

Original Research Article

Clinical trials on healthy volunteers in Mumbai and Ahmedabad: expanding the framework of expropriation

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ABSTRACT

Background: Healthy volunteers (HVs) in phase I clinical trials in India are often motivated by financial compensation. Historical expropriation and every day struggle for life of HVs which contributes to normalization of the risk are often ignored as contributing factors to normalization of risk. Therefore this research was aimed to study expropriation experiences of the HVs.

Methods: This research has employed qualitative and exploratory research design. The purposive sampling method was used to recruit nine HVs from two cities Mumbai and Ahmedabad.

Results: All of the HVs and their family members were alienated from land and livelihood in their villages through different social, economic, political and cultural processes. The financial compensation was a primary motivation and not altruism. The compensation amount was spent to pay debts, medical and other emergencies, consumer goods and alcohol. To maximize their earnings, HVs have participated in consecutive and/or more than one trial simultaneously.

Conclusions: The serial participation of the HVs in phase I trials has exposed them to serious risks which they are unable to recognize unless severe adverse events (SAE) occurred. The existing scholarship suggests that the perceived risk by healthy volunteers normalized through attractive financial incentives and serial participation. But findings of this research indicate that state induced violence, caste, class, gender based violence and everyday struggle of survival are also major contributing factors.

Keywords: Clinical trials, Healthy volunteers, Expropriation, Phase I

INTRODUCTION

Clinical trial is a fundamental part of the drug development process worldwide. It is the only method to certify the efficacy and safety of a new drug molecule for human use. There are different phases of drug development process such as phase I, II, III and IV. The phase I trials are non-therapeutic and participants of these trials are called healthy volunteers. They are designed to test the toxicity of the substance, response of human body and extent to which drug is absorbed and excreted from the body. Ultimately, they are designed to determine

critical dose amount above which it will produce adverse effects on the human body. Hence the phase I trials are always likely to produce some adverse effects in the participants.¹ There is a fundamental question, why do people participate in trials despite knowing the risks associated with trials and high probability of SAE. Several studies have been conducted to explore the motivational factors of participation in clinical trials. Traditionally the discussions regarding participation of healthy volunteers are mainly focused on archetypal conception of ethics which assumes that often individuals are motivated by altruism and wish to contribute to the scientific research and larger good of the humanity. But

they selectively ignores the influence of larger social, cultural, economic and political realities which influence the individual's decisions.² The phase I trial participants often participate in trials with a financial motive.³ Several researchers have argued that apart from socio economic background, repetitive participation leads to banalization of risk.¹ The motivational reasons behind the first time participation in trials are still unexplored. The major limitations of all these studies are that they comprehensively analyse the risks involved within clinical trial setup but they fail to understand influence of historic and current factors related of structural coercion which normalises the risk. These studies do not take into consideration the daily threat, violence and uncertainty of life posed in the daily experiences outside the clinical trial setup. It also fails to incorporate the historical shared experiences of violence and threat of the trial participants which results in underestimating the risk in the trial setup. Therefore this study attempts to explore the historical and present expropriation experiences of the clinical trial participants, especially healthy volunteers of phase I trials.

Expropriation in Marxian view and its expansion

Karl Marx distinguishes two types of private property and they are scattered private property arising from individual labour and capitalist private property. He explains the transition of former kind of property to later type by elaborating socio-economic processes in late medieval England. He summarizes the expropriation as the spoliation of the church's property, the fraudulent alienation of the state domains, the theft of the common lands, the usurpation of feudal and clan property and its transformation into modern, private property under circumstances of ruthless terrorism, all these things were just so may idyllic methods of primitive accumulation. They conquered the field for capitalist agriculture, incorporated the soil into capital and created for the urban

industries the necessary supplies of free and rightless proletarian.

The land was a mean of expropriation in the eighteenth century Europe and hence there were attempts to grab the traditional land rights of masses. There is a gradual shift in the means of exploitation throughout the history. Starting from the period in medieval England, through process of enclosure movement, people's land was grabbed for commercial production. The starving masses hence shifted to the cities in search of employment. The industrial capitalist then started exploitation of surplus labour out of disenfranchised masses pouring in to cities. In a present form, the means of expropriation has just changed but the process is same and more intense. The commercial processes have entered into the lives of the people. The pharmaceutical industry is encroaching at the micro-components of life in order to own the life at cellular level. It has made individual more vulnerable and marginalized.⁴ Clinical trials on healthy volunteers are one such form of expropriation.

