

Conducting fieldwork in clinical trial settings Anthropological and ethical remarks

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De auteur beschrijft haar ervaringen tijdens onderzoek bij medisch personeel en proefpersonen die deelnamen aan een 'clinical trial' in India. De proeven hadden betrekking op een nieuwe anticonceptie-techniek, het anti-fertility vaccin. De auteur pleit voor meer antropologisch onderzoek naar 'clinical trials'.

[clinical trials, anti-hCG vaccin, ethiek, sociale klasse, gender, India]

During the last couple of years, as part of a larger research project on Social Science and Immunisation,¹ I did fieldwork in two public hospitals where clinical trials on a new contraceptive method, the so called anti-hCG vaccine had been conducted. This vaccine is at the most advanced stage of research compared to other anti-fertility vaccines being developed by various scientists all over the world. The anti-hCG vaccine induces the body to produce antibodies against the hormone human chorionic gonadotrophin (hCG) and this in turn prevents the implantation of the fertilised egg, thus averting pregnancy. A prototype of this vaccine is being developed by a team at the National Institute of Immunology (NII), New Delhi, and the clinical trials were conducted at selected public hospitals.²

In this paper I would like to share my experience of doing fieldwork amongst the trial participants and the team of doctors and social workers involved in these trials. I do so, firstly, because anthropologists generally do not do anthropological research in such trial settings. In my view, such research is important because it can reveal how acceptable a new technology is to users at an early stage of development. Further, it can elucidate how claims of safety and efficacy are constructed.

At another level, the study of clinical trials also provides an opportunity to see science in the making. It helps disintegrate the supposedly scientific unequivocal process of clinical trials into a series of interactions with different players with different ideas and interests vested in the clinical trial.

Access to information about the trials

Conducting social science research in the context of clinical trials is not easy. Since the main agencies involved in clinical trials are government agencies and public hospitals, we were dependent upon them for access to factual information about the trials and their protocols. We also needed permission from them to conduct interviews with the hospital staff and patients involved in the trials. Due to the bureaucratic hierarchy it was a long and slow process to get any information.

There was a reluctance on the part of the Indian Council for Medical Research (ICMR) and the public hospitals which had been involved in the clinical trials to divulge the names of the trial participants. At the ICMR we were told that the trials were a confidential issue between the trial participant and the doctor and that for most women contraception was a private issue.

Another reason for their reluctance to provide us with information was that in the past years there has been strong criticism from Indian and International feminists about the very concept of an anti-fertility vaccine and about the manner in which the clinical trials had been conducted. Women's health organisations have in fact launched an international campaign calling for a halt on further research on the vaccine. I was often asked whether I worked in a women's health group. Though I had been involved with the work of women's groups over the last few years I had to be careful not to refer to them and to emphasise that this research was being conducted at the Delhi University. This was perceived as less threatening.

Due to the fact that many of the institutions and individuals involved in the clinical trials were based in Delhi, Kalpana and I tried to use our personal contacts, of which we found quite a few, and we started by meeting these doctors and officials. The fact that we came from a well known academic establishment and our supervisors involved in the research project were well known also helped us get appointments to meet government officials.

Meeting the officials and main researchers at the ICMR and NII aided us in gaining access to the clinical trials in the public hospitals. The doctors at these public hospitals were more willing to assist us when they heard that we had met these main researchers and officials. Though we did not have any written permission or reference, just informing the doctors that we had met with these officials was sufficiently beneficial in getting some assistance.

However, we were not given the addresses of any women. At one of the hospitals, two of the trial participants were asked to come to the hospital so that we could interview them. This was not satisfying since the doctors and health workers were present and sometimes even answered the questions that we asked the trial participants. Meanwhile, we noted down the names and addresses of four women from the sample records that we were allowed to see. Over the next six months, as we were unable to get the names of trial participants through the proper official channels, we decided to go ahead and interview these four women on our own.

At this point it may be useful to have some discussion on the ethical issues involved in interviewing these trial participants. As mentioned earlier, the official at the ICMR

had stated that the names and addresses of the trial participants could not be given because the confidentiality of the trial participants had to be respected. According to international ethical guidelines (CIOMS 1993;35), this confidentiality is to be met by ensuring that participants give their prior consent before information about them is made available. In this case, the hospitals and other concerned agencies could have contacted the participants and sought their permission on our behalf. They were, however, not willing to do so.

