**Title**

**Audio-video informed consent process in vaccine trials: Experience from North India**

**Names and details of the authors**

Madhu Gupta

Additional Professor of Community Medicine

Department of Community Medicine

School of Public Health

Post Graduate Institute of Medical Education and Research

Chandigarh

e-mail: [madhugupta21@gmail.com](mailto:madhugupta21@gmail.com)

Jaya Prasad Tripathy

Operational Research Fellow

International Union Against Tuberculosis and Lung Disease

The Union South East Asia Office

New Delhi-110016

e-mail: [ijay.doc@gmail.com](mailto:ijay.doc@gmail.com)

Sanjay Verma

Additional Professor

Advanced Pediatrics Centre

Post Graduate Institute of Medical Education and Research

Chandigarh

e-mail: [sanjay06verma@yahoo.com](mailto:sanjay06verma@yahoo.com)

**Corresponding author**

Dr Madhu Gupta

Additional Professor of Community Medicine,

Department of Community Medicine,

School of Public Health

Post Graduate Institute of Medical Education and Research

Chandigarh

Email Id: [madhugupta21@gmail.com](mailto:madhugupta21@gmail.com)

Mobile +91 9914208226

Fax +91 172 2744401

**Competing interests**: None declared

**Funding support**: The vaccine trial was funded by Shantha Biotech Limited (A part of SANOFI company).

**Abstract**

The audio-video (AV) recording of the informed consent process of each participant in a clinical or vaccine trial has become one of the essential requirement to obtain prior ethical approval from the institute’s ethics committee and Drug Controller General of India to conduct such trial. This ensures the voluntary participation of each participant. This paper describes the experience of the authors with the audio-video consenting process during a phase III rotavirus vaccine trial among healthy infants in Chandigarh, North India. Among 105 subjects who expressed their initial willingness to be a part of the trial, all agreed to undergo AV informed consenting process, out of which 100 were finally consented to participate, and were enrolled in the study. Most of the queries were related to the risks and side effects of the vaccine. However, the authors felt that discussion with the anxious parents allayed most of their fears related to adverse events following immunization. One must patiently listen to their queries and resolve them one by one. This clarifies the doubts and misconception about the risks of vaccines, develops a sense of confidence in the investigators, informs the participants in real sense about the trial and enables them to take independent decision regarding participation. More clear guidelines need to be formulated regarding type of AV recorder to be used, archiving and access to AV recordings, and content and process of AV recording.

**Introduction**

In the last decade, serious concerns have been raised regarding the lack of adherence to ethical conduct during recruitment of vulnerable subjects in clinical trials in India (1). Although it is mandatory under Schedule Y of the Drugs and Cosmetics Rules 1945 to obtain a freely given informed, written consent from study subject before enrolment in a clinical trial, there have been several complaints about the misuse of this provision by research institutes, pharma companies and Clinical Research Organizations who are engaged in clinical trials (2). It was reported that many a time the informed consent was taken from the participating subjects without informing them about the benefits and, especially, the harmful side effects of the investigational product in the trial (3). It is assumed that subject will not be able to understand too much technicalities involved in the trial, hence only the most essential information being provided to the subject and informed consent used to be taken (3).

Taking a serious note of that, the Office of the Drug Controller General of India (DCGI) with the approval from Ministry of Health and Family Welfare has made audio-visual recording of the informed consent process of each trial participant essential in addition to the written informed consent (4). The AV recording and related documentation should be preserved safely, confidentially and secured in password protected software after the completion / termination of the study for at least a period of 5 years if it is not possible to maintain the same permanently. These directives by the DCGI has not only made the pharmaceutical companies more wary of the situation but also cautioned the investigators who will be involved in conducting the trials, which may influence their decision in participating/conducting such trials.