Globalization of clinical trials

Traditionally the wealthy and developed countries, especially countries from north America and western Europe have been the epicentre of the clinical research. But in recent years, a shift of pharmaceutical industry sponsored clinical research to the emerging regions such as eastern Europe, Latin America and Asian countries has been observed.⁵ In these regions, specifically India, China and Russia have noticed tremendous growth in clinical research.⁶ The reasons were obvious, the process of experimentation of investigational drugs and producing reliable data is intensely time and resource consuming. Also, the rules and regulations in traditional hubs of clinical research became strict as several clinical trials related tragedies targeting marginalized communities got exposed (Figure 1).

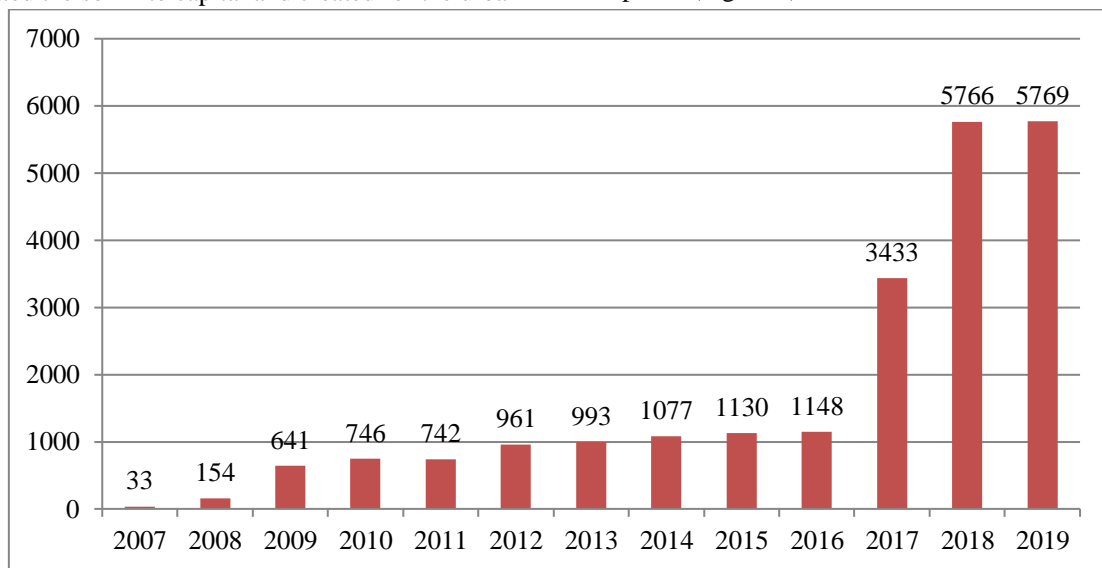


Figure 1: Number of trials registered with CTRI in past twelve years.

In India, till January 2005, clinical trials of new drugs being developed outside India were permitted only with a phase lag. This means that a phase II trial was permitted only after completion of phase III trials elsewhere in the world. Phase I trials of foreign drugs were only allowed if, and only if, the drug is of special relevance to India or in a situation of an epidemic. This means phase I trial of human immunodeficiency virus (HIV) was allowed because prevalence of HIV is very high in India.⁷

In January 2005, the schedule Y of the drugs and cosmetics rules was amended to remove phase lag clause in the act so that concurrent multicenter global clinical trials of multinational pharmaceuticals could be conducted in the India.⁸ Phase II and phase III trials of drugs discovered in foreign countries could now be conducted in India in the same phase and at the same time as they are conducted in other parts of the world.⁷ The investments in clinical trial industry in India skyrocketed to almost US \$300 million at the end of year 2009.⁹ But as per the parliamentary committee report, the office of drug controller general of india (DCGI) seriously lacked in capacity to technically evaluate the applications seeking approvals of tremendous number of trials. The parliamentary committee has also cited documentary evidence to prove that some opinion of experts is nothing but dictates by drug companies.¹⁰