While doing fieldwork, we found that women who had participated in the trial were very willing to speak to us and we clearly told them that we would only interview them if they agreed to it. It was important to give these women the opportunity to share their experience of the vaccine and the trials. We did not feel that we were breaching their trust or doing anything unethical.

At the other hospital, after repeated visits during which we were told that "the senior doctor who is responsible is not around" or that "we will have to look for the files", we were finally given eight names by a junior doctor, who had recently joined and seemed unaware about the reluctance of the other doctor to provide us with the information.

Added to the difficulties of getting names of trial participants through official sources, there were other practical problems we faced in contacting trial participants. The trials had been conducted over four years back. Many of the women were no longer coming to the family planning clinic, as they had already completed their desired family sizes before they joined the trials, and the majority had probably gone in for sterilisation soon after. The process is made more difficult by the fact that the trials are conducted in large government hospitals providing free or subsidised services to hundreds of low-income people in and around the city. Many of the patients are migrants, moving frequently due to temporary jobs. Thus, locating 150 trial participants in a big city becomes tedious.

Besides the problems of having access to protocols and permission to interview the people involved, there was also the issue of us, as social scientists, attempting to understand technical and biomedical information about the drug and the trials. We spent the initial months of the research reading literature about the vaccine and went through a number of scientific papers. Our understanding of the terminologies and processes involved in such biomedical research slowly increased.

There was an advantage in our being social scientists, since most of the doctors and researchers started from the assumption that we did not have the technical knowledge, and they would start explain biomedical concepts in great detail. We were also comfortable in asking questions when we did not understand. However, there were also disadvantages of being social scientists doing research on clinical trials. We were often faced by different or contradictory information on possible side effects, and we were not always clear about how technically correct these various arguments were.

Class factors

As I went about conducting the interviews with the trial participants I made it a point to stress that they were free to refuse to be interviewed. However, I later realised that class hierarchies were dictating our interactions quite differently. Since many of the women did not have phone numbers, I often landed up at their houses unannounced. Usually the women would be busy with house work and would put it aside to talk to me. I sometimes felt that due to the fact that I came across as an educated middle-class woman I was given a certain superior position. This may have made it difficult for the women to refuse to be interviewed or to ask me to come again later when they had more free time.

During the initial couple of interviews with the trial participants of the first hospital, where we had taken the names and addresses on our own, I told the participants that I wanted to know about their experience with the family planning clinic. This we hoped would help us get sufficient information about their experience with the vaccine, besides other related issues. This was because we were not sure about how the government hospital and other involved authorities would react to our directly going and interviewing the women and also because it would wrongly give the impression to the women that we had been given permission by the clinic to interview them. However, this did not prove to be a good idea, since if the woman herself did not mention the trials I would have difficulty bringing up the issue for discussion. Secondly, they were so simple and trusting, that it felt that one was breeching their trust by not being completely honest with them. Therefore, during subsequent interviews, I explained to the participants that I had got the names from the hospital records and that the hospital staff did not know that we were interviewing them. Most of the women were willing to talk about the trials, though initially they did not mention what they did not like about the trials since they seemed to think that I would report it back to the hospital. Later as some of them realised that in fact I was as keen that they not mention my interview to the hospital staff they began to open up. Not only did they begin to trust me, they also felt happy at the thought that I was dependent upon their keeping our interview confidential. In some ways this turned the table around.

My background also influenced their expectations of me and they assumed that since I was educated I knew more. When I asked the women what they had been told about the vaccine and why they had participated in the trials, they would often ask while replying whether they had been given right information and whether the vaccine was a good method or not. At such occasions I would find it difficult to remain objective. I usually waited till the end of the interview to state that more explanations should have been given regarding the vaccine or the conduct of the trials. On the other hand I found on the few occasions when I stated such views during the interview (on the participants persistence), the women would also be more critical and sometimes, in my view, more open about their experiences.

Are trial participants passive victims?

Most doctor-patient interactions in public hospitals, particularly the Family Planning Clinics, are reflective of class hierarchies with doctors coming from well educated and well off backgrounds and patients mainly being low income, uneducated women.

The doctors usually prescribe what they think is right for the particular woman and the women rarely ask questions. Therefore, in most cases if the doctor tells a woman that she should use the vaccine because it will be good for her or because it is the latest method, she will accept that.

