participant in the video frame and other logistics issues	<p>Test the sound and lighting before the start of the recording. Do a dry run and ensure adequacy of both</p> <p>Ensure that video is recording the consent process right from the beginning</p> <p>Ensure that the physician and patient (with LAR or impartial witness if applicable) are visible in the video frame throughout the consent</p> <p>Ensure that the process of handing over the consent form and the signature must be captured clearly</p> <p>At least two trained personnel need to be present in the room; one who consents the participant and the other who ensures logistics of the process itself</p>
Duration of the recording	Logbook/ledger recording both actual time (time since the first contact with participant) and A-V recording time of the consent procedure should be maintained and then the total time of the consent process calculated
Testing understanding of the participant	List of specific questions that address comprehension to be kept ready with the physician doing the consent and these must be asked during the process of consenting
Training of the study personnel	<p>Create a site-specific checklist/standard operating procedure of all A-V consent-related aspects</p> <p>Mock/dry runs to be carried out with these checklists and errors identified and addressed.</p> <p>Real-time internal monitoring to be carried out of all A-V consents to preclude errors. One study team member may be identified as the internal monitor</p>
Neonates/infants as participants	At least introduction of the A-V recording with the child in frame for ensuring veracity of the consent
Storage, archival and retrieval	<p>Video recording should be deleted from the recording device as soon as it is stored in a CD, external hard drive, or a cloud-based storage system with a defined time frame. This time frame can be detailed in the SOP (follow time frame)</p> <p>Always kept under lock and key (or password protected for automated/cloud-based systems)</p> <p>Restricted access that is limited only to the study team members who are delegated this task</p>
Errors committed by investigators	Once an A-V recording is completed and archived, errors made cannot be erased and can be potentially misused. Training and re-training and creation of checklist and SOPs remain the only way to address this

SOP=Standard operating procedure, CD=Compact disc, LAR=Legally acceptable representative, A-V=Audio-visual

and infants), the IEC insisted on the neonate/infant being present with the parent and be seen in the video frame at all times. This may not always be possible with a sick or irritable child. The parent has freedom and the ability to pay attention to the A-V consent when the child is with a relative or in the vicinity and visible to the parent at all times. A crying or a sick child also can preclude A-V consent and prompt refusal and this needs to be borne in mind for pediatric studies.

Testing the participants' understanding

One of the aspects insisted upon by both IEC as well as sponsors is assessing the understanding/comprehending the information in the consent form. The process of A-V consenting, at least in during the first few times, is also fairly stressful for the physician taking the consent and this assessment is often forgotten.

Training of study personnel

Study team members delegated the responsibility of the A-V consent process need training in it through mock/dry runs. The training should involve the use of checklists as the consenting process can be equally stressful for the novice members. This needs to be followed up by real-time monitoring and supervision by members experienced in A-V consenting.

Storage, archival, and retrieval

All the study team members involved in taking A-V consent of the participant should be aware about the storage of the video files. All the videos should be saved in external hard drives, Compact discs, or a cloud-based storage system in a coded format (as per site/sponsor SOPs) to prevent misuse and protect the identity and confidentiality of the study participants. Furthermore, it should be made sure that the video files are deleted immediately from the recording device. The Principal Investigator should take special care pertaining to the protection of the identity of the participants and make sure that only the site staff delegated the responsibility of storage, archival, and retrieval of the A-V recording have access to the video recordings.

OTHER CHALLENGES

The authors work in a tertiary referral center in a metropolitan city. It is likely that given the cultural diversity that exists in the country, there may be many more challenges during the process of A-V consenting. These have been eloquently summarized by Kulkarni *et al.* and include inadequate infrastructure (for example, a separate room for consent may be difficult in many

places), cultural sensitivity (women unwilling to consent due to a male physician or use of a head scarf/veil during the consenting process that may mask the face), lack of willingness to discuss ailments on camera, language barriers that make the dialog between the physician and participant difficult, and cost considerations both for the sponsor and investigator to set up and effectively carry out the A-V consenting.^[6]

CONCLUSIONS

The process of A-V recording of the consent process was established in an attempt to improve and strengthen the written informed consent process. Its implementation is, however, fraught with challenges, some of which we have tried to address. All stakeholders (investigators, sponsors, regulators, and ethics committees) in research need to jointly work together to ensure that the process of A-V recording of the consent process fulfills the very reason that it was established in the first place – greater participant protection.

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Conflicts of interest

There are no conflicts of interest.

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