Earlier studies have shown that more than one-third of the study subjects ranging from 30-50% refused to give consent for A-V recording of consent process. Not interested in recording or don’t like to be recorded, discomfort with and suspicion of being videotaped, feeling shy and hesitancy were the common reasons for refusal by the study subjects (5-8).

This paper describes the experience of the authors obtaining audio-video consent from subjects’ (healthy infants) parents in phase III rota vaccine trial, so as to document the process involved in audio-video consenting. These findings will be useful for investigators/researchers in following the audio-video consenting process while conducting trials, and may allay their apprehension regarding increase in refusal rate by the participants.

**Methods**

Audio video (AV) consenting was done to take consent from the parents/guardians/legally accepted representatives (LAR) of healthy infants of age 6 to 8 weeks in a phase III rotavirus vaccine multicentric trial in India. This trial was sponsored by Shantha Biotech Limited (A part of Sanofi Company). In this paper we are sharing the experience of AV consenting at one of the site at Post Graduate Institute of Medical Education and Research (PGIMER), Chandigarh. AV informed consenting process was used for recruiting 100 healthy infants into this trial in accordance with the new rules laid down by the DCGI at this site. The Institute Ethics Committee of PGIMER had approved the main study.

**Setting of audio-video consenting**

A portion of a room was dedicated for AV process through artificial barriers to maintain confidentiality and to cut-off outside noise for better clarity of audio recording. Recording was done using a webcam (Logitech HD Webcam) mounted on a desktop. The investigators were trained to carry out the AV recording by showing dummy video on how to obtain audio video consent by the experts from the sponsors. At the first step consent to record audio and video of consent was obtained from the parents/guardians/LAR. Only if they agree then the AV informed consent was obtained.

The content of informed consent form is given in Box 1. The written informed consent form was in English, Hindi and Punjabi Languages. A structured AV consent module was followed to ensure that all the components of the informed consent were covered. All the contents were given equal importance while explaining to the prospective subjects. Adequate time was given for the discussion and settling the queries. Information was given in most understandable language. In case of illiterate subjects AV consenting was done in the presence of impartial witness. Consent form was signed by the parents/guardians/LAR under AV recording and a copy of ICF was given to the participant for records.

**Results**

Out of 155 subjects who were contacted to be a part of the study, 105 expressed initial willingness to be a part of the study. Among those 105 subjects, all of them agreed to undergo AV informed consent, out of which 100 were finally enrolled into the study. Table 1 describes the content of the AV informed content process along with its detailed description. Table 2 describes the queries raised by the subjects’ parents and the point wise reply given by the author during the AV informed consenting process.

**Discussion**

Despite fears and apprehensions about the AV consenting process, all the subjects in a vaccine trial who expressed initial willingness to be a part of the study agreed to undergo AV informed consent without any refusals. Explaining the process and purpose of AV consent and addressing the queries seemed to instil confidence among subjects in the conduct of the trial.

AV recording of clinical trial consenting increases the transparency of the informed consent process, which in turn will reassure the regulatory authority about the practice of clinical trial standards and ethics and also re-establish society’s faith in clinical research. AV recording will not just protect the rights, safety and well-being of the subjects enrolled in the trial, it will actually play a key role in safeguarding the interests of all stakeholders in the clinical trials. In case of any dispute/litigation the investigator will be able to demonstrate solid evidence that all relevant information was provided to the potential participant before he/she understood and voluntarily agreed to take part in the clinical study. Introduction of the AV recording could also improve the conduct of the informed consent process because the process is recorded. It ensures that conduct is given more importance over mere documentation of the whole process. This ensures that incidents like the one which reported irregularities in the conduct of study and informed consent in a Human Papilloma Virus (HPV) vaccine trial does not happen again (9-10).

Challenges of AV recording of informed consent process in clinical trials include the need for a dedicated room for recording and equipment which has significant cost implications, training of personnel, time consuming process, reluctance of participants to undergo recording and issues of data storage and safety. In this age of technology where almost everyone has a gadget with a video recording facility and sharing videos and photos has become so routine in our daily lives, reluctance to undergo video recording is a myth now. However, in India, due to the cultural barriers females especially in rural India are not comfortable being videotaped and that too in front of a male investigator.