There were serious violations related conducts of trials like proper consent process was not followed. On one hand doctors received huge financial incentives while victims did not get any compensation.¹¹ Several tragedies such as human papilloma virus (HPV) vaccine trials, trials on Bhopal gas tragedy victims and clinical trial scandal in Madhya Pradesh exposed the irregularities and violations of rules.^{12,13} Following a petition in supreme court of India in the year 2012, it was revealed that around 17,778 participants suffered with SAEs out of which 3458 were deaths during clinical trials only 89 deaths and 506 SAEs have attributed to clinical trials.¹⁴

Objective

The main objective of this research was to study the historical and present expropriation experiences of the

clinical trial participants. The qualitative and exploratory research designs were used to study the phenomenon of expropriation.

METHODS

This study was conducted in Ahmedabad, Gujarat and Mumbai, Maharashtra and data has been collected between November 2014 and February 2015. The researcher has tried to explore how daily life experiences, historical expropriation of the family members has contributed to normalization of risk for HVs in phase I clinical trials. Clinical research especially phase I trials in India are conducted clandestinely in a very secretive manner. Due to stigma attached to this profession, HVs are usually not willing to disclose about their participation in the trials. Also in the name of conducting ethical research and maintaining confidentiality of clinical trial participants, the contract research organizations (CRO) usually are not ready to disclose the names of participants and therefore it is difficult to find healthy volunteers who are participants of these trials. Therefore the list of phase I trial healthy volunteers was prepared by briefly interviewing primarily identified healthy volunteers using snow ball sampling technique. The healthy volunteers who have participated in trials in previous two years have been selected for this study. In order to verify their participation in clinical trials in last two years, the copy of consent form given by CROs were checked. The participants who could not produce copy of consent form were not included in this study. A total of nine cases were interviewed comprehensively with the help of the interview guidelines prepared. As mentioned above, although the snowball and purposive sampling was used, the researcher has also tried to select the cases so that sample could be diversely represented based on variables such as women, SAEs cases, schedule castes and schedule tribes, minorities and recruiting agents in clinical trial industry. The main criteria for sample size were to ensure if the findings sufficiently describe the phenomena of expropriation and attainment of saturation. The researcher has accordingly conducted a thorough interview of the healthy volunteers, three from Mumbai and five from Ahmadabad in between November 2014 to February 2015.

Table 1: Demographic characteristics of HVs interviewed.

Variables	Number (n=9)	Percentage
Gender	Women	55.56
	Men	44.44
Age (years)	18-25	11.11
	26-35	55.56
	36-45	33.33
Religion	Hindu	66.67
	Muslim	11.11
	Sikh	22.22
Caste	Schedule castes (SCs)	44.44
	Other backward castes (OBCs)	44.44

The researcher has also interviewed two agents who are husband wife duo who had initially worked as HVs (Table 1). In total, nine HVs and clinical trial recruiting agents have participated in this study. This study has been approved by ethics review committee at centre of social medicine and community health, Jawaharlal Nehru university, New Delhi. The purpose of this study was communicated to the study participants and written informed consents were taken beforehand to assure that participation is voluntary.

RESULTS

Expropriation experiences of the HVs

Life in the village

The story of Ajay, Rajesh, Iqbal, Heena and Pallavi like people brings to light human distress, agony and pain of the HVs. Village life has been hard on Ajay's family specially because of their Valmiki (manual scavengers) caste. In India, manual scavenging castes had given a role of picking up the human excreta from upper caste houses and dump it outside the village. The agony of the family of the Rajesh is same who lost their only source of livelihood, their farm land in one canal project and forced to migrate to the cities. Iqbal's story is a representation of the fishermen communities residing near Mumbai. According to him, around 50 per cent of the trial participants in CROs are from Aagri community and reason is that polluted water in Mumbai has destroyed their traditional fishing business.

My father did not have enough money to buy a bigger boat for fishing in the deep waters, Fishermen in those areas were no longer allowed to enter the estuaries for fishing. The estuary area was captured by the steel company for using it for carrying their raw materials in small boats (Iqbal).