While this situation remains true for the clinical trial settings too, the trial participants are treated better in terms of the amount of time and attention they receive from the hospital staff. Most of the hospitals where the trials were conducted had separate rooms for the trials and also a separate staff of two doctors and health workers. The trial centre at one of the hospitals was a very pleasant room with posters and photos and a place to sit around. Some of the trial participants mentioned that they liked coming and sitting there. Since many of the participants are housewives with little time to themselves at home, the clinical trials provide an opportunity for them to come and spend time at the trial centre where they can sit around and chat and are served cold drinks and snacks. I noticed that the two women who came to the hospital to be interviewed by us, dressed up in formal saris and jewellery, and they mentioned that over the last few years as trial participants, they had been asked to come and meet various doctors and researchers, some of whom came from abroad and took their photos. Thus the trials provided an opportunity for these women to come out of their homes and be in the lime-light.

One of the trial participants mentioned that she liked the fact that the doctors and health workers in the trial centre knew her name and even recognised her when they passed her on the street. They would call out and ask how she and her family were. The trial participant then said that "For that kind of love, I would do anything". The fact that these hospital staff people were educated and well off and that they still stopped to talk to these women was viewed as a sign that they cared for the participants. It was with the same attitude that they sat with me to be interviewed or enthusiastically left their house work to accompany me to look for the house of another trial participant that I had got to know of. I got a lot of importance due to the fact that I was educated, travelling alone and that I was from Delhi. One of them asked me to send her a postcard when I got back to Delhi. While I am not denying that the doctors and health workers involved in the trials are genuinely affectionate and caring, it is also important to realise that one can misuse one's background and the trust it gets from these women both as a doctor and as a researcher.

The trial participants, though they came from low income households, rarely mentioned monetary compensation as one of the factors that motivated them to join the trials. However, during the later phase of my interviews when the women were less suspicious of me and when I happened to meet two of them together by chance, they started to calculate how much they had earned. They talked about some of the other participants who had "made lots of money" by participating in the trials longer. Thus,

though I had conducted the interviews individually with the women, it may have been informative to have had informal group discussions also.

One of the advantages of participating in the clinical trials most commonly mentioned by the participants was that they were given regular medical check-ups. More importantly, if they or anyone in their family fell ill they were given priority treatment and did not have to queue in long lines outside the hospital rooms. Some of the trial participants mentioned that even after two years of the trials being completed they could still go to the trial centre and ask for medical treatment. This free priority treatment can be a very strong motivating factor for women who cannot afford to go to private clinics or who will have to leave all work to go and stand in queues in public hospitals for treatment.

Thus, my field work made me realise that women participating in clinical trials often use it as a means for improving their existing situation. They are in their own way getting access to an extra income, improved health care and a sense of identity and social space outside their homes. On the other hand one can argue that these motivations provided by the research centre in some ways takes undue advantages of the situation of low income, uneducated women by providing them with opportunities they would otherwise not have. However, in a situation where these women will either not at all have access to these benefits or where they are choosing to consciously negotiate for these benefits, maybe the present situation is in some ways more empowering than not to participate in the trials and have the advantages of being a trial participant.

Informed consent

These different motivations for participating in the trials bring us to the issue of how 'informed consent' actually takes place at the ground level. If I was to ask the doctors or the trial participants whether there was informed consent, most would say that there was. However, my interviews with the trial participants showed that the understanding of the vaccines and the process of clinical trials, by the women was rather simplistic. One of the women described the vaccine as a new *tikka* (injection) and that since it is in fluid form and enters the blood directly, it should have a quicker action as compared to other medicines. Some of the women stated that the trials and regular tests were done because, it was not known whether the vaccine would be effective in preventing pregnancy for them. Thus the tests were to see if the vaccine would suit them. Not much was said in terms of possible risks. One of the doctors remarked that since the women were uneducated they were unable to understand how the vaccine works and they were therefore told about the antifertility vaccine by comparing it to other vaccines or injections which the women are more familiar with.

In this situation I was faced with the dilemma of what is informed consent – how informed should it be? Most of the participants and the doctors seemed very satisfied with the information given and the vaccine itself. However, it was definitely not complete information and by telling the participants about the possible risks in-

volved I felt that I was in some ways saying do not be involved in these trials and do not trust the doctors and being very far from the objective researcher that I had set out to be.