In the present study, none of the participants who had given verbal consent for inclusion in the trial refused to undergo audio-video consenting process although they belonged to different cultural groups, gender, socio-economic status, education levels and occupation. The transparent process of AV consent and the fact that it safeguards their interests seemed to convince the subjects regarding fair conduct of the trial. AV consent process takes a considerable amount of time, but it is a one-time activity and deserves the time it warrants. Audio-visual intervention enhanced the quality of the information conveyed to participants as reported in a systematic review although the evidence is not strong (11).

Not surprisingly, most of the queries were related to the risks and side effects of the vaccine. The minor side effects were already known to most of them, but the major risk i.e. intussusception in case of rotavirus vaccine in this study was a cause of concern for most parents. However, the authors felt that discussion with the anxious parents allayed most of their fears. One must patiently listen to their queries and resolve them one by one. This will not only clarify their doubts and any misconception about the risks of vaccines, but also develop a sense of confidence in the investigator. It will also build a healthy rapport between the parents and the investigator.

**Way forward**

More clear guidelines need to be formulated to standardise the process of AV consent. The specification of the device to be used for recording should be laid down to ensure sufficient quality of audio and video recording. Clear written protocols for archiving, backups and access to AV recordings should be in place. There are certain things, which require more clarity. For example, if the participant refuses to be videotaped but still wishes to be enrolled in the study, then should he/she be enrolled or not? Additionally, it also does not mention how to conduct audio-video recording of the informed consent process in vulnerable participants such as those who are mentally challenged, patients with stigmatizing diseases such as HIV infection (12).

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**Table 1. Content of the Audio-Visual informed consent process**

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| --- | --- |
| **Content** | **Description** |
| Introduction | Introduction of self and the participant; welcoming the participant into the trial; inviting queries; build rapport |
| Thanking the participant for agreeing to the AV recording | Build rapport; make the participant comfortable |
| Background and rationale of the study | Rotavirus infection among infants and children; severity; incidence; symptoms; role of rotavirus vaccine |
| Number of children participating in the study | Total sample size; sample to be recruited from each centre in a multi-centric trial |
| Purpose of the study | Evaluate the ability of the new rotavirus vaccine under trial to produce antibodies which may have the ability to prevent infection from rotavirus compared to an approved vaccine |
| Length of participation | Participation will last for 12-15 weeks upon completion of 28 days post third dose |
| Study procedures | No undue influence to participate; ample opportunity to enquire about the details the study; signing the ICF; evaluation of the child as per the inclusion and exclusion criteria; recruitment into the trial |
| Description of the intervention | Details of the vaccines to be administered; blood sampling; stool sampling; home visits; diary cards for monitoring of adverse reactions and other health events; |
| Study visits | Timing of visits; activities during each visit; home visits |
| Risks and side effects of participation | Minor and major side effects of each vaccine; intussusception; referral mechanism in case of any adverse reaction |
| Payment for taking part in the study | No payment except travel expense incurred to reach the site; free vaccines; health care costs on the chid during the study period will be borne |
| Possible benefits for taking part in the study | No direct benefit; benefit of health examination and general health discussions with the study doctor; |
| Possible benefits to others | Benefit to the community |
| Other available treatments | You can choose to purchase available vaccines against rotavirus from the market |
| Voluntary nature of participation | Voluntary participation; no undue influence |
| Compensation and treatment |  |
| Responsibilities of the participant | Follow the instructions; return to the clinic for scheduled visits; complete the diary card; promptly report to the staff of any unexpected or serious health events; inform the study doctor of any medications your child take during the study |
| Termination of participation | Do not follow the instructions; sponsors or regulatory bodies decided to stop the study |
| Confidentiality | Child’s participation will be kept confidential; auditors, ethics committee, regulatory authorities will be granted access to your medical records |
| Right to refuse or withdraw | You may choose to stop your child’s participation in the study at any time you wish |
| Dissemination of new information | You will be informed of any new things about the vaccine |