Heena's father had the responsibility of three daughters on his shoulders. He had to sell off half of his land to get three of his daughters married. Snehalben, Pallavi and Savita belong to same caste called Vaghari (vegetable grower and vender caste). Snehal's father also had to pay ten thousand rupees dowry to groom's family for her marriage. Pallavi and Savita got married at the age of seventeen and nineteen and migrated along with their husbands to Ahmadabad.

Life in the city

One of the largest slums in Mumbai seemed like the right place to stay for Ajay and Rajesh's family considering the financial difficulties. Ajay's brother was involved in close connection with some criminal gangs in Mumbai. Due to his involvement with these gangs, the family was mentally tortured by police a number of times. Ajay was a

young man of 20 years old when his father passed away due to alcoholism. All the savings that they had been doing for so many years was spent on his two sister's marriage. Crippled with no savings and no stable job, Ajay had to now quit his education and joined the job as a gym trainer on a salary of seven thousands rupees per month. After migrating to Mumbai, Rajesh's father decided to work in a shop for some time until he becomes financially stable to set up his own shop. The income that he acquired through his small job was not enough to sustain his small family. Therefore he used to run a small petty snacks outlet near a liquor shop near his home. Tragedy befalls on the family when his father met with an accident which took his life when Rajesh was in tenth standard. All the financial responsibility of the family was passed now on to Rajesh's shoulders. Since the family was in a heavy debt after his father's demise and the income acquired from the shop was not enough to cover the costs plus pay off the debt, Rajesh decided to close down the shop and work as a contract labor in a mechanical industry. Iqbal's family shifted from a coastal village of Maharashtra to Mumbai with the help of his uncle and his father is currently working as daily wager with earnings of rupees 350 per day.

Heena's husband is an auto-rickshaw driver and earns four to five thousand per month. Feeding a family of six members along with additional basic needs of everyday life became a difficult task for Heena's family. They had no choice but to take loan from the local money lender at exorbitant interest rate of 36 per cent per year. Snehalben lives in a suburb area of Ahmedabad city with her husband. Her husband was working as an auto rickshaw driver with an income of rupees four thousand per month. Things started getting worse when her husband met with an accident and become partially disabled. With no way out, they took loan from the money lender with a very high interest rate. After shifting to city, Pallavi and her husband opened vegetables shop in suburbs of Ahmedabad. According to her testimony, all the petty businesses in this area are dependent upon high interest rate loans of the money lenders. Savita's husband is daily wager alcoholic and spends most of his earnings on buying alcohol. Few years back, her girl child fall sick and therefore she had to borrow eighty thousand rupees for her treatment. Money lender frequently harasses her and at the times, she gets feeling of committing suicide out of helplessness. Anil Keshwani and Seema are recruiting agents and get commission from CROs and fertility clinics for convincing and recruiting people to participate in trials, become egg or oocyte donors and surrogate mothers. His father was working in a cotton mill in Ahmedabad and his mother used to run petty shop.

Expropriation within clinical trial setup

This is how the financial constraints and daily struggle for life forced study participants to participate as healthy volunteers in phase I trials. Ajay was introduced into the

business of earning extra money through participation in drug trial through his brother who was already into it. In his first participation, he received the compensation of six thousand rupees. Experiencing of owning such a big amount of money for the first time for just one trial, he spent his money on material things like clothes and alcohol. It was during the period of suffering from heavy debt that Rajesh was introduced of earning extra money through participating in clinical trial. This information was brought to him by one of his friend in the neighbourhood. He testified that till date he has undergone sixteen trials. Iqbal has participated in eight trials so far and he is proud being financially independent. All of his earnings through those trials are spent on material things. His family is not aware about his source of income and he intends to keep it like that for the moment.

Anil and Seema who are agents recruiting healthy volunteers in clinical trial industry came to know about this business from his known associate working in a wholesale market in Surat. After he came back, he searched CROs in Ahmedabad to enroll himself in the study. He also convinced his wife to participate in some of the trials. So far, his wife Seema has participated in 27 trials while Anil has participated in fourteen trials. They were so much overwhelmed by the earning that they started working as recruiting agents convincing people in neighbourhood to participate in trials. They receive the commission of ₹100 to 400 per participant.