Provider's motivation

The young doctors and health workers at the centres were enthusiastic about the vaccine and felt that it was a very good method. Their high opinion of the vaccine was reflected in the way they talked about the method and probably led to motivating the participants to use it. During the time I was doing this field work I visited a hospital where trials with the diaphragm were being conducted and the doctor I met there on being asked about the method said that the method was difficult to use and compared to methods like the Norplant had low efficacy. She said that over the last six months since the diaphragm was being clinically tested only one woman had volunteered to use it.

Clinical trial settings

During the field work, I was struck by the difference between the clinic where the clinical trial was done and the regular family planning clinics, where the vaccine would finally be delivered after the trials are completed. In the clinical trial, the trial participants are screened to ensure that they are healthy young women. Such screening is not routine practice in the family planning clinics, where there is also hardly any time for each patient and no monetary compensation. Since the duration of effectiveness of the vaccine varies amongst women, in the clinical trials there was a whole team geared towards following the women's level of antibody titres and blood tests were carried out every two weeks. When a booster vaccine was required for a participant, she was contacted – sometimes by going to her house at night in the hospital van. This kind of a follow up would be impossible in typical public hospitals.

The ideal user

While most of the women I met were positive about their experience with the trial, I met two women who were critical of the trials. One of them related her experience of having amenorrhea during the trials and feeling worried about being pregnant and felt that the research team did not show concern and only told her that her pregnancy test was negative. After she kept complaining for a few weeks she was told by the social worker that it was in her nature to complain. She was reminded of the fact that even when she had used the intra-uterine device, during the first month of the vaccine trial as a back up contraception, she had complained that it had fallen out when it had not. This participant was also critical of the fact that whenever visitors came from abroad and the trial participants were asked to come and meet the visitors, all the discussions

were in English and that she could not participate and say what she felt about the vaccine. Later this woman was asked to leave the trial.

One of the other participants who I met had been very regular with her visits and was very appreciative of the attention and care given by the team. She said that after the vaccine trials she was asked to leave behind her address and keep in touch so that she could be informed if other trials were conducted. She subsequently participated in three other clinical trials. This brings us to the question of whether there is something like an ideal user in clinical trials and again of how the final users would differ from these trial participants in the family planning clinic settings.

On the same lines, due to the doctors and health workers emphasis on the fact that the vaccine was so good and the participants concern of remaining in the trials, I felt that participants in subtle ways competed to be good users. While talking to some of the women I got a feeling that they sometimes felt disappointed if the vaccine did not suit them or that they did not participate in the trials for the full term. This may have also led to undermining their own experience of using the vaccine. During the later stages of my interviews I heard women talking about amenorrhea and breathlessness, but they did not report it to the research centre.

Conclusion

The study of clinical trials by social scientists can present us with insights into the ways in which biomedical facts about safety and efficacy of new technologies are constructed and into the ways in which people participate in the trials.

The above discussion firstly shows how the concept of informed consent works in such clinical trials. At one level, for the participants what is important is not so much the signing of the consent form. It is their trust in the doctors and social worker which is at stake. At another level, through their participation in the trials, people register for good quality health care by the trusted doctors. I have argued that the fact that the trial participants are mainly housewives from low income backgrounds, and that the doctors are from high income educated families, facilitates the conduct of the trials. Women give their informed consent and comply with the trial procedures in order to remain in contact with such influential others.

The discussion further suggests that due to the fact that the trial participants are competing to be good users, they report less problems with the vaccine than they actually experience. The monetary incentives to come to the clinic, the high quality health care provided and the attention given to the participants (particularly to the 'good users') further ensures compliance with these trial procedures, such as the taking of blood, needed to continuously monitor efficacy of the vaccine. One wonders, however, if the vaccine were to be provided at the regular busy family planning clinics, where such incentives are not available, if women would continue to comply with the medical requirements. Safety and efficacy claims resulting from the trials, one could argue, have to be seen in relation to the context in which they are constructed.

Notes

Preeti Kirbat is presently doing a Masters in Medical Anthropology at the University of Amsterdam, The Netherlands. Prior to this, she was working as field investigator in the project on Social Science and Immunisation at Delhi University. She also has a Masters in Development Studies from the University of East Anglia, United Kingdom.

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1. This is a five country study and the India study was coordinated by Professor Veena Das and R.K. Das at the Delhi School of Economics, Delhi University. While a number of vaccines were studied, two of us, Kalpana Viswanath as research assistant and myself as field investigator, studied the development of the anti-hCG vaccine.
2. Phase I and II trials with the vaccine have been completed. For details of the trials, see: Talwar et al. 1976 and 1994.

Literature

CIOMS

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