**Table 2. Queries by the participant and reply by the author during the AV informed consent process**

|  |  |  |
| --- | --- | --- |
| **Contents of the AV consent module** | **Queries by the participant** | **Reply/comments of the author** |
| Introduction of self and the participant |  | Comment: It helped in developing a rapport between the investigator and the subjects’ parents/guardian |
| Thanking the participant for agreeing to the AV recording |  | Comment: A wonderful gesture which further strengthened the rapport |
| Background and rationale of the study |  |  |
| Study procedures | *“Kya hum bahar se bhi yeh tika laga sakte hain?”* | Reply: This particular vaccine is not available in the market. However, there are two other varieties of rotavirus vaccines available in the market manufactured by different companies. But it is not available in government facilities, you have to purchase it from outside. |
| Length of participation | As the length of participation was 12-15 weeks long, many participants had some other plans during this period.  *“Hume to gaon jana hai, kya hum tike gaon mein laga sakte hain”* | Reply: You can go to your village for a week or so but you have to inform us well before you plan for the trip. However, in case you plan a long trip of 1 month or more, we are afraid we cannot enrol the subject in this study. The rota virus vaccine might not be available in your village, and if it is available then it would be very costly. So it is better if you consult with your family members regarding your travel plans in the next 3 months. |
| Description of the intervention | *“Diary card bharna kya jaruri hai, kaise bharna hai”* | Reply: Diary card helps us to keep a record of the daily health events after vaccination so that any adverse reaction can be picked up early for immediate action. Diary card is very easy to fill (diary card shown to them) with simple questions about the health of your child in local language. You just have to circle the correct response. (demonstration done) In case of any difficulty in filling the card, feel free to contact us. |
| Risks and side effects of participation | Parents were found anxious over the side effects of the vaccine.  *“Bachhe ko koi dikkat to nahin hogi”“Agar bachhe ko koi dikkat ho to hum kya kare”*  *“Agar raat ko bachhe ko koi dikkat ho to kya kare”*  *“Humein intussusception ke bare mein kaise pata chale”*  *“Kitne bachhon ko intussusception hota hai”*  *“Abhi tak jitney bachhon ko apne yeh vaccine pilayi hai, kisi ko aisi dikkat aayi hai”* | Reply: Vaccines are not without any side effects. There are some minor and some major side effects. However the risk of major side effects is very rare. We have to weigh the benefits and risks of administering a vaccine. Moreover, rota virus vaccines available in the market also have similar risk of side effects. In case of any difficulty, please feel free to contact our project staff at the numbers mentioned in the form at any time of day. Come immediately to this facility and consult the specialist at room no-3. In this project we also have paediatricians from premier tertiary care institutes as co-investigators. In case of a serious event, we will facilitate your visit to a paediatrician in either of the facilities. We have a referral mechanism in place for any untoward event.  Reply: In case of inconsolable cry, blood in stools, fever or vomiting, immediately contact our project staff.  Reply: There is very small risk of intussusception, around 1 in 100000 infants. However, this risk is also present in other licensed rotavirus vaccines available in the market.  Reply: Till now, no reports of any serious adverse event related to the vaccine such as intussusception has come to notice in this project. |
| Study visits | *“Agar hum tike lagana bhul jaye to...”* | Reply: Don’t worry. We will remind you about the vaccination date of your baby in advance and also on the day of vaccination through phone calls. |
| Responsibilities of the participant and termination of participation | *“Hum to bachhe ko sare tike lagwana chahte hain, lekin agar koi problem hui toh?”* | Reply: In case of any difficulties, don’t hesitate to contact us, we will help you. |