When Heenaben came to know about the clinical trials, she got attracted to the means of earning money through it. She thought she will participate in one or two studies and clear her loan of fifteen thousand rupees. She has participated in two trials till date and after being diagnosed with brain cancer during the second trial, she has completely stopped participating. She has spent approximately one lakh rupees on treatment and medication. Her children have discontinued their schooling and now her mother-in-law is participating in the trials pay back the debt. Burden of debt and alcoholism of her husband forced Snehalben to participate in the trials. Initially she had decided to not to tell her husband about her participation in trials. As husband became suspicious of her and beat her up badly, with no choice left, she had to tell him about her involvement in trials. As he learnt that she has been earning a lot of

money through the trials, he started harassing and physically abuses her for money. Over a period of one year, she participated in over five trials. On her sixth trial, she was offered a compensation amount of ₹10,190. On 25th day of the study, after realizing that she is pregnant, the CRO representative convinced her to abort the baby because according to them there was a possibility that the baby may born with some disabilities. When her husband came to know about it, he was so furious to hear about it and tortured her. Unable to tolerate the torture anymore, she divorced him and currently staying with her mother. Pallavi also had to go through the same situation like Snehalben and she was also convinced to abort her baby by the CRO staff. Her husband knew about her participation therefore did not create any problem. In both the cases, after the abortion, CRO representative denied giving them remaining compensation amount with the excuse that they did not complete the study.

Motivation behind participation and adherence to study

In this study, only one respondent mentioned altruism as the motivation while remaining all eight respondents mentioned financial compensation as a primary motivation. It is the primary responsibility of the principal investigator and research staff to teach altruism and make participants adhere to the study.² But in the Indian context, threat is used to sustain the participation. As one healthy volunteer said, you cannot question them. One of my co-participants questioned about the post-trial severe adverse events of psychotropic drug and in response they threatened him that they will throw him out of the study and won't give the remaining compensation (Ajay). In fact, the large instalment out of the compensation amount is given in the end so that people are adhered to continue the study. Hence participants have to adhere to the study forcefully in order to get full compensation amount (Table 2).

What are my financial benefits?

You will be offered a compensation amount for you participation. This compensation amount will be decided based on the rules prescribed by ethics committee members. The ethics committee has already evaluated and approved the study. You will get the compensation of ₹9550 which will be given in instalment described below (Table 2).

Table 2: Different slabs in which financial compensation paid.

S. no.	Visits	Amount (₹)
1	Time period-1	500
2	Time period-1 at the time of ambulatory	1000
3	Time period -2	500
4	Time period-1 at the time of ambulatory and compensation amount after the completion of study	7550
	Total	9550

In another case of Pallavi and Snehalben, during the second stage of the trial, it was found that they were pregnant and hence could not participate in the study. The CRO representative discontinued both of them from the study. These two women had to get their pregnancies aborted. When these women asked for the payment of the compensation, CRO representative said that: we are helping you to abort the pregnancy for free which itself is a favour we are offering to you. You have not completed the study so we won't give you the remaining compensation amount (Snehal and Pallavi).

Therefore in Indian cases, neither do HVs participate with any altruistic motive nor do the CROs try to develop such motive in the later stages. Participation and adherence of the healthy volunteers is purely based on the financial compensation offered.

Strategies to maximize participation

Once the trial is completed, HVs cannot participate in the other trial for next 30 days.¹⁵ In a sample of HVs researcher had selected, seven healthy volunteers were serial participants. They were participating in consecutive trials and also have participated in two or more trials at a time (Table 3).

Not only the volunteers but also the CROs try to maximize the recruitment. They also allowed the

volunteers to participate in multiple trials irrespective of the fact that such volunteer had already participating in another trial. Some of the tricks used by volunteers are producing fake document at the time of identification, travel to the other states for trials, removing syringe rubbing ice cubes. This phenomenon of participating in more than one trial at a time can increase the risk of severe adverse event. It also raises the question on validity of the data that will be generated.

Adverse events and banalization of the risk

Based on the analysis of the consent form gathered from the HVs, it was clearly evident that most of the phase I trials have homogeneous research design. Drug dosing, blood and urine collection, electrocardiogram, physical examination and providing meals are most of the common activities which are performed while conducting phase I trial.¹ The important information which needs to be communicated with special emphasis like communicating properties of trial medicine, probable short term and long term side effects and exceptional study demands are ignored due to this perceived homogeneity. The consent form is a mere formal translation of the English to Hindi or to any other local language and format of consent form is same for all the trials. This perceived homogeneity convey non-exclusiveness of the studies to HVs and hence volunteers at a point stops differentiating between studies.

Table 3: Total number of trials and simultaneous participation.

Case identification codes	Number of trials participated	Number of times participated in two trials at a time
Case M1	32	3
Case M2	16	2
Case M3	8	0
Case A1	2	0
Case A2	12	2
Case A3 (agent)	27	3
Case A4 (agent)	14	1

DISCUSSION

Throughout the history, there is a transition in means of expropriation, from the land to surplus labour. Sundar Rajan in his study found that most of the trial participants in Wellquest clinical research, Mumbai were unemployed mill workers. As mill workers lost their jobs due to demise of mill industry and shelter in chawls due to emerging lucrative real estate business, they saw trial industry as one kind of job opportunity to earn their livelihood.¹⁶ Likewise almost all healthy volunteers or their family members were belonged to villages with agriculture and allied activities as their source of livelihood. The different social, economic, political and cultural coercive processes alienated them from their land and forced them to migrate to the cities in search of

livelihood. In cities, they usually become a major part of unorganized labour whose surplus labour was exploited for the generation of profits for the manufacturing and service industry. With no source of sustained livelihood, they participate in trials and allowed further expansion of commercial process on their bodies. The participants recognize themselves as workers of this industry by claiming it a part time job. The serial participation of the HVs has posed them to serious risks which they are unable to recognize unless there is occurrence of SAEs. The profession of healthy volunteering allows them to participate freely, offer them choices of withdrawal, free mobility during contract period expect for few days when they have to present themselves for the sample collection. They see it as advantageous by not being like an embodied labour but often ignore the underlying hazard to their health. Though this study brings forward

expropriation experiences of HVs through life-history approach, the primary limitation of this study is that it has small sample size. Also the structural coercion and expropriation is a complex and abstract phenomena and its direct relationship to vulnerability of clinical trial participants could not be established.

CONCLUSION

India should take some radical steps to free the clinical trials from profit making ventures. It is require reversing the amendment and brought at par with old drug and cosmetics act. An independent mechanism for investigation and awarding compensation totally independent from the investigator and ethics committees should be established. It also required taking some radical steps in strengthening public medical education institutions and research institute.

The social, economic, political and cultural factors have very much on participation of HVs in the clinical trials. Some researchers may argue that addressing structural issues requires policy level changes and it cannot be addressed at individual level in a research setup. But some of these issues can be addressed at institutional level by making risk more transparent to HVs. The principle investigator (PI) can transparently communicate the different trials that are being conducted and risk underlying in each trial to make the decision making more informed.

The PIs can also be attentive to the structural needs of HVs through certain actions such as providing participants more substantive care or health education during clinical studies, provide post-trial access to healthcare and pay fair stipends that reflect the burden of time and effort associated with participation. Though ethics committees view it as act of undue influence, in a larger framework of expropriation, it is righteous to pay the fair compensation and provide healthcare services during and after the trial. PIs can also learn how to minimize their own biases against disenfranchised groups, especially the poor, by recognizing that these problems are not of moral or individual failings but of structural constraints. On the policy level, this translates into advocating for a higher minimum wage, land reforms, universal health care and social security which could significantly mitigate structural coercion.

Concurrently in order to prohibit serial participation, the government can develop centralized registry which contains participant's detailed information, number of trials they have participated in, date of participation, nature and risk involved in those trials. The data regarding SAEs and deaths related to each trial should be published periodically on this registry. This registry can help to strengthen the accountability of pharmaceutical industries and track the HVs for long term effects of serial participation on their health